

August 25, 2014

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

Re: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2015; Proposed Rule

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) Proposed Rule.

In this comment letter, we address the following important issues:

- Valuing New, Revised, and Potentially Misvalued Codes
- Proposed Potentially Misvalued Codes Through High Expenditure Specialty Screen
- Inputs for Digital Mammography Services
- Urban Institute Interim Report
- Migration from Film to Digital Practice Expense (PE) Inputs
- Abdominal Aortic Aneurysm (AAA) Ultrasound Screening
- Radiation Treatment Vault
- Direct Practice Expense Inputs for Stereotactic Radiosurgery (SRS) Services
 (Current Procedural Terminology (CPT®) Codes 77372 and 77373)
- Transcatheter Placement Intravascular Stent (CPT Codes 37236 and 37237)
- Physician Fee Schedule Modifier Indicators for Current Procedural Terminology (CPT Codes 34841 – 34848)



- Using Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgery Center (ASC) Rates in Developing Practice Expense Relative Value Units (RVUs)
- Relative Value Scale Update Committee (RUC) Recommendation for Standard Moderate Sedation Package
- Valuing Services that Include Moderate Sedation as an Inherent Part of Furnishing the Procedure
- New Standard Supply Package for Contrast Imaging
- Equipment Cost Per Minute
- Payment of Secondary Interpretation of Images
- Protecting Access to Medicare Act of 2014 (PAMA) and the Multiple Procedure Payment Reduction (MPPR)
- Payment Policy for Substitute Physician Billing Arrangements
- Reports of Payments or Other Transfers of Value to Covered Recipients
- Continuing Medical Education (CME) proposal to delete the "Continuing Education Exclusion" found in 42 CFR 403.904(g) in its entirety
- Quality Provisions, including Physician Compare, Physician Quality Reporting System (PQRS), and the Value Modifier Programs

Valuing New, Revised, and Potentially Misvalued Codes

The ACR supports the idea of providing as much notice as possible to physicians when CPT codes and their values are updated. We feel strongly that the current system of publishing rates for new and revised CPT codes and revalued services in November with an implementation date of January 1 is flawed, and we thank CMS for considering alternatives that will enable more advanced notice and an opportunity for comment. However, we believe that there are flaws in the new timeline proposal. The ACR is a cosigner to a multi-specialty letter describing the recommendations below.

Implementation Year

CMS proposes implementation of the new timeline for CY 2016. The cycle for the *CPT* 2016 code set began with code change applications for the May 2014 CPT Editorial Panel Meeting submitted by February 14, 2014 and will conclude on February 7, 2015. The ACR believes that it would be inappropriate for CMS to implement this proposal in the November 1, 2014 Final Rule because the CPT Editorial process for the 2016 cycle will already be nearly complete by that date, and requiring publication in a proposed rule next summer will delay their implementation in Medicare by another year. Those that have solicited new and/or revised CPT codes deserve timely consideration of their applications. They also deserve fair notice of the implementation date. If CMS were to



announce a 2017 implementation date on November 1, 2014, it would provide appropriate notification to those submitting code change applications by the first *CPT* 2017 deadline of February 13, 2015. We urge CMS to begin implementing the new timeline and procedures for the CPT 2017 cycle and the 2017 MPFS.

New Timeline Proposal

In order to accommodate the publication of proposed valuation of new, revised, and potentially misvalued services, CMS proposes to require that all RUC recommendations be submitted by January 15 of each year. For 2016, this would mean that the May 2014 CPT/September RUC meeting would be the only opportunity for the medical community to offer description and recommended valuation of new technology and code bundles, since the RUC will not have the opportunity to consider codes from the October CPT Editorial Panel meeting until January 29, 2015.

In addition, this proposal would extend the time required to generate a code/relative value from 22 to 30 months for each subsequent CPT code set cycle at a time when CMS, the CPT Editorial Panel, and the RUC are being asked to reduce the amount of time needed to accommodate changes.

The ACR has carefully reviewed both the CMS proposal and the proposal offered by the American Medical Association (AMA) to expedite the review processes for new, revised and potentially misvalued services. The AMA proposal would retain the current meeting infrastructure for both CPT and the RUC, while shifting the workflow to accommodate the review of commonly performed services to the May CPT/October RUC and October CPT/January RUC meetings. Under this proposal, the February CPT meeting would predominantly address editorial changes, clinical lab payment schedule services, and new technology services, with expected low volume. The April RUC meeting would replace the formerly lighter September RUC meeting agenda and would be utilized to review the low volume new technology services and discuss methodological and process issues. We believe that CMS should be able to publish consideration of the low volume new technology codes in the Final Rule as interim values, as these changes would have minimal impact on the other services on the MPFS. The AMA proposes to submit RUC recommendations to CMS within one month of each meeting (each November and February for new, revised, and potentially misvalued codes; and each May for low volume new technology codes). The ACR strongly urges CMS to adopt the AMA proposal for modifications in CPT/RUC workflow to accommodate publication in the Proposed Rule, while ensuring that new technology may be described and valued in an efficient and timely manner.

If CMS adopts the AMA proposal, this will eliminate the need for CMS to create G codes (instead of adopting certain CPT codes in a more timely manner). We believe



that the G code proposal is entirely unworkable and should not be considered in finalizing the new process. The creation and adoption of temporary G codes would unnecessarily add to the administrative burden of physicians, non-physician practitioners, and providers who would be tasked with the implementation of new codes within a relatively short period. When this applies to large families of codes, the burden is even greater, increasing the risk for coding errors. Moreover, this threatens to create a situation of parallel but distinct coding between Medicare and private payers, as private payers are likely to implement new CPT codes as soon as they are published. This would be a great step backward from what Congress intended in mandating Health Insurance Portability and Accountability Act of 1996 (HIPAA) administrative simplification policies, including standard code sets.

Refinement Panel Process

CMS proposes the elimination of the current Refinement Panel process. For nearly two decades, the CMS Refinement Panel Process was considered by stakeholders to be an appeals process. Recently, CMS modified the process to only consider codes for which new information was provided in the comment letter. CMS also began to independently review each of the Refinement Panel decisions in determining which values to actually finalize. In many cases, the Refinement Panel supported the original RUC recommendation and the commenter's request, yet CMS chose instead to maintain the lower interim final value. The complete elimination of the Refinement Panel indicates that CMS will no longer seek the independent advice of contractor medical officers and practicing physicians and will solely rely on agency staff to determine if the comment is persuasive in modifying a proposed value. The lack of any perceived organized appeal process will likely lead to a fragmented lobbying effort, rather than an objective review process. Those organizations with limited resources are disadvantaged in comparison to those vendors or organizations that will spend significant resources to overturn a CMS proposed value. We recommend that CMS consider these issues and create a fair, objective, and consistently applied appeals process that would be open to any commenting organization.

Proposed Potentially Misvalued Codes Through High Expenditure Specialty Screen

Several radiology codes are among those listed in Table 10 of the proposed rule as codes identified through the high expenditure specialty screen. The ACR would like to point out that CPT codes 36475 (Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; first vein treated), 36478 (Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; first vein treated), 76700 (Ultrasound, abdominal, real time with image documentation; complete), 76770 (Ultrasound, retroperitoneal (eg, renal, aorta, nodes), real time with image



documentation; complete)) and 76775 (Ultrasound, retroperitoneal (eg, renal, aorta, nodes), real time with image documentation; limited)) were recently reviewed by the RUC and recommendations already submitted for 2015.

CMS indicates that codes which they have reviewed since CY 2009 are excluded from the Table 10 list of high expenditure codes. CPT code 76536 (Ultrasound, soft tissues of head and neck (eg, thyroid, parathyroid, parotid), real time with image documentation) was reviewed by the RUC in April of 2009 and entered the MPFS as interim final in 2010. CMS made the value final for the 2011 MPFS. Therefore, we believe this code has been reviewed since 2009, and we request removal of this code from consideration. Furthermore, there has been no significant change in work or practice expense to merit repeat review within such a truncated timeframe.

36215 (Selective catheter placement, arterial system; each first order thoracic or brachiocephalic branch, within a vascular family)

As outlined by a multi-specialty panel in April 2012, CPT code 36215 will be greatly impacted by the new Cervicocerebral Angiography codes, which bundle 36215 with the associated supervision and interpretation code. At that time, the multispecialty group requested that 36215 be maintained until 3 years of utilization data are available and the specialties can determine the typical vignette and dominant specialty. 2013 is the first year for which data under the new cervicocerebral angiography coding system is available, and trends are already seen to be shifting significantly. The utilization of 36215 has dropped dramatically from 78,041 (2012) to 44,623 (2013). We continue to recommend this code be maintained until 3 years of utilization data are available for review.

36870 (Thrombectomy, percutaneous, arteriovenous fistula, autogenous or nonautogenous graft (includes mechanical thrombus extraction and intra-graft thrombolysis))

CPT code 36870 has been referred to CPT "to bundle the appropriate services". A CPT code change proposal (CCP) will be submitted for the 2017 RUC/CPT cycle.

Inputs for Digital Mammography Services

To meet the requirements of the Benefits Improvement and Protection Act of 2000 (BIPA), CMS created a new family of G-codes and established physician payment rates for these G-codes. CMS is proposing to delete the mammography G-codes, G0202-G0206. Beginning with CY 2015, CMS proposes to pay all mammography using the existing analog mammography CPT codes, 77055-77057, since "a review of Medicare claims data shows that the mammography CPT codes are billed extremely infrequently,



and that the G-codes are billed for the vast majority of mammography claims." CMS is proposing to value the mammography CPT codes using the RVUs previously established for the G-codes. CMS is also proposing these codes as potentially misvalued and requesting that the RUC and other interested stakeholders review these services in terms of appropriate work RVUs, work time assumptions and direct PE inputs.

The ACR agrees that analog mammography, reported by 77055 (mammography; unilateral), 77056 (mammography, bilateral), and 77057 (screening mammography, bilateral) has largely been replaced by full field digital mammography (FFDM), reported by G0202 (Screening mammography, producing direct digital image, bilateral, all views), G0204 (Diagnostic mammography, producing direct digital image, bilateral, all views), and G0206 (Diagnostic mammography, producing direct digital image, unilateral, all views). The ACR believes the physician work value of the analog mammography codes appropriately captures the physician work of digital mammography. We also believe the BIPA directed payment of 1.5 times the technical component (TC) appropriately captures the increased practice expense resources inherent to FFDM compared to analog mammography. The ACR recommends that CMS maintain this payment rate beyond CY 2015. CMS has requested that the RUC review the mammography CPT codes, but we discourage survey or formal recommendations until: (1) the RUC recommendations for digital breast tomosynthesis are finalized by CMS; and (2) the film to digital conversion is fully implemented beyond the proposal in the CY 2015 proposed rule.

The ACR cautions CMS regarding downstream consequences of deleting the G-codes and using the mammography codes exclusively. Medicaid and most private payers will lack sufficient time to update their fee schedules to apply the G-code payment amounts to the analog codes. As such, payment rates for digital mammography could decrease significantly, possibly jeopardizing patient access, especially in the outpatient setting. Many physicians will be forced to use separate codes for analog and digital mammography until such transition occurs, placing unnecessary administrative costs on providers.

Urban Institute Interim Report

Section 1848(c)(2)(L) of the Social Security Act requires the Secretary to establish a formal process to validate RVUs under the MPFS. The Act states that the Secretary may conduct the validation using methods similar to those used to review potentially misvalued codes, including conducting surveys, other data collection activities, studies, or other analyses as the Secretary determines to be appropriate to facilitate the validation of RVUs of services. To that end, CMS has contracted with the Urban Institute to collect time data from several practices for services selected by the contractor in consultation with CMS. The ACR has reviewed the interim report, Development of a Model for the



Valuation of Work Relative Value Units, which discusses the challenges encountered in collecting objective time data.

The ACR has significant concerns that shortcomings in the process will limit the accuracy and outcome of this effort. Our concerns fall into the following categories:

Pre-Study Bias

The ACR is concerned that a predetermined outcome may yield a less than objective analysis. Dr Berenson, the lead investigator and the only physician listed as one of the preparers of the report, is on the record as inferring that radiologists capture an inappropriate proportion of part B spending (http://healthaffairs.org/blog/2009/07/22/the-centers-for-medicare-and-medicaid-services-a-roundtable-with-robert-berenson-bruce-vladeck-kerry-weems-and-gail-wilensky/).

Study Design

The study is largely relying on time elements as the key determinant of relativity, minimizing the important contribution of magnitude estimation in assigning relativity. A key premise of the Resource Based Relative Value Scale (RBRVS) is the relativity of the values across the entire fee schedule. This is especially important if a new method of measuring relativity may be developed which could impact all services in the fee schedule, either through direct adjustments or relativity alteration. Therefore, any validation study should seek to ensure relativity not only among all specialties, but also within specialties, not absolute validation of select specialties. The report acknowledges this shortcoming, noting that the number of specialties represented by the codes selected for the pilot project must be limited "because of the clinical panels that will examine the data later in the project".

Section 3 describes the selection of sites and the first criterion is candidates "known to be interested in participating in projects of this type." This is another potential source of bias if such "interest" has a pre-determined bias. Later, in the same section, the authors indicate that they had difficulty enrolling "organizations that do not employ physicians". It would seem that such sites would offer worthwhile data and their non-participation could further limit the data represented.

Codes Studied

The final group of 100 codes chosen represents 17% of total MPFS spending in 2011. Approximately 21 of the 100 codes affect radiology, with approximately 20 of the 100 codes affecting orthopedics. Over 40% of the codes studied originating from two specialties is disproportionate and counter to the stated goal of selecting codes that



represent "a broad range of non-evaluation and management (E&M) services" and "permit a broad test of the ability to use administrative data systems efficiently to contribute reliable time data and of the ability to determine service time by direct observation".

It is not clear why E&M services are excluded from this effort, especially considering that these codes comprise greater than 40% of MPFS spending. The report mentions "the issues associated with determining empirically derived times for E&M services are different and, in some ways, more complex than those posed by obtaining objective time data for procedures, imaging, and tests." The report further states that "E&M services are unique, complex, and important enough to justify a separate and detailed examination of the time issues associated with these services." With the rapid diffusion of electronic medical records (EMRs) into settings in which E&M services are provided, this data would seem to be readily accessible. Maintaining relativity is important across the entire fee schedule so excluding E&M codes which comprise such a large proportion of Medicare spending is a major limitation.

Sample Size and Sites Chosen

The project acknowledges challenges in enrolling sites, and the researchers have only been able to enroll 3 out of 20 potential sites. The report indicates that service volumes for many services are much lower than anticipated. Low volumes could yield sampling errors compared to services with higher volumes at a given site and impact the validity of the overall data and recommendations.

Study Protocols

The report indicates that, in some cases, the project staff themselves will not be performing the direct observation in patient care areas. Rather, the project staff will train on-site staff to do the observation. This introduces potential bias, particularly if there is inconsistency between services studied by project staff and services studied by on-site staff.

The service time definitions and their application are described in the report. However, project staff will not be recording times for the individual elements of pre-, intra-, and post-service work, just the total times for those respective service periods. Thus, the project staff will not be able to accommodate the effect of "moving" an individual service period element from one service period to another. This will make it difficult for the clinical panels in later phases of the project to confirm that proper amounts of time are allocated to each element of the pre-, intra-, and post-service periods.



At least one site requires patient and physician consent for the study which could impact observation times, and may impact different specialties, disproportionately leading to further erosion of relativity.

Appendix F describes the methodology of the administrative data portion (Health Information Technology (HIT) portion) and lacks in sufficient detail. It is unclear how the HIT data will be extracted and correlated with the pre-, intra-, and post-service times in the RUC database. For example, Figure 2 acknowledges that pre and post times may not be consistently recorded in the electronic record. Considerable variability between different sites and their ability to produce such data could also contribute to inconsistent data.

It is not clear from the report how interruptions will be measured and subtracted from the service period times of the subject procedure and (where appropriate) added to the service period times for other procedures. There is some discussion of categorizing these interruptions, and recognition that the interruptions may include pre- or post-service work for other patients, but it is unclear how these times will be appropriately added. For example, if one service is under study, but the physician is interrupted to perform a task for a study measured earlier in the day, how will those tasks be allocated? Further, there may be additional pre-and/or post-service work that occurs outside of the study hours. An example in radiology may be protocoling the next day's work or signing the previous day's reports.

In summary, the ACR has significant concerns regarding study design, pre-study bias, inadequate sampling, inadequate sampling of services studied, and flaws in the data collection protocols.

Migration from Film to Digital Practice Expense Inputs

The RUC created the Practice Expense Subcommittee Migration from Film to Digital Imaging Workgroup to formulate recommendations regarding the transition from film to digital imaging. The ACR was an active participant in this workgroup, which submitted recommendations to CMS following the April 2013 RUC meeting. The RUC recommended that CMS replace the film supplies and equipment from 604 existing imaging codes with Picture Archiving and Communication System (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 (Attachment A) include such items as the quality assurance (QA) station, PACS servers, PACS software and PACS physician workstations.



CMS states that "since they did not receive any invoices for the PACS system, they are unable to determine the appropriate pricing to use for the inputs...CMS proposes to accept the RUC recommendation to remove the film supply and equipment items, and to allocate minutes for a desktop computer (ED021) as a proxy for the PACS workstation as a direct expense."

The ACR agrees that removal of the RUC recommended list of supply and equipment items associated with film technology is appropriate for the 604 imaging codes provided by the RUC, but only if appropriate PACS related inputs are added as replacements. To unilaterally remove the film-based inputs and simply allocate minutes to a desktop computer (ED021) greatly underestimates the expenses incurred by physicians. Further, it is not clear which minutes from the current film based inputs would be allocated to the desktop computer. A clearer allocation method should be described to enable public comment. The impacts of this code change are sizable for a number of codes, such as 76377 (3D rendering with interpretation and reporting of computed tomography, magnetic resonance imaging, ultrasound, or other tomographic modality; requiring image postprocessing on an independent workstation), which suffers a 45.7% reduction from the removal of the film based inputs but only gains back 1.7% of its PE RVUs when the desktop computer is substituted. Moreover, removal of these film-related inputs entirely from the database is inappropriate. This impacts a number of codes which were purposefully excluded from the Workgroup recommendation since PACS is not typical for those codes or those codes do not relate to imaging but require one or more of the film related inputs nonetheless.

The RUC also recommended revisions to the clinical labor times to reflect the migration from film to digital. We appreciate that CMS agrees with including these more detailed clinical activities in new imaging codes going forward. We are concerned, however, that CMS' proposal to retroactively apply these changes to all imaging codes may be unworkable. The CMS direct PE input database includes only the total pre, intra, and post-service times. The individual tasks and the respective times which comprise these service period times are not available, making large scale implementation problematic. Further, the database does not include the RUC recommendations alongside subsequent CMS refinements, nor does the database include applicable supporting materials. The ACR supports CMS' plans to include task-level clinical labor time information in the database and supports greater transparency and accuracy to the PE database overall. However, until this update to the database occurs, retroactive changes to specific PACS-related task items do not seem feasible.

The ACR requests (1) that CMS delay, for one year, removal of the supply and equipment items associated with film technology and the use of a desktop computer as a proxy for the PACS workstation. During the next six months, the ACR commits to working with CMS to ensure that the proper digital inputs are identified and



integrated into the CMS database along with appropriate invoices. Our goal would be to collaborate on recommendations in time for public comment during the CY 2016 notice of proposed rule making (NPRM); and (2) that CMS update the PACS related clinical tasks in new imaging codes going forward, but not attempt to retroactively update these inputs across all imaging codes until task specific clinical labor time inputs are readily available.

Abdominal Aortic Aneurysm Ultrasound Screening

Section 5112 of the Deficit Reduction Act of 2005 (DRA) provides for coverage of AAA screening by ultrasound effective January 1, 2007. When Medicare began paying for AAA ultrasound screening in CY 2007, CMS created HCPCS code G0389 (Ultrasound B-scan and/or real time with image documentation; for AAA screening) and set the RVUs at the same level as CPT code 76775 (Ultrasound, retroperitoneal (eg, renal, aorta, nodes), real time with image documentation; limited)). CMS noted in the CY 2007 final rule with comment period that CPT code 76775 was used to report the service when furnished as a diagnostic test and that the agency believed the service reflected by G0389 involved equivalent resources and work intensity to CPT code 76775.

In the CY 2014 proposed rule, based on a RUC recommendation, CMS proposed to replace the general ultrasound room included as a direct PE input for CPT code 76775 with a portable ultrasound unit. Since all the RVUs (including the PE RVUs) for G0389 were cross-walked from CPT code 76775, the proposed PE RVUs for G0389 in the CY 2014 proposed rule were reduced significantly as a result of this change to the direct PE inputs for 76775. However, CMS did not discuss the applicability of this change to G0389 in the proposed rule's preamble and did not receive any comments on G0389 in response to the proposed rule. The change to CPT code 76775 was finalized in the CY 2014 final rule with comment period, and the corresponding PE RVUs for G0389 were also reduced.

In response to comments received after the publication of the CY 2014 final rule, CMS is proposing G0389 as a potentially misvalued code and is seeking recommendations regarding the appropriate inputs that should be used to develop RVUs for this code. In the interim, CMS is proposing to maintain the work RVU for this code and to revert to the same PE RVUs that were used for CY 2013, adjusted for budget neutrality.

The ACR agrees that the reduction in the PE RVUs in CY2014 for G0389 was inappropriate and unintended. CPT code 76775 describes a limited ultrasound of the retroperitoneum. By definition, limited ultrasound studies include less than the number of elements required to bill a "complete" ultrasound of the same body part. For example, 76775 may be billed when only the kidney is studied or when only the aorta is studied. When 76775 was reviewed recently by the RUC PE Subcommittee, the most common



indication for 76775 related to the kidney, and the dominant specialty was urology. As such, the recommended equipment direct input was the portable ultrasound unit used by urology for the limited study of the kidney. Screening studies of the aorta should be performed in a general ultrasound room, not portably. The ACR recommends that G0389 maintain the general ultrasound room and have its PE RVUs set and maintained as such.

In the event that G0389 is converted to a Category I CPT code, we stress the following points: (1) the statutory ultrasound screening requirement for AAA should be maintained for any new code created; and (2) a general or vascular ultrasound room should be maintained as the appropriate direct PE input to ensure proper quality examinations for Medicare beneficiaries.

Radiation Treatment Vault

CMS believes that the special building requirements indicated for the radiation treatment vault to house a linear accelerator do not represent a direct cost in the PE methodology, and that the vault construction is, instead, accounted for in the indirect PE methodology, just as the building and infrastructure costs are treated for other MPFS services, including those with infrastructure costs based on equipment needs. CMS proposes to remove the radiation treatment vault as a direct PE input from the radiation treatment procedures listed in Table 8 in the proposed rule, because it believes that the vault is not, itself, medical equipment, and therefore, is accounted for in the indirect PE methodology.

This significant shift in PE policy comes just before CMS will unveil wholesale changes to the radiation treatment delivery code set, representing 50% of radiation oncology allowed charges, in the CY 2015 final MPFS. The combination of these two monumental changes to radiation oncology treatment codes is of great concern to the ACR. Due to the potential enormity of these payment changes facing radiation oncology, the ACR urges CMS to reconsider the proposed radiation treatment vault policy change and delay any final decision until after the radiation oncology coding changes are implemented.

CMS believes that the requirements for the vault reflect building and infrastructure costs (indirect practice expenses), rather than medical equipment costs (direct practice expenses). The ACR acknowledges the complexity of the decision on how to classify the vault. The radiation treatment vault is unlike anything else in medicine, serving a unique medical need that cannot be repurposed for other uses (leases typically require tenants to remove vaults before vacating the property). 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 of 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, Internal Revenue Service (IRS) rules treat radiation treatment vaults as medical equipment, separately depreciable from the building itself, thereby supporting its inclusion as a direct practice expense.

Removing the vault as a direct practice expense accounts for nearly the entire 2015 payment reduction for radiation oncology. On the individual code level, the impact ranges from -2% to almost -16%. In the proposed rule, CMS estimates the aggregate impact of changes to PE RVUs on radiation oncology ranges from -4% to -8%, with some stakeholders estimating the impact of the proposed rule on freestanding radiation oncology centers to be -6%. It is important to also remember that these 2015 proposed cuts come after five years of cumulative reimbursement reductions to community-based radiation therapy centers, totaling approximately 20%.

We believe it is premature for CMS to make a determination on removing the vault as a direct practice expense when the agency is scheduled to introduce significant payment rate changes to the radiation treatment delivery code set in the CY 2015 final MPFS. CMS requested these coding and valuation changes in the CY 2013 final MPFS as part of a review of a series of codes described as having "stand alone procedure time." This list included the radiation therapy codes impacted by the proposed vault policy. The ACR worked with the American Society for Radiation Oncology (ASTRO) and other stakeholders through the AMA CPT Editorial Panel and RUC to revise and update these codes so they better reflect the current process of clinical care. These new and revised codes will be published in the 2015 CPT code book. The code changes represent 50% of radiation oncology allowed charges from the MPFS and represent tremendous uncertainty, as the 2015 interim final values are unknown outside the agency, which will not publish the values until November 2014, with the release of the final 2015 MPFS.

The ACR recognizes that CMS must determine how the vault fits into the overall practice expense methodology; however, radiation oncology stakeholders cannot adequately assess and comment on the vault proposal without the essential, significant context of the revised treatment delivery code values. As reflected in the reduced PE RVUs for the services published in Addendum B of the proposed rule, the implications of this decision are significant for radiation therapy providers and their patients. Continued reductions of Medicare reimbursement rates have destabilized the provision of radiation oncology services in the physician office setting in recent years. We are very concerned that further reductions could have a negative impact on patients' access to high quality, safe radiation therapy.

The ACR supports CMS' efforts to determine accurate payment rates, but these efforts should be fair and fully transparent, in keeping with the agency's intentions for



revaluations and new codes beginning in CY 2016. Before making a decision on the vault, the agency should consider the totality of variables impacting radiation oncology payments in 2015, and provide complete transparency and meaningful opportunity for public comment. Therefore, the ACR strongly urges CMS to take the most reasonable and balanced approach by delaying any final decision on the vault until after implementing the 2015 radiation oncology coding changes.

<u>Direct PE Inputs for Stereotactic Radiosurgery Services (CPT Codes 77372 and 77373)</u>

In the MPFS, SRS and SBRT services furnished using robotic methods are billed using contractor-priced G-codes:

- G0339 (Image-guided robotic linear accelerator based stereotactic radiosurgery, complete course of therapy in one session or first session of fractionated treatment)
- G0340 (Image-guided robotic linear accelerator-based stereotactic radiosurgery, delivery including collimator changes and custom plugging, fractionated treatment, all lesions, per session, second through fifth sessions, maximum five sessions per course of treatment)

Based on comments received in the CY 2014 cycle, including those from the ACR, CMS concluded that the PE RVUs for the CPT codes accurately captured the resources utilized for robotic SRS and SBRT services. For CY 2015, CMS proposes to recognize only the CPT codes for payment of SRS and SBRT services, and to delete the G-codes used to report robotic delivery of SRS and SBRT. The practical implication of this policy change is that freestanding centers will no longer be able to report G0339 and G0340, and these centers would instead report CPT code 77372 or 77373.

SRS and SBRT are precise and effective types of radiation therapy that use concentrated radiation beams in high doses to destroy tumors in difficult and hard to reach areas, such as the brain or spine, and other sites within the body. These forms of treatment are high-value services that achieve tumor eradication expediently and non-invasively. Many providers have been reporting G-codes for SRS and SBRT services, relying on established contractor-negotiated rates when billing for these services. Several ACR members have reported concerns that previous reimbursement reductions have forced several freestanding SRS/SBRT centers to close, and other centers are concerned that the transition to CPT codes could result in further limiting access to SRS and SBRT services in the physician office setting. In light of the potential significant impact of this change on reimbursement for an effective treatment for a high-risk population of cancer patients, the ACR urges CMS to closely monitor access to SRS and SBRT services to ensure that this policy change does not limit patient access.



<u>Transcatheter Placement Intravascular Stent (CPT Codes 37236 and 37237)</u>

A multispecialty group has requested that CMS correct a practice expense problem with CPT codes 37236 (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; 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)). The multi-specialty group submitted PE recommendations on 4 new stent CPT codes in April 2013. A "new item" for a stent system was submitted for CPT codes 37236 and 37237. Proper documentation indicating a price of \$1500 was included. When CMS implemented the codes, 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 SD152 for CPT codes 37236 and 37237. The ACR urges CMS to correct this error in the 2015 fee schedule.

Physician Fee Schedule Modifier Indicators for CPT Codes 34841 – 34848

The ACR requests that CMS review the modifier indicators assigned to CPT codes 34841 – 34848 (Endovascular repair of visceral aorta (eg, aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) by deployment of a fenestrated visceral aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including visceral artery endoprosthesis (superior mesenteric, celiac or renal artery)). We recommend CMS assign these codes an indicator of "2" versus an indicator of "0" for the categories of multiple procedure, assistant at surgery, and co-surgeon. Other contractor priced codes allow modifiers, and we believe it is appropriate to allow for use of these modifiers along with these contractor priced services as well.

<u>Using Hospital Outpatient Prospective Payment System and Ambulatory Surgery</u> <u>Center Rates in Developing Practice Expense Relative Value Units</u>

As stated in our comment letter on the CY 2014 proposed rule, the ACR believes that the proposal to use the current year OPPS or ASC rates as a point of comparison in establishing PE RVUs for services under the MPFS is inappropriate. We appreciate CMS' recognition of the concerns raised in last year's rulemaking process and thank the agency for not proposing a similar policy for CY 2015.



CMS is seeking comment on the possible use of the Medicare hospital outpatient cost data in potential revisions of the MPFS PE methodology. The ACR does not support this concept, as we know from our experience with the CT and MR cost centers that the OPPS cost reports are often inadequate and inappropriate for application to the MPFS. Hospitals use unconventional cost accounting methods such as square foot allocation. In general, hospitals can allocate costs across multiple cost centers, further reducing costs to centers relevant to the physician fee schedule. Lastly, it is inappropriate to assume that hospitals incur the same costs as physicians, as both practice in different settings.

RUC Recommendation for Standard Moderate Sedation Package

CMS is proposing to modify the standard moderate sedation input package to include a stretcher for the same length of time as the other equipment items in the moderate sedation package. The ACR agrees that the stretcher should be allocated with the same time as the other moderate sedation specific inputs since it is used by the patient for the duration of their recovery and not available to other patients during that time.

<u>Valuing Services that Include Moderate Sedation as an Inherent Part of Furnishing the Procedure</u>

The proposed rule states that CMS data clearly indicate that moderate sedation is no longer typical for all of the procedures listed in CPT's Appendix G, and, in fact, the data suggest that the percentage of cases in which it is used is declining. The ACR disagrees with this assertion and believes that the radiology codes in Appendix G are typically reported with moderate sedation. Because these codes are included in Appendix G, moderate sedation (i.e. 99144) is not separately reimbursed. Therefore, providers, by convention, do not report the moderate sedation codes separately. It is not clear how CMS could conclude that "moderate sedation is no longer typical" for radiology codes through any meaningful claims-based analysis. CMS references studies indicating that moderate sedation may not be typical for colonoscopies, but we are not aware of similar findings regarding the radiology codes in Appendix G. If other data is available, this should be shared for public comment.

New Standard Supply Package for Contrast Imaging

The RUC recommended creating a new direct PE input standard supply package "Imaging w/contrast, standard package" for contrast enhanced imaging, with a price of \$6.82. This price reflects the combined prices of the medical supplies included in the package. CMS proposes to accept this recommendation, but is seeking comment on whether all of the items included in the package are used in the typical case.



The ACR worked extensively with the RUC to identify these inputs and believes that they are typical and should continue to be used with new codes brought before the PE subcommittee.

Equipment Cost Per Minute

CMS notes the current 90 percent equipment utilization rate assumption for expensive diagnostic imaging equipment as mandated by The American Taxpayer Relief Act of 2012 (ATRA).

Another piece of the formula used to calculate equipment cost per minute is maintenance costs. CMS notes that several stakeholders have suggested that the maintenance factor assumption should be variable and they are soliciting comments on reliable data on maintenance costs that vary for particular equipment items.

The Radiology Business Management Association (RBMA) has gathered data from its members via survey and found that general radiology equipment maintenance costs average 10%, with mammography maintenance costs averaging 15%. The ACR recommends that CMS review the RBMA survey data and increase the maintenance assumption in the equipment cost formula to 10% for all imaging modalities and 15% for mammography.

The RBMA surveyed whether the maintenance cost percentage for imaging equipment: (1) differed from general medical equipment, and (2) varied by imaging modality (radiation oncology was not surveyed). Twenty-six practices responded to the survey. The results of this survey are as follows:



		Equipment Maintenance Factor		
		(Percentage)		
Modality*	Number of	25 th	50 th	75 th
	Observations	Percentile	Percentile	Percentile
			(Median)	
MR	20	8	9	10
CT	17	10	12	18
Angiography	2	10	10	10
Radiography (plain film)	12	10	10	12
Radiography (fluoroscopic)	9	8	10	10
DEXA	12	6	7	10
Ultrasound	19	9	10	11
Mammography	20	12	15	16
Nuclear medicine (excluding PET	7	9	10	11
and PET-CT)				
All Modalities	118	9	10	14
All Modalities except	98	8	10	12
Mammography				

^{*} PET and PET/CT TC RVUs are carrier-priced.

Payment of Secondary Interpretation of Images

Questions have arisen as to whether, and under what circumstances, it would be appropriate for Medicare to permit payment under the MPFS when physicians furnish subsequent interpretations of existing images, and whether uncertainty associated with payment for secondary interpretations inhibits physicians from seeking out, accessing, and utilizing existing images in cases where avoidance of a new study would result in savings to Medicare. CMS is seeking comment on a specific set of questions and the ACR addresses those questions below.

For which radiology services are physicians currently conducting secondary interpretations, and what, if any, institutional policies are in place to determine when existing images are utilized? To what extent are physicians seeking payment for these secondary interpretations from Medicare or other payers?



The ACR believes that the entire spectrum of radiology services often involves secondary interpretations and comparison to existing studies. This is an important role of radiologists across all practice settings. In general, Medicare does not pay radiologists for second interpretations, so radiologists typically do not seek payment for these services.

Medicare may pay for a second interpretation under "unusual circumstances" using modifier -77, but this secondary interpretation must directly contribute to the diagnosis and treatment of the patient and be accompanied by a written report. In the event that a non-radiologist bills for a secondary interpretation of a radiologist's primary interpretation, this should be more than simply stating agreement with the findings. Rather, there should be additional contribution made to the care of the patient with a full diagnostic report generated.

Should routine payment for secondary interpretations be restricted to certain high-cost advanced diagnostic imaging services, such as those defined as such under section 1834(e)(1)(B) of the Act, for example, diagnostic magnetic resonance imaging, computed tomography, and nuclear medicine (including positron emission tomography)?

The ACR feels that routine payment should occur for secondary interpretation of all radiology studies since, as explained above, all such studies have the potential to be clinically relevant. For example, the secondary interpretation of mammography studies is a common occurrence.

How should the value of routine secondary interpretations be determined? Is it appropriate to apply a modifier to current codes, or are new HCPCS codes for secondary interpretations necessary?

A secondary interpretation should be treated the same as a primary interpretation, and the CPT code for the primary interpretation for the examination should apply since equal or even more work, such as comparison to multiple prior examinations, is often required. CPT code 76140 (Consultation on X-ray examination made elsewhere, written report) relates to second interpretations but is also an uncovered service by Medicare and would not be expected to capture the differences in work across multiple modalities.

CMS believes most secondary interpretations would be likely to take place in the hospital setting. Are there other settings in which claims for secondary interpretations would be likely to reduce duplicative imaging services?

Secondary interpretations do occur in the hospital, but also occur in outpatient and freestanding imaging center settings.



Is there a limited time period within which an existing image should be considered adequate to support a secondary interpretation?

The decision as to whether an existing image remains pertinent and a secondary interpretation useful must be considered on a case by case basis and be at the discretion of the provider and in the best interest of the patient.

Would allowing for more routine payment for secondary interpretations be likely to generate cost savings to Medicare by avoiding potentially duplicative imaging studies?

Paying for secondary interpretations would reduce unnecessary repeat studies and lessen radiation exposure.

What operational steps could Medicare take to ensure that any routine payment for secondary interpretations is limited to cases where a new imaging study has been averted while minimizing undue burden on providers or Part B contractors?

Payment for secondary interpretations should not be limited to instances when a repeat study would otherwise occur. Rather, second interpretations should be paid when clinical benefit is gained and documented in the second report. Additionally, when a second interpretation is requested and there is alteration of the care delivered, the second interpreter shall assume responsibility for that second interpretation, including the malpractice risk.

<u>Protecting Access to Medicare Act of 2014 and the Multiple Procedure Payment Reduction</u>

CMS acknowledges in the proposed rule the provision within the PAMA that mandates the Secretary to make publicly available the information CMS considered when establishing the MPPR policy for the professional component of advanced imaging procedures, which became effective on January 1, 2012 for individual physicians, and on January 1, 2013 for physicians in the same group practice. No timeline was given for the publication of this information, but since this data must be readily available (as it was used to create the policy) it should be released immediately. In a previous letter to Secretary Burwell and Administrator Tavenner on June 17, the ACR requested that the information be released by September 1, 2014.

Payment Policy for Substitute Physician Billing Arrangements

CMS is soliciting comments on the policy for substitute physician billing arrangements in order to better understand current industry practices with respect to the use of substitute physicians and the impact that policy changes limiting the use of substitute physicians



might have on beneficiary access to physician services. CMS notes that any regulations would be proposed in a future rulemaking with opportunity for public comment.

There are a number of different ways that temporary substitute physicians are used in radiology practices, and restricting the use of these substitute physicians could present significant challenges, especially for practices in smaller and rural locales.

There are multiple reasons for using such temporary substitute physicians. It can be on an emergent basis as the result of a health problem or death of a member of a group. It can be used to fill in while recruiting a replacement radiologist or adding additional staff. Recruiting remains a lengthy process, and the professional work has to be covered in the interim. Alternatively, substitute coverage may occur on a longer term basis, such as to provide vacation coverage for a group that cannot afford another full time physician.

In radiology, circumstances are almost always a situation of a group, not the individual group member, hiring and paying the locum physician. It would be cumbersome to require specific contracts depending upon which group member is off and which group member is being covered. That could change even daily. Additionally, if the locums physician is filling in for someone who has left the group, or to provide additional manpower while a full time new member is recruited, there is not a physician being replaced who could serve as the contracting agent.

A variety of payment models are used, and a set daily fee is the most common. A productivity-based model is also used. The ACR believes that being more restrictive in how such physicians can bill or work could yield unintended negative consequences. Substitute physicians serve an important need to assure ongoing access to care in many different ways.

That ACR acknowledges CMS' concerns about identifying the rendering physician in a substitute billing arrangement and ensuring that the rendering physician is eligible to provide services under the Medicare program. Should CMS require enrollment of locum physicians, it is imperative that CMS and commercial insurers offer an expedited online enrollment process for locum physicians so practices may bill for the services provided by these physicians and minimize payment delays.

Reports of Payments or Other Transfers of Value to Covered Recipients

In issuing the final "Open Payments" rule on February 1, 2013, CMS acknowledged that industry support for accredited or certified CME is different than support for non-accredited CME. As such, CMS wisely exempted accredited CME providers from reporting transfers of value-related to accredited CME, a circumstance supported by all nationally-recognized Accredited Providers of continuing education.



CMS is well aware that communication between physicians, pharmaceutical companies and device manufacturers is critical if physicians, in our case, radiologists, are to stay current with the latest research and, thus, provide optimal care to the public. Industry-supported CME already generally adheres to the "Standards for Commercial Support (SCS): Standards to Ensure Independence of CME Activities" of the Accreditation Council for Continuing Medical Education (ACCME), which outlines, monitors, and maintains the strict standards for such relationships, as a fundamental resource and guiding principle for accredited CME Providers.

The ACR continues to support the **original** decision by CMS in the February 2013 final rule, that indirect payments made to faculty at CME activities are not indirect payments or other transfers of value for the purpose of the Open Payment program and, therefore, do not need to be reported when all of the following conditions are met:

- The event at which the covered recipient is speaking/serving as faculty meets the accreditation or certification requirements and standards for continuing education of one of the following:
 - o The ACCME;
 - o The American Academy of Family Physicians;
 - The American Dental Association's Continuing Education Recognition Program;
 - o The American Medical Association;
 - o The American Osteopathic Association
- The applicable manufacturer does not pay the covered recipient directly
- The applicable manufacturer does not select the covered recipient or provide a third party (i.e., a continuing education vendor) with a distinct, identifiable set of individuals to be considered as faculty for the continuing education event

The parameters of the CME exemption in Section 403.904(g) are unambiguous, and accredited CME providers like the ACR have relied upon them in planning, developing and documenting our programs since the final rule was published 18 months ago.

The current proposal by CMS to delete 42 CFR 403.904(g), in part because the agency considers it redundant with the exclusion in 403.904(i)(1), is seriously flawed. While there may be overlap between the two sections, they are **not** the same. Section 403.904(i)(1) excludes "indirect payments" or other transfers of value where the applicable manufacturer is "unaware" of the covered recipient's identity during the reporting year, and for two quarters thereafter. Physician faculty and attendees at accredited CME events are not reportable under the Open Payments program because of



the firewall created through their strict adherence to the Standards for Commercial Support (SCS), *not* by the timing of when an applicable manufacturer may discover their identity.

CME programs are planned and promoted months, and sometimes years, in advance — most far enough in advance that solicitation or attainment of independent commercial support grants by the CME provider is incomplete and ongoing. As faculty are selected and identified by the accredited CME provider during the activity planning process, their names are promoted in the activity marketing to the intended audience. It is not realistic, nor would it be perceived as transparent, if faculty names were hidden until the day of the program. Physicians make plans to attend such programs based on multiple factors, one of which is the quality and reputation of the faculty; announcing faculty at the last minute surely will result in far fewer attendees. Over time during the planning process, even if the applicable manufacturer does not request faculty names, they are almost certain to learn the names of the faculty before the program, and certainly within two quarters after the program, through transparent promotion of the educational programing itself. Therefore, establishing a policy whereby an arbitrary determination of the presence of a relationship is made based on the timing of learning the identity of faculty is unworkable.

While leaving both Sections 403.904(g) and (i)(1) in place creates some overlap or redundancy, but no additional confusion or adverse consequences, removing Section 403.904(g) in favor of Section 403.904(i)(1) would be replacing the more certain provision with a more problematic and confusing one. The unintended consequence of such a change may dissuade participation in valuable CME activities and hinder the adoption and spread of important medical education intended to keep the public safe and enable optimal care and outcomes for patients.

Further, CMS specified the five organizations in Section 403.904(g) because these five organizations have a long history of, and proven track record for, adherence to stringent standards to ensure integrity and independence from direct and indirect industry influence. The ACR is one of the leading developers of high-quality, independent CME programs, one of the largest Radiology-specific specialty societies, and a proud ACCME-accredited Provider with Commendation. The ACR strongly supports CMS' insistence on maintaining safeguards to ensure the independence, validity and relevance of CME. The ACR, and other ACCME-accredited providers with Commendation, are distinguished by their strict adherence to the "SCS: Standards to Ensure the Independence of CME activities," which, among other things, clearly outline, indeed mandate, that faculty of certified and accredited CME programs be selected, directed, reviewed, evaluated, and paid by the Accredited CME provider and must have no relevant relationships with the applicable manufacturers. The ACR closely monitors our adherence to the SCS, as well as the CMSS Code for Interactions with Companies, to ensure our continued development of conflict-free, high-quality CME.



The ACR strongly urges CMS to continue to exempt certified or accredited CME by the five named organizations in the final rule in order to preserve the important distinction between certified/accredited CME and other educational programming. Any additional organizations that are allowed to take advantage of the Section 403.904(g) CME exemption should comply with standards as stringent as those that govern the five named organizations. CMS may be concerned about endorsement of these five organizations and may choose not to specifically name these organizations in rule making. If so, the ACR urges CMS to modify, rather than eliminate, Section 403.904(g) so that this section exempts only CME activities that bear credit from a national credit system and/or are offered by an organization that has strict policies in place to ensure adherence to the SCS.

Quality Provisions

Physician Compare

CMS proposes to expand public reporting of group-level measures by making all 2015 PQRS Group Practice Reporting Option (GPRO) web interface, registry, and electronic health record (EHR) measures for group practices of two or more eligible professionals (EPs) and accountable care organizations (ACOs) available for public reporting on Physician Compare in 2016. If it is technically feasible, CMS also proposes to expand Physician Compare to include 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 intends to post measure data only 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 pass through consumer testing and stakeholder feedback.

The ACR supports and appreciates CMS' intention to only post performance data on measures that have been thoroughly tested for validity, reliability, and after extensive consumer testing.

Using composite scores

In addition to making all 2015 PQRS measures available for public reporting, CMS seeks comments on creating composites and publishing composite scores based on the PQRS GPRO measures groups, if technically feasible. CMS intends to conduct analyses on how the measures fit into measuring the composite concept and may use PQRS GPRO measures groups such as Care Coordination/Patient Safety, Coronary Artery, Diabetes



Mellitus and Preventive Care. CMS requests comment on creating composites using 2015 data and publishing composite scores in 2016 by grouping measures based on the PQRS GPRO measure groups, if technically feasible.

The ACR believes that measure composites may support a more realistic and fair consideration of the quality of care provided by a group practice, as long as the component measures have been carefully considered and the composite scoring is statistically viable. The ACR tentatively supports CMS' use of composite scores, but strongly urges CMS to seek relevant specialty society and other stakeholder input in the composite construction and format, as well as feedback on testing results prior to inclusion on Physician Compare.

Using benchmarks

CMS proposes to begin using benchmarks to present performance data on Physician Compare, instead of the actual measure score, using the same methodology as in the Medicare Shared Savings Program (MSSP). Quality scoring would be based on the group practice's actual level of performance on each measure. Quality points are earned on a sliding scale based on level of performance: performance below the minimum attainment level (the 30th percentile) for a measure would receive zero points; performance at or above the 90th percentile of the performance benchmark would earn the maximum points.

In a measure group, the total points earned for measures would be summed and divided by the total points available for that measure group to produce an overall measure group score. The percentage score for each measure group reported would be averaged together to generate a final overall quality score for each group practice. The goal of including such benchmarks would be to help consumers see how each group practice performs on each measure, measure group, and overall in relation to other group practices.

The proposed benchmarking methodology for quality scoring to be used for presenting performance information on Physician Compare appears to be reasonable; however, the ACR defers supporting the methodology until the opportunity to review sample data on actual group practice performance is made available. Just as we have worked with CMS in the refinement of Quality and Resource Use Reports, the ACR welcomes the opportunity to work with CMS on presentation of information on Physician Compare.

Using specialty society measures

CMS is proposing to make available on Physician Compare 2015 Qualified Clinical Data Registry (QCDR) measure data. CMS also proposes that measures collected via QCDRs



must meet the established public reporting criteria, including a 20 patient minimum sample size.

CMS seeks comments as to whether the measure data from a specialty society QCDR should be posted on the specialty society website, linked to Physician Compare, or alternatively to post only on the Physician Compare website (societies could link to Compare).

CMS also proposes to publicly report QCDR measure data collected at the individual level or aggregated to a higher level of the QCDR's choosing, such as the group practice level, if technically feasible.

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

Additionally, requiring patients or consumers to jump from Physician Compare to numerous websites for various pieces of quality data on one physician group or another could prove frustrating and confusing. We think providing a link to Physician Compare website from the ACR QCDR webpage is reasonable and sufficient.

We further recommend 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.

Physician Payment, Efficiency and Quality Improvement – PQRS

CMS proposes to add surgical codes to measures based on "face to face" encounters where currently office visit/outpatient visit codes are used to identify the patient population.

The ACR believes that adding surgical codes to these types of measures would potentially allow reporting of additional measures by individual EPs with few measures. We hope that CMS would make available modified specifications identifying these additional denominator procedure codes as soon as possible, for planning purposes by EPs who may be able to report these additional measures.



Proposed Criteria for the Satisfactory Reporting for Individual EPs for the 2017 PQRS Payment Adjustment

CMS intends to maintain the measure applicability validation (MAV) process used in 2014 for EPs reporting less than 9 measures through claims or traditional registry mechanisms. However CMS proposes that they will use the MAV process to identify if an EP or group could have reported any of the cross-cutting PQRS measures.

As reporting requirements increase and the PQRS program becomes penalty-based only, the MAV process is now critical to participants who have few measures available to report. The ACR urges CMS to make known the methodology used for assigning measures to "clusters" in the MAV, as well as the method for determining measure National Quality Strategy domains. This MAV 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.

Proposed Criteria for Satisfactory Reporting for Group Practices Participating in the Group Practice Reporting Option (GPRO) for the 2017 PORS Payment Adjustment

CMS emphasizes that a group practice must register to participate in the PQRS GPRO and proposes to change the deadline for registering as a GPRO from September 30 to June 30 of the reporting year in order to provide PQRS and Value Modifier participants with feedback reports more timely.

The ACR requests that CMS clarify if this will enable more timely availability of the Quality Resource Use Reports or solely the PQRS feedback reports.

Reporting options for GPROs do not include a QCDR. We understand that CMS sees the value in allowing GPROs to use a QCDR and CMS has made efforts to encourage Congress to include this allowance in new legislation authority. The ACR strongly supports this effort.

Selection of PQRS measures

Cost-cutting measures

Table 21 includes the proposed 18 "cross-cutting" measures that CMS has suggested for 2015 and beyond. Particularly with the addition of surgical codes to the measure denominators, many additional EPs may be able to report these measures.



The ACR urges CMS to consider requiring that EPs or GPROs only be required to report cost-cutting measures when a minimum threshold of patients/cases have been met, such as in the MAV process for other measures.

CMS proposes a number of new measures for 2015 and beyond, including Avoidance of inappropriate use of imaging for adult emergency department (ED) patients with traumatic low back pain.

The ACR recommends that CMS not include the *Avoidance of inappropriate use of imaging for adult ED patients with traumatic low back pain* measure until such time that the measure has undergone public comment and been finalized. In its current form, some of the "red flags" used for identifying appropriate use of imaging are not correctly characterized.

National Quality Strategy domain changes

In Table 23, CMS proposes to change the National Quality Strategy (NQS) domain for a number of measures. The domain comes into play in composite scoring of the Value Modifier.

In most cases of re-categorized measures in Table 23, CMS states the change was made "in accordance with NQS priorities which follow the General Rules for Categorizing Measures". It would be helpful to healthcare professionals as well as measure developers to have access to, and understanding of, these General Rules. We ask that CMS make these readily available.

Measures proposed for removal

Table 24 of the proposed rule lists 73 measures that CMS is proposing to delete from the current PQRS measure set, and includes the rationale for each proposed deletion. Measures proposed for removal beginning in 2015 include #146 *Inappropriate use of probably benign code; recommend removal due to consistent high performance indicating no gap in care.*

The ACR strongly recommends that CMS maintain Measure #146, *Inappropriate use of probably benign code (BIRADS 3)*. This measure is important in that it ensures the integrity of the complete mammography audit, which includes Mammography Follow-up Rate (a measure included in the CMS Hospital Outpatient Quality Reporting (HOQR) program). The HOQR measure includes a 45-day window for follow-up. ACR standards include 6 month follow up (BIRADS 3) in the definition of call back, which is not included in the HOQR measure. As



with most areas of medicine, there is a behavioral offset among radiologists when they are audited for recall. It has been observed that 6-month follow-up increases after audit of code 0 results.

Measures with reporting updates

Table 25 of the proposed rule lists 56 PQRS measures for which CMS is proposing to change the way in which the measures will be reported beginning in 2015. In many cases, the option of submitting measure data via claims is being eliminated, or an individual measure is proposed for measures group reporting only (registry reporting only). In fact, if all of CMS' proposed measure-related changes were finalized for 2015, it would leave only a total of 38 measures reportable via claims across all of medicine. CMS also indicates in their annual call for new measures that they will not accept claims-based only reporting measures. In 2014, CMS removed the ability to report measures groups through claims reporting.

The ACR understands that CMS is moving away from claims-based reporting in order to streamline the PQRS program using more automated mechanisms. However, the ACR strongly recommends that CMS maintain an adequate number of claims-based reportable measures in order to maintain integrity of that mechanism. This is especially important since 2015 is only the second year of the ACR QCDR availability, and radiology measures group and practices may not have had sufficient time to implement those programs. Additionally, there are numerous quality topics of high impact that lend themselves more easily to claims specifications and reporting.

Measures Groups

CMS is again proposing to increase the number of measures within a measures group from a minimum of 4 measures to a minimum of 6, and says it has worked with relevant measure owners and developers on this. CMS also proposes two new measures groups beginning in 2015, including the sinusitis measures group which contains an overuse of CT measure.

Measures group reporting is a viable option for many practices and potentially reduces a great deal of burden in reporting, but is not available as a mechanism for GPROs. The ACR strongly encourages CMS to reconsider allowing GPROs to use this mechanism.



Measures reported by a QCDR

CMS proposes to increase the minimum number of outcome measures that a QCDR must have available for reporting from 1 to 3; or in lieu of having 3 outcome measures, a QCDR may have 2 and at least 1 resource use, patient experience of care, or efficiency/appropriate use measure.

The ACR supports CMS' proposal that a QCDR include the various types of measures as described above, but recommends that CMS phase-in over several years such a requirement, so as to allow new QCDRs to incrementally add measures.

CMS proposes to formalize the date that QCDR measure descriptions and narrative specifications are due to CMS by March 31 of the applicable reporting period year, and that 15 days following approval by CMS, the measures information should be posted publicly.

The ACR believes that an annual March 31 due date for measure descriptions and narrative specifications is reasonable.

Proposed Requirements for Reporting Mechanisms (entity requirements)

Oualified clinical data registries

In addition to the proposed requirement that QCDRs are able to report at least 3 outcome measures, or at least 2 outcome measures and at least 1 resource use, patient experience of care or efficiency/appropriate use measure, CMS proposes the following:

- Increasing the number of non-PQRS measures that a QCDR can report from 20 to 30
- Requiring that a QCDR entity publicly report quality measures data its EPs have reported; data to be reported includes measures title/description of QCDR measures and performance results for each
- Allowing more frequent submission of measure data

The ACR is pleased that CMS proposes to allow an increase in the number of non-PQRS measures that a QCDR has available for reporting. Having 20 measures available for QCDR participants may allow only a subset of EPs in a specialty to benefit from using a QCDR given the requirement for reporting 9 measures. Twenty measures may not be sufficient for specialties such as radiology where subspecialization is common.



As mentioned previously in the section on Physician Compare, we recommend 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. This will avoid the potential perception of a conflict of interest, either from the public or ACR physician members. Additionally, requiring patients or consumers to jump from Physician Compare to numerous websites for various pieces of quality data on one physician group or another could prove frustrating and confusing. We think providing a link to the Physician Compare website from the ACR QCDR webpage is reasonable and sufficient.

We further recommend 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). Therefore, the radiology group is a meaningful entity for assessing care quality.

With regards to more frequent submission of measure data, the ACR supports this as an option but not a requirement, decided by individual QCDRs or qualified registries. More frequent submission of measure data should be optional, since an EP may decide later in the year to change his or her reporting mechanisms or measures reported; if measure data had been submitted previously in the year on behalf on an EP, would they have an option of selecting which data to use for determining their program success?

Informal review/Informal inquiry process

CMS proposes a deadline of February 28, 2015, for requesting an informal review of the CY 2015 payment adjustment, and for years starting with CY 2016, payment adjustment now proposes a deadline of 30 days following release of the Quality Resource Use Report (QRUR) for the applicable performance period. For example, if the QRURs are released on August 31, 2015, an EP or group practice would be required to submit a request for informal review by September 30, 2015.

The ACR appreciates CMS' intention to allow for a resubmission and correction process to ensure that the application of the PQRS and Value Modifier payment adjustments are done accurately and fairly. We urge CMS to continue to outline specifics of the process as experience is gained in the next few years. We also request that CMS explicitly describe a process that an EP should follow if there are no measures available for PQRS reporting.



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. Previously, CMS finalized VM application in 2016 to physicians in groups of 10+.

CMS makes the following proposals related to the VM program:

- Increase the amount of potential payment at risk under the VM from -2.0% in CY 2016 to -4.0% in CY 2017, as well as up to a +4.0x adjustment based on high performance (x factor determined based on total pool from those receiving penalty).
- Application of the VM in 2017 to all physicians and non-physician EPs in groups of 2+ and solo practitioners, including those participating in the Medicare Shared Savings Program (MSSP), Pioneer ACOs, CPC Initiative or similar Innovation Center models or CMS initiatives.
- Similar to CY 2016 VM, CMS proposes to align application of the VM in CY2017 with the PQRS CY2015 performance period and to maintain the level of group participation to meet VM reporting requirements, but now proposes to include solo practitioners and groups of 2+.
- CMS proposes quality-tiering for the CY 2017 VM to be applied to groups and solo practitioners in Category 1 as follows:
 - Groups of 10+ will be subject to an upward, neutral or downward adjustment.
 - Groups of 2-9 and solo practitioners will only be subject to an upward or neutral adjustment.
- CMS notes that they anticipate applying the CY 2018 VM with upward, neutral or downward adjustments based on CY 2016 performance period to all groups and solo practitioners.
- CMS reconfirmed that groups for which cost measures cannot be calculated (who does not have at least one cost measure with at least 20 cases) would have a cost composite score classification of average under the quality tiering methodology, and propose to apply the same policy to all groups and solo practitioners in 2017.

Payment adjustment amount

CMS proposes that the amount of payment at risk (penalty) be increased from -2.0% (CY 2016) to -4% (CY 2017). This is separate from the PQRS payment adjustment of -2.0% for those groups and solo practitioners who do not satisfactorily report PQRS in 2015.



Table 58: Proposed CY 2017 VM Amounts:

TABLE 58: CY 2017 Value-Based Payment Modifier Amounts

Cost/Quality	Low Quality	Average Quality	High Quality
Low Cost	+0.0%	+2.0x*	+4.0x*
Average Cost	-2.0%	+0.0%	+2.0x*
High Cost	-4.0%	-2.0%	+0.0%

^{*} Groups and solo practitioners eligible for an additional +1.0x if reporting Physician Quality Reporting System quality measures and average beneficiary risk score is in the top 25 percent of all beneficiary risk scores.

As adopted in CY 2013 PFS final rule, the upward adjustment factor (x in Table 58), is determined after the performance period has ended (following the informal inquiry period) and the amount of downward payment adjustments has been aggregated.

CMS is proposing to increase the VM penalty to -4% for all groups, regardless of size. CMS has designed the phase-in of the VM by group size and amount of payment at risk. This results in a lower payment at risk in the initial year of application of the VM for the first two cohorts of groups (100+ and 25+), which is somewhat inequitable. That is, cohort 1 (groups of 100+) have a phased-in payment adjustment from -1% (2015) to -2% (2016) and -4% (2017). Cohort 2 (groups of 25-99) are faced with -2% their first year (2016), increased to -4% their second year (2017). Cohort 3 (groups of 2-10 and solo providers) are subject immediately to a much higher payment at risk -4%. Where the larger groups have more time to adjust practice and improve scores with a minimal payment at risk, smaller groups and individual physicians do not have that luxury. Perhaps this is to enable budget neutrality in providing upward adjustments for a larger number of groups, but it is more equitable to ramp up the new cohort of groups similar to the first cohort (first year -1.0%, second year increase to -2.0% third year increase to -4.0%), particularly since those groups are also facing steeper PQRS reporting requirements in their initial VM year. The ACR urges CMS to consider such an approach as it continues to phase-in the VM.

Treatment of hospital based physicians under the VM

Based on input from a number of commenters in previous rule-making, CMS is considering including or allowing groups that include hospital-based physicians or solo practitioners who are "hospital-based" to elect the inclusion of the Hospital Value-Based Purchasing (VBP) program performance in their VM calculation. CMS noted that there are limited measures that apply to certain specialties and that those specialties may exercise wide influence over the quality of care provided in a hospital.



CMS proposes that groups could elect to include hospital performance in their VM for a payment adjustment period based on a hospital's historic VBP program performance, which would be known to the tax identification number (TIN) at the time of election. CMS notes any change would be through future notice and comment rulemaking.

CMS seeks comments related to this proposal in four areas:

- 1. How to identify "hospital based" physicians?
- 2. How to identify which hospital(s) performance scores to use?
- 3. What part(s) of the hospital performance scores should be used? What criteria should be considered in selecting a subset of Hospital VBP program measures or domains?
- 4. How to incorporate the hospital performance score in the VM quality and cost composite scores?

Identifying hospital-based physicians:

One option CMS considers is to allow a group to attest that it is composed primarily of hospital-based physicians. Another option is for CMS to specify criteria that a TIN would have to satisfy in order to use the VBP data, and whether after determination of "hospital-based groups", CMS would automatically include the hospital performance data in the groups' VM or allow the group to elect that option.

CMS suggests that groups may be identified based on specialty or percentage of services billed at the hospital level, citing as an example the definition of hospital based EP under the EHR Incentive program CMS requests comment on the appropriate methodology to identify hospital-based groups and solo practitioners for this purpose.

The vast majority of radiologists would not meet the definition of a "hospital-based" physician in the EHR Incentive program, so this option would exclude most radiologists from using hospital VBP data for their value modifier scoring. The ACR recommends a different methodology, but cannot offer a sound one at this time. We will continue to evaluate the option and explore potential options for identifying "hospital-based" physicians.

Determining which hospital(s) performance scores to use:

CMS could base this determination on either 1) at which hospital the plurality of services the TIN provided, or 2) attribute hospital performance to a TIN that provided some threshold of its hospital-based services at that hospital, such as at least 30 percent. In the second scenario, a TIN could have multiple hospitals' performance score used for the



TIN VM, weighting hospital performance scores based on dollars paid or number of services provided by the physician TIN at each hospital. **CMS seeks comments on these and other alternatives to determine which hospital performance to use.**

While using several hospitals' performance score would encourage care coordination in each site that a hospital-based physician practices, this approach is more complicated and potentially burdensome for groups to determine possible scenarios on an annual basis.

Determining what part of the hospital's Total Performance Score (TPS) to include:

CMS discusses three options for including Hospital VBP performance in the VM, 1) include the entire TPS in the physician VM cost composite, which would include quality measure performance calculation under the cost composite for the physician TIN VM; 2) include the Efficiency and Cost Reduction domain score in the cost composite and include all or some subset of the other domain scores in the quality composite (the option CMS considers to be the most appropriate); and 3) include some subset of the measures in the cost and quality composites.

CMS believes that using the entire TPS would encourage shared accountability and incentive for services provided during a hospitalization, but that some subset of scores may better target factors over which a physician can exert more influence. CMS believes the third approach (subset of measures in the cost and quality composites) is more complex and places less emphasis on hospital/physician coordination, and would require a "judgment call" as to which measures should be used. Overall, CMS believes the second approach (inclusion of all TPS domains or some subset of domains) is the best balance of simplicity, encouragement of care coordination and appropriate capture of different aspects of care as they relate to the VM composites.

The ACR agrees that the second approach (inclusion of Efficiency and Cost Reduction domain score in the cost composite and some portion of other domain scores in the quality composite) is most appropriate. We recommend that direct correlation between the hospital performance scoring and the VM scoring be considered. Many hospital based specialists may have a substantial number of quality measures available for reporting in the PQRS program, particularly with the inclusion of the QCDR participation method. EPs would likely prefer to include their own performance scores while opting to use the hospital cost data to complete the picture.

CMS seeks comments on the approaches discussed and other possible alternatives for inclusion of all or part of the Hospital VBP Program TPS into the VM.



Although the measures used in the HOQR program are not included in the Hospital Value Based Purchasing Total Performance Score (HOQR is under the HOPPS/ASC payment structure, Hospital VBP is under the IPPS payment structure), CMS may also wish to consider use of HOQR measures in the VM. The ACR suggests that a hospital score on the Imaging Efficiency measures could be used to determine the cost composite in the VM for hospital based radiology groups.

How to incorporate the portion of the TPS included in the VM into the quality and cost composite scores.

CMS discusses how to create a standardized score at the TPS level, the domain level, or the individual measure level, which could be weighted into the cost composite for the VM. CMS proposes to weight hospital performance data to be included in a physician TIN if the multiple hospital attribution approach was used, with greater weight being given to a hospital score where more services were provided by the TIN.

That performance score level may be the TPS, a domain or an individual measure, where scores at any of these levels may be treated as an additional measure in the quality and/or cost composites. For example, a given hospital's Efficiency and Cost Reduction Domain score (currently only the Medicare Spending per Beneficiary measure) would be arrayed along with that of all other TINs electing inclusion (of a given hospital score). The standardized score would be calculated and then weighted into the cost composite for the value modifier. The weight could depend on the number of measures underlying the domain score or TPS, it could be weighted evenly with other composite measures if calculated at the individual measure level, or it could be assigned a weight based on relative importance of the measure, to be determined through rulemaking. CMS seeks comment on this potential methodology or other approaches for including hospital performance in the value modifier.

This seems a reasonable approach, but the ACR would like to see modeling data in order to have a better understanding of potential scoring results. The ACR is willing to work with CMS, along with volunteer radiology groups, to understand this approach, just as we provided feedback to CMS on several iterations of the Quality Resource Use Reports.

Physician Feedback Program

Episode Costs and Supplemental QRURs

In summer 2013, CMS distributed Supplemental QRURs, based on 2012 data that provided group practices with payment-standardized, risk-adjusted cost information on



the management of their Medicare fee-for-service (FFS) patients based on episodes of care.

CMS is considering adding episode-based cost measures to the VM through future rulemaking for 12 episode subtypes, or some subset of episode subtypes, of the selected respiratory and selected heart conditions that have appeared in both the 2011 and 2012 Supplemental QRURs. CMS is also considering proposing to add hospital episode-based payment measures to the VM.

Currently, attribution rules for acute and chronic episodes are based on E&M services so it is likely that most radiology groups will not have a measure score calculated. While groups with interventional radiology practice may provide E&M services, the condition-based episode measures currently planned for VM inclusion are not likely attributable to such groups. However, such groups may find that certain procedural episode measures included in the 2012 QRURs, but not proposed at this point, may be calculated for their practices.

The ACR appreciates the opportunity to continue working with CMS in refining the Quality Resource Use Reports as we have in the past. The QRUR changes that CMS has made to date based in part on healthcare provider input have substantially improved the content and usefulness of the reports.

Conclusion

The ACR appreciates the opportunity to provide comments on the CY 2015 MPFS proposed rule. We encourage CMS to continue to work with physicians and their professional societies through the rulemaking process in order 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