December 29, 2008

Kerry Weems
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1403-FC
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Subject: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2009; Final Rule

Dear Mr. Weems:

The American College of Radiology (ACR), representing more than 32,000 diagnostic radiologists, interventional radiologists, radiation oncologists, nuclear medicine physicians, and medical physicists, is pleased to submit comments on the Final Rule “Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for Calendar Year 2009” published in the Federal Register on November 19, 2008. We will address independent diagnostic testing facilities (IDTFs) issues; cardiac MRI; potentially misvalued services under the Medicare fee schedule (MFS); HDR brachytherapy; high cost supplies; self-referral and anti-markup issues; and the Physician Quality Reporting Initiative (PQRI).

Independent Diagnostic Testing Facilities

In the Final Rule, CMS defers the implementation of the proposal requiring enrollment of all providers of non-hospital imaging procedures as an Independent Diagnostic Testing Facility (IDTF) based on the enactment of the Medicare Improvements for Patients and Providers Act (MIPPA) of 2008 legislation and its requirements that all non-hospital advanced imaging be accredited by 2012 implying the IDTF enrollment would be unnecessary and redundant. The ACR disagrees with CMS’ decision, and is concerned that imaging quality and patient safety may suffer as a result of the decision not to require all physicians and nonphysician practitioner groups providing diagnostic testing services to enroll as IDTFs to comply with most of the IDTF performance standards specified in 42 CFR §410.33.

The ACR maintains that to ensure quality and patient safety for imaging services, rigorous education and training standards need to be applied to all physicians, regardless of their specialty, who perform and/or interpret diagnostic imaging studies regardless of whether they are performed in a hospital, IDTF, or physician office. Quality and safety standards must be applied to all equipment and to the ancillary personnel who operate it. In addition to the improvements in
patient safety and image quality afforded by application of the proposed standards to all diagnostic imaging, we believe the application of these standards is likely to reduce the number of medically unnecessary diagnostic imaging examinations being performed today.

Although not all of the current standards for IDTFs are applicable to physician offices, the ACR believes that CMS should continue to refine the standards applied to both IDTFs and physician offices to require physician offices to not only have similar quality and patient safety requirements in place, but to also require transparency when contracting with a third party for interpretations.

The ACR strongly believes that MIPPA does not duplicate the proposed regulations. The accreditation requirement under MIPPA will not be implemented until 2012. If the new standards do not go into place until 2012, the time that has lapsed until the policy is implemented, results are known and analyzed, and the process further refined results in an even longer delay in improving the care to beneficiaries. The ACR strongly recommends that CMS begin the process of implementing the IDTF proposal that requires sites that provide imaging services to meet basic IDTF quality standards right away to help assure quality and patient safety. The ACR recommends that the registration initially be limited to providers of advanced medical imaging, but urges CMS to apply these standards to all medical imaging in subsequent years. The IDTF standards are not duplicative requirements of accreditation but instead are complementary to the accreditation programs and framework for quality assurance.

**Mobile Entity Billing Requirements**

The ACR agrees with CMS that any provider of diagnostic imaging services should meet IDTF standards. However, the ACR believes that the site that uses mobile diagnostic services should be registered as an IDTF instead of only requiring the mobile unit itself. The site that provides that mobile diagnostic imaging service is the one that is providing the care to the patient. Therefore, the entire patient experience at that site should be of the highest quality and basic quality requirements should be met. CMS’ requirement of only mobile units to meet IDTF standards creates many logistical problems and does not get at the basic need of better overall quality of those site that provide imaging diagnostic services. The ACR requests that CMS re-evaluate its decision and also provide clarification to the public on these policies as soon as possible.

**Revocation of Enrollment and Billing Privileges of IDTFs in the Medicare Program**

The ACR agrees with CMS’ decision to require a revoked physician organization, a physician, a non-physician practitioner, or an IDTF to submit all outstanding claims not previously submitted within 60 calendar days of the revocation effective date. The ACR commends CMS on requiring physician office practices to adhere to the standards required by IDTFs. We look forward to working with CMS to ensure that all medical imaging is performed at certified facilities with accredited modalities and qualified radiological technologists, medical physicists, and interpreting physicians. We look forward to working with CMS to promote high quality, safe and appropriate diagnostic imaging for Medicare beneficiaries.
Cardiac MRI

The ACR is disappointed that CMS has determined that the existing National Coverage Determination (NCD) for MRI is applicable to the four cardiac MR codes because blood flow/velocity quantification is considered to be a component of these services, which according to the NCD is not considered reasonable and necessary, and therefore, is non-covered. The ACR believes it was possible for CMS to cover the portions of the bundled services in a manner consistent with the intent of the NCD which was to not allow coverage only for the flow velocity determinations. We have submitted a request for a National Coverage Assessment on the issue and in the mean time we will work with the CPT Editorial Panel to determine if there is an alternate coding solution that prevents Medicare beneficiaries’ access to needed and medically necessary services.

Potentially Misvalued Services under the Physician Fee Schedule

The ACR appreciates CMS’ efforts to ensure procedures in the MFS are appropriately valued. CMS has identified methods that they are requesting that the RUC to undertake to assist in identifying potentially misvalued codes to include 1) review of the fastest growing procedure codes; 2) review of Harvard valued codes; and 3) review of practice expense RVUs. The ACR appreciates this opportunity and looks forward to working closely with the RUC.

Regarding review of the fastest growing procedures, the ACR would like to emphasize that increasing utilization of imaging services is an important component in the natural evolution of patterns of care and has resulted in replacement of other, more costly, procedures. It must also be understood that utilization of imaging is not driven by price or RVU except when the imaging procedure is ordered and performed by the same physician, a situation that does not apply to radiologists. Therefore, except in the instance of self-referral, utilization rates of imaging services should not be considered as a screen for misvaluation.

Regarding the review of the Harvard valued services; the ACR agrees with the Relative Value Update Committee (RUC) that the prospect of reviewing all 2,856 Harvard-valued codes is a daunting task that would require an unreasonable amount of time and financial resources. The ACR believes that it will be a burdensome process and a huge undertaking for all specialties to spend time and effort to revalue all the Harvard codes. It is worth reiterating that although there are a moderate number of Harvard-valued codes within radiology, the valuation of these codes has a unique history. Based on a congressional mandate, in 1988 the ACR developed a Relative Value Scale (RVS) for radiologic procedures. These data were collected and maintained by an outside research firm (Abt Associates). The relative values reflected the physician work and practice costs involved in each procedure. The RVS was accepted by Medicare and implemented January 1, 1989. These values have been repeatedly validated by the five-year review processes and by crosswalks to new RUC-valued services in all families of diagnostic imaging. For example, during the last five-year review, values for the majority of radiology services that were under review remained the same. We, therefore, believe that Harvard-valued radiology codes have a unique history and have been extensively vetted by subsequent RUC activity.
**HDR Brachytherapy**

The ACR is concerned about the calculation of the non-facility practice expense values for the three new codes for high dose rate brachytherapy (77785-77787) which are effective in January 1, 2009. These codes have been assigned interim practice expense RVUs in the technical component that are 50-75% lower than the RVUs assigned to the four deleted codes (77781-77784). The radiation oncology community did not foresee that these cuts would take place and therefore the ACR and other societies have not had time to educate their members nor for the free-standing centers to prepare for this type of financial burden. These cuts will have devastating effects on the free-standing brachytherapy centers that specialize in treating cancer patients with HDR brachytherapy.

The ACR requests that CMS consider a four-year phase-in of the changes made from the old brachtherapy codes (77781-77784) to the new codes (77785-77787) to allow for free-standing brachytherapy centers to adjust to the reduced payments and spread out the significant financial burden. It is not reasonable for CMS to expect these non-facility sites to take a 50-75% hit in their codes that are the basis of treatment for cancer patients.

In addition, CMS has listed the useful life for the Iridium-192 renewable source (equipment code ER060) as five years. The actual useful life of Iridium-192 is 90-days. The listed cost in the CMS database of $45,326 represents the annual cost of Iridium-192. The ACR requests that CMS change the useful life to one year and adjust any applicable calculations.

**Updating High Cost Supplies**

The ACR is disappointed with CMS’ decision not to finalize the proposed process and not to revise the prices for the supplies requested by CMS. The ACR recommends that the specialty societies be involved in some way in the process to ensure accurate prices for high cost supplies.

**Physician Self-Referral**

The ACR continues to urge CMS to publish in 2009 a proposed rule and comment period to curtail the significant and much abused Stark self-referral in-office ancillary services exception. We realize that CMS did not take action in the CY2009 MPFS final rule because it did not offer any changes to the exception in the CY2009 proposed rule. Nonetheless, ACR maintains that, based on comments received from its 2007 rulemaking request, CMS should now make a formal proposal to change the language of the in-office ancillary services exception according to the regulatory foundation it established in that request.

In the Final Rule, CMS reaffirmed that self-referral represents a fundamental problem. The Agency rebutted commenters’ claims that no evidence showed self-referral led to imaging overutilization. It countered that several studies establish such a link, including a recent GAO study that found overutilization of some in-office imaging. CMS has for years examined “industry use” of the in-office exception. More importantly, CMS has acknowledged publicly that the exception has deficiencies which pose risks to patients and the Medicare program.
Therefore, the ACR strongly believes that the time is right for changes to the Stark in-office exception. We would be pleased to meet and discuss our position with Agency officials who have assumed new responsibilities for the self-referral and anti-markup issues.

**Anti-markup Provisions**

The ACR expresses its disappointment that in the CY2009 final rule, CMS produced anti-markup changes that appear to have, at best, a marginal impact on radiology and quality patient care. We believe that CMS should adopt a restrictive “site-of-service” approach that would have ensured a qualified physician supervises and interprets diagnostic tests. Additionally, CMS should prohibit “shared space” arrangements that might occur through leasing or subleasing of space from qualifying as a “shared practice” at the same “site of service.” The ACR does not agree that shared space arrangements appropriately balance promoting efficient care with safeguarding against overutilization or other abuse that may occur with “centralized” buildings for diagnostic studies. We are concerned that CMS’ policy will encourage numerous new leased “shared space” arrangements that will be potentially abusive and will not meet CMS’ stated goals.

The ACR believes that CMS developed two exceptions that may subvert much of the new anti-markup rule. CMS emphasized that, in either Alternative 1 or 2, the billing physician or other supplier must exercise “sufficient control and a proper nexus” to the individuals who conduct and supervise a diagnostic study. However, by creating anti-markup exceptions around a shared practice model and relaxing the “site-of-service” parameters where tests occur, CMS has left open some disturbing loopholes that some group practices may exploit.

Notably, the ACR is very concerned that CMS rejected establishing specific requirements for physicians supervising the TC of diagnostic studies. CMS did not finalize IDTF standards for physician offices and thereby compel practices to meet the more rigorous IDTF criteria for a supervising physician. It instead will continue with the current supervision levels governing tests to which anti-markup should apply. This decision could undermine CMS’s stated intent of curbing inappropriate utilization of diagnostic testing because most practices likely will be able to meet the “shared practice” model. With no IDTF safety net for physician offices that perform diagnostic tests, the ACR believes that many practices simply will designate one of their own members as the general “supervising physician” for diagnostic studies. In that instance, TC billing will escape anti-markup if the billing physician can meet Alternative 1.

However, we applaud CMS’ decision to finalize some anti-markup proposals that could further patient care and program integrity. For instance, the ACR appreciates that CMS took a modest step toward removing the profit motive for billing physicians who engage other physicians or suppliers to perform and interpret diagnostic tests. CMS correctly refused to exempt from anti-markup diagnostic tests that are performed in space in a “centralized building” because it understands that concept is too overbroad. We welcome CMS’s decision not to expand its “net charge” definition to allow practices to recoup overhead costs, which the Agency recognized might incentivize higher utilization. Finally, we encourage CMS to reissue next year its proposal to mandate direct billing of the TC or PC instead of permitting reassignment in certain situations.
States like California have moved toward direct billing of diagnostic tests. CMS should follow suit.

**Physician Quality Reporting Initiative (PQRI)**

As stated in the Final Rule, CMS does not have authority to establish an appeals process due to lack of provision for such in the relevant legislation. However, we commend CMS for its efforts to address and attempt remedy of issues and questions raised about 2007 Physician Quality Reporting Initiative (PQRI) results and feedback as outlined in its recent report, *Physician Quality Reporting Initiative – 2007 Reporting Experience*, particularly the announcement that analytic modifications will be applied to 2007 submissions. Efforts to continually improve the administration of the PQRI are essential to increase participation and acceptance of the program.

**2009 Measures**

The ACR is pleased that CMS included in the Final Rule three new measures for PQRI relevant to diagnostic radiology and nuclear medicine: “Inappropriate Use of BIRADS 3”, “Recording of Fluoroscopy Time for Procedures Using Fluoroscopy” and “Correlation of Imaging Studies for Patients Undergoing Bone Scintigraphy”. However, we were disappointed that one other measure endorsed by the National Quality Forum, “Reminder System for Mammography” was not included in PQRI for 2009. Explanation or reasoning for its exclusion would be helpful for future measure development efforts.

We were disappointed that CMS dropped the CT Dose Reduction measure from the final list but understand that the measure lacks National Quality Forum (NQF) endorsement as required, according to Section 1848 (k) (2) (B) (i) of the MIEA-TRHCA. However, we continue to support the measure as one that addresses a critical area of patient safety – unnecessary radiation exposure.

The ACR continues efforts to raise awareness, and to increase the use of dose reduction protocols. The CT Dose Reduction measure was developed to focus on assessing performance of individual clinicians and was appropriately restricted to measuring aspects of care actionable by the individual clinician. The measure reflects growing awareness of non linear threshold dose effect models of carcinogenesis and recognizes an obligation to consider the cumulative impacts of medical radiation. As the use of CT and other imaging modalities that depend on ionizing radiation increases, it is crucial that optimize radiation exposure to individuals and the population as a whole is optimized. It remains prudent to assume that the cancer risks associated with radiation exposure during imaging actually exist and to take steps, such as the performance outlined in this measure, to reduce them, even if the slightest, it is a move in a much needed direction as has been the widely supported Image Gently pledge campaign.
Conclusion

Thank you for the opportunity to comment on this final rule. The ACR encourages CMS to continue to work with physicians and their professional societies. The ACR looks forward to a continuing dialogue with CMS officials about these and other issues affecting radiology. If you have any questions or comments on this letter or any other issues on radiology, please contact Angela Kim at 800-227-5463 ext. 4556 or via email at akim@acr.org.

Respectfully Submitted,

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