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Kerry Weems
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1385-FC
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Subject: CMS-1385-FC Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for Calendar Year 2008

Dear Mr. Weems:

The American College of Radiology (ACR), representing over 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 2008" published in the *Federal Register* on November 27, 2007. We will address budget neutrality; resource-based practice expense relative value units (RVUs); cardiac MRI codes; independent diagnostic testing facility requirements; physician quality reporting initiative; and changes to reassignment and physician self-referral rules relating to diagnostic tests [Anti-Markup Provisions].

Budget Neutrality

The ACR disagrees with, and remains concerned with the impact of the Centers for Medicare & Medicaid Services (CMS) decision to apply the budget neutrality adjustment required for the 5-Year Review to the physician work RVUs. The vast majority of professional societies whose members treat Medicare beneficiaries recommended that the budget neutrality adjustment be made to the conversion factor and not to the physician work values. Budget neutrality adjustments required by changes in work RVUs typically have been applied to the conversion factor, consistent with the long-standing recommendations of the Relative Value Update Committee (RUC).

The ACR believes that historical consistency with previous adjustments to the conversion factor is a necessary and appropriate policy decision that would result in the most equitable application of budget neutrality adjustments.

Furthermore, CMS should be cognizant that maintaining the stability of the work RVUs is essential, since Medicare's RVUs are used by many other payers. They are often the basis of

physician compensation and productivity analyses. Merely publishing unadjusted work values in Addendum B does not change the fact that CMS finalized to scale the work values as a result of the 5-Year Review. While we understand it is not the intention of the Agency, by scaling the RVUs it gives the appearance, to outside observers, that the physician work of the services unaffected by the 5-Year Review has decreased as a result of the 5-Year Review.

The ACR strongly recommends that CMS reconsider its current policy and apply the budget neutrality adjustment to the conversion factor. In addition, the ACR reiterates its recommendation that CMS use the unadjusted work RVUs in the calculation of indirect practice expense.

Resource Based Practice Expense Relative Value Units

Interest Rate and Equipment Usage Percentage

The ACR agrees with and appreciates CMS's decision to make no change in the equipment utilization and interest rate in the practice expense methodology until there are further data to justify the changes. We are pleased to offer our resources to assist CMS in obtaining accurate data relative to those factors.

Practice Expense Per Physician Hour

The ACR agrees with and appreciates CMS's decision to increase the radiology practice expense per physician hour based on the correct weighting of the ACR supplemental survey data collected on practice expense.

Cardiac MRI Codes

As a result of the technological changes in MRI scanning, the CPT® Editorial Panel created eight new cardiac MRI codes and deleted five existing cardiac MRI codes. The new codes are: CPT code 75557, 75558, 75559, 75560, 75561, 75562, 75563 and 75564. The deleted codes are 75552, 75553, 75554, 75555 and 75556. The ACR, with the American College of Cardiology (ACC) surveyed the eight new codes and CMS accepted the RUC recommendation. However, for the four new cardiac MRI codes that contain "with flow/velocity quantification," CMS stated the following in the Final Rule.

"…four of the new codes incorporate blood flow measurement, which remains one of the nationally non-covered indications for MRI in the Medicare program. Due to a national non-coverage determination for MRI that provides blood flow measurement, CPT codes 75558, 75560, 75562 and 75564 will not be recognized by the Medicare program..."

These four codes were assigned status indicator of "N" (Non-covered) in Addendum B of the Final Rule.

The ACR is very disappointed with CMS's decision not to cover these four new cardiac MRI codes. The ACR realizes that 75556 (*Cardiac magnetic resonance imaging for velocity flow mapping*) has been a non-covered service for many years; however, there has been considerable confusion regarding the reasons for CMS's decision not to cover this examination. Flow quantification and velocity assessment is a requisite to any functional cardiac MRI examination when determination of valve function is necessary. It is necessary to determine the extent of valvular insufficiency and stenosis. Moreover, flow quantification is critical in some congenital cardiac MRI examinations to determine the severity of intracardiac shunting (Qp/Qs ratio). These flow measurements are used in much the same way as Doppler measurements are used in echocardiography. The temporal resolution of this methodology is good, and the information obtained is accurate.

The information obtained via flow quantification cardiac MRI is functional, and although the morphology of valves can be inferred by this functional information, the examination is not used to create an anatomic image and, as such, is not similar to magnetic resonance angiography or MR spectroscopy. In a transmittal from 2004 where CMS defines national coverage policy for MR spectroscopy, we did find a statement regarding non-coverage of flow determinations stating "the CMS has determined that blood flow measurement, imaging of cortical bone and calcifications, and procedures involving spatial resolution of bone and calcifications, are not considered reasonable and necessary indications within the meaning of section 1862(a)(1)(A) of the Social Security Act, and are therefore non-covered" which apparently reiterates CMS policy from 1997; however, CMS does not reference 75556 directly in that transmittal, and it is not clear to providers or contractors that this statement is the sole reason for non-coverage of 75556. In fact, we can find no statements in any CMS transmittal where CMS discusses the reasons why velocity measurements for cardiac imaging are "investigational" or not "reasonable and necessary." Had these been the sole reasons for CMS's non-coverage of 75556, the ACR and other medical societies would have been more forceful in their opposition to non-coverage of 75556. However, it was assumed that non-payment for 75556 was based on bundling 75556 with the other cardiac MRI codes.

Even though 75556 was listed in CPT and valued by the RUC as a stand-alone code, in clinical practice, 75556 was seldom (if ever) performed as a stand-alone service. Since 75556 was almost always an add-on code to other cardiac MRI examinations, medical specialty societies, including the ACR, assumed a major part of CMS's decision to not cover 75556 stemmed from the fact that many of the resources required to provide this service would be included in the base code (75552, 75553 or most commonly 75554). The ACR and other medical specialty societies have for years assumed that the primary reason for non-coverage of 75556 was based on the rationale that CMS believed that valvular function determinations were included with the base cardiac MRI examination, not that velocity determinations were investigational or not reasonable and necessary.

The Medicare contractors have further added to the ambiguity in language from a number of Local Coverage Determinations (LCDs). Many Medicare contractors have lumped 75556 into MR angiography services and have denied payment for 75556 based on the fact that CMS has national coverage policy that iterates the specific indications for which MRA is covered, which

do not include determinations of cardiac valve area. Velocity flow mapping has little in common with magnetic resonance angiography except that one type of pulse sequence used for MRA in the past included a phase-contrast MR angiography sequence, in which a phase image was subtracted from one acquired without the velocity encoding gradients in order to obtain an MR angiogram. In fact, even after CMS's comments in the rule regarding the National Coverage policy from 1994, we are still uncertain why 75556 would be included in the group of magnetic resonance angiography codes or MR spectroscopy. Specifically, it is still not clear to us where CMS defines 75556 as magnetic resonance angiography. We have reviewed a number of transmittals for magnetic resonance angiography and magnetic resonance spectroscopy and find that current CMS policy seems to merely instruct the Medicare contractors not to cover 75556 but leaves the reasons for non-coverage ambiguous. The *Carriers Manual* regarding the issue defines the covered indications for MRA, but is silent with respect to specific instruction regarding payment policy for 75556. One contractor's LCD defines the reason for non-coverage as follows: "Other usages of MRA (72159, 72198, 73225) including cardiac MRI for velocity flow mapping (75556) are considered investigational and are not eligible for reimbursement." However, we have been unable to find that specific statement in a CMS transmittal. The ACR would appreciate clarification and a specific reference in CMS transmittals iterating why flow velocity measurements by MRI for determining cardiac valvular function should be classified as magnetic resonance angiography and why this service should be considered investigational or not reasonable and necessary service.

The ACR strongly believes any existing National Coverage Determination for magnetic resonance angiography is not applicable to flow and velocity measurements. The argument that these measurements remain investigational is irrational based on current literature and clinical acceptance. Studies published as early as 1995 have demonstrated the accuracy of MR determinations of valve disease[1,2,3,4] and Qp/Qs ratios[5,6] compared with both invasive and other non-invasive methods. Functional evaluation of the cardiac valves with MRI in most instances is equal in accuracy to echocardiography, and to require that Medicare beneficiaries undergo an additional and potentially more invasive examination (e.g., echocardiography or catheterization) following cardiac MRI to assess valvular stenosis or regurgitation based purely upon payment policy is irrational and, ultimately, not cost effective.

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[1] Caruthers SD, Lin SJ, Brown P, et al. Practical Value of Cardiac Magnetic Resonance Imaging for Clinical Quantification of Aortic Valve Stenosis: Comparison with Echocardiography. Circulation 2003; 108:2236-43.
[2] Hundley WG, Li HF, Willard JE, et al. Magnetic Resonance Imaging Assessment of the Severity of Mitral Regurgitation. Comparison with Invasive Techniques. Circulation 1995; 92:1151-8.
[3] Kizilbash AM, Hundley WG, Willet DL, Franco F Peshock RM, Grayburn PA. Comparison of Quantitative Doppler with Magnetic Resonance Imaging for Assessment of the Severity of Mitrral Regurgitation. Am J Cardiol 1998; 81: 792-795.
[4] Kon MW, Myerson SG, Moat NE, Pennell DJ. Quantification of Regurgitant Fraction in Mitral Regurgitation by Cardiovascular Magnetic Resonance: Comparison of Techniques. J Heart Valve Dis 2004; 13:600-607
[5] Hundley WG, Li HF, Lang RA, et al. Assessment of Left-to-right Intracardiac Shunting by Velocity-encoded, Phase-difference Magnetic Resonance Imaging. A Comparison with Oximetric and Indicator Dilution Techniques. Circulation 1995; 91:2955-60.
[6] Weber OM, Higgins CB. MR Evaluation of Cardiovascular Physiology in Congenital Heart Disease: Flow and Function. J Cardiovasc Magn Reson 2006; 8:607-17.

The ACR is particularly disappointed with CMS's decision regarding payment policy for the cardiac MRI codes that include flow velocity determinations because it was our intent to bring forward a set of bundled codes that accurately described the permutations of performing cardiac MRI without having to have a series of component codes where providers would pick and choose the services performed. At the urging of CMS, the CPT Editorial Panel and the RUC, specialty societies have been asked to create codes that describe the entire episode of care rather than a series of component codes or add-on codes in order to eliminate the possibility of duplication of work and practice expense. The ACR and ACC took this advice to heart and created such a set of codes for cardiac MRI. The codes that include velocity determinations are the workhorse examinations for cardiac MRI studies. CMS payment policy puts radiologists in the unanticipated conundrum of choosing between four suboptimal options. Physicians can do the complete examination, code the complete examination and not be reimbursed. Alternatively, the physician can do the complete examination and down-code the examination to the codes that do not include velocity determinations. However, this method violates CPT coding policy, and places providers at risk of Medicare fraud for coding the incorrect examination for the sole purpose of obtaining reimbursement. While either of these alternatives will do what is correct for the patients, both are untenable for the physicians. Unfortunately, CMS payment policy, based on a 1997 assessment that flow velocity determinations by MRI are not reasonable and necessary, now dictates that physicians must perform an incomplete cardiac MRI examination and then refer the patient for additional and/or potentially more invasive studies such as echocardiography, transthoracic echocardiography or cardiac catheterization in order to determine valve area, extent of regurgitation or gradient, or Qp/Qs ratio.

The ACR believes this recommendation is flawed because it subjects patients to unnecessary examinations and increases the cost of their cardiac evaluation. Nonetheless, the ACR will have to provide this recommendation to its members unless CMS reconsiders its payment policy. The final option is to obtain an Advanced Beneficiary Notice from patients undergoing the cardiac MRI examinations that include flow velocity determinations. Certainly, an allowable scenario for physicians under the proposed payment policy. Unfortunately, patients would then have to pay for an entire examination when flow is ordered even though CMS covers all of the other components of the examination when flow is not included. Providers will have to explain to beneficiaries that while CMS will cover a lesser examination, that includes 90 percent of the cost (based on work RVUs), when flow velocity determinations are not necessary, CMS requires that patients must pay the cost of the entire examination (not just the additional flow velocity component) when determination of valve function is needed. We believe that beneficiaries will have difficulty understanding the nuances of CMS's reimbursement policy and ask the providers to perform only the covered examinations, which will require them to undergo additional and sometimes more invasive testing. We believe that CMS may not have anticipated these outcomes when establishing payment policy for cardiac MRI and are hopeful CMS will reconsider its position.

Because current payment policy is based on a 1997 analysis of flow measurements that may not have even included an assessment of the accuracy of such measurements for cardiac valvular function, the ACR believes CMS can change its decision regarding coverage of 75558, 75560, 75562 and 75564 without opening a new National Coverage Assessment (NCA) and value these

services at the RUC recommended values. Alternatively, if CMS believes that a new NCA is required before coverage policy can be changed, the ACR recommends that these four codes be valued at the RUC recommended values for 75557, 75559, 75561 and 75563 while the NCA is pending. This latter recommendation, would in effect, continue current payment policy whereby physicians are frequently providing velocity determinations and valvular assessment for their patients but are not being reimbursed. Any other decision by CMS will be detrimental to beneficiaries and ultimately more costly for the Medicare program. The ACR looks forward to working with CMS on this important issue.

Independent Diagnostic Testing Facility (IDTF) Issues

New IDTF Standards: § 410.33(g) (15)

The ACR supports CMS's decision to implement its proposal prohibiting the sharing of space or equipment by an IDTF with any other Medicare-enrolled provider or entity. We also agree with and appreciate the exclusion of radiologist ownership or investment interest from this prohibition. We firmly believe that patient care will benefit because of physicians' inability to enter into "lease" or similar purchased test arrangements with imaging centers primarily to allow physicians to profit from their own referrals.

Physician Quality Reporting Initiative (PQRI)

Selection of Measures for 2008

The Final Rule states that measures not identified in the MPFS proposed rule but recommended for inclusion via the comment period cannot be included in the 2008 list because there was not opportunity for public comment within the rulemaking process. The ACR is extremely disappointed that the eight new AQA approved radiology measures will not be included in the 2008 PQRI.

An enormous amount of effort was expended in developing and obtaining approval of these measures that, if implemented, would likely improve quality of care and also afford many more physicians the opportunity to participate in the PQRI program. We understand the constraints imposed on CMS by the statute and we appreciate the acknowledgement of these additional measures in the Final Rule. We also appreciate the stated commitment to keep these measures available for consideration in identifying measure sets for future years' PQRI. We ask that the eight new AQA approved radiology measures be a priority for adoption at the earliest possible time.

Registry Based Reporting for 2008 PQRI

The Final Rule states that medical registry reporting of PQRI measures will be tested in 2008 using two options (identified in Proposed Rule as Options 2 and 3). The ACR supports Option 3, in which a registry will calculate and submit reporting and performance rates for various measures to CMS.

Physician Self-Referral Provisions

In-Office Ancillary Services Exception

The ACR strongly believes that changes to the Stark in-office ancillary services exception are necessary. We are pleased that CMS has indicated its intent to address revisions to this exception through a future notice of proposed rulemaking. The ACR strongly encourages CMS to propose those revisions in CY 2008 and is willing to assist CMS by providing new data to support the need for such timely revision.

We reiterate the recommendations made in our comments on the proposed rule because we regard changes to the in-office ancillary services exception as fundamental to protecting against program or patient abuse.

The ACR recommends that certain medical services should not qualify for the in-office ancillary services exemption. Services that should not qualify, and should never be defined as "ancillary," are CT, CTA, MRI, MRA, PET, PET/CT and radiation therapy.

The ACR also recommends that CMS place restrictions on any service provided under the in-office ancillary services exemption to require that the exempted ancillary service must be provided within one hour of the time of the office visit.

In response to the questions of whether and how to change the definitions of "same building" and "centralized building" the ACR believes that, if convenience and timeliness of diagnosis are the rationale for the in-office ancillary services exception, CMS should require that a "centralized building" be within five miles of the building where the physician or medical group furnishes medical services. We would support this definition only if CMS adopted the ACR recommendations for time restriction and deletion of certain medical services from those qualifying for the in-office medical exemption.

The ACR recommends that non-specialist physicians should not be able to use the in-office ancillary services exemption to refer patients for specialized services involving the use of equipment owned, leased, or controlled through a joint venture by the referring physician unless the equipment provides the simple and truly "ancillary" services that Congress originally intended in this exception.

Changes to Reassignment and Physician Self-Referral Rules Relating to Diagnostic Tests [Anti-Markup Provisions]

The ACR strongly supports the CMS decision to extend the anti-markup rule to both the technical component and the professional component of diagnostic tests. The ACR is pleased that CMS has refined the definition of the "office of the billing physician" to more accurately identify those situations in which use of a "centralized building" could potentially result in abusive practices. The ACR believes that the anti-markup rule properly restricts financial influence on patient care decisions and will help to curb inappropriate utilization and strengthen

Medicare program integrity.

Other Self-Referral Provisions

The ACR is pleased to learn that CMS has sufficient information, both from the commenters and its independent research, to finalize revisions to the physician self-referral regulations without the need for new proposals and additional public comment. We urge CMS to publish its Final Rule implementing these proposals early in CY 2008.

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 Choe at 800-227-5463 ext. 4556 or via email at achoe@acr.org.

Respectfully Submitted,

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