The American College of Radiology (ACR) has prepared this detailed analysis of proposed rule changes to the payment provisions of the Medicare Physician Fee Schedule (PFS) in calendar year 2017. The proposed rule has a 60-day comment period closing on Sept. 6, 2016, and the ACR will provide detailed comments. If finalized, the rule changes will be effective Jan. 1, 2017.

**Conversion Factor (Page 784)**

CMS estimates the calendar year (CY) 2017 PFS conversion factor to be 35.7751, which reflects a budget neutrality adjustment, the 0.5 percent update adjustment factor specified under the Medicare Access and CHIP Reauthorization Act (MACRA), and an adjustment due to the non-budget neutral 5 percent multiple procedure payment reduction (MPPR) for the professional component of imaging services. CMS did not need to apply an adjustment for a target recapture.

CMS estimates the CY 2017 net reduction in expenditures resulting from proposed adjustments to relative values of misvalued codes to be 0.51 percent. Since, if finalized, this amount would exceed the 0.5 percent target established by the Achieving a Better Life Experience Act of 2014 (ABLE), there is no residual difference between the target for the year and the estimated net reduction in expenditures by which to reduce payments made under the PFS. However, CMS notes that the final Target Recapture Amount will be calculated based on the adjustments to misvalued codes as finalized in the CY 2017 PFS Final Rule.

The Act requires that increases or decreases in relative value units (RVUs) may not cause the amount of expenditures for the year to differ by more than $20 million from what expenditures would have been in the absence of these changes. If this threshold is exceeded, CMS must make adjustments to preserve budget neutrality. The budget neutrality decrease in this proposed rule is largely a result of proposals to begin compensating primary care physicians for “prolonged services and complex care management services, cognitive impairment assessment and care plan services, psychiatric collaborative care management and services provided to patients with mobility impairments”.

**TABLE 41: Calculation of the Proposed CY 2017 PFS Conversion Factor**

<table>
<thead>
<tr>
<th>Conversion Factor in effect in CY 2016</th>
<th>35.8043</th>
</tr>
</thead>
<tbody>
<tr>
<td>Update Factor</td>
<td>0.50 percent (1.0050)</td>
</tr>
<tr>
<td>CY 2017 RVU Budget Neutrality Adjustment</td>
<td>-0.51 percent (0.9949)</td>
</tr>
<tr>
<td>CY 2017 Target Recapture Amount</td>
<td>0 percent (1.0000)</td>
</tr>
<tr>
<td>CY 2017 Imaging MPPR Adjustment</td>
<td>-0.07 percent (0.9993)</td>
</tr>
<tr>
<td>CY 2017 Conversion Factor</td>
<td>35.7751</td>
</tr>
</tbody>
</table>
CMS estimates an overall impact of the PFS proposed changes to radiology to be a 1 percent decrease, while interventional radiology would see an aggregate decrease of 7 percent and radiation oncology and nuclear medicine a 0 percent change if the provisions within the proposed rule are finalized. The reimbursement decrease for interventional radiology is a result of CPT code restructuring and revaluation of some high volume codes in the “misvalued codes” initiative. ACR staff is preparing a detailed code level analysis of the impacts of the proposed rule and will make this available to members in the coming weeks.

**Appropriate Use Criteria for Advanced Diagnostic Imaging Services (Page 525)**

The Protecting Access to Medicare Act of 2014 included a provision for the mandatory use of appropriate use criteria (AUC) for advanced diagnostic imaging services. Through the CY 2016 rulemaking process, CMS addressed the initial component of the AUC program, specifying applicable AUC. CMS established a process for the development of AUC, defined provider-led entities (PLEs), and established the process by which PLEs may become qualified to develop AUC. The first list of qualified PLEs was posted on the CMS website in late June 2016.

This rule proposes requirements and processes for specification of qualified clinical decision support mechanisms (CDSMs) under the Medicare AUC program; the initial list of priority clinical areas; and exceptions to the requirement that ordering professionals consult specified applicable AUC when ordering applicable imaging services.

CMS defines CDSM as a functionality that provides persons involved in care processes with general and person-specific information, intelligently filtered and organized, at appropriate times, to enhance health and health care.

In communicating an appropriateness rating to the ordering practitioner, some CDSMs provide a scale with numeric ratings, some output a red, yellow, or green light while others provide a dichotomous yes or no. CMS does not believe there is one correct approach to communicating the level of appropriateness to the ordering professional. However, the legislation requires that information be reported on the claim form as to whether the service would or would not adhere to the specified AUC consulted through a particular CDSM, or whether the AUC was not applicable to the service. CMS is requesting feedback from commenters regarding how appropriateness ratings provided by CDSMs could be interpreted and recorded for the purposes of this program.

CMS acknowledges that there are different views about the comprehensiveness of AUC that should be accessible within CDSMs. Some stakeholders, including the ACR, believe that the CDSM should contain as comprehensive collection of AUC as possible, incorporating individual criteria from across all specified AUC libraries. This would limit the frustration of ordering professionals spending time navigating the CDSM only to find that no criterion for their patients’ specific clinical condition exists. Other stakeholders believe that it is best to start with a CDSM that contains AUC for a few clinical areas where impact is large and evidence is strong. They believe this would ensure that quality AUC are developed, and that clinicians and entire care
teams could fully understand the AUC they are using, including when they do not apply to a particular patient.

CMS believe there is merit to both approaches, and it has been suggested that the best approach may depend on the particular care setting. The second, “focused” approach may work better for a large health system that produces and uses its own AUC. The first, “comprehensive” approach may in turn work better for a smaller practice with broad image ordering patterns and fewer resources that wants to simply adopt and start using a complete AUC system developed elsewhere. CMS believes a successful program would allow flexibility, and foresees a number of sets of AUC developed by different PLEs, and an array of CDSMs from which clinicians may choose.

*Priority Clinical Areas (Page 528)*

CMS indicated in the CY 2016 PFS final rule with comment period that they would identify priority clinical areas through rulemaking, and that these may be used in the determination of outlier ordering professionals (a future phase of the Medicare AUC program). The concept of priority clinical areas allows CMS to implement an AUC program that combines the focused and comprehensive approaches to implementation discussed above. Although potentially large volumes of AUC (as some PLEs have large libraries of AUC) would become specified across clinical conditions and advanced imaging technologies, CMS believes this rapid and comprehensive roll out of specified AUC should be balanced with a more focused approach when identifying outlier ordering professionals. CMS believes this will provide an opportunity for physicians and practitioners to become familiar with AUC in identified priority clinical areas prior to Medicare claims for those services being part of the input for calculating outlier ordering professionals.

CMS believes the combination of the comprehensive and focused approaches should be applied to CDSM requirements as they consider a minimum floor of AUC that must be made available to ordering professionals through qualified CDSMs. AUC that reasonably address the entire clinical scope of priority clinical areas could establish a minimum floor of AUC to be included in qualified CDSMs, and the number of priority clinical areas could be expanded through annual rulemaking and in consultation with physicians and other stakeholders. This allows priority clinical areas to roll out judiciously, and build over time.

*Discussion of Statutory Authority (Page 529)*

There are four major components of the AUC program, each with its own implementation date: (1) establishment of AUC by November 15, 2015; (2) identification of mechanisms for consultation with AUC by April 1, 2016; (3) AUC consultation by ordering professionals and reporting on AUC consultation by furnishing professionals by January 1, 2017; and (4) annual identification of outlier ordering professionals for services furnished after January 1, 2017. CMS did not identify mechanisms for consultation by April 1, 2016 and will not have specified or published the list of qualified CDSMs by January 1, 2017; therefore, ordering professionals will not be required to consult CDSMs, and furnishing professionals will not be able to report information on the consultation, by this date.
CMS established the AUC by announcing the qualified PLEs on June 30, 2016. The second major component of the Medicare AUC program is the specification of qualified CDSMs that could be used by ordering professionals for consultation with specified applicable AUC. CMS envisions a CDSM as an interactive tool that communicates AUC information to the user. Information regarding the clinical presentation of the patient would be incorporated into the CDSM from another health IT system or through data entry by the ordering professional. At a minimum, the tool would provide immediate feedback to the ordering professional on the appropriateness of one or more imaging services. Ideally, CDSMs would be integrated within or seamlessly interoperable with existing health IT systems and would automatically receive patient data from the EHR or through an API or other connection. Such integration would minimize burden on practitioners and avoid duplicate documentation. Also useful to clinicians would be the ability to switch between CDSMs that can interoperate based on common standards.

The Act states that the Secretary must specify qualified CDSMs in consultation with physicians, practitioners, health care technology experts, and other stakeholders. This paragraph authorizes the Secretary to specify mechanisms that could include: CDS modules within certified EHR technology; private sector CDSMs that are independent of certified EHR technology; and a CDSM established by the Secretary. The Secretary does not propose to establish a CDSM at this time.

All CDSMs must: make available to the ordering professional applicable AUC and the documentation supporting the appropriateness of the applicable imaging service that is ordered; where there is more than one applicable appropriate use criterion 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 CDSM 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). The Secretary must publish an initial list of specified mechanisms no later than April 1, 2016, and the Secretary must identify on an annual basis the list of specified qualified CDSMs. Therefore, the final CDSM requirements and process for CDSMs to become qualified would be published in the CY 2017 PFS final rule with comment period on or about November 1, 2016.

Given the timing of the PFS rulemaking process, CMS was not able to include proposals in the PFS proposed rule to begin implementation in the same year the PAMA was enacted. CMS has used the time prior to the CY 2017 PFS proposed rule to meet with stakeholders, specifically those related to CDSMs. CMS is continuing their stepwise approach to implementing this AUC program.

For this second phase of implementation, CMS will use this CY 2017 PFS rulemaking process as the vehicle to establish requirements for CDSMs, and the process to specify qualified CDSMs, in a transparent manner that allows for stakeholder and public involvement. Therefore, the final CDSM requirements and process for CDSMs to become qualified would be published in the CY 2017 PFS final rule with comment period on or about November 1, 2016.
The third major component of the AUC program is Consultation with Applicable Appropriate Use Criteria. This section establishes, beginning January 1, 2017, the requirement for an ordering professional to consult with a qualified CDSM 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 CDSM. The statute distinguishes between the ordering and furnishing professional, recognizing that the professional who orders an applicable imaging service is usually not the same professional who bills Medicare for that service when furnished. The Act provides for certain exceptions to the AUC consultation and reporting requirements including in the case of certain emergency services, inpatient services paid under Medicare Part A, and ordering professionals who obtain an exception due to a significant hardship. The applicable payment systems for the AUC consultation and reporting requirements are the PFS, hospital outpatient prospective payment system, and the ambulatory surgical center payment systems.

Since a list of qualified CDSMs is not yet available and will not be available by January 1, 2017, CMS will not require ordering professionals to meet this requirement by that date.

CMS is not proposing to implement the fourth component of the AUC program, identification of outlier ordering professionals, at this time; however, they are proposing a list of priority clinical areas which may serve as part of the basis for identifying outlier ordering professionals.

Proposals for Implementation (Page 534)

CMS proposes to define CDSM as an interactive, electronic tool for use by clinicians that communicates AUC information to the user and assists them in making the most appropriate treatment decision for a patient’s specific clinical condition. A CDSM would incorporate specified applicable AUC sets from which an ordering professional could select. A CDSM may be a module within or available through certified EHR technology or private sector mechanisms independent from certified EHR technology. If within or available through certified EHR technology, a qualified CDSM would incorporate relevant patient-specific information into the assessment of the appropriateness of an applicable imaging service.

Priority Clinical Areas (Page 535)

To compile the proposed list of priority clinical areas, CMS performed an analysis of Medicare claims data using the CMS Chronic Conditions Data Warehouse (CCW) as the primary data source. CMS encourages stakeholders to review this dataset as a source that may help inform comments related to the proposed priority clinical areas. The dataset can be downloaded from the CMS website.

Using the 2014 Medicare claims data referenced above, CMS ranked ICD-9 codes by the frequency with which they were used as the primary indication for specific imaging procedures, which in turn were identified by the volume of individual Current Procedural Terminology (CPT) codes for which payments were made in 2014. The top 135 ICD-9 codes were extracted
from this list and formed clinically-related categories. Next, CMS searched manually through an electronic list of all ICD-9 codes to find others that would plausibly fit into each clinical grouping. This process required subjective clinical judgment on whether a particular ICD-9 code should be included in a given clinical group. The top eight clinical groupings (by volume of procedures) are what are being proposed as the initial list of priority clinical areas. The eight clinical areas account for roughly 40 percent of part B advanced diagnostic imaging services paid for by Medicare in 2014. Some stakeholders suggested beginning the AUC program with no more than five priority clinical areas while others suggested a far greater number. CMS believes the proposed eight priority clinical areas strike a reasonable balance that allows focus on a significant range and volume of advanced diagnostic imaging services.

CMS considered extracting pulmonary embolism as a separate priority clinical area from the chest pain grouping based on stakeholder consultation and feedback. **CMS decided not to identify pulmonary embolism separately, but is asking for public comment on whether pulmonary embolism should be included as a stand-alone priority clinical area.** Based on consultations with physicians, practitioners and other stakeholders, as required the PAMA, CMS attempted to be inclusive when grouping ICD-9 codes into cohesive clinical areas. To see all of the priority clinical area groupings of diagnosis codes, a table is available on the CMS website.

<table>
<thead>
<tr>
<th>Proposed Priority Clinical Area</th>
<th>Total Services</th>
<th>% Total Services</th>
<th>Total Payments</th>
<th>% Total Payments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chest Pain (includes angina, suspected myocardial infarction, and suspected pulmonary embolism)</td>
<td>4,435,240.00</td>
<td>12%</td>
<td>$470,395,545</td>
<td>14%</td>
</tr>
<tr>
<td>Abdominal Pain (any locations and flank pain)</td>
<td>2,973,331.00</td>
<td>8%</td>
<td>$235,424,592</td>
<td>7%</td>
</tr>
<tr>
<td>Headache, traumatic and non-traumatic</td>
<td>2,107,868.00</td>
<td>6%</td>
<td>$89,382,087</td>
<td>3%</td>
</tr>
<tr>
<td>Low back pain</td>
<td>1,883,617.00</td>
<td>5%</td>
<td>$180,063,352</td>
<td>5%</td>
</tr>
<tr>
<td>Suspected stroke</td>
<td>1,810,514.00</td>
<td>5%</td>
<td>$119,574,141</td>
<td>4%</td>
</tr>
<tr>
<td>Altered mental status</td>
<td>1,782,794.00</td>
<td>5%</td>
<td>$83,296,007</td>
<td>3%</td>
</tr>
<tr>
<td>Cancer of the lung (primary or metastatic, suspected or diagnosed)</td>
<td>1,114,303.00</td>
<td>3%</td>
<td>$154,872,814</td>
<td>5%</td>
</tr>
<tr>
<td>Cervical or neck pain</td>
<td>1,045,381.00</td>
<td>3%</td>
<td>$83,899,299</td>
<td>3%</td>
</tr>
</tbody>
</table>

1 Percentage of 2014 Part B non-institutional claim line file for advanced imaging services from Medicare claims for beneficiaries who are enrolled in the fee-for-service (FFS) program (source: CMS Chronic Conditions Data Warehouse).

CMS also engaged the CMS Alliance to Modernize Healthcare (CAMH) Federally Funded Research and Development Center (FFRDC), the MITRE Corporation (MITRE), to begin developing efficient and effective processes for managing current and future health technology assessments. MITRE generated an independent report that presents a summary of findings from claims data from the Medicare population and their utilization of advanced imaging procedures. Coupled with the CMS internal analysis, this report assisted in identification of proposed priority clinical areas for the Medicare AUC program for advanced diagnostic imaging services. Analysis and methods for this report are available [here](#).
While this year CMS is proposing priority clinical areas based on an analysis of claims data alone, they may use a different approach in future rulemaking cycles. CMS may consider factors other than volume when proposing priority clinical areas including incidence and prevalence of disease, variability of use of particular imaging services, strength of evidence supporting particular imaging services and the applicability of a clinical area to a variety of care settings and to the Medicare population.

**CMS encourages public comments on this proposed initial list of priority clinical areas, including recommendations for other clinical areas that should be included among the list of priority clinical areas. In particular, CMS is interested in comments on the above methodology or alternate options; whether the proposed priority clinical areas are appropriate including information on the extent to which these proposed priority clinical areas may be represented by clinical guidelines or AUC in the future. CMS is also interested in public comments, supported by published information, with respect to varying levels of evidence that exist across as well as within priority clinical areas.**

**CDSM Qualifications and Requirements (Page 539)**

CMS believes that, at least initially, it is in the best interest of the program to establish CDSM requirements that are not prescriptive about specific IT standards. Rather, CMS is proposing an approach that focuses on the functionality and capabilities of qualified CDSMs. The CDSM, EHR and health IT environments are constantly changing and improving and CMS wants to allow room for growth and innovation. However, in the future, as more stakeholders and other entities including the ONC, AHRQ, and relevant standards development organizations come to consensus regarding standards for CDSMs, then CMS may consider pointing to such standards as a requirement for qualified CDSMs under this program. CMS believes standards would make it possible to achieve interoperability, allowing any CDSM to incorporate any standardized AUC and for sets of AUC to be easily interchangeable among various CDSMs. CMS will continue to work with the ONC and AHRQ to facilitate movement in this direction.

The Act requires qualified CDSMs to make available to the ordering professional specified applicable AUC and the supporting documentation for the applicable imaging service ordered. CMS does not interpret this requirement to mean that every qualified CDSM must make available every specified applicable AUC. In the CY 2016 PFS final rule with comment period, CMS allowed for the approval of massive libraries of AUC (resulting from approvals for qualified PLEs with comprehensive and extensive libraries), yet they expressed an intention to establish priority clinical areas. While there is a statutory requirement to consult AUC for each applicable imaging service, CMS recognizes that ordering professionals may choose to thoroughly improve their understanding of, and focus their internal quality improvement (QI) programs on, those priority clinical areas; and these areas will in turn serve as the basis for future outlier calculations.

Consistent with that approach, CMS proposes to add a requirement that qualified CDSMs must make available to ordering professionals, at a minimum, specified applicable AUC that reasonably encompass the entire clinical scope of all priority clinical areas. CMS encourages and
expects some CDSMs, based on the needs of the professionals they serve, will choose to include a far more comprehensive set of AUC going above and beyond the minimum. When this Medicare AUC program is fully implemented, all ordering professionals must consult specified applicable AUC through a qualified CDSM for every applicable imaging service that would be furnished in an applicable setting and paid for under an applicable payment system in order for payment to be made for the service. However, when identifying the outlier ordering professionals who will be subject to prior authorization beginning in 2020, CMS anticipates focusing on consultation with specified applicable AUC within priority clinical areas rather than the universe of specified applicable AUC. The concept of priority clinical areas will allow CMS to implement an AUC program that combines two approaches to implementation allowing clinicians flexibility to either engage with a rapid rollout of comprehensive specified applicable AUC or adopt a focused approach to consulting AUC. Thus, they can choose their approach and select a CDSM and AUC set(s) that fit their needs and preferences, while being sure that each qualified CDSM will include AUC that address all priority clinical areas.

CMS further proposes to add a requirement that qualified CDSMs must be able to incorporate specified applicable AUC from more than one qualified PLE. CMS believes this approach ensures that CDSMs can expand the AUC libraries they can provide access to in order to represent AUC across all priority clinical areas. CMS does not necessarily expect that a single qualified PLE will develop AUC addressing every priority clinical area domain, especially since over time and through future rulemaking, the list of priority clinical areas will expand and cross additional clinical domains. Ensuring that qualified CDSMs are not limited in their technology to incorporating AUC from only one qualified PLE will help to ensure that ordering professionals will not be in a position of consulting a CDSM that cannot offer them access to AUC that address all priority clinical areas. As stakeholders continue to advance CDSM technology, CMS looks forward to standards being developed and widely accepted so that AUC are incorporated in a standardized format across CDSM platforms. Increasing standardization in this area will move the industry closer to the goal of interoperability across CDSMs and EHRs.

CMS proposes to add a requirement that the qualified CDSM must clearly identify the appropriate use criterion consulted if the tool makes available more than one criterion relevant to a consultation for a patient’s specific clinical scenario. This is important since CDSMs that choose to incorporate a comprehensive AUC library may be offering the ordering professional access to AUC from multiple qualified PLEs. In such scenarios, it is important that the ordering professional knows which appropriate use criterion is being consulted and have the option to choose one over the other if more than one criterion applies to the scenario.

CMS proposes to add a requirement that the qualified CDSM must provide to the ordering professional a determination, for each consultation, of the extent to which an applicable imaging service is consistent with specified applicable AUC or a determination of “not applicable” when the mechanism does not contain a criterion that would apply to the consultation. This determination would communicate the appropriateness of the applicable imaging service to the ordering professional.

CMS proposes to add a requirement that the qualified CDSM must generate and provide to the ordering professional certification or documentation that documents which qualified CDSM was
consulted, the name and NPI of the ordering professional that consulted the CDSM and whether the service ordered would adhere to applicable AUC, whether the service ordered would not adhere to such criteria, or whether such criteria was not applicable for the service ordered. This certification or documentation must be issued each time an ordering professional consults the qualified CDSM. Since Medicare claims will be filed only for services that are rendered to beneficiaries, CMS will not see CDSM consultation information on the claim form specific to imaging services that are not ordered. CMS believes that for the CDSM to be able to provide meaningful feedback to ordering professionals, information regarding consultations that do not result in imaging is just as important as information on consultations that do result in an order for advanced imaging.

Thus, CMS proposes to require that the documentation or certification provided by the qualified CDSM must include a unique consultation identifier. This would be a unique code issued by the CDSM that is specific to each consultation by an ordering professional. This type of unique code may serve as a platform for future collaboration and aggregation of consultation data across CDSMs. In addition, at some point in the future, this unique code may assist in more seamlessly bringing Medicare data together with CDSM clinical data to maximize quality improvement in clinical practices and to iteratively improve the AUC itself.

CMS proposes that the specified applicable AUC content within qualified CDSMs be updated at least every 12 months to reflect revisions or updates made by qualified PLEs to their AUC sets or to an individual appropriate use criterion. CMS proposes 12 months as the maximum acceptable delay for updating content. CMS believes that in most cases it will be possible to update AUC content more frequently than every 12 months, particularly for cloud-based CDSMs. CMS further proposes that qualified CDSMs have a protocol in place to more expeditiously remove AUC that are determined by the qualified PLE to be potentially dangerous to patients and/or harmful if followed. In addition, CMS proposes that qualified CDSMs must make available for consultation specified applicable AUC that address any new priority clinical areas within 12 months of the priority clinical area being finalized by CMS. The agency believes this would allow the CDSM sufficient time to incorporate the AUC into the CDSM. Thus, any new priority clinical areas finalized, for example, in the CY 2018 PFS final rule with comment period that would be effective January 1, 2018, would need to be incorporated into a qualified CDSM by January 1, 2019. To accommodate this time frame, CMS would accept a not applicable determination from a CDSM for a consultation on a priority clinical area for dates of service through the 12-month period that ends, in this example, on January 1, 2019. CMS notes that all qualified CDSMs that are approved by June 30, 2017 should be capable of supporting AUC for all priority clinical areas that are finalized in the CY 2017 PFS final rule with comment period.

CMS proposes to add a requirement that the qualified mechanism must meet privacy and security standards under applicable provisions of law. Potentially applicable laws may include the HIPAA Privacy and Security rules.

CMS proposes to add a requirement that qualified CDSMs must provide ordering professionals aggregate feedback in the form of an electronic report on an annual basis (at minimum) regarding their consultations with specified applicable AUC. The intent is to require records to
be retained in a manner consistent with the HIPAA Security Rule. To provide such feedback, and
to make detailed consultation information available to ordering professionals, furnishing
professionals (when they have authorized access to the CDSM), auditors and CMS, CMS
proposes that a qualified CDSM must maintain electronic storage of clinical, administrative and
demographic information of each unique consult for a minimum of 6 years. CDSMs could fulfill
this requirement in a number of ways, including involving a third party in the storage of
information as well as for providing feedback to ordering professionals. CMS recognizes that
these requirements represent a minimum floor that clinicians may choose to expand upon in their
local QI programs.

In the event requirements are modified through rulemaking during the course of a qualified
CDSM’s 5-year approval cycle, CMS proposes that the CDSM would be required to comply
with the modification(s) within 12 months of the effective date of the modification.

Process for CDSMs to Become Qualified and Determination of Non-Adherence (Page 545)

CMS proposes to require that CDSM developers must submit applications for review that
document adherence to each of the CDSM requirements. Applications to be specified as a
qualified CDSM must be submitted by January 1 of a year in order to be reviewed within that
year’s review cycle. For example, the first applications would be accepted from the date of
publication of the PFS final rule until January 1, 2017. A determination on whether the
applicants are qualified would be made by June 30, 2017. Applications must be submitted
electronically to ImagingAUC@cms.hhs.gov. This process and timeline mirror the qualified PLE
application and approval process and timeline. As was done for qualified PLEs, CMS will post a
list of all applicants that are determined to be qualified CDSMs to their website at
https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Appropriate-
Use-Criteria-Program/index.html by June 30. CMS proposes that all qualified CDSMs must
reapply every 5 years and their applications must be received by January 1 during the 5th year
that they are qualified CDSMs. It is important to note that, as with PLE applications, the
application for qualified CDSMs is not a CMS form; rather it is created by the applicant. A
CDSM that is specified as qualified for the first 5-year cycle beginning on July 1, 2017 would be
required to submit an application for requalification by January 1, 2022. A determination would
be made by June 30, 2022, and, if approved, the second 5-year cycle would begin on July 1,
2022. CMS details the information that should be included in the CDSM applications on pages
768-772 of the display copy of the PFS proposed rule. CMS notes that they anticipate
approximately 30 applications based on the number of existing CDSMs that have expressed an
interest in incorporating AUC for advanced diagnostic imaging. After the initial anticipated 30
respondents, CMS expects less than 10 applicants to apply to become qualified CDSMs
annually.

CMS proposes that at any time, they may remove from the list of qualified CDSMs a CDSM that
fails to meet the criteria to be a qualified CDSM or consider this information during the
requalification process. Such determinations may be based on public comment or CMS’ own
review and CMS may consult with the National Coordinator for Health Information Technology
or her designee to assess whether a qualified CDSM continues to adhere to requirements.
CMS invites comments on how they could streamline and strengthen the approval process for CDSMs in future program years. For instance, CMS may consider a testing framework for CDSMs that would validate adherence to specific standards that enable seamless incorporation of AUC across CDSMs.

Consultation by Ordering Professional and Reporting by Furnishing Professional (Page 547)

CMS states that although they continue to aggressively move forward to implement this AUC program, ordering professionals will not be expected to consult qualified CDSMs by January 1, 2017. At the earliest, under this proposal, the first qualified CDSM(s) will be specified on June 30, 2017. CMS anticipates that some ordering professionals could be able to begin consulting AUC through qualified CDSMs very quickly as some may already be aligned with a qualified CDSM.

CMS anticipates that furnishing professionals may begin reporting as early as January 1, 2018.

This reporting delay is necessary to allow time for ordering practitioners who are not already aligned with a qualified CDSM to research and evaluate the qualified CDSMs so they may make an informed decision. While there will be further rulemaking next year, CMS is announcing this date because the agency expects physicians and other stakeholders/regulated parties to begin preparing themselves to begin reporting on that date. CMS will adopt procedures for capturing this information on claims forms and the timing of the reporting requirement through PFS rulemaking for CY 2018.

As CMS expects to implement the AUC consultation and reporting requirements on January 1, 2018, they are interested in receiving feedback from the public to include a discussion of specific operational considerations that they should take into account and include in such rulemaking. For example, commenters could consider alternatives for reporting data on claims and for seeking exceptions, as discussed below. CMS also seeks information on the barriers to implementation along this timeline that allows ordering and furnishing professionals to be prepared to consult AUC and report consultation information on the claims and whether separate rulemaking outside of the payment rule cycle would be preferred.

CMS is considering the mechanisms for appending the AUC consultation information to various types of Medicare claims and expect to develop requirements for appending such information in the CY 2018 PFS rulemaking process. Stakeholders interested in sharing feedback related to reporting and claims processing are welcome to do so as part of the comment period for this proposed rule. CMS is particularly interested in receiving feedback on, for example, whether the information should be collected using HCPCS level II G codes or HCPCS modifiers. CMS will use this feedback to inform CY 2018 rulemaking.
The statute provides for an exception where an applicable imaging service is ordered for an individual with an emergency medical condition. CMS believes this exception is warranted because there can be situations in which a delay in action would jeopardize the health or safety of individuals. CMS believes that these situations occur primarily in the emergency department, but recognizes that emergent situations could potentially arise in other settings and also that most encounters in an emergency department are not for an emergency medical condition. CMS proposes to provide for an exception to the AUC consultation and reporting requirements for an applicable imaging service ordered for an individual with an emergency medical condition as defined in section 1867(e)(1) of the Act. To meet the exception for an emergency medical condition, the clinician only needs to determine that the medical condition manifests itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in: placing the health of the individual (or a woman’s unborn child) in serious jeopardy; serious impairment to bodily functions; or serious dysfunction of any bodily organ or part. CMS will propose in future rulemaking how this exception will be identified on Medicare claims.

The second exception is for applicable imaging services ordered for an inpatient and for which payment is made under Medicare Part A. The third exception is for applicable imaging services ordered by an ordering professional who the Secretary determines, on a case-by-case basis and subject to annual renewal that consultation with applicable AUC would result in a significant hardship, such as in the case of a professional practicing in a rural area without sufficient Internet access. CMS proposes to codify this exception by specifying that ordering professionals who are granted a significant hardship exception for purposes of the Medicare EHR Incentive Program payment adjustment would also be granted a significant hardship exception for purposes of the AUC consultation requirement. CMS will revisit this option for years after 2018 as the Current EHR Incentive Program payment adjustment is set to expire after the 2018 payment year. CMS also discusses considerations for a supplemental process to account for hardships for ordering professionals that are not eligible to apply for a significant hardship under the HER Incentive Program (for example, non-physician practitioners). CMS is seeking feedback from commenters regarding processes that could be put in place to accommodate ordering professionals with primary specialties that categorically receive significant hardship exceptions under the EHR Incentive Program, real-time hardships that arise during a year, and ordering professionals that are not eligible to apply using the EHR Incentive Program significant hardship exception process and need to seek a significant hardship exception for the purposes of the AUC program. CMS intends to propose a process in the CY 2018 PFS proposed rule.

Procedures Subject to the Multiple Procedure Payment Reduction (MPPR) and the OPPS Cap (Page 233)

The Consolidated Appropriations Act of 2016 revised the MPPR for the professional component of advanced imaging services from the current 25 percent to 5 percent, effective January 1, 2017. CMS proposes to implement this change, noting that the change is exempt from budget neutrality
and as such, it will result in an adjustment to the conversion factor. This is detailed in the conversion factor discussion of the proposed rule.

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

CMS is proposing to price the professional PACS workstation at $14,616.93 based on submitted invoices. They are not proposing a change in price for the current technical PACS workstation, which will remain at a price of $5,557.00.

CMS is proposing to add the professional PACS workstation to many CPT codes in the 70000 series that use the current technical PACS workstation and include professional work for which such a workstation would be used. CMS is not proposing to add the equipment item to add-on codes since the base codes would include minutes for the item. They are also not proposing to add the item to codes that are therapeutic in nature (i.e. radiation therapy, nuclear medicine cardiology), as the professional PACS workstation is intended for use in diagnostic services. CMS is also not proposing to add the item to image guidance codes where the dominant provider is not a radiologist (77002, 77011, 77071, 77077, and 77081) according to the most recent year of claims data, since a single workstation would be more typical in those cases. CMS identified approximately 426 codes to which they are proposing to add a professional PACS workstation. These codes are listed in Table 4 of the proposed rule beginning on page 48 of the display copy.

For the professional PACS workstation, CMS is proposing to assign equipment time equal to the intraservice work time plus half of the preservice work time associated with the codes, since the work time generally reflects the time associated with the professional interpretation. For older codes that do not have a breakdown of physician work time by service period, and only have an overall physician work time, CMS is proposing to use half the total work time as an approximation of the intraservice work time plus one half of the preservice work time.

**CMS notes that they also considered using an equipment time formula of the physician intraservice time plus 1 minute (as a stand-in for the physician preservice work time) and is seeking public comment on the most accurate equipment time formula for the professional PACS workstation.**

**CMS is also seeking public comment on the proposed list of codes that would incorporate the professional PACS workstation.** Specifically, CMS is interested in public comment on the codes for which a professional PACS workstation should be included, and whether one of these professional workstations should be included for codes outside the 70000 series. In cases within the 70000 series where radiologists are not the typical specialty reporting the code, such as CPT codes 77002 and 77011, CMS is asking whether it would be appropriate to add one of the professional PACS workstations to these services.

**Clinical Labor Tasks Associated with Digital Imaging (Page 52)**

In the CY 2016 PFS final rule, CMS finalized standard minutes for four clinical labor activities associated with services that use digital imaging technology.
TABLE 5: Clinical Labor Tasks Associated with Digital Imaging Technology

<table>
<thead>
<tr>
<th>Clinical Labor Task</th>
<th>Typical Minute</th>
</tr>
</thead>
<tbody>
<tr>
<td>Availability of prior images confirmed</td>
<td>2</td>
</tr>
<tr>
<td>Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam</td>
<td>2</td>
</tr>
<tr>
<td>Review examination with interpreting MD</td>
<td>2</td>
</tr>
<tr>
<td>Exam documents scanned into PACS. Exam completed in RIS system to generate billing process and to populate images into Radiologist work queue.</td>
<td>1</td>
</tr>
</tbody>
</table>

CMS did not finalize standard minutes for the activity “Technologist QC’s images in PACS, checking for all images, reformats, and dose page”. CMS agreed with ACR comments that this task may require a variable length of time depending on the number of images to be reviewed. CMS solicited comment on the subject in the CY 2016 final rule.

The proposed rule indicated that many commenters expressed that this clinical labor activity should not have a standard value time, but rather time should be assigned on a code by code basis. CMS does not agree that the varying amounts of time precludes the possibility of establishing standards for clinical labor tasks as they have done in the past by creating multiple standard times, for example, those assigned to cleaning different kinds of scopes.

CMS is proposing to establish a range of appropriate standard minutes for the clinical labor activity Technologist QC images in PACS, checking for all images, reformats, and dose page. These standard minutes will be applied to new and revised codes that make use of this clinical labor activity when they are reviewed for valuation. CMS is proposing 2 minutes as the standard for the simple case (x-rays), 3 minutes as the standard for the intermediate case (CTs and MRIs), and 4 minutes as the standard for the most highly complex services which would exceed these more typical cases.

**CMS is soliciting comments regarding the most accurate category for existing codes and in particular what criteria might be used to identify complex cases systematically.**

**Equipment Maintenance (Page 42)**

CMS states that they continue to investigate potential options for determining equipment maintenance costs for a broad range of equipment items; however, no proposals were included in the rule.

**Interest Rates (Page 43)**

CMS is not proposing any changes to the interest rates used in developing the equipment cost per minute calculations for CY 2017.
Technical Corrections to Direct PE Input Database (Page 60)

For CPT codes 72081-72084, the ACR informed CMS in our CY 2016 final rule comments that the equipment time for the PACS workstation should be equal to the clinical labor during the service period; the equipment time formula used for these codes for CY 2016 erroneously included 4 minutes of preservice clinical labor. CMS agreed that the PACS workstation should use the standard equipment time formula for a PACS workstation for these codes. As a result, they are proposing to refine the ED050 equipment time to 21 minutes for CPT code 72081, 36 minutes for CPT code 72082, 44 minutes for CPT code 72083, and 53 minutes for CPT code 72084 to reflect the clinical labor time associated with these codes. Additionally, a number of clinical labor activities had been entered in the database in the incorrect service period for CPT codes 37215, 50432, 50694, and 72081. These clinical labor activities were incorrectly listed in the “postservice” period instead of the “service post” period. CMS is proposing to make these technical corrections as well so that the minutes are assigned to the appropriate service period within the direct PE input database.

Determination of Malpractice Relative Value Units (Page 64)

CMS is required to review and adjust if necessary, malpractice RVUs no less often than every 5 years. The third review and update was implemented in CY 2015.

The proposed CY 2017 GPCI update of this proposed rule reflects updated MP premium data, collected for the purpose of proposing updates to the MP GPCIs. CMS states that they could use the updated MP premium data obtained for the GPCI update to propose updates to the specialty risk factors used in the calculation of MP RVUs, however, this would not be consistent with the policy previously finalized in the CY 2016 final rule. In that rule, CMS indicated that specialty-specific risk factors would continue to be updated through notice and comment period every 5 years, but would remain unchanged in between. CMS is seeking comment on whether they should consider doing so, perhaps as early as 2018, prior to the next review and update of the MP RVUs that must occur no later than CY 2020.

Medicare Telehealth Services (Page 67)

CMS is proposing to add the following codes to the list of Medicare telehealth services beginning on January 1, 2017:

- ESRD-related services 90967 through 90970. The required clinical examination of the catheter access site must be furnished face-to-face “hands on” (without the use of an interactive telecommunications system) by a physician, CNS, NP, or PA.
- Advance care planning (CPT codes 99497 and 99498)
- Telehealth Consultations for a Patient Requiring Critical Care Services (GTTT1 and GTTT2)

CMS reminds stakeholders that they are currently soliciting public requests to add services to the list of Medicare telehealth services. To be considered during the PFS rulemaking for CY 2018, these requests must be submitted and received by December 31, 2016.
CMS has received multiple requests from various stakeholders to establish a POS code to identify services furnished via telehealth. CMS notes that the process for establishing POS codes is managed by the POS Workgroup within CMS. CMS is proposing how a POS code for telehealth would be used under the PFS with the expectation that, if such a code is available, it would be used as early as January 1, 2017. CMS proposes that the physicians or practitioners furnishing telehealth services would be required to report the telehealth POS code to indicate that the billed service is furnished as a telehealth service from a distant site.

CMS is also proposing to use the facility PE RVUs to pay for telehealth services reported by physicians or practitioners with the telehealth POS code. In addition, CMS is proposing a change to resolve any potential ambiguity and clarify that payment under the PFS is made at the facility rate when services are furnished in a hospital but for which the hospital is not being paid. This proposed change is aligned with regulatory changes being proposed in the HOPPS proposed rule.

**Potentially Misvalued Services under the Physician Fee Schedule (Page 92)**

*0-Day Global Services that are Typically Billed with an Evaluation and Management Service with Modifier 25 (Page 99)*

CMS proposes to include 0-day global codes billed with an E/M service 50 percent of the time or more, on the same day of service, with the same physician and same beneficiary. CMS identified a list of 83 CPT codes that have not been reviewed in the last 5 years, and with greater than 20,000 allowed services. These codes are listed in Table 7 beginning on page 101 of the display copy of the proposed rule. Below is a list of the radiology codes included in Table 7. CMS requests public input on additional ways to address appropriate valuations for all services that are typically billed with an E/M with Modifier 25.

- 20550  Injection(s); single tendon sheath, or ligament, aponeurosis (eg, plantar "fascia")
- 20600  Arthrocentesis, aspiration and/or injection, small joint or bursa (eg, fingers, toes); without ultrasound guidance
- 20604  Arthrocentesis, aspiration and/or injection, small joint or bursa (eg, fingers, toes); with ultrasound guidance, with permanent recording and reporting
- 20605  Arthrocentesis, aspiration and/or injection, intermediate joint or bursa (eg, temporomandibular, acromioclavicular, wrist, elbow or ankle, olecranon bursa); without ultrasound guidance
- 20606  Arthrocentesis, aspiration and/or injection, intermediate joint or bursa (eg, temporomandibular, acromioclavicular, wrist, elbow or ankle, olecranon bursa); with ultrasound guidance, with permanent recording and reporting
- 20610  Arthrocentesis, aspiration and/or injection, major joint or bursa (eg, shoulder, hip, knee, subacromial bursa); without ultrasound guidance
  
  Arthrocentesis, aspiration and/or injection, major joint or bursa (eg, shoulder, hip, knee, subacromial bursa), with ultrasound guidance, with permanent recording and reporting
- 20611  

16
31500  Intubation, endotracheal, emergency procedure
Tube thoracostomy, includes connection to drainage system (eg, water seal), when
performed, open (separate procedure)

32551  Thoracentesis, needle or catheter, aspiration of the pleural space; without imaging
guidance

32554  Change of gastrostomy tube, percutaneous, without imaging or endoscopic guidance
(To report fluoroscopically guided replacement of gastrostomy tube use, 49450)

43760  Insertion of non-indwelling bladder catheter (eg, straight catheterization for residual
urine)

51701  ... ... ... ... ... ...

Direct PE Input Discrepancies (Page 105)

CMS proposes to explore potential inconsistencies with the inputs and the prices related to
diagnostic procedures in the direct PE database. Upon review, CMS noted that there are 45
different pieces of endoscope related equipment and 25 different pieces of endoscope related
supplies that are currently associated with these services. Given the frequency with which
individual codes can be reviewed and the importance of standardizing inputs for purposes of
maintaining relativity across PFS services, CMS believes that this unusual degree of variation is
likely to result in code misevaluation. CMS requests that stakeholders like the RUC review
and make recommendations on the appropriate endoscopic equipment and supplies
typically provided in all endoscopic procedures for each anatomical body region, along
with their appropriate prices.

Valuing Services that include Moderate Sedation as in Inherent Part of Furnishing the
Procedure (Page 107)

The CPT manual identifies more than 400 diagnostic and therapeutic procedures (listed in
Appendix G) for which the CPT Editorial Committee has determined that moderate sedation is
an inherent part of furnishing the procedure. CMS points out that the resource costs associated with sedation were no longer incurred by the practitioner reporting the Appendix G procedure. CMS noted in the 2015
PFS proposed rule that it appeared that practice patterns for endoscopic procedures were
changing, with anesthesia increasingly being separately reported for these procedures, meaning
that the resource costs associated with sedation were no longer incurred by the practitioner
reporting the Appendix G procedure. CMS solicited input on establishing a uniform approach to
the appropriate valuation of Appendix G services for which moderate sedation is no longer
inherent. In response, the CPT Editorial Panel created CPT codes for separately reporting
moderate sedation services in association with the elimination of Appendix G from the CPT
manual for CY 2017. This coding change would provide payment for moderate sedation services
only in cases where it is furnished. The RUC provided recommended values for the new codes as
well as a methodology for revaluing all services previously identified in Appendix G, without
moderate sedation, in order to make appropriate corresponding adjustments for the procedural
services.

The RUC’s recommended methodology would remove work RVUs for moderate sedation from
Appendix G codes based on a code-level assessment of whether the procedures are typically
performed on straightforward patients or more difficult patients. Based on its recommended methodology, the RUC is recommending removal of fewer RVUs from each of the procedural services than it recommends for valuing the moderate sedation services. If CMS were to use the RUC-recommended values for both the moderate sedation codes and the Appendix G procedural codes without refinement, overall payments for these procedures, when moderate sedation is furnished, would increase relative to the current payment.

CMS details their proposed valuation of the new moderate sedation codes and their proposed uniform methodology for revaluation of the procedural codes in the section of the rule on CPT code valuation.

CMS also notes that stakeholders presented information to CMS regarding specialty group survey data for physician work. The stakeholders shared survey results for physician work involved in furnishing moderate sedation that demonstrated a significant bimodal distribution between procedural services furnished by gastroenterologists and procedural services furnished by other specialties. CMS has addressed the variations between the GI and other specialties in their review of the new moderate sedation CPT codes and their recommended values.

Collecting Data on Resources Used in Furnishing Global Services (Page 109)

In previous rulemaking, CMS discussed the problems with accurate valuation of 10- and 90-day global packages and developed a policy to transform all 10-day and 90-day global codes to 0-day global codes in CY 2017 and CY 2018 respectively, to improve the accuracy of valuation and payment. Subsequently, the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) was passed, prohibiting the Secretary from implementing the policy. Instead, MACRA requires CMS to collect data to value surgical services and develop, through rulemaking, a process to gather the information needed to value surgical services from a representative sample of physicians, and requires that the data collection begin no later than January 1, 2017. MACRA authorizes the Secretary, through rulemaking, to delay up to 5 percent of the PFS payment for services for which a physician is required to report information until the required information is reported. Finally, MACRA requires that beginning in 2019, CMS must use the information collected as appropriate, along with other available data, to improve the accuracy of valuation of surgical services under the PFS.

CMS sought comment from stakeholders on implementation of this data collection in the CY 2016 proposed rule. In response to the comments received, CMS held a listening session on January 20, 2016, which was attended by 658 participants.

CMS is proposing a three-pronged approach to collect timely and accurate data on the frequency of and inputs involved in furnishing global services, including:

1. Comprehensive claims-based reporting about the number and level of pre- and post-operative visits furnished for 10- and 90-day global services.
2. A survey of a representative sample of practitioners about the activities involved in and the resources used in providing a number of pre- and post-operative visits during a specified, recent period of time, such as two weeks.
3. A more in-depth study, including direct observation of the pre- and post-operative care delivered in a small number of sites, including some ACOs.

CMS modified their contract with RAND to include the development of G-codes that could be used to collect data. RAND recommended a set of time-based, post-operative visit codes that could be used for reporting care provided during the post-operative period. The recommended codes are distinguished by the setting of care and whether they are furnished by a physician/NPP or by clinical staff. All codes are intended to be reported in 10-minute increments. CMS is proposing the following codes be used for reporting on claims the services actually furnished but not separately payable because they are part of global packages.

**TABLE 9: Proposed Global Service Codes**

<table>
<thead>
<tr>
<th>Inpatient</th>
<th>GXXX1</th>
<th>Inpatient visit, typical, per 10 minutes, included in surgical package</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>GXXX2</td>
<td>Inpatient visit, complex, per 10 minutes, included in surgical package</td>
</tr>
<tr>
<td></td>
<td>GXXX3</td>
<td>Inpatient visit, critical illness, per 10 minutes, included in surgical package</td>
</tr>
<tr>
<td>Office or Other</td>
<td>GXXX4</td>
<td>Office or other outpatient visit, clinical staff, per 10 minutes, included in surgical package</td>
</tr>
<tr>
<td>Outpatient</td>
<td>GXXX5</td>
<td>Office or other outpatient visit, typical, per 10 minutes, included in surgical package</td>
</tr>
<tr>
<td></td>
<td>GXXX6</td>
<td>Office or other outpatient visit, complex, per 10 minutes, included in surgical package</td>
</tr>
<tr>
<td>Via Phone or</td>
<td>GXXX7</td>
<td>Patient interactions via electronic means by physician/NPP, per 10 minutes, included in surgical package</td>
</tr>
<tr>
<td>Internet</td>
<td>GXXX8</td>
<td>Patient interactions via electronic means by clinical staff, per 10 minutes, included in surgical package</td>
</tr>
</tbody>
</table>

Table 10 (below) lists activities that RAND recommended to be reported as a typical visit. Visits that involve any combination or number of the services listed in Table 10 would be reported using GXXX1. Based on their findings, RAND believes that the vast majority of inpatient post-operative visits would be expected to be reported using GXXX1.
Inpatient pre- and post-operative visits that are more complex than typical visits but do not qualify as critical illness visits would be coded using GXXX2 (Inpatient visit, complex, per 10 minutes, included in surgical package). To report this code, the practitioner would be required to furnish services beyond those included in a typical visit and have documentation that indicates what services were provided that exceeded those included in a typical visit.

The highest level of inpatient pre- and post-operative visits, critical illness visits (GXXX3 - Inpatient visit, critical illness, per 10 minutes, included in surgical package) would be reported when the physician is providing primary management of the patient at a level of care that would be reported using critical care codes if it occurred outside of the global period. This involves acute impairment of one or more vital organ systems such that there is a high probability of imminent or life threatening deterioration in the patient's condition. Similar to how time is now counted for the existing CPT critical care codes, all time spent engaged in work directly related to the individual patient’s care would count toward the time reported with the inpatient visit codes; this includes time spent at the immediate bedside or elsewhere on the floor or unit, such as time spent with the patient and family members, reviewing test results or imaging studies, discussing care with other staff, and documenting care.

For reporting post-operative visits in the office or other outpatient setting, time would be defined as the face-to-face time with patient, which reflects the current rules for time-based outpatient codes. Under the CMS proposal, GXXX4 would be used for visits in which the clinical care is provided by clinical staff. GXXX5 would be used for reporting any combination of activities in Table 10, which are expected to be the vast majority of office or other outpatient visits. GXXX6 would be used infrequently in complex situations, for example, management of a patient with comorbidities or high likelihood of dying, management of a significant complication, or management or discussion of a complex diagnosis. Practitioners would include documentation in the medical record as to what services were provided that exceeded those included in a typical visit.

### TABLE 10: Activities Included in Typical Visit (GXXX1 & GXXX5)

<table>
<thead>
<tr>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Review vitals, laboratory or pathology results, imaging, progress notes</td>
</tr>
<tr>
<td>Take interim patient history and evaluate post-operative progress</td>
</tr>
<tr>
<td>Assess bowel function</td>
</tr>
<tr>
<td>Conduct patient examination with a specific focus on incisions and wounds, post-surgical pain, complications, fluid and diet intake</td>
</tr>
<tr>
<td>Manage medications (for example, wean pain medications)</td>
</tr>
<tr>
<td>Remove stitches, sutures, and staples</td>
</tr>
<tr>
<td>Change dressings</td>
</tr>
<tr>
<td>Counsel patient and family in person or via phone</td>
</tr>
<tr>
<td>Write progress notes, post-operative orders, prescriptions, and discharge summary</td>
</tr>
<tr>
<td>Contact/coordinate care with referring physician or other clinical staff</td>
</tr>
<tr>
<td>Complete forms or other paperwork</td>
</tr>
</tbody>
</table>
Services that are provided via phone, the internet, or other electronic means outside the context of a face-to-face visit would be reported using GXXX7 when furnished by a practitioner and GXXX8 when furnished by clinical staff. CMS is proposing that practitioners would not report these services if they are furnished the day before, the day of, or the day after a visit as CMS believes these would be included in the pre- and post-service activities in the typical visit. However, CMS is proposing that these codes be used to report non-face-to-face services provided by clinical staff prior to the primary procedure since global surgery codes are typically valued with assumptions regarding pre-service clinical labor time. Given that some practitioners have indicated that services they furnish commonly include activities outside the face-to-face service, CMS believes it is important to capture information about those activities in both the pre- and postservice periods. For services furnished via interactive telecommunications that meet the requirements of a Medicare telehealth service visit, the appropriate global service G-code for the services should be reported with the GT modifier to indicate that the service was furnished “via interactive audio and video telecommunications systems.”

CMS seeks comments on all aspects of these codes, including the nature of the services described, the time increment, and any other areas of interest to stakeholders. CMS is particularly interested in any pre- or post-operative services furnished that could not be appropriately captured by these codes. CMS is seeking comment on whether the codes discussed above are appropriate for collecting data on pre-operative services or whether additional codes should be added to distinguish in the data collected the resources used for pre-operative services from those used for post-operative services.

Many stakeholders expressed strong support for the use of CPT code 99024 (Postoperative follow-up visit, normally included in the surgical package, to indicate that an evaluation and management service was performed during a postoperative period for a reason(s) related to the original procedure) to collect data on post-operative care. CMS does not believe that this code along would provide the information that they need, however, they are soliciting comments on specifically how they could use this code to capture the statutorily required data on the number and level of visits and the data that CMS would need to value global services in the future.

CMS is also seeking comment on whether time of visits could alone be a proxy for the level of visit. If pre- and post-operative care varies only by the time the practitioner spends care so that time could be a proxy for complexity of the service, then they could use the reporting of CPT code 99024 in 10-minute increments to meet the statutory requirement of collecting claims-based data on the number and level of visits. In addition to comments on whether time is an accurate proxy for level of visit, CMS is seeking comment on the feasibility and desirability of reporting CPT 99024 in 10-minute increments.

CMS intends to allow practitioners the flexibility to report the services on a rolling basis as they are furnished or to report all of the services on one claim once all have been furnished, as long as the filed claims meet the requirements for filing claims. Documentation that would be expected is an indication that a visit occurred or a service was furnished and sufficient information to determine that the appropriate G-code was reported.
To use the data reported on post-operative visits for analysis and valuation, CMS proposes to link the data reported on post-operative care to the related procedure using date of service, practitioner, beneficiary, and diagnosis. They believe this approach to matching will allow them to accurately link the preponderance of G-codes to the related procedure. However, **CMS solicits comment on the extent to which post-operative care may not be appropriately linked to related procedures, whether they should consider using additional variables to link these aspects of the care, and whether additional data should be required to be reported to enable a higher percentage of matching.**

**CMS is also seeking comment on whether special provisions are needed to capture the pre- and post-operative services provided by residents in teaching settings.** If CMS values services without accounting for services provided by residents that would otherwise be furnished by the surgeon in non-teaching settings, subsequent valuations based upon the data collected may underestimate the resources used, particularly for the types of surgeries typically furnished in teaching facilities. However, there is also a risk of overvaluing services if the reporting includes services that are provided by residents when those services would otherwise be furnished by a physician other than the surgeon, such as a hospitalist or intensivist, and as such, should not be valued in the global package.

Due to concerns about achieving an appropriate, sufficient, and unbiased representative sample of practitioners, as well as operational concerns with collecting data from a limited sample of practitioners or on a limited sample of services, CMS is proposing that any practitioner who furnishes a procedure that is a 10- or 90-day global report the pre- and post-operative services furnished on a claim using the codes proposed above.

In addition to the claims-based reporting, CMS is proposing to survey a large, representative sample of practitioners and their clinical staff in which respondents would report information about approximately 20 discrete pre-operative and post-operative visits and other global services like care coordination and patient training. The proposed survey would produce data on a large sample of pre-operative and post-operative visits and is being designed so that CMS could analyze the data collected in conjunction with the claims-based data that would be collected. CMS expects to obtain data from approximately 5,000 practitioners. CMS has contracted with RAND to develop and conduct the survey if it is finalized. Primary data collection would be via a survey instrument and in addition, RAND would conduct semi-structured interviews and direct observations of data in a small number of pilot sites to inform survey design, validate survey results, and collect information that is not conductive to survey-based reporting.

Each sampled practitioner will be assigned to a specified and brief (for example, 2-week) reporting period. Given the proposed overall data collection period, the selected sample of providers will be randomly divided into 6 subsets within each specialty, each of which will be assigned to a specified reporting period. Practitioners will be asked to describe 20 post-operative visits furnished to Medicare beneficiaries or other patients during the reporting period. The information collected through the survey instrument, which will be developed based upon direct observation and discussions in a small number of pilot sites, will include contextual information to describe the background for the post-operative care.
A summary of the work RAND will be doing is available on the CMS website under downloads for the CY 2017 PFS proposed rule with comment period at: http://www.cms.gov/physicianfeesched/downloads/.

CMS notes that statute allows them to withhold payment of up to 5 percent of the payment for services on which the practitioner is required to report until the practitioner has completed the required reporting; however, CMS is not proposing to implement this option at this time. That said, if CMS finds that compliance with required claims-based reporting is not acceptable, they would consider in future rulemaking imposing the 5 percent penalty.

**Improving Payment Accuracy for Primary Care, Care Management, and Patient-Centered Services (Page 143)**

CMS believes that the current set of E/M codes limits Medicare’s ability under the PFS to appropriately recognize the relative resource costs of primary care, care management/coordination and cognitive services relative to specialized procedures and diagnostic tests. The rule notes that the AMA is undergoing efforts to address these issues by developing new CPT codes. CMS understands that at this time, two sets of new codes are scheduled to be included in the CY 2018 CPT code set in response to CMS’ 2016 comment solicitation. MedPAC has recommended that CMS should replace the expired Primary Care Incentive Payment (PCIP) with a capitated payment mechanism and has expressed preference for codes like chronic care management (CCM) that are beneficiary-centered and do not pay for each distinct care coordination activity. CMS assessed claims data for CY 2015 and believes that CCM services may be underutilized relative to the intended eligible patient population.

CMS is proposing a number of changes to coding and payment policies to improve how Medicare pays for services provided by primary care physicians and other practitioners for patients with multiple chronic conditions, mental and behavioral health issues, as well as cognitive impairment or mobility-related impairments. These proposals do not have a direct impact on radiology, however, highlights of some of the proposals are provided below.

CMS proposes to recognize CPT codes 99358 (Prolonged evaluation and management service before and/or after direct patient care, first hour) and 99359 (Prolonged evaluation and management service before and/or after direct patient care, each additional 30 minutes (List separately in addition to code for prolonged service)) for separate payment under the PFS. CMS proposes to require the service to be furnished on the same day by the same physician or other billing practitioner as the companion E/M code.

CMS also proposes to more appropriately recognize and pay for the other codes in the family of CCM services, CPT codes 99487 (Complex chronic care management services, 60 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month) and 99489 (Each additional 30 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure)). CMS proposes to adopt the CPT provision that CPT codes 99487, 99489, 99490 may only be reported once per service period (calendar month) and only by the
single practitioner who assumes the care management role with a particular beneficiary for the service period. That is, a given beneficiary would be classified as eligible to receive either complex or non-complex CCM during a given service period (calendar month), not both, and only one professional claim could be submitted to the PFS for CCM for that service period by one practitioner. CMS is proposing changes in the requirements for the initiating visit, 24/7 access to care and continuity of care, format and sharing of the care plan and clinical summaries, beneficiary receipt of the care plan, beneficiary consent, and documentation.

CMS is proposing a G-code that would provide separate payment to recognize the work of a physician (or other appropriate billing practitioner) in assessing and creating a care plan for beneficiaries with cognitive impairment, GPPP6 (Cognition and functional assessment using standardized instruments with development of recorded care plan for the patient with cognitive impairment, history obtained from patient and/or caregiver, in office or other outpatient setting or home or domiciliary or rest home). CMS understands that a similar code was recently approved by the CPT Editorial Panel and is scheduled to be included in the CY 2018 CPT code set.

To improve payment accuracy and help ameliorate potential disparity in access and quality for beneficiaries with mobility-related disabilities, CMS proposes to create a new add-on G-code, effective for CY 2017, to describe the additional services furnished in conjunction with E/M services to beneficiaries with disabilities that impair their mobility:

- **GDDD1**: Resource-intensive services for patients for whom the use of specialized mobility-assistive technology (such as adjustable height chairs or tables, patient lifts, and adjustable padded leg supports) is medically necessary and used during the provision of an office/outpatient evaluation and management service visit (Add-on code, list separately in addition to primary procedure).

**Target or Relative Value Adjustments for Misvalued Services (Page 203)**

CMS is proposing to include changes in values of the CY 2016 interim final codes toward the CY 2017 0.5 percent misvalued code target, consistent with the approach finalized in last year’s final rule. The changes in values of CY 2015 interim final codes were not counted towards the misvalued code target in CY 2016 since the valuation change occurred over multiple years (due to the first year being an interim final value), including years not applicable to the misvalued code target provision. However, both of the changes in valuation for the CY 2016 interim final codes, from year 1 to year 2 (CY 2015 to CY 2016) and from year 2 to year 3 (CY 2016 to CY 2017), have taken place during years that occur within the misvalued code target provision. Therefore, CMS believes that any adjustments made to these codes based on public comment should be considered towards the achievement of the target for CY 2017, just as any changes in valuation for these same CY 2016 interim final codes previously counted towards the achievement of the target for CY 2016. **CMS seeks public comments regarding this proposal.**
Phase-in of Significant RVU Reductions (Page 208)

The ACR advocated for the provision in PAMA which specifies 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. In the CY 2016 final rule, CMS finalized their proposal to implementing the phase-in by considering a 19 percent reduction as the maximum 1-year reduction for any service not described by a new or revised code. Since CY 2016 was the first year for which the phase-in provision applied, CMS did not address how they would handle codes with values that had been partially phased in during the first year, but that have a remaining phase-in reduction of 20 percent or greater.

CMS proposes to reconsider in each year, for all codes that are not new or revised codes and including codes that were assigned a phase-in value in the previous year, whether the total RVUs for the service would otherwise be decreased by an estimated 20 percent or more as compared to the total RVUs for the previous year. Under this proposed policy, the 19 percent reduction in total RVUs would continue to be the maximum one-year reduction for all codes (except those considered new and revised), including those codes with phase-in values in the previous year. In other words, for purposes of the 20 percent threshold, every service is evaluated anew each year, and any applicable phase-in is limited to a decrease of 19 percent. CMS is soliciting comments on this proposal.

Geographic Practice Cost Indices (GPCIs) (Page 211)

CMS notes that a provision within the MACRA legislation extended the 1.0 floor for the work GPCIs through CY 2017.

CMS is required to review and, if necessary, adjust the GPCIs at least every 3 years. If more than 1 year has elapsed since the date of the last previous GPCI adjustment, the adjustment to be applied in the first year of the next adjustment shall be half of the adjustment that otherwise would be made. Therefore, since the previous GPCI update was implemented in CY 2014 and CY 2015, CMS is proposing to phase in 1/2 of the latest GPCI adjustment in CY 2017.

Addenda D and E of the proposed rule contain the proposed CY 2017 GPCIs. The proposed updated GPCI values were calculated by a contractor through comparison to a national average for each of the three GPCIs (work, PE, and MP).

California Locality Update to the Fee Schedule Areas Used for Payment Under the Protecting Access to Medicare Act

The PAMA modified the fee schedule areas used for payment purposes in California beginning in CY 2017. Beginning in CY 2017, the fee schedule areas used for payment in California must be Metropolitan Statistical Areas (MSAs) as defined by the Office of Management and Budget (OMB) as of December 31 of the previous year; and all areas not located in an MSA must be treated as a single rest-of-state fee schedule area. The resulting modifications to California’s locality structure would increase its number of localities from 9 under the current locality...
structure to 27 under the MSA-based locality structure. The GPCI values used for payment in a transition area are to be phased in over 6 years, from 2017 through 2021, using a weighted sum of the GPCIs calculated under the new MSA-based locality structure and the GPCIs calculated under the current PFS locality structure.

Additionally, the law mandates a hold harmless for transition areas beginning with CY 2017 whereby the applicable GPCI values for a year under the new MSA-based locality structure may not be less than what they would have been for the year under the current locality structure. There are a total of 58 counties in California, 50 of which are in transition areas as defined in section 1848(e)(6)(D) of the Act. Therefore, 50 counties in California are subject to the hold harmless provision. The other 8 counties, which are metropolitan counties that are not defined as transition areas, are not held harmless for the impact of the new MSA-based locality structure, and may therefore potentially experience slight decreases in their GPCI values as a result of the provisions in section 1848(e)(6) of the Act, insofar as the locality in which they are located now newly includes data from adjacent counties that decreases their GPCI values relative to those that would have applied had the new data not been incorporated.

Table 13 in the proposed rule details the isolated impact of the MSA-based locality changes and hold-harmless for transition areas, the impact of the proposed use of the updated data for GPCIs, and the combined impacts of both of these proposed changes.

Proposed Update to the Methodology for Calculating GPCIs in the U.S. Territories

CMS notes that for several years, stakeholders in Puerto Rico have raised concerns regarding the applicability of the proxy data in Puerto Rico relative to their applicability in the U.S. states. For example, some stakeholders previously indicated that shipping and transportation expenses increase the cost of acquiring medical equipment and supplies in islands and territories relative to the mainland. While CMS has previously attempted to locate data sources specific to geographic variation in such shipping costs, they found no comprehensive national data source for this information. Therefore, they have not been able to quantify variation in costs specific to island territories in the calculation of the GPCIs.

In an effort to provide greater consistency in the calculation of GPCIs given the lack of comprehensive data regarding the validity of applying the proxy data used in the States in accurately accounting for variability of costs for these island territories, CMS is proposing to treat the Caribbean Island territories (the Virgin Islands and Puerto Rico) in a consistent manner by assigning the national average of 1.0 to each GPCI index for both Puerto Rico and the Virgin Islands. CMS is not proposing any changes to the GPCI methodology for the Pacific Island territories (Guam, American Samoa, and Northern Marianas Islands) where they already consistently assign the Hawaii GPCI values for each of the three GPCIs.

Proposed Refinement to the MP GPCI Methodology

In the process of calculating MP GPCIs for the purposes of this proposed rule, CMS identified several technical refinements to the methodology that yield improvements over the current method. Specifically, CMS is proposing modifications to the methodology to account for missing
data used in the calculation of the MP GPCI. Under the methodology used in the CY 2014 GPCI update (78 FR 74380 through 74391), they first calculated the average premiums by insurer and specialty, then imputed premium values for specialties for which they did not have specific data, before adjusting the specialty-specific premium data by market share weights. CMS is proposing to revise the methodology to instead calculate the average premiums for each specialty using issuer market share for only available companies. This proposed methodological improvement would reduce potential bias resulting from large amounts of imputation, an issue that is prevalent for insurers that only write policies for ancillary specialties for which premiums tend to be low.

**Payment Incentive for the Transition from Traditional X-Ray Imaging to Digital Radiography and Other Imaging Services (Page 231)**

Section 502(a)(1) of the Consolidated Appropriations Act of 2016 (H.R. 2029) mandated, effective for services furnished beginning January 1, 2017, a payment reduction of 20 percent under the PFS for the technical component (TC) (including the TC portion of a global service) of imaging services that are X-rays taken using film. The reduction is made prior to any other adjustment under this section and without application of this new paragraph.

The Act also provides for a 7 percent reduction in payments for imaging services made under the PFS that are X-rays (including the X-ray component of a packaged service) taken using computed radiology furnished during CY 2018, 2019, 2020, 2021, or 2022, and for a 10 percent reduction for such imaging services taken using computed radiology furnished during CY 2023 or a subsequent year. Computed radiology technology is defined for purposes of this paragraph as cassette-based imaging, which utilizes an imaging plate to create the image involved. These reductions will be discussed in future rulemaking.

CMS is proposing to establish a new modifier (modifier “XX”) to be used on film X-ray claims. The list of CY 2017 applicable HCPCS codes describing imaging services that are X-ray services are on the CMS website under downloads for the CY 2017 PFS proposed rule with comment period at [http://www.cms.gov/physicianfeesched/downloads/](http://www.cms.gov/physicianfeesched/downloads/). CMS is proposing that, beginning January 1, 2017, this modifier would be required on claims for X-rays that are taken using film. The modifier would be required on claims for the technical component of the X-ray service, including when the service is billed globally, since the PFS payment adjustment is made to the technical component regardless of whether it is billed globally or separately using the –TC modifier. The use of this proposed modifier to indicate an X-ray taken using film would result in a 20-percent reduction for the technical component of the X-ray service and is exempt from budget neutrality as specified under the Act.

**Valuation of Specific Codes (Page 234)**

*Methodology for Proposing Work RVUs (Page 235)*

CMS noted in the proposed rule that many commenters and stakeholders have expressed concerns with their ongoing adjustment of work RVUs based on changes in the best information they have regarding the time resources involved in furnishing individual services. CMS notes that adjusting work RVUs for changes is not always a straightforward process, so they apply
various methodologies to identify several potential work values for individual codes. CMS reiterated that they are statutorily obligated to consider both time and intensity in establishing work RVUs for PFS services.

CMS responded to several specific comments regarding this issue in response to the CY 2016 final rule with comment period. These responses are detailed on pages 240-244 of the display copy of the proposed rule.

CMS believes that they should account for efficiencies in time when the recommended work RVU does not account for those efficiencies, otherwise relativity across the PFS can be significantly skewed over periods of time. For example, if when a code is first valued, a physician was previously able to do only 5 procedures per day, but due to new technologies, the same physician can now do 10 procedures per day, resource costs in time have empirically been lessened, and CMS believes that relative reduction in resources involved in furnishing that service should be accounted for in the assignment of work RVUs for that service, since the statute explicitly identifies time as one of the two components of work. CMS acknowledges that it may be that the intensity per minute of the procedure may have changed with the greater efficiency in time. The rules states that is why CMS does not generally reduce work RVUs in strict proportion to changes in time. CMS understands that intensity is not entirely linear, and that data related to time as obtained in the RUC survey instrument may improve over time, and that the number of survey respondents may improve over time. However, they also understand time as a tangible resource cost in furnishing PFS services, and a cost that by statute, is one of the two kinds of resources to be considered as part of the work RVU.

CMS is interested in receiving comments on whether, within the statutory confines, there are alternative suggestions as to how changes in time should be accounted for when it is evident that the survey data and/or the RUC recommendation regarding the overall work RVU does not reflect significant changes in the resource costs of time for codes describing PFS services. CMS is also seeking comment on potential alternatives, including the application of the reverse building block methodology, to making the adjustments that would recognize overall estimates of work in the context of changes in the resource of time for particular services.

CY 2017 Proposed Codes that were also CY 2016 Proposed Codes

Percutaneous Biliary Procedures Bundling (CPT codes 47531, 47532, 47533, 47534, 47535, 47536, 47537, 47538, 47539, 47540, 47541, 47542, 47543, and 47544) (Page 257)

In our comments on the CY 2016 PFS final rule, the ACR disagreed with CMS’ decision to crosswalk CPT code 49815 (Sclerotherapy of a fluid collection (eg, lymphocele, cyst, or seroma), percutaneous, including contrast injection(s), sclerosant injection(s)) to describe percutaneous image-guided sclerotherapy of fluid collections to CPT code 62305 (Myelography via lumbar injection, including radiological supervision and interpretation; 2 or more regions (eg, lumbar/thoracic, cervical/thoracic, lumbar/cervical, lumbar/thoracic/cervical)). The RUC recommended a direct crosswalk to reference code 31622 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with cell washing, when
performed (separate procedure)), which has an intraservice time of 30 minutes and work RVU of 2.78.

The ACR requested referral to the refinement panel. CMS responded that the request did not meet the requirements related to new clinical information for referral to the refinement panel. CMS continues to believe that a crosswalk of CPT code 49815 from the value for CPT code 62305 is most appropriate due to similarities in overall work. Therefore, CMS is proposing a work RVU of 2.35 for CPT code 49185 for CY 2017 and seek additional rationale for why a different work RVU or crosswalk would more accurately reflect the resources involved in furnishing this service.

CMS also indicates that they did not receive any information regarding supply item SH062 (sclerosing solution) that supports maintaining an input of 300 mL and believes this level far exceeds the volume associated with other CPT codes. CMS is proposing to refine the direct practice expense inputs for SH062 from 300 mL to 10mL, which is the highest level associated with other CPT codes.

Genitourinary Procedures (CPT codes 50606, 50705, and 50706) (Page 259)

The RUC recommended the inclusion of “room, angiography” (EL011) for this family of codes. CMS did not believe that an angiography room would be used in the typical case for these procedures, and they therefore replaced the recommended equipment item “room, angiography” with equipment item “room, radiographic-fluoroscopic” (EL014) for all three codes on an interim final basis. CMS also stated their belief that since the predecessor procedure codes generally did not include an angiography room and they did not have a reason to believe that the procedure would have shifted to an angiography room in the course of this coding change, they did not believe that the use of an angiography room would be typical for these procedures.

CMS indicates that several commenters disagreed with the CMS substitution of the fluoroscopic room in place of the angiography room. The commenters suggested that CPT code 50387 was an example of a predecessor code that included the use of an angiography room, along with other codes that are being bundled together to create the new Genitourinary codes. CMS responded that they do not agree with the commenter’s implication that because CPT code 50387 was an appropriate reference code for use in valuation, that it necessarily would have previously been used to describe services that are now reported under CPT codes 50606, 50705, or 50706. They believe their perspective is consistent with the RUC-recommended utilization crosswalk for the three new codes, which did not suggest that the services were previously reported using 50706. CMS does not believe that use of one particular code for reference in developing values for another necessarily means that the all of the same equipment would be used for both services. CMS also does not believe that these codes describe the same clinical work either and points out that they have different global periods.

However, CMS acknowledges that among the procedures that are provided as references, many of them include the use of an angiography room, such as CPT code 36227 (Selective catheter placement, external carotid artery) and CPT code 37233 (Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, each additional vessel). Therefore, CMS agrees
that the use of the angiography room in these procedures, or at least some of its component parts, may be warranted.

CMS agrees with commenters that it is important to provide equipment that is medically reasonable and necessary. Their concern with the use of the angiography room for these codes is that they do not believe all of the equipment would be typically necessary to furnish the procedure. For example, one commenter agreed that the Provis Injector would not be required for these Genitourinary codes. Therefore, CMS is proposing to remove the angiography room from these three procedures and add in its place the component parts that make up the room. Table 16 (below) details these components.

**TABLE 16: Angiography Room (EL011) Components**

<table>
<thead>
<tr>
<th>Component</th>
</tr>
</thead>
<tbody>
<tr>
<td>100 KW at 100 kV (DIN6822) generator</td>
</tr>
<tr>
<td>C-arm single plane system, ceiling mounted, integrated multispace</td>
</tr>
<tr>
<td>T motorized rotation, multiple operating modes</td>
</tr>
<tr>
<td>real-time digital imaging</td>
</tr>
<tr>
<td>40 cm image intensifier at 40/28/20/14cm</td>
</tr>
<tr>
<td>30 x 38 image intensifier dynamic flat panel detector</td>
</tr>
<tr>
<td>floor-mounted patient table with floating tabletop designed for angiographic exams and interventions (with peistepping for image intensifiers 13in+)</td>
</tr>
<tr>
<td>18 in TFT monitor</td>
</tr>
<tr>
<td>network interface (DICOM)</td>
</tr>
<tr>
<td>Careposition: radiation free positioning of collimators</td>
</tr>
<tr>
<td>Carewatch: acquisition and monitoring of configurable dose area product</td>
</tr>
<tr>
<td>Carefilter: Cu-prefiltration</td>
</tr>
<tr>
<td>DICOM HIS / RIS</td>
</tr>
<tr>
<td>Control room interface</td>
</tr>
<tr>
<td>Injector, Provis</td>
</tr>
<tr>
<td>Shields, lower body and mavig</td>
</tr>
</tbody>
</table>
CMS welcomes additional comment regarding if these or other components are typically used in these genitourinary procedures. CMS currently lacks pricing information for these components; they are therefore proposing to include each of these components in the direct PE input database at a price of $0.00 and they are soliciting invoices from the public for their costs so that the items may be priced for use in developing final PE RVUs for CY 2017.

CMS notes that this issue illustrates a potentially broad problem with the use of equipment “rooms” in the direct PE input database. For most services, only equipment items that are used and unavailable for other uses due to their use during the services described by a particular code are included. However, for items included in equipment “rooms,” costs are allocated regardless of whether the individual items that comprise the room are actually used in the particular service. To maintain relativity among different kinds of procedures, CMS is interested in obtaining more information specifying the exact resources used in furnishing services described by different codes. They intend to address this subject in greater detail in future rulemaking.

Intracranial Endovascular Intervention (CPT codes 61645, 61650, and 61651) (Page 266)

For CY 2016, CMS established interim final work RVUs of 15.00 for CPT code 61645, 10.00 for CPT code 61650 and 4.25 for CPT code 61651. The RUC-recommended values for CPT codes 61645, 61650 and 61651 were 17.00, 12.00 and 5.50, respectively. CMS valued CPT code 61645 by applying the ratio between the RUC-recommended reference code’s, CPT 37231 (revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with transluminal stent placement(s) and atherectomy, includes angioplasty within the same vessel, when performed), work and time to CPT code 61645. They valued CPT code 61650 based on a crosswalk to CPT code 37221 (revascularization, endovascular, open or percutaneous, iliac artery, unilateral, initial vessel; with transluminal stent placement(s) and atherectomy, includes angioplasty within the same vessel, when performed), due to similar intensity and intraservice time. CPT code 61651 was valued based on a crosswalk to CPT code 37223 (revascularization, endovascular, open or percutaneous, iliac artery, each additional ipsilateral iliac vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed (list separately in addition to the code for primary procedure, due to similar intraservice time and intensity.
Both CPT codes 61645 and 61650 included postservice work time associated with CPT code 99233 (Subsequent hospital care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: A detailed interval history; A detailed examination; Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is unstable or has developed a significant complication or a significant new problem. Typically, 35 minutes are spent at the bedside and on the patient's hospital floor or unit).

In the CY 2016 PFS final rule with comment period, CMS stated that they believe that for the typical patient, these services would be considered hospital outpatient services, not inpatient services. As a result the intraservice time of the hospital observation care service was valued in the immediate postservice time. CMS refined the work time for CPT code 61645 by removing 55 minutes of work time associated with CPT code 99233, and added 30 minutes of time from CPT code 99233 to the immediate postservice. Therefore the total time for CPT code 61645 was reduced to 241 minutes and the immediate postservice time increased to 83 minutes. CMS also removed the inpatient visit from CPT code 61650, which reduced the total time to 206 minutes and increased the postservice time to 75 minutes.

The ACR disagreed with our categorization of these codes as outpatient only, and therefore, subject to the 23-hour outpatient policy. Additionally, we pointed out that the new codes would typically be performed on acute stroke patients. We requested that these codes be referred to the refinement panel.

CMS responded that they continue to believe that these codes are appropriate comparisons based on intensity and intra-service time because no persuasive information was presented at the refinement panel that indicated that these comparisons are not appropriate. Therefore they are proposing an RVU of 15.00 for CPT code 61645, 10.00 for CPT code 61650, and 4.25 for CPT code 61651. They are also proposing time inputs based on refinements of the RUC recommendations, including removing the time associated with hospital inpatient visit CPT code 99233 from the intraservice work time, and adding 30 minutes to the immediate postservice time for both CPT codes 61645 and 61650.

CMS is seeking comment on the inclusion of post-operative visits in a 0-day global. Both CPT codes 61645 are 0-day global codes, and the refinements described above reflect changes to more appropriate value these codes as 0-day codes. CMS does not believe that 0-day global codes should include post-operative visits; rather, if global codes require post-operative visits, they are more appropriately assigned 10- or 90-day global periods based on current criteria. CMS policy has been to remove the visit from the post-operative period and the associated minutes from the total time while adding 30 minutes to the immediate postservice period without necessarily making an adjustment to the work RVU.

Paravertebral Block Injection (CPT codes 64461, 64462, and 64463) (Page 268)

In CY 2015, the CPT Editorial Panel created three new codes to describe paravertebral block injections at single or multiple levels, as well as for continuous infusion for the administration of
local anesthetic for post-operative pain control and thoracic and abdominal wall analgesia. For the CY 2016 PFS final rule with comment period, CMS established the RUC recommended work RVUs, 1.75 and 1.10, as interim final for CPT codes 64461 and 64462, respectively.

For CPT code 64463, CMS utilized a direct crosswalk from three other injection codes (CPT codes 64416 (Injection, anesthetic agent; brachial plexus, continuous infusion by catheter (including catheter placement), 64446 (Injection, anesthetic agent; sciatic nerve, continuous infusion by catheter (including catheter placement), and 64449 (Injection, anesthetic agent; lumbar plexus, posterior approach, continuous infusion by catheter (including catheter placement)) which all had a work RVU of 1.81 as they believed this crosswalk more accurately reflected the work involved in furnishing this service.

The RUC commented that CPT code 64463 is more comparable to CPT code 64483 (Injection(s), anesthetic agent and/or steroid, transformaminal epidural, with imaging guidance (fluoroscopy or CT); lumbar or sacral, single), which has a work RVU of 1.90 and requires the same physician work and time to perform. The RUC recommended CMS accept the 25th percentile survey work RVU of 1.90. Another commenter stated that our value for CPT code 64463 was inappropriate since imaging guidance is not part of our comparison codes.

After reviewing and considering the comments, CMS continues to believe that CPT codes 64416, 64446, and 64449, all of which have 20 minutes of intraservice time, are better crosswalks to CPT code 64463, which also has 20 minutes of intraservice time and a similar total time. In contrast, the crosswalk code recommended by commenters, CPT 64483, only has 15 minutes of intraservice time. Therefore, CMS is proposing a work RVU of 1.81 for CPT code 64463 for CY 2017.

Fetal MRI (CPT codes 74712 and 74713) (Page 276)

For CY 2016, CMS established the RUC-recommended work RVU of 3.00 as interim final for CPT code 74712. They established an interim final work RVU of 1.78 for CPT code 74713 based on a refinement of the RUC-recommended work RVU of 1.85 using the ratio of work to time for both codes. This proposed value also corresponds to the 25th percentile survey result.

The ACR commented that the work RVU of 1.78 for CPT code 74713 did not reflect the higher intensity inherent in the procedure’s typical patient. We explained that the typical patient is pregnant with twins and has a higher likelihood of complications related to congenital anomalies, as well as of ischemic brain injury with twin gestations. We requested that CPT code 74713 be referred to the multispecialty refinement panel.

CPT code 74713 was referred to the CY 2016 multispecialty refinement panel. After considering the comments and the results of the refinement panel, CMS agrees that an RVU of 1.78 underestimates the work for CPT code 74713. Therefore, they propose a work RVU of 1.85 for the service for CY 2017.
Interstitial Radiation Source Codes (CPT codes 77778 and 77790) (Page 277)

In CY 2016 PFS final rule with comment period, CMS established an interim final value for CPT code 77790 without a work RVU, consistent with the RUC’s recommendation. CMS did not use the RUC-recommended work RVU to establish the interim final values for CPT code 77778. They stated that the specialty society survey included a work time that was significantly higher than the RUC-recommended work time without a commensurate change in RVU. For CY 2016, CMS established the 25th percentile work RVU survey result of 8.00 as interim final for CPT code 77778.

Commenters, including the ACR, agreed that the preservice survey times and the RUC recommended survey times were inconsistent and explained that this inconsistency resulted from the RUC’s use of preservice packages in developing recommendations. In addition, commenters stated that because the work associated with CPT code 77790 (including pre-time supervision, handling, and loading of radiation seeds into needles) was bundled into CPT code 77778, that the additional work should be reflected in the RVU for CPT code 77778. The ACR and others encouraged CMS to accept the RUC-recommended work RVU of 8.78 and requested that CPT code 77778 be referred to the refinement panel.

CMS did not refer CPT code 77778 to the CY 2016 multispecialty refinement panel because new clinical information was not provided. CMS continues to believe that, based on the reduction in total work time, an RVU of 8.00 accurately reflects the work involved in furnishing CPT code 77778. Therefore for CY 2017, CMS is proposing a work RVU of 8.00 for CPT code 77778 and 0 work RVUs for CPT code 77790. CMS is also seeking comment on whether they should use time values based on preservice packages if the recommended work value is based on time values that are significantly different than those ultimately recommended.

Colon Transit Imaging (CPT codes 78264, 78265, and 78266) (Page 278)

In establishing CY 2016 interim final values, CMS accepted the RUC-recommended work RVUs for CPT codes 78265 and 78266. CMS believed that the RUC-recommended RVU of 0.80 overestimated the work involved in furnishing CPT code 78264 and as a result, established an interim final work RVU of 0.74 based on a crosswalk to CPT code 78226 (hepatobiliary system imaging, including gallbladder when present), due to similar intraservice times and intensities.

The ACR commented that we did not support the interim final work RVU for CPT code 78264. We disagreed with CMS’ assessment of CPT code 78264 as having a higher work RVU and shorter intraservice time relative to the other codes in the family. One commenter stated that a difference of two minutes in intraservice time was insignificant and should not be used as a rationale for revaluing. The ACR commented that CMS should have maintained the RUC-recommended crosswalk of CPT code 78264 to CPT code 78227 (Hepatobiliary system imaging, including gallbladder when present; with pharmacologic intervention, including quantitative measurement(s) when performed) due to similarities in service, work and intensity. Based on these concerns, the ACR requested that CPT code 78264 be referred to the refinement panel.
CPT code 78264 was referred to the CY 2016 multi-specialty refinement panel for further review. CMS calculates the refinement panel results as the median of each vote. That result for CPT code 78264 was 0.79 RVUs. After consideration of the comments and the refinement panel results, CMS agrees that 0.79 accurately captures the overall work involved in furnishing this service and is proposing a value of 0.79 for CPT code 78264.

Calendar Year 2017 Proposed Codes (Page 286)

Open and Percutaneous Transluminal Angioplasty (CPT codes 372X1, 372X2, 372X3, and 372X4) (Page 303)

In January 2015, a CPT/RUC workgroup identified the following CPT codes as being frequently reported together in various combinations: 35475 (Transluminal balloon angioplasty, percutaneous; brachiocephalic trunk or branches, each vessel), 35476 (Transluminal balloon angioplasty, percutaneous; venous), 36147 (Introduction of needle and/or catheter, arteriovenous shunt created for dialysis (graft/fistula); initial access with complete radiological evaluation of dialysis access, including fluoroscopy, image documentation and report), 36148 (Introduction of needle and/or catheter, arteriovenous shunt created for dialysis (graft/fistula); additional access for therapeutic intervention), 37236 (Transcatheter placement of an intravascular stent(s) (except lower extremity artery(s) for occlusive disease, cervical carotid, extracranial vertebral or intrathoracic carotid, intracranial, or coronary), open or percutaneous, including radiological supervision and interpretation and including all angioplasty within the same vessel, when performed; initial artery), 37238 (Transcatheter placement of an intravascular stent(s), open or percutaneous, including radiological supervision and interpretation and including angioplasty within the same vessel, when performed; initial vein), 75791 (Angiography, arteriovenous shunt (eg, dialysis patient fistula/graft), complete evaluation of dialysis access, including fluoroscopy, image documentation and report (includes injections of contrast and all necessary imaging from the arterial anastomosis and adjacent artery through entire venous outflow including the inferior or superior vena cava), radiological supervision and interpretation), 75962 (Transluminal balloon angioplasty, peripheral artery other than renal, or other visceral artery, iliac or lower extremity, radiological supervision and interpretation), and 75968 (Transluminal balloon angioplasty, each additional visceral artery, radiological supervision and interpretation).

At the October 2015 CPT Editorial Panel meeting, the panel approved the creation of four new codes and deletion of 13 existing codes used to describe bundled percutaneous transluminal angioplasty services. The Open and Percutaneous Transluminal Angioplasty family of codes overlaps with the Dialysis Circuit family of codes (CPT codes 369X1-369X9), as they are both being constructed from the same set of frequently reported together codes. CMS reviewed these two families of codes concurrently to maintain relativity between these clinically similar procedures based upon the same collection of deleted codes. After consideration of these materials, CMS is proposing to accept the RUC-recommended work RVU for CPT codes 372X1, 372X2, 372X3, and 372X4.

For the clinical labor direct PE inputs, CMS is proposing to use the RUC-recommend inputs with several refinements. The proposed inputs refine the recommended clinical labor time for “Prepare and position patient/ monitor patient/ set up IV” from 5 minutes to 3 minutes for CPT
The RUC recommendation included a written justification for additional clinical labor time beyond the standard 2 minutes for this activity, stating that the extra time was needed to move leads out of X-ray field, check that X-ray is not obstructed and that there is no risk of collision of X-ray equipment with patient. As CMS wrote for the same clinical labor activity in the Dialysis Circuit family, they agree that extra time may be needed for this activity as compared to the default standard of 2 minutes; however, CMS is assigning 1 extra minute for the additional positioning tasks, resulting in a total of 3 minutes for this task. CMS does not believe that 3 extra minutes would be typically needed for preparation of the X-ray. The equipment times for the angiography room (EL011) and the PACS workstation (ED050) have been refined to reflect this change in clinical labor.

CMS is proposing to remove the “drape, sterile, femoral” supply (SB009) and replace it with a “drape, sterile, fenestrated 16in x 29in” supply (SB011) for CPT codes 372X1 and 372X3. The two base codes out of which these new codes are being constructed, CPT codes 35471 and 35476, both made use of the SB011 fenestrated sterile drape supply, and there was no rationale provided for the switch to the SB009 femoral sterile drape in the two new codes. **CMS is seeking comment on the use of sterile drapes for these procedures, and what rationale there is to support the use of the SB009 femoral sterile drape as typical for these new procedures.**

Percutaneous Biliary Procedures Bundling (CPT codes 47531, 47532, 47533, 47534, 47535, 47536, 47537, 47538, 47539, 47540, 47541, 47542, 47543, and 47544) (Page 305)

This group of fourteen codes was reviewed by the RUC at the April 2015 meeting. CMS established interim final values for this group of codes during the CY 2016 PFS rulemaking cycle, and subsequently received updated RUC recommendations from the October 2015 meeting for the CY 2017 PFS rulemaking cycle. The proposals for these codes incorporate both the updated RUC recommendations, as well as public comments received as part of the interim final status of these procedures.

The ACR disagreed with the methodology CMS applied to the physician work refinements to CPT codes 47540, 47542, 47543, and 47544. CMS noted that the relevance of many of the comments has been diminished by the new series of RUC recommendations for work values that they received as a result of the October 2015 meeting.

**Given that CMS is proposing the updated RUC-recommended work RVUs for CPT codes 47531, 47532, 47533, 47534, 47535, 47536, 47537, 47538, 47539, 47540, 47542, 47543, and 47544, they seek additional comments relative to these proposed values.** CMS agrees that the second round of physician surveys conducted for the October 2015 RUC meeting more accurately captured the work and time required to perform these procedures. The one exception is CPT code 47541; the survey times for this procedure were identical as conducted for the April and October 2015 RUC meetings, yet the RUC recommendation increased from a work RVU of 5.61 in April to a work RVU of 7.00 in October. Given that the time values for the procedure remained unchanged between the two surveys, CMS does not understand why the work RVU would have increased by nearly 1.50 in the intervening months. Since this code also has an identical intraservice time (60 minutes) and total time (121 minutes) as CPT code 47533, CMS
does not agree that it should be valued at a substantially higher rate compared to a medically similar procedure within the same code family.

CMS is proposing to crosswalk the work value of CPT code 47541 to the work value of CPT code 47533, and is proposing a work RVU of 5.63 for both procedures. CMS also notes that many of the codes in the Percutaneous Biliary Procedures family were previously included in Appendix G, and were valued under the assumption that moderate sedation was typically performed on the patient. As part of the initiative to pay separately for moderate sedation when it is performed, CMS is removing a portion of the work RVU and preservice work time from CPT codes 47532, 47533, 47534, 47535, 47536, 47538, 47539, 47540, and 47541. For example, CMS is proposing that CPT code 47541 undergoes a 0.25 reduction in its work RVU from 5.63 to 5.38, and a 10 minute reduction in its preservice work time from 33 minutes to 23 minutes, to reflect the work that will now be reported separately using the new moderate sedation codes. CPT codes 47542, 47533, and 47544 are also included in the moderate sedation initiative; however, as add-on codes, they are not subject to alterations in their work RVUs or work times since the moderate sedation code with work RVUs and work time (991X2) will only be billed once for each base-code and not additionally with the add-on codes. These changes are reflected in Appendix B and the work time file posted to the web.

For the direct PE inputs, CMS is proposing to remove the L051A clinical labor for “Sedate/apply anesthesia” and the L037D for “Assist Physician in Performing Procedure” for CPT codes 47531 and 47537. As noted in last year’s final rule with comment period, CMS believes that this clinical labor describes activities associated with moderate sedation, and moderate sedation is not typical for these procedures. CMS is also proposing to refine the L037D clinical labor for “Clean room/equipment by physician staff” from 6 minutes to 3 minutes for all of the codes in this family. Three minutes is the standard for this clinical labor activity, and CMS continues to maintain that the need for additional clinical labor time for this cleaning activity would not be typical for these procedures.

A commenter disagreed with the CMS refinement to replace supply item “catheter, balloon, PTA” (SD152) with supply item “catheter, balloon ureteral (Dowd)” (SD150). The commenter stated that a Dowd catheter is designed and FDA approved for use in the prostatic urethra by retrograde placement through the penile urethra, and it is not designed for use in an antegrade ureteral dilation procedure. The commenter stated that this replacement is inappropriate. The updated RUC recommendations for this family of codes also restored the balloon PTA catheter.

CMS is proposing again to replace the recommended supply item “catheter, balloon, PTA” (SD152) with supply item “catheter, balloon ureteral (Dowd)” (SD150). CMS believes that the use of this ureteral balloon catheter, which is specifically designed for catheter and image guidance procedures, would be more typical than the use of a PTA balloon catheter. While CMS recognizes that the Dowd catheter is not FDA approved, it is their understanding that the PTA balloon catheter has also not been FDA approved for use in these procedures. CMS is uncertain if the commenter was requesting that they should no longer include catheters that lack FDA approval in the direct PE database; this would preclude the use of most of the catheters in the direct PE database. CMS welcomes additional comment on the use of FDA approved catheters. In the meantime, CMS will continue their long-standing practice of using the
catheters in the direct PE database without explicit regard to FDA approval in particular procedures.

CMS is also proposing to remove the recommended supply item “stone basket” (SD315) from CPT code 47543 and add it to CPT code 47544. Based on the code descriptors, CMS believes that the stone basket was intended to be included in CPT code 47544 and was erroneously listed under CPT code 47543. **CMS is soliciting comments from the public to help clarify this issue.**

CMS notes again that many of the codes in the Percutaneous Biliary Procedures family were previously included in Appendix G, and as part of the initiative to pay separately for moderate sedation when performed, they are removing some of the recommended direct PE inputs related to moderate sedation from CPT codes 47532, 47533, 47534, 47535, 47536, 47538, 47539, 47540, and 47541. CMS is removing the L051A clinical labor time for “Sedate/apply anesthesia”, “Assist Physician in Performing Procedure (CS)”, and “Monitor pt. following moderate sedation”. CMS is also removing the conscious sedation pack (SA044) supply, and some or all of the equipment time for the stretcher (EF018), the mobile instrument table (EF027), the 3-channel ECG (EQ011), and the IV infusion pump (EQ032).

**Mechanochemical Vein Ablation (MOCA) (CPT codes 364X1 and 364X2) (Page 315)**

At the October 2015 CPT meeting, the CPT Editorial Panel established two Category I codes for reporting venous mechanochemical ablation, CPT codes 364X1 and 364X2. CMS is proposing the RUC-recommended work RVU of 3.50 for CPT code 364X1. For CPT code 364X2 CMS believes that the RUC-recommended work RVU of 2.25 does not accurately reflect the typical work involved in furnishing this procedure. The specialty society survey recommended that this add-on code has half the work of the base code, CPT code 364X1. This value is supported by the ratio between work and time in the key reference service, CPT code 36476 (Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; second and subsequent veins treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure)). Therefore, CMS is proposing a work RVU of 1.75 for CPT code 364X2.

The RUC-recommended direct practice expense inputs for CPT codes 364X1 and 364X2 included inputs for an ultrasound room (EL015). Based on the clinical nature of these procedures, CMS does not believe that an ultrasound room would typically be used to furnish these procedures. CMS is proposing to remove inputs for the ultrasound room and put in a portable ultrasound (EQ250), power table (EF031), and light (EF014). The RUC also recommended that the ultrasound machine be allocated clinical staff time based on the PACS workstation formula. CMS does not believe that an ultrasound machine would be used like a PACS workstation, as images are generated and reviewed in real time. Therefore, CMS is proposing to remove all inputs associated with the PACS workstation.

**Epidural Injections (CPT codes 623X5, 623X6, 623X7, 623X8, 623X9, 62X10, 62X11, and 62X12) (Page 322)**

CMS is proposing the RUC-recommended work RVU for all eight of the codes in this family.
CMS is proposing to remove the 10-12ml syringes (SC051) and the RK epidural needle (SC038) from all eight of the codes in this family. These supplies are duplicative, as they are included in the epidural tray (SA064). As an alternative, CMS could remove the epidural tray and replace it with the individual supply components used in each procedure; CMS is seeking public comment on either the inclusion of the epidural tray or its individual components for this family of codes.

Abdominal Aortic Ultrasound Screening (CPT code 767X1) (Page 324)

For CY 2017, the CPT Editorial Panel created a new code, CPT 767X1, to describe abdominal aortic ultrasound screening, currently described by HCPCS G-code G0389. The specialties that surveyed CPT code 767X1 for the RUC were vascular surgery and radiology, and the direct practice expense inputs recommended by the RUC included an ultrasound room. Based on an analysis of Medicare claims data, the dominant specialties furnishing the service are family practice and internal medicine. CMS believes that these specialties may more typically use a portable ultrasound device rather than an ultrasound room. Therefore, CMS is proposing to accept the RUC-recommended work value of 0.55, and the RUC-recommended PE inputs for this service, but they are seeking comment regarding whether or not it would be more accurate to substitute a portable ultrasound device or possibly a hand-held device for an ultrasound room for CPT code 767X1. CMS notes that while the phase-in of significant reductions in RVUs ordinarily would not apply to new codes, they believe that it would be appropriate to consider this change from a G-code to a CPT code to be fundamentally similar to an editorial coding change since the service is not described differently, and therefore, CMS proposes to apply the phase-in to this service by comparing the previous value of the G-code to the value for the new CPT code.

Fluoroscopic Guidance (CPT codes 77001, 77002, and 77003) (Page 324)

In the CY 2015 PFS final rule with comment period, CMS indicated that while CPT codes 77002 and 77003 had been previously classified as stand-alone codes without global periods, they believe their vignettes and CPT Manual parentheticals are consistent with an add-on code as has been established for CPT code 77001. Therefore, the global periods for CPT codes 77002 and 77003 now reflect an add-on code global period with modifications to the vignettes and parentheticals.

For CPT code 77001, CMS is proposing the RUC-recommended work RVU of 0.38. The RUC-recommended work RVUs for CPT codes 77002 and 77003 do not appear to account for the significant decrease in total times for these codes relative to the current total times. CMS notes that these three codes describe remarkably similar services and have identical intraservice and total times. Based on the identical times and notable similarity for all three of these codes, CMS is proposing a work RVU of 0.38 for all three codes.
Radiation Treatment Devices (CPT codes 77332, 77333, and 77334) (Page 325)

CMS identified CPT codes 77332, 77333, and 77334 through the high expenditures by specialty screen. These services represent an incremental increase of complexity from the simple to the intermediate to the complex in design of radiation treatment devices. The RUC recommended no change from the current work RVUs for these codes, which are currently 0.54 for CPT code 77332, 0.84 for CPT code 77333 and 1.24 for CPT code 77334. CMS believes the recommended work RVUs overstate the work involved in furnishing these services, as they do not sufficiently reflect the degree to which the RUC concurrently recommended a decrease in intraservice or total time. For CPT code 77332, CMS believes the RUC recommendation to maintain its current value despite a 34 percent decrease in total time appears to ignore the change in time.

Therefore, CMS is proposing a value for this code based on a crosswalk from the value from CPT code 93287 (Peri-procedural device evaluation (in person) and programming of device system parameters before or after a surgery, procedure, or test with analysis, review and report by a physician or other qualified health care professional; single, dual, or multiple lead implantable defibrillator system), due to its identical intraservice time, similar total time, and similar level of intensity. CMS is therefore proposing a work RVU of 0.45 for CPT code 77332. They are further supporting this valuation with HCPAC code 97760 (Orthotic(s) management and training (including assessment and fitting when not otherwise reported) upper extremity(s), lower extremity(s) and/or trunk, each 15 minutes), which has similar physician time and intensity measurements and a work RVU of 0.45. As these codes are designed to reflect an incremental increase in work value from simple, to intermediate, and complex device designs, CMS used an incremental difference methodology to value CPT codes 77333 and 77334. CMS is proposing a work RVU of 0.75 for CPT code 77333, maintaining its recommended increment from CPT code 77332. For CPT code 77334, CMS is proposing a work RVU of 1.15 which maintains its increment from CPT code 77332.

Special Radiation Treatment (CPT code 77470) (Page 326)

CMS identified CPT code 77470 through the high expenditure charges by specialty. They are proposing the RUC-recommended work RVU of 2.03. However, they believe the description of service and vignette describe different and unrelated treatments being performed by the physician and clinical staff for a typical patient, and this presents a disparity between the work RVUs and PE RVUs. CMS seeks public comment on information that would clarify this apparent disparity to help determine appropriate PE inputs. In addition, CMS seeks comment to determine if creating two G-codes, one which describes the work portion of this service, and one which describes the PE portion, may be a potentially more accurate method of valuing and paying for the service or services described by this code.

Mammography – Computer Aided Detection Bundling (CPT codes 770X1, 770X2, and 770X3) (Page 330)

Section 104 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) required CMS to create separate codes with higher payment amounts for digital mammography compared to film mammography, which was the technology considered to be
typical at the time. In addition, the statute required additional payment to be made when computer-aided detection (CAD) was used.

In CY 2002, CMS began valuing digital mammography services using three G-codes, G0202, G0204, and G0206 to describe screening mammography, unilateral diagnostic mammography, and bilateral diagnostic mammography, respectively. CMS implemented the requirements of BIPA section 104(d)(1), which applied to tests furnished in 2001, by using the work RVUs of the parallel CPT codes, but establishing a fixed PE RVU rather than using PE RVUs developed under the standard PE methodology. The fixed amount of PE RVUs for these codes has generally remained unchanged since implementation of the G-codes that specifically described digital imaging.

Most mammography services under Medicare have since been billed with these G-codes when digital mammography was used, and with CPT codes 77055, 77056, and 77057 when film mammography was used. The use of CAD has been reported with CPT codes 77051 and 77052. For CY 2017, the CPT Editorial Panel deleted CPT codes 77051, 77052, 77055, 77056, 77057 and created three new CPT codes, 770X1, 770X2, and 770X3, to describe mammography services bundled with CAD. For CY 2017, the RUC recommended a work RVU of 0.81 for CPT code 770X1, a work RVU of 1.00 for CPT code 770X2, and a work RVU of 0.76 for CPT code 770X3, as well as new PE inputs for use in developing resource-based PE RVUs based on standard methodologies. The RUC has recommended these inputs and one medical specialty society provided CMS with a set of single invoices to price the equipment used in furnishing these services.

CMS has reviewed these coding changes and recommended changes to valuation for CY 2017. The revised CPT coding mitigates the need for both separate G-codes and the CAD add-on codes. Based upon these coding changes and the recommended input values, overall Medicare payment for mammography services would be drastically reduced. This is especially the case for the technical component of these services, which could possibly be reduced up to 50 percent relative to the PE RVUs currently used for payment for these services.

Based on initial review of the recommended inputs for the new codes, CMS believes that these changes would likely result in values more closely related to the relative resources involved in furnishing these services. However, CMS recognizes that these services, particularly the preventive screenings, are of particular importance to the Medicare program and the health of the Medicare beneficiaries. CMS is concerned that making drastic changes in coding and payment for these services could be disruptive in ways that could affect beneficiary access to necessary services. CMS also recognizes that unlike almost any other high-volume PFS service, the RVUs used for payment for many years have not been developed through the generally applicable PFS methodologies, and instead reflect the statutory directive under section 104 of the BIPA. Similarly, CMS recognizes that the changes in both coding and valuation are significant changes for those who provide these services. Therefore, instead of proposing to simultaneously adopt the revised CPT coding and drastic reductions in overall payment rates, CMS believes it is advisable to adopt the new coding, including the elimination of separate billing for CAD, for CY 2017 without proposing immediate implementation of the recommended resource inputs. CMS anticipates that they will consider the recommended inputs, including the pricing of the required
equipment, as carefully as possible prior to proposing revised PE values through subsequent rulemaking.

Therefore, for CPT codes 770X1, 770X2, and 770X3, CMS is proposing to accept the RUC-recommended work RVUs, but to crosswalk the PE RVUs for the technical component of the current corresponding G-codes, as they seek further pricing information for these equipment items.

In addition to seeking comment on this proposal, CMS is also seeking comment on rates for these services in the commercial market to help them understand the potential impacts of any future proposed revisions to PFS payment rates. Finally, CMS notes that by adopting the new coding for CY 2017, any subsequent significant reduction in RVUs (greater than 20 percent) for the codes would be subject to the mandated RVU phase-in policy described in this rule.

CMS is seeking public comment on the list of items recommended as equipment inputs for mammography services, including the submission of invoices. These are listed in Table 17 below.

**TABLE 17: Recommended Equipment Items for Mammography Services**

<table>
<thead>
<tr>
<th>#</th>
<th>Item description</th>
<th>Quantity</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2D Selenia Dimensions Mammography System</td>
<td>1</td>
<td>Mammography unit and in-room console itself.</td>
</tr>
<tr>
<td>2</td>
<td>Mammo Accreditation Phantom</td>
<td>1</td>
<td>Required for MQSA. The phantom is currently valued into the existing mammography room.</td>
</tr>
<tr>
<td>3</td>
<td>Phantom Case</td>
<td>1</td>
<td>Protects expensive required phantom from damage.</td>
</tr>
<tr>
<td>4</td>
<td>Paddle Storage Rack</td>
<td>3</td>
<td>It requires 3 racks to hold and prevent damage to all of the paddles that are part of the typical standard mammography system.</td>
</tr>
<tr>
<td>5</td>
<td>Needle Localization Kit</td>
<td>1</td>
<td>Needed for a full functioning mammography room. Allows for the performance of needle localizations. Input is not separately in the PE for the mammography guided procedure codes, 19281-19282, as a fully functioning mammography room is needed for those procedures.</td>
</tr>
<tr>
<td></td>
<td>Description</td>
<td>Quantity</td>
<td>Details</td>
</tr>
<tr>
<td>---</td>
<td>------------------------------------------------------------------------------</td>
<td>----------</td>
<td>--------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>6</td>
<td>Advanced Workflow Manager System</td>
<td>1</td>
<td>Workflow system connecting mammography room and workstations.</td>
</tr>
<tr>
<td>7</td>
<td>Cenova 2D Tower System</td>
<td>1</td>
<td>CAD server, and also used for post-processing.</td>
</tr>
<tr>
<td>8</td>
<td>Image Checker CAD (9.4) License for One FFDM</td>
<td>1</td>
<td>License required for using CAD. This is a one-time fee.</td>
</tr>
<tr>
<td>9</td>
<td>Film Digitizing System</td>
<td>1</td>
<td>Digitizes analog films to digital for comparison purposes.</td>
</tr>
<tr>
<td>10</td>
<td>Mammography Chair</td>
<td>1</td>
<td>A special chair needed for patients who cannot stand to safely have their mammogram performed.</td>
</tr>
<tr>
<td>11</td>
<td>Laser Imager Printer</td>
<td>1</td>
<td>Prints high resolution copies of the mammograms to send to surgeons and oncologists, and to use in the OR.</td>
</tr>
<tr>
<td>12</td>
<td>Barcode Scanner</td>
<td>1</td>
<td>Allows selection of individual patient file for interpretation.</td>
</tr>
<tr>
<td>13</td>
<td>MRS V7 SQL Reporting System</td>
<td>1</td>
<td>MQSA requires that the facility develop and maintain a database that tracks recall rates from screening, true and false positive and false negative rates, sensitivity, specificity, and cancer detection rate. A reporting system is required to build the required database and produce the federally required quality audit. Components below needed for the reporting system. The reporting system is currently valued into the existing mammography room.</td>
</tr>
<tr>
<td>14</td>
<td>Worksheet Printing Module</td>
<td>1</td>
<td>Database reports are required for federal tracking purposes. This is used to generate reports for MQSA.</td>
</tr>
<tr>
<td>15</td>
<td>Site License</td>
<td>1</td>
<td>License for site to use the reporting system. This is a one-time fee.</td>
</tr>
<tr>
<td>16</td>
<td>Additional Concurrent User License</td>
<td>3</td>
<td>Licenses for radiologists to use the reporting system. A minimum of three additional licenses is typical.</td>
</tr>
<tr>
<td>17</td>
<td>Densitometer</td>
<td>1</td>
<td>Required for MQSA.</td>
</tr>
</tbody>
</table>
CMS also acknowledges the ACR’s recommendations for the physician PACS mammography workstation. **CMS is requesting public comment as to the appropriateness of the list of items included in Table 18 below and if some items are indirect expenses or belong in other codes. CMS also invites commenters to provide any invoices that would help with future pricing of these items.**

**TABLE 18: Physician PACS Mammography Workstation**

<table>
<thead>
<tr>
<th>Item</th>
</tr>
</thead>
<tbody>
<tr>
<td>PC Tower</td>
</tr>
<tr>
<td>Monitors 5 MP (mammo) (x2)</td>
</tr>
<tr>
<td>3rd &amp; 4th monitor (for speech recognition, etc.)</td>
</tr>
<tr>
<td>Admin Monitor (the extra working monitor)</td>
</tr>
<tr>
<td>Keyboard &amp; Mouse</td>
</tr>
<tr>
<td>Powerscribe Microphone</td>
</tr>
<tr>
<td>Software - SV APP SYNC 1.3.0</td>
</tr>
<tr>
<td>Software - R2 Cenova</td>
</tr>
</tbody>
</table>

CMS also notes that for CY 2015, the CPT Editorial Panel created CPT codes 77061, 77062, and 77063 to describe unilateral, bilateral, and screening digital breast tomosynthesis, respectively. CPT code 77063 is an add-on code to 77057, the CPT code for screening mammography. To be consistent with the use of G codes for digital mammography, CMS did not implement two of these three CPT codes for Medicare purposes and only adopted CPT code 77063 an add-on code to G0202. Instead of adopting stand-alone codes 77061 and 77062, CMS created a new code, G0279 Diagnostic digital breast tomosynthesis, as an add-on code to the diagnostic digital mammography codes G0204 and G0206 and assigned it values based on CPT code 77063. Pending revaluation of the mammography codes using direct PE inputs, CMS proposes to maintain the current coding structure for digital breast tomosynthesis with the technical change that G0279 be reported with 770X1 or 770X2 as the replacement codes for G0204 and G0206.

**Proposed Valuation of Services Where Moderate Sedation is an Inherent Part of the Procedure and Proposed Valuation of Moderate Sedation Services (Page 352)**

CMS noted in the CY 2015 proposed rule that anesthesia services are increasingly being separately reported for endoscopic procedures, meaning that resource costs associated with sedation were no longer incurred by the practitioner reporting the procedure. In the CY 2016 proposed rule, CMS sought comment and recommendations on approaches to address the appropriate valuation of moderate sedation related to the approximately 400 diagnostic and therapeutic procedures for which the CPT Editorial Committee has determined that moderate sedation is an inherent part of furnishing the service. The CPT Editorial Committee created separate codes for reporting of moderate sedation services.

For the newly created moderate sedation CPT codes, CMS is proposing to use the RUC-recommended work RVUs for CPT codes 991X1, 991X2, 991X3, 991X6. CPT codes 991X1 and 991X2 make a distinction between moderate sedation services furnished to patients younger than 5 years of age and patients 5 years or older, with CPT codes 991X3 and 991X4 making a similar distinction. The RUC recommendations include a work RVU increment of 0.25 between CPT code 991X1 and 991X2. For CPT code 991X4, CMS is proposing a work RVU of 1.65 to
maintain the 0.25 increment relative to CPT code 991X3 (a RUC-recommended work RVU of 1.90) and maintain relativity among the CPT codes in this family. CMS is proposing to use the RUC-recommended direct PE inputs for all six codes.

Given the significant volume of moderate sedation furnished by GI practitioners and the significant difference in RVUs reported in the survey data, CMS is proposing to make payment using a gastrointestinal (GI) endoscopy-specific moderate sedation code GMMM1 that would be used in lieu of the new CPT moderate sedation coding used more broadly: GMMM1: moderate sedation services provided by the same physician or other qualified health care professional performing a gastrointestinal endoscopic service (excluding biliary procedures) that sedation supports, requiring the presence of an independent trained observer to assist in the monitoring of the patient’s level of consciousness and physiological status; initial 15 minutes of intra-service time; patient age 5 years or older.

CMS is proposing to value GMMM1 at 0.10 work RVUs based on the median survey result for GI respondents in the survey data. They are proposing that when moderate sedation services are furnished by the same practitioner reporting the GI endoscopy procedure, practitioners would report the sedation services using GMMM1 instead of 991X2. In all other cases, CMS proposes that practitioners would report moderate sedation using one of the new moderate sedation CPT codes consistent with CPT guidance.

In addition to providing recommended values for the new codes used to separately report moderate sedation, the RUC has provided recommendations that value the procedural services without moderate sedation. However, the RUC recommends removing fewer RVUs from the procedures than it recommends for valuing the sedation services. In other words, the RUC is recommending that overall payments for these procedures should be increased now that practitioners will be required to report the sedation services that were previously included as inherent parts of the procedures. CMS believes that using the RUC recommendations for revaluation of the procedural services without refinement, the RVUs currently attributable to the redundant payment for sedation services when anesthesia is separately reported would be used exclusively to increase overall payment for these services.

To account for the separate billing of moderate sedation services, CMS is proposing to maintain current values for the procedure codes less the work RVUs associated with the most frequently reported corresponding moderate sedation code so that practitioners furnishing the moderate sedation services previously considered to be inherent in the procedure will have no change in overall work RVUs. Since CMS is proposing 0.10 work RVUs for moderate sedation for the GI endoscopy procedures, this means CMS is proposing a corresponding .10 reduction in work RVUs for these procedures. For all other Appendix G procedures that currently include moderate sedation as an inherent part of the procedure, CMS is proposing to remove 0.25 work RVUs from the current values.

Table 22, on pages 356-367 of the display copy of the proposed rule lists the existing work RVUs for each applicable service and the proposed refined work RVU using the proposed revaluation methodology described above. The table also identifies the GI endoscopic services for which CMS is proposing that GMMI1 would be used to report moderate sedation services.
Details of the Work and Practice Expense RVU Proposals

Table 23, from pages 374-394 of the display copy of the proposed rule, lists the proposed CY 2017 work RVUs for new, revised, and potentially misvalued codes.

Table 24, from pages 394-398 of the display copy of the proposed rule, lists CY 2016 proposed codes with direct PE input recommendations accepted without refinement.

Table 25, from pages 399-491 of the display copy of the proposed rule, lists CY 2016 proposed codes with direct PE input recommendations accepted with refinement.

Table 26, from pages 492-493 of the display copy of the proposed rule, lists invoices received for existing direct PE inputs.

Table 27, from pages 494-495 of the display copy of the proposed rule, lists invoices received for new direct PE inputs.

**Recoupment or Offset of Payments to Providers Sharing the Same Taxpayer Identification Number (Page 600)**

Medicare payments to providers and suppliers may be offset or recouped by a Medicare contractor if the Medicare contractor or CMS has determined that a provider or supplier has been overpaid. Historically, CMS has used the Medicare provider billing number or National Provider Identifier (NPI) to recoup overpayments from Medicare providers and suppliers until these debts were paid in full or eligible for referral to the Department of Treasury (Treasury) for further collection action under the Debt Collection Improvement Act of 1996 and the Digital Accountability and Transparency Act of 2014. Once an overpayment is referred to Treasury, the Treasury’s Debt Management Services uses various tools to collect the debt, including offset of federal payments against entities that share the same provider Taxpayer Identification Number (TIN). Hence, Treasury has the ability to collect overpayments using the provider TIN and CMS pays a fee for every collection made.

The Affordable Care Act allows the Secretary to make any necessary adjustments to the payments to an applicable provider of services or supplier, defined as a provider or supplier that has the same taxpayer identification number, to satisfy any amount due from an obligated provider of services or supplier. For example, a health care system may own a number of hospital providers and these providers may share the same TIN while having different NPI or Medicare billing numbers. If one of the hospitals in this system receives a demand letter for a Medicare overpayment, then that hospital (Hospital A) will be considered the obligated provider while its sister hospitals (Hospitals B and C) will be considered the applicable providers. This authority allows CMS to recoup the overpayment of the obligated provider, Hospital A, against any or all of the applicable providers, Hospitals B and C, with which it, Hospital A, shares a TIN.
Physician Self-Referral Updates (Page 747)

The proposed rule details the history of rulemaking on the issue of self-referral. In addition, the
rule summarizes a recent court decision on the topic. On June 12, 2015, the D.C. Circuit (the
Court) issued an opinion in Council for Urological Interests v. Burwell that addressed the
prohibition on per-click rental charges for the lease of equipment. In its ruling, the Court agreed
with CMS that the Act provides the Secretary the authority to prohibit per-click leasing
arrangements.

The Court also concluded, however, that CMS’ discussion of the House Conference Report in
the FY 2009 IPPS final rule contained an unreasonable interpretation of the conferees’
statements concerning sections 1877(e)(1)(A)(iv) and (B)(iv) of the Act, and it remanded the
case to the agency to permit a fuller consideration of the legislative history. This rulemaking
addresses that decision.

In this proposed rule, CMS is re-proposing certain requirements for arrangements involving the
rental of office space or equipment. Specifically, using the same language in existing regulation,
CMS is proposing to include a requirement that rental charges for the office space or equipment
are not determined using a formula based on per unit of service rental charges, to the extent that
such charges reflect services provided to patients referred by the lessor to the lessee. CMS is
using the authority granted to the Secretary in sections 1877(e)(1)(A)(vi) and (B)(vi) of the Act
to re-propose this requirement in the exceptions for the rental of office space and equipment,
respectively. CMS is using the authority granted to the Secretary in section 1877(b)(4) of the Act
to re-propose this requirement in the exceptions for fair market value compensation and indirect
compensation arrangements, respectively.

CMS emphasizes that they are not proposing an absolute prohibition on rental charges based on
units of service furnished. In general, per-unit of service rental charges for the rental of office
space or equipment are permissible. CMS is proposing to limit the general rule by prohibiting
per-unit of service rental charges where the lessor generates the payment from the lessee through
a referral to the lessee for a service to be provided in the rented office space or using the rented
equipment. Thus, per-unit of service rental charges for the rental of office space or equipment
would be permissible, but only in those instances where the referral for the service to be
provided in the rented office space or using the rented equipment did not come from the lessor.