December 23, 2014

Marilyn B. Tavenner  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS–1612–FC  
Mail Stop C4–26–05  
7500 Security Boulevard  
Baltimore, MD 21244–1850

Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & Other Revisions to Part B for CY 2015

Dear Administrator Tavenner:

The American College of Radiology (ACR), representing more than 36,000 diagnostic radiologists, interventional radiologists, radiation oncologists, nuclear medicine physicians and medical physicists, appreciates the opportunity to submit comments to the Centers for Medicare & Medicaid Services (CMS) on the calendar year (CY) 2015 Medicare Physician Fee Schedule (MPFS) Final Rule. In this comment letter, we address the following important issues:

- Inputs for Digital Mammography Services
- Breast Biopsy
- Migration from Film to Digital Practice Expense (PE) Inputs
- Establishing CY 2015 Interim Final RVUs
- Physician Work RVU Refinements
- Practice Expense
- Quality Provisions, including Physician Compare, Physician Quality Reporting System (PQRS), and the Value Modifier Programs

**Inputs for Digital Mammography Services**

The Current Procedural Terminology (CPT®) Editorial Panel created three new codes to describe digital breast tomosynthesis (DBT). CMS indicates that only one of these DBT codes, 77063 (Screening digital breast tomosynthesis, bilateral), will be included in the 2015 MPFS. 77063 is an add-on code so will be reported along with the digital screening mammography code G0202 (Screening mammography, producing direct digital image, bilateral, all views). Instead of accepting the new diagnostic DBT CPT codes 77061 (Digital breast tomosynthesis; unilateral) and 77062 (Digital breast tomosynthesis; bilateral) into the MPFS, CMS created a
new add-on G-code, G0279 (Diagnostic digital breast tomosynthesis, unilateral or bilateral (list separately in addition to G0204 or G0206), to be used with the existing digital diagnostic mammography codes G0204 (Diagnostic mammography, producing direct digital image, bilateral, all views) and G0206 (Diagnostic mammography, producing direct digital image, unilateral, all views) to reflect the work of diagnostic DBT when provided with diagnostic digital mammography.

Since the diagnostic DBT codes, 77061 and 77062, are not included in the 2015 MPFS, CMS did not comment on the RUC recommendations for these two codes. Accordingly, no RVU values are assigned in the MPFS. The ACR believes that CMS should have accepted the CPT codes, physician work RVUs, and practice expense inputs that were approved by the RUC into the MPFS. This would enable more consistent coverage for Medicare beneficiaries and payment for providers. This would also ensure consistent coding and pricing by private payers who may base their own fee schedules on Medicare payment rates.

The ACR is also concerned that the CMS-revised DBT coding structure will create coding challenges for providers. Because the stand-alone diagnostic DBT codes have been replaced by add-on codes, there appears to be no means to accurately report a unilateral or bilateral diagnostic DBT when this study is provided alone without a full-field digital mammogram (FFDM). When the ACR presented 77061 and 77062 to the CPT Editorial Panel, it was explained that a diagnostic DBT may occur without a concurrent FFDM. The ACR requests guidance from CMS regarding the proper coding of a stand-alone diagnostic DBT.

The ACR is also concerned with the payment rate for the diagnostic DBT G-code, G0279. CMS assigned a work RVU for G0279 equal to the screening DBT payment rate (0.60 RVU) which is lower than the recommendation made by the American Medical Association (AMA)/Specialty Society Relative Value Scale (RVS) Update Committee (RUC) for the diagnostic DBT CPT codes (0.70 RVU for unilateral and 0.90 RVUs for bilateral). The ACR presented ample evidence which was accepted by the RUC that the work associated with diagnostic DBT is higher than the work associated with a screening DBT.

The ACR and RUC also made recommendations to CMS regarding the direct inputs used to determine PE RVUs, (technical component (TC) payment). They recommended the creation of a “room, breast tomosynthesis” that includes equipment items involved in digital breast tomosynthesis, such as the DBT unit, multimodality software, and a workstation, among other equipment items. CMS instead opted to include, individually, the equipment items that they characterize as direct inputs. Recommended equipment items that CMS does not feel constitute a direct input, such as a “Picture Archiving and Communication System (PACS) cache” for storage, were omitted. Additionally, CMS lowered the price of the DBT unit from the RUC recommended invoice price of $498,412 to $381,380 based on separately acquired invoices. The ACR is disappointed that CMS refined the DBT direct inputs and chose not to accept the invoice submitted by the RUC despite the Agency's frequent requests for specialty societies to aid in the collection of invoices.
CMS indicated in the MPFS Final Rule that it will continue to pay for mammography services at the 2014 rates until the family of mammography services is revalued. The 2014 RVUs from each of the following codes will be maintained to price mammography for 2015: G0202, G0204, G0206, 77055 (Mammography; unilateral), 77056 (Mammography; bilateral), and 77057 (Screening mammography, bilateral (2-view film study of each breast)). The ACR welcomes the opportunity to work with the RUC and CMS on ensuring the proper valuation of mammography services.

Additionally, CPT code 77063, screening DBT, was surveyed, presented, and approved by the RUC in April 2014 as ZZZ global. It was recommended to CMS as ZZZ global. However, addendum B in the 2015 MPFS currently lists 77063 with XXX global. The ACR believes that this is an error and requests that 77063 be implemented with ZZZ global, consistent with our original recommendation.

Finally, The ACR requests that the short descriptors for codes G0279 and 77063 be revised in the 2015 MPFS and Addendum B. G0279 is a diagnostic DBT code (not screening), and 77063 should be revised to clarify that it is for screening bilateral DBT and to differentiate it from 77062. We believe that the current short descriptors are inaccurate and may create confusion.

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Breast Biopsy

Per the request of specialty societies, CMS reviewed the physician work of the breast biopsy codes (19081-19086) and percutaneous placement of device(s) codes (19281-19288) through the Refinement Panel process. The specialties represented on the Panel, including the ACR, Society of Interventional Radiology (SIR), American College of Surgeons (ACS) and American Society of Breast Surgeons (ASBS), reiterated concerns that reductions across the family could
negatively impact access for patients, and encouraged the Panel to increase the value for the entire family of breast biopsy codes.

The Refinement Panel recommended an increase in the value for the two stereotactic biopsy codes, 19081 (Biopsy, breast, with placement of breast localization device(s) (eg, clip, metallic pellet), when performed, and imaging of the biopsy specimen, when performed, percutaneous; first lesion, including stereotactic guidance) and 19082 (Biopsy, breast, with placement of breast localization device(s) (eg, clip, metallic pellet), when performed, and imaging of the biopsy specimen, when performed, percutaneous; each additional lesion, including stereotactic guidance (List separately in addition to code for primary procedure)), and the two magnetic resonance (MR) clip placement codes, 19287 (Placement of breast localization device(s) (eg clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; first lesion, including magnetic resonance guidance) and 19288 (Placement of breast localization device(s) (eg clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; each additional lesion, including magnetic resonance guidance (List separately in addition to code for primary procedure)). However, in the 2015 final rule, CMS ignored the decision of the Refinement Panel, electing to finalize the existing 2014 values for all 14 codes in the family. The specialty societies followed the proper procedures to work through the process of commenting on interim codes and presenting before CMS’ Refinement Panel process. The ACR strongly believes that the results of that process should be honored by CMS and the recommended revised values for 2015 should have been accepted.

Migration from Film to Digital Practice Expense (PE) Inputs

The RUC recommended that CMS replace the film supplies and equipment from 604 existing imaging codes with PACS specific supplies and equipment. A list of 30 film-related supply and equipment items was provided to CMS, along with a comprehensive list of replacement PACS related supplies and equipment. The PACS related supplies and equipment (listed in Table 6 of the final rule) include such items as the quality assurance (QA) station, PACS servers, PACS software, and PACS physician workstations. In the MPFS Final Rule, CMS states, “Since we did not receive any invoices for the PACS system prior to the proposed rule, we were unable to determine the appropriate pricing to use for the inputs”. CMS finalized its proposal to accept the RUC recommendation to remove the film supply and equipment items, but not restore the inputs associated with PACS, and to allocate minutes to a desktop computer (‘PACS Workstation Proxy’ (ED050)) as a proxy for the PACS workstation as a direct expense.

The ACR disagrees with the use of a desktop computer as a proxy for PACS directed inputs. We requested that this transition be delayed and are profoundly disappointed that CMS did not delay for one year the removal of the supply and equipment items associated with film technology to enable more meaningful replacement digital inputs. The ACR remains committed to working with CMS to ensure that the proper digital inputs are identified and integrated into the CMS database along with appropriate invoices. As we expressed in our proposed rule comment letter, we anticipate providing this information early in 2015.
Radiation Therapy Codes

CPT Codes 76950, 77014, 77421, 77387, 77401, 77402, 77403, 77404, 77406, 77407, 77408, 77409, 77411, 77412, 77413, 77414, 77416, 77418, 77385, 77386, 0073T, and 0197T and HCPCS Codes G6001, G6002, G6003, G6004, G6005, G6006, G6007, G6008, G6009, G6010, G6011, G6012, G6013, G6014, G6015, G6016 and G6017

The CPT Editorial Panel revised the radiation therapy code set for CY 2015. The RUC subsequently provided recommendations to CMS for valuing these services. In its comments on the 2015 MPFS proposed rule, the ACR expressed concern regarding the revaluing of these codes, in addition to CMS’ proposal to remove the radiation treatment vault as a direct practice expense, noting that these codes account for the vast majority of Medicare payment for radiation therapy.

In light of the substantial nature of this code revision, CMS is delaying revaluation of these codes until CY 2016. The coding changes involve significant changes in how radiation therapy services and associated image guidance are reported. CMS is maintaining the inputs for radiation therapy codes at the CY 2014 levels. Since the code set has changed and some of the CY 2014 codes were deleted, CMS is creating G-codes to allow practitioners to continue to report services to CMS in CY 2015 as they did in CY 2014 and for payments to be made in the same way. All payment policies applicable to the CY 2014 CPT codes will apply to the replacement G-codes.

The ACR appreciates the Agency’s concern regarding the magnitude of the radiation oncology treatment delivery changes and the potential impacts on physicians and their practices. We agree with CMS’ decision to propose the radiation oncology treatment delivery changes in the 2016 proposed MFS. We are, however, concerned about the implementation of the G-codes and the potential for confusion by Medicare Administrative Contractors (MACs) and private insurers. We believe CMS may need to issue specific coding guidance to MACs to avoid denials.

CMS also discussed CPT code 77401 (Radiation treatment delivery, superficial and/or ortho voltage, per day) in the final rule. The agency noted that changes to the prefatory text modify the services that are appropriately billed with CPT code 77401, which is used to report superficial radiation therapy. This change effectively means that CPT code 77401 is now bundled with many other procedures supporting superficial radiation therapy. However, the RUC did not review superficial radiation therapy procedures, and therefore, did not assess whether changes in its valuation were appropriate in light of this bundling. The change to the prefatory text prohibits providers from billing for codes that were previously frequently billed in addition to this code, and, as a result, there will be a significant reduction in payments.

CMS requested information on whether the new code set combined with modifications in the prefatory text allows for appropriate reporting of services associated with superficial radiation and whether the payment continues to reflect the relative resources required to furnish superficial radiation therapy services. While there have been significant changes to the CPT prefatory
text, which applies to CPT code 77401, we believe the final language published by CPT is acceptable. We believe the Medicare payment generally reflects the resources used to furnish the service, relative to the other services in the specialty.

Establishing CY 2015 Interim Final RVUs

We have attached a spreadsheet, which includes the ACR comments on CMS’ refinement of RUC-recommended practice expense direct inputs.

Comments on Physician Work RVU Refinements

CPT Code 70487 (Computed tomography, maxillofacial area; with contrast material(s)) and 70488 (Computed tomography, maxillofacial area; without contrast material, followed by contrast material(s) and further sections)

The ACR is disappointed that CMS did not accept the RUC recommendations for CPT codes 70487 and 70488. The RUC recommended the 25th percentile survey values across the family, providing appropriate comparison codes. CMS reduced the values of 70487 and 70488 to equal the comparable head CT codes, 70460 (Computed tomography, head or brain; with contrast material(s)) and 70470 (Computed tomography, head or brain; without contrast material, followed by contrast material(s) and further sections), respectively. While the head CT codes are comparable in service period times, the maxillofacial CT is more complex and intense, as was described in the specialty society recommendations as follows:

The ACR believes these important clinical differences were not adequately considered by CMS. We request refinement panel review for additional discussion of these important clinical differences for both CPT codes 70487 and 70488.
CPT Code 93886 (Transcranial Doppler study of the intracranial arteries; complete study) and 93888 (Transcranial Doppler study of the intracranial arteries; limited study)

The ACR is disappointed that CMS did not accept the RUC recommendations for CPT codes 93886 and 93888.

CMS lowered the RUC recommendation for 93886 from 1.00 RVU to 0.91 RVU based on a comparison to the value accepted for CPT code 93880 (Duplex scan of extracranial arteries; complete bilateral study) of 0.80 RVU with an intra-service time of 15 minutes. CPT code 93886 has an intraservice time of 17 minutes so CMS applied the work RVU to time ratio of CPT code 93880 to the intra-service time of CPT code. The ACR disagrees with this methodology since intra-cranial examinations are greater in intensity than extra-cranial examinations and this difference should be recognized.

CMS made the following generalization which affected 93888: across the entire Doppler/duplex family, all codes with 10 minutes of intra-service time would be assigned a work RVU of 0.50 RVU. The ACR disagrees with such time-based generalizations since this ignores the importance of magnitude estimation within the larger Resource Based Relative Value Scale (RBRVS). Transcranial Doppler examinations are generally more intense than Doppler studies of other parts of the body, including the extra-cranial circulation. Further, the specialty society recommendation is well supported by the survey key reference service (KRS) 95819 (Electroencephalogram (EEG); including recording awake and asleep) valued at 1.08 RVUs with 15 minutes of intra-service time and 76821 (Doppler velocimetry, fetal; middle cerebral artery) valued at 0.70 RVU with 10 minutes of intra-service time.

Given the important clinical considerations described above, the ACR requests referral of both of these codes to the Refinement Panel.

93975 (Duplex scan of arterial inflow and venous outflow of abdominal, pelvic, scrotal contents and/or retroperitoneal organs; complete study) and 93976 (Duplex scan of arterial inflow and venous outflow of abdominal, pelvic, scrotal contents and/or retroperitoneal organs; limited study)

The ACR is disappointed that CMS did not accept the RUC recommendations for CPT codes 93975 and 93976. CMS made the following generalization which affected 93975 and 93976: across the entire Doppler/duplex family, all codes with 15 minutes of intra-service time would be assigned the 25th percentile survey value. However, 93975 includes 20 minutes of intra-service time so this generalization would not apply, even if it were appropriate. The ACR believes that CMS’ rationale for not accepting the RUC recommendations for this code is inadequate.

The ACR disagrees with such time-based generalizations since this ignores the importance of magnitude estimation within the larger RBRVS. Transabdominal/transpelvic Doppler examinations are generally more intense than Doppler studies of other parts of the body such as the extremities so warrant consideration of the median survey value. Even though code 93976 is
a limited study, it involves both arterial inflow and venous outflow evaluation of an organ justifying the increased intensity.

The ACR also believes that clinical considerations were not adequately considered in applying these reductions so we request refinement panel review of codes 93975 and 93976.

**Isodose Calculation with Isodose Planning Bundle**

For CY 2015, the CPT Editorial Panel replaced six CPT codes with five new CPT codes to bundle basic dosimetry calculation(s) with teletherapy and brachytherapy isodose planning. CMS is establishing the RUC recommended work RVUs for CY 2015 for all of the codes in this family except CPT code 77316 (*Brachytherapy isodose plan; simple (calculation[s] made from 1 to 4 sources, or remote afterloading brachytherapy, 1 channel), includes basic dosimetry calculation(s)*).

CMS disagreed with the RUC-recommended crosswalk for CPT code 77316 because it does not believe it is an appropriate match in work. The RUC cross walked CPT code 77318 (*Brachytherapy isodose plan; complex (calculation[s] made from over 10 sources, or remote afterloading brachytherapy, over 12 channels), includes basic dosimetry calculation(s)*) to CPT code 77307 (*Teletherapy isodose plan; complex (multiple treatment areas, tangential ports, the use of wedges, blocking, rotational beam, or special beam considerations), includes basic dosimetry calculation(s)*), both of which are complex isodose planning codes in the same family. CMS believes that the RUC should have crosswalked CPT code 77316, a simple isodose planning code, to the corresponding simple isodose planning code in the same family, CPT code 77306 (*Teletherapy isodose plan; simple (1 or 2 unmodified ports directed to a single area of interest), includes basic dosimetry calculation(s)*). Therefore, for CY 2015 they are establishing an interim final work RVU of 1.40 for CPT code 77316.

Although the surveyed physician times are the same for CPT codes 77306 and 77316, 77306 captures the work of external beam radiation planning for one or two unmodified ports, whereas 77316 is typically used for high dose rate brachytherapy planning with a single channel, which has multiple dwell positions (typically more than four). This represents a significantly higher number of variables that have to be taken into account to create the plan. Thus there is an incremental increase in the amount of physician work for brachytherapy isodose plans. **The ACR agrees with the relativity recommended by the RUC, whereby the simple brachytherapy isodose plan is slightly greater than the work for the simple isodose plan. As such, we recommend that the Agency establish final work RVUs of 1.50 in 2016 for CPT code 77316.**
Practice Expense Comments

Percutaneous Vertebral Augmentation

The ACR believes the CMS Direct_Practice_Expense_PublicUseFiles_Labor_2015_PFS_1612-F is incorrect for CPT Codes 22510 (Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; cervicothoracic), 22511 (Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; lumbosacral), 22512 (Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; each additional cervicothoracic or lumbosacral vertebral body (List separately in addition to code for primary procedure)), 22513 (Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (eg, kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; thoracic), 22514 (Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (eg, kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; lumbar) and 22515 (Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (eg, kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; each additional thoracic or lumbar vertebral body (List separately in addition to code for primary procedure)).

Clinical time for the radiologic technologist (RT) (L041B) is missing in the direct practice expense database for all six of the new percutaneous vertebroplasty and vertebral augmentation codes and there is no discussion in the regulatory language or in Table 31 indicating that CMS intentionally removed the time. The RT clinical times for ‘assist physician’ (who is scrubbed in and working side by side with the physician during the procedure) are the times missing from the file. These minutes were RUC approved and follow the standard algorithm for interventional procedures. The clinical times for the registered nurse (RN), the RT who acquires images and the RN/LPN/MTA (circulator) are all noted correctly in the file.

The following RT (L041B) minutes are missing:

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There is also clinical time missing for the post-operative visit for four of these procedures in the same file. The RUC approved a level 3 office visit (99213) during the global period in the non-facility and facility setting. We believe this missing time is an error as well, as the direct practice expense database supply file and the direct practice expense database equipment file both indicate that CMS accepted the recommendation to include a 99213. There should be 36 minutes of nurse blend time (L037D) in the post-operative period for CPT codes 22510, 22511, 22513 and 22514 (in the non-facility and facility settings).

The ACR requests that these errors be corrected prior to January 1, 2015, to ensure that payments are appropriate for these six new percutaneous vertebral procedures.

**Radiation Treatment Vault**

CMS proposed to remove the radiation treatment vault as a direct PE input from the radiation treatment procedures [stereotactic body radiation therapy delivery (77373) and radiation treatment delivery (77402-77418) in CY2015. However, after continued review of the issues pertaining to the vault in the context of the comments, CMS believes that these issues require further study. Therefore, at this time, CMS decided to continue to include the vault as a direct PE input for stereotactic body radiation therapy delivery (77373) and radiation treatment delivery (77402-77418).

The radiation treatment vault is unlike anything else in medicine, serving a unique medical need that cannot be repurposed for other uses. Each treatment vault is distinct from a medical imaging treatment room, as it is designed and constructed to safely house a specific high-energy radiation treatment machine within its space. A change in treatment machine may require extensive modifications to the vault. The vault must comply with specific federal and state licensing regulations to protect patients, clinic staff, and the public from radiation exposure during the delivery of high-energy radiation therapy. In addition, the Internal Revenue Service rules treat radiation treatment vaults as medical equipment, separately depreciable from the building itself, thereby supporting its inclusion as a direct practice expense.

The ACR appreciates CMS’ acceptance of our recommendation to delay a final decision on the vault until after the implementation of the 2015 radiation oncology coding changes and requests that CMS work with the specialty societies to determine how the vault fits into the overall practice expense methodology.

**Transcatheter Placement Intravascular Stent**

A balloon expandable nitinol stent (a "new item") was approved by the RUC and invoices for this item submitted for CPT codes 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) and 37237 (Transcatheter placement of an intravascular stent(s)
(except lower extremity, 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; each additional artery (List separately in addition to code for primary procedure). Proper documentation indicating a price of $1,500 was included. When CMS implemented the codes in 2014, it replaced the new item with an existing input - SD152 a balloon catheter for $243. The issue was not discussed in the CY 2015 proposed rule. The CMS 2015 direct practice input files still include the balloon catheter (SD152) for CPT codes 37236 and 37237. The ACR urges CMS to correct this error in the 2015 fee schedule.

**Radiation Therapy Dose Plan, Teletherapy Isodose Plan Simple and Teletherapy Isodose Plan Complex**

CMS eliminated the RUC recommendation of five minutes for the record and verify computer system (ED011) for CPT codes 77300 (Basic radiation dosimetry calculation, central axis depth dose calculation, TDF, NSD, gap calculation, off axis factor, tissue inhomogeneity factors, calculation of non-ionizing radiation surface and depth dose, as required during course of treatment, only when prescribed by the treating physician), 77306 (Teletherapy isodose plan; simple (1 or 2 unmodified ports directed to a single area of interest), includes basic dosimetry calculation(s)) and 77307 (Teletherapy isodose plan; complex (multiple treatment areas, tangential ports, the use of wedges, blocking, rotational beam, or special beam considerations), includes basic dosimetry calculation(s)). In the final rule, CMS justified rejecting the minutes because ED011 was not previously included in these services and rationale for including ED011 was not provided.

The American Society for Therapeutic Radiology and Oncology (ASTRO) recommended adding the record and verify (R&V) system to the inputs for CPT Codes 77300, 77306 and 77307 when these codes were submitted and presented at the April 2014 RUC meeting. The five record and verify minutes were included on the practice expense summary of the recommendation form, the practice expense spreadsheet and discussed during the presentation. This is an additional step/change in technology since the codes were last valued and an integral part of the three procedures. Once all of the calculations are completed and accepted, the Certified Medical Dosimetrist/Medical Physicist (CMD/MP) will verify correct monitor units (or time) in the R&V system, print/pdf and archive all calculation records and approve monitor unit (time) setting in R&V system. This is a necessary step in the current process of care.

The ACR urges CMS to approve the five minutes of time for the record and verify computer system (ED011) for CPT Codes 77300, 77306 and 77307 and update the direct practice expense inputs before January 1, 2015.

**Hyperthermia**

In establishing interim final direct PE inputs for CY 2014, CMS refined the RUC’s recommendations for CPT code 77600 (Hyperthermia, externally generated; superficial (ie,
heating to a depth of 4 cm or less) by refining the time allocated to equipment item “hyperthermia system, ultrasound, external” (ER035) and removing the time associated with clinical labor task “clean scope,” among other refinements. CMS continues to believe that the refined time allocated to this equipment item is appropriate. Therefore, it will finalize the CY 2014 interim final direct PE inputs for CPT code 77600 as established.

The ACR urges CMS to adopt the RUC-recommended time associated with the clinical labor task “clean scope” for CPT code 77600. The time included in this line item relates to the cleaning of the equipment used in hyperthermia (i.e. ultrasound probe, hyperthermia applicator) – not specifically a ‘scope’. The probes must be cleaned after the procedure before they are used on a subsequent patient.

Other Practice Expense Comments

The ACR noticed several discrepancies in the CMS direct PE inputs files, and some of the refinements were not captured in Table 31.

Film to Digital Transition

For codes with film supply and equipment inputs removed, CMS indicates it will replace these film inputs with a “PACS workstation proxy”. However, some of the radiology codes for which film inputs were removed do not include a “PACS workstation proxy.” For example, breast ultrasound, ultrasound, CTA head/neck, cryoablation and CT caxillofacial codes all had film inputs removed and should include the proxy as a temporary replacement.

CMS reduced a number of individual clinical staff times to “standard times for clinical labor tasks associated with digital imaging.” Table 20 of the final rule lists times deemed standard for the digital imaging related activities. These are not RUC-proposed standards. The film to digital workgroup did not specify staff times in its recommendation; only general tasks were recommended. The ACR feels the below time ranges for each of the clinical activities are appropriate. Accordingly, the numerous codes which were reduced from 3 to 2 minutes should have the 3 minutes restored.
Vascular Ultrasound Room

CMS indicates that ED021 computer, desktop, w-monitor is part of the vascular ultrasound room. The desktop computer is not part of the vascular US room.

Diagnostic Ultrasound

76700 (Ultrasound, abdominal, real time with image documentation; complete)

76705 (Ultrasound, abdominal, real time with image documentation; limited (eg, single organ, quadrant, follow-up))

The RUC reviewed recommendations for six codes in the ultrasound family at the October 2013 RUC meeting. However, CMS did not capture recommendations for the PE direct inputs for CPT codes 76700 and 76705. For those two codes, there were no changes to labor, supplies, and equipment (except those reflecting the film to digital transition). We believe this failure to capture recommended direct PE inputs occurred in error because the codes are not listed in either the “without refinement” table (table 28) or “with refinement” table (table 31). Presumably, if not capturing these recommendations were intentional, these codes would be listed in the “with refinement” table. We believe it was an error and not intentional because there were changes to reflect the RUC recommendations for the other codes in the family, submitted by the RUC at the same time.
Breast Ultrasound

76641 (Ultrasound, breast, unilateral, real time with image documentation, including axilla when performed; complete)

76642 (Ultrasound, breast, unilateral, real time with image documentation, including axilla when performed; limited)

The ACR disagrees with the supposition that a limited breast ultrasound involves less technologist time than a complete breast ultrasound. While a complete examination may involve more general tissue examined, a limited examination involves follow up of a specific condition in the breast such as a clinically palpable lump, a focal abnormality detected on mammography, or focal breast pain.

CMS is basing the ultrasound “room time” on the same clinical activities used to determine “room time” for CT and MR studies. However, the clinical workflow of ultrasound is different than CT and MR in that additional staff activities are performed directly on the ultrasound machine itself, including “pre-service education/consent”, “technologist QC”, and “review with MD”. Since these activities directly involve the machine and the patient, the room is unavailable for other patients during those activities and the time for these activities should be allocated to the room time. This workflow difference was discussed at length during the PE subcommittee presentation of these codes.

CT Maxillofacial

70487 (Computed tomography, maxillofacial area; with contrast material(s))

70488 (Computed tomography, maxillofacial area; without contrast material, followed by contrast material(s) and further sections)

70487 and 70488 describe CT procedures involving contrast. The CMS PE direct input files do not include the “contrast package” (SA114) as recommended by the RUC.

Transcatheter Placement of Intravascular Stents

37218 (Transcatheter placement of an intravascular stent(s), intrathoracic common carotid artery or innominate artery, open or percutaneous antegrade approach, including angioplasty, when performed, and radiological supervision and interpretation)

Clinical time associated with the post op visit for CPT code 37218 does not appear in the CMS direct PE file. Two post-op visits were approved by the RUC.
Myelography

62284 (Injection procedure for myelography and/or computed tomography, spinal (other than C1-C2 and posterior fossa))

62302 (Myelography via lumbar injection, including radiological supervision and interpretation; cervical)

62303 (Myelography via lumbar injection, including radiological supervision and interpretation; thoracic)

62304 (Myelography via lumbar injection, including radiological supervision and interpretation; lumbosacral)

62305 (Myelography via lumbar injection, including radiological supervision and interpretation; 2 or more regions (eg, lumbar/thoracic, cervical/thoracic, lumbar/cervical, lumbar/thoracic/cervical))

72240 (Myelography, cervical, radiological supervision and interpretation)

72255 (Myelography, thoracic, radiological supervision and interpretation)

72265 (Myelography, lumbosacral, radiological supervision and interpretation)

72270 (Myelography, 2 or more regions (eg, lumbar/thoracic, cervical/thoracic, lumbar/cervical, lumbar/thoracic/cervical), radiological supervision and interpretation)

Staff types: The RUC recommended a single staff type (L037D – RN/LPN/MTA) for the bundled myelography codes, allocating the physician intra-service time to that staff. CMS divided the time between L037D and L041B (RT). We do not believe it is typical to have two staff involved in the procedure and suggest allocating all minutes to L037D. Note that for some of the bundled codes, the time allocations to the different staff types indicated in the detailed labor file do not always appropriately sum to/match the total times per staff type in the clinical labor file. For example, for CPT code 62303, 15 minutes of pre-service activities were allocated to L037D in the detailed labor file. However, the labor file indicates 11 minutes allocated to L037D and 4 minutes to L041B.

Digital Breast Tomosynthesis

77063 (Screening digital breast tomosynthesis, bilateral (List separately in addition to code for primary procedure))

The direct PE input files include a PACS workstation proxy for 77063, but did not allocate clinical staff time to this proxy.
Bone and Liver Cryoablation

20983 (Ablation therapy for reduction or eradication of 1 or more bone tumors (eg, metastasis) including adjacent soft tissue when involved by tumor extension, percutaneous, including imaging guidance when performed, cryoablation)

47383 (Ablation, 1 or more liver tumor(s), percutaneous, cryoablation)

Clinical time associated with the post op visit for 47383 does not appear in the CMS direct PE file.

The total clinical labor times are incorrect for 20983. Some of the service period activity time was allocated to the total post-service clinical labor time.

CTA Head and Neck

70496 (Computed tomographic angiography, head, with contrast material(s), including noncontrast images, if performed, and image postprocessing)

70498 (Computed tomographic angiography, neck, with contrast material(s), including noncontrast images, if performed, and image postprocessing)

Clinical staff times for “availability of prior images confirmed” and “patient clinical information and question reviewed…” were re-allocated from CT Tech (L046A) to Rad Tech (L041B). This is inconsistent from other codes in the CT family, such as 74175 and 71275.

CMS removed 2 minutes from “Technologist QC” which is, again, inconsistent with the CTA family.

Ultrasound Guidance for Needle Placement

76942 (Ultrasonic guidance for needle placement (eg, biopsy, aspiration, injection, localization device), imaging supervision and interpretation)

The detailed labor file indicates that 15 minutes of staff time is being allocated to “moderate sedation.” We believe this is an error and should state “acquire images.”

CMS incorrectly removed 2 minutes from “Technologist QC.”

Global Period

CPT code 10030 (Image-guided fluid collection drainage by catheter (eg, abscess, hematoma, seroma, lymphocele, cyst), soft tissue (eg, extremity, abdominal wall, neck), percutaneous) was
implemented in the 2014 and 2015 MPFS FR with XXX global period. However, 10030 was surveyed, RUC approved, and recommended to CMS as a 000-day global code. The ACR feels that this may have been an error and request that CPT code 10030 be revised to reflect 000-day global.

QUALITY PROVISIONS

Physician Compare

CMS finalized its proposal to expand public reporting of group-level measures by making all 2015 Physician Quality Reporting System (PQRS) Group Practice Reporting Option (GPRO) web interface, registry, and electronic health record (EHR) measures for group practices of 2 or more eligible professionals (EPs) and accountable care organizations (ACOs) available for public reporting on Physician Compare in 2016. CMS also finalized its proposal to publicly report measures for individual EPs by making all 2015 PQRS individual measures collected via registry, EHR, or claims available for public reporting on Physician Compare in late 2016.

CMS states that it will only post data for measures that are valid, reliable, and with a minimum sample size of 20 patients. Not all such measures would necessarily be included on Physician Compare, but only those that undergo consumer testing and stakeholder feedback.

The ACR appreciates CMS’ intention to only post performance data on measures that have been thoroughly tested for validity, reliability and undergone extensive consumer testing. This testing should address issues regarding appropriate patient sample size for reporting measure results, which is particularly important when applied to individual physicians. Although CMS has stated that a minimum sample size of 20 patients will be used as a cut-off for public reporting of measure data, the ACR requests that CMS test measures and composites with a 20 patient attribution and provide an opportunity for public review and comment on the testing results prior to inclusion on Physician Compare.

The ACR also recommends that performance information be posted only at a group practice level. There will likely be insufficient observations in many cases to report at the individual physician level. In addition, patients are generally served by a radiology group as a whole and not individual radiologists (unlike primary care or some specialty care), and therefore, the radiology group is a meaningful entity for assessing care quality.

Using specialty society measures

In the proposed rule, CMS sought comments on whether the measure data from a specialty society Qualified Clinical Data Registry (QCDR) should be posted on the specialty society website, linked to Physician Compare, or posted only on the Physician Compare website (societies could link to Physician Compare). CMS also proposed that a QCDR could choose whether measure data would be publicly reported at the individual level or aggregated to a higher level such as the group practice level, if technically feasible. In the final rule, CMS stated that if
QCDR measures are reported on the Physician Compare website, they must be presented at the individual physician level versus the option of aggregated to a group level. CMS believes that QCDR data is not necessarily aggregated to a level consistent with how PQRS defines a group practice. Accordingly, such aggregated data cannot be accommodated on Physician Compare at this time.

The ACR is pleased to have been approved by CMS as a QCDR in 2014 and intends to again self-nominate in 2015. In our comments to CMS on the proposed rule, we recommended that QCDR measure performance data be posted solely on the Physician Compare website rather than a specialty society website, such as the ACR QCDR webpage, which would avoid the potential perception of a conflict of interest, either from the public or ACR physician members.

We further recommended that the ACR QCDR measure data be reported on Physician Compare at the group practice level. There will likely be insufficient observations in many cases to report at the individual physician level. In addition, patients are generally served by a radiology group as a whole and not individual radiologists (unlike primary care or some specialty care), and therefore, the radiology group is a meaningful entity for assessing care quality. We believe that the QCDRs will be able to define a group practice in a manner consistent with the PQRS definition. The ACR strongly encourages CMS to postpone reporting QCDR measures data until the data can be posted at a group level on the Physician Compare website.

**Physician Payment, Efficiency and Quality Improvement - PQRS**

**Increasing requirements**

CMS will maintain the claims-based reporting option for 2015. However, CMS finalized several changes described in the proposed rule that would limit the viability of claims reporting for many individual EPs such as not accepting any new claims-based measures and reducing the number of current measures reportable through claims.

For 2015, CMS has again increased the requirements for successful PQRS reporting to avoid penalty, now requiring the reporting nine measures across three National Quality Strategy domains. CMS also introduced a new requirement to report cross-cutting measures and continues the rapid implementation of the value-based modifier with increased and substantial penalty for many groups, many of which are just recognizing the impact of the value-modifier and its association to PQRS. Even determining how and what to report is complicated for providers. All these factors have compounded the burden placed on groups.

The ACR understands that CMS is transitioning from claims-based reporting in order to streamline the PQRS program using more automated mechanisms. However, the ACR strongly recommends that CMS restrain from changing and increasing requirements on an annual basis and allow a level of stability to develop over a period of two or three years.
before implementing additional changes or additional penalties. This would also allow further implementation and expansion of the QCDR mechanism to support greater availability of reportable measures.

CMS intends to maintain the measure applicability validation (MAV) process used in 2014 for EPs reporting less than nine measures or three domains through claims or traditional registry mechanisms.

As reporting requirements increase and the PQRS program becomes penalty-based only, the MAV process is more critical for participants who have few measures available to report. The ACR urges CMS to share in detail the methodology used for assigning measures to “clusters” in the MAV, as well as the method for determining measure National Quality Strategy domains. This process should be transparent, include specialty and stakeholder input, and the resulting information should be available as early as possible before the beginning of each reporting year. The MAV maintenance could be conducted through the CMS/measure owner annual maintenance process.

**Selection of PQRS measures**

CMS deleted a number of measures, many of which were recommended for removal due to consistent high performance indicating no gap in care.

The ACR appreciates that CMS will continue to include Measure #146, Inappropriate use of probably benign code, in 2015; the measure had been proposed for removal, being considered “topped out”. Removing measures based on this rationale (high measure performance rates) may be premature, particularly when the PQRS participation rate remains low and the performance of “early adopter participants” could be higher than average. We encourage CMS to phase out a measure’s removal from the program over several years so that either the measure can be modified or to allow introduction of new measures to the program.

CMS finalized its proposal to increase the minimum number of outcome measures that a QCDR must have available for reporting from one to three; or in lieu of having three outcome measures, a QCDR may have two and at least one resource use, patient experience of care or efficiency/appropriate use measure.

The ACR appreciates CMS’ recognition of the usefulness of QCDRs and their viability in the PQRS program, as well as the allowance of 30 non-PQRS measures for QCDRs in the 2015 reporting year. We also support CMS’ proposal that a QCDR include the various types of measures as described above, but as with other PQRS program changes mentioned above, recommend that CMS phase-in new requirements over several years, so as to allow new QCDRs to incrementally add measures.
The ACR also urges CMS to continue to seek Congressional authority to allow group practices registered under the GPRO to use the QCDR participation option.

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

By statute, CMS is required to implement the value-based payment modifier (VM) to all physicians and groups of physicians by January 1, 2017. With the 2015 final rule, CMS has accelerated the implementation and impact of the value-based modifier in both the number of physicians affected and the magnitude of potential penalties. While many group practices are just beginning to implement PQRS, the VM complicates and compounds their efforts. The Quality Resource Use Reports, which are meant to be a tool for group practices to understand how they fare under the VM, arrive far too late after the performance period and contain very little information at all, much less actionable information. The rapidity with which CMS is applying the VM to all physicians will result in over 100,000 practitioners receiving substantial penalties (up to 6% in some cases with combined PQRS and VM penalties), which could result in many providers electing to reduce or discontinue providing services to Medicare beneficiaries.

The ACR strongly urges CMS to slow the VM and associated penalty progression and, if necessary, work with Congress for authorization to allow a more methodical and realistic application of the current statute. Additionally, we encourage CMS to consider reverting to quality tiering as an option for groups until there is greater uptake of PQRS and understanding of the VM. With PQRS non-participation penalties beginning in 2015, many practices are becoming very aware of the need to participate.

**Program Alignment with EHR Incentive Program (MU)**

While CMS recognizes the importance of aligning CMS quality programs and has taken steps in this direction, most physicians still must report multiple times to avoid payment adjustments. In order for MU quality reporting to count towards PQRS, a physician must take into consideration numerous detailed rules and requirements.

To truly streamline reporting, physicians who successfully participate in PQRS, regardless of the reporting mechanism, should be deemed as successfully meeting the MU quality measure requirements, and vice-versa. We also urge CMS to reduce the number of quality measures required to report until there are enough electronic clinical quality measures (eCQMs) that work for all physician specialties.

It is frustrating that CMS has not addressed rules around QCDR reporting for satisfactorily meeting quality requirements for the MU program. This represents a missed opportunity for CMS to align reporting requirements for PQRS and EHR Incentive programs and make the programs meaningful for physicians. The proposed criterion for QCDRs to report quality measures within the MU Program is simply not feasible. Essentially, QCDRs must have the ability to electronically specify their measures. As CMS is aware, this is not a simple task and not all quality measures lend themselves to electronic specifications. In addition, QCDRs must
go through the MU modular Certified Electronic Health Record Technology (CEHRT) process which assumes that an EHR is interoperable with a registry. Finally, requiring QCDRs to go through the CEHRT process will force registries to meet qualification requirements for both PQRS and EHR Incentive programs. The QCDR EHR Incentive program requirements do not allow for the true utility and purpose of registries, or the evolution of the quality measurement process. It would be extremely supportive of registry evolution and participation for CMS to work closely with the Office of the National Coordinator for Health Information Technology (ONC) to develop a single standard so that EHRs are interoperable with registries. The current certification requirements also fail to address the need for bi-directional exchange for national clinical data registries or clinical data standardization for any other purpose. EHR vendors charge providers to map and transmit data from an EHR to a registry. The ability to transmit clinical data to national clinical registries using standardized data definitions will assist physicians and health care systems to move to a more advanced state of quality measurement.

CMS should play a greater role in facilitating the use of clinical data registries by encouraging the development of standards for sharing/transmitting data between EHRs and registries and to work with ONC to require EHR vendors to provide clinical data in a standard format backed by standardized data definitions.

CONCLUSION

The ACR appreciates the opportunity to provide comments on the CY 2015 MPFS final rule. We encourage CMS to continue to work with physicians and their professional societies through the rulemaking process to create a stable and equitable payment system. The ACR looks forward to continued dialogues with CMS officials about these and other issues affecting radiology and radiation oncology. If you have any questions or comments on this letter or any other issues with respect to radiology or radiation oncology, please contact Kathryn Keysor at 800-227-5463 ext. 4950 or via email at kkeysor@acr.org.

Respectfully Submitted,

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Attachment