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Mark McClellan, MD, PhD  
Administrator  
Centers for Medicare & Medicaid Service  
Department of Health and Human Services  
Attention: CMS-1321-P  
7500 Security Boulevard  
Baltimore, MD 21244-1850

**Re: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007; Proposed Rule**

Dear Dr. McClellan:

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 proposed notice "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007" published in the Federal Register on August 22, 2006. We will address the Deficit Reduction Act proposals; miscellaneous radiology supply and equipment issues; the global period for brachytherapy; independent diagnostic testing facility requirements; the reassignment rule; and the impact of the geographic practice cost index on physician practices in Puerto Rico.

### **Deficit Reduction Act Proposals**

#### **A. Multiple Procedure Reduction**

The ACR appreciates the Centers for Medicaid and Medicare Services' (CMS) decision to not implement a 50 percent payment reduction for the technical component of multiple procedures performed on contiguous body areas in the same session for 2007. The ACR agrees that there are some efficiencies in clinical labor activity when certain combinations of multiple imaging procedures are performed in the same session. However, we do not agree that these efficiencies are uniform across all families and we do not believe the data support a 50 percent reduction. CMS proposes to exercise its discretion in the case of imaging services potentially affected by both the multiple imaging procedure reduction and the Outpatient Prospective Payment System (OPPS) cap by applying the multiple imaging procedure reduction **first** and then the OPPS cap. We compliment CMS for taking this step to minimize the negative consequences of these interrelated policies, and we support this approach, since it will somewhat abate what could have been an unintended compounding of payment reduction. However, in light of the DRA, the ACR believes that **any** technical component reduction for contiguous imaging is inappropriate and should be eliminated, since the Ambulatory Payment Classification (APC) payment rate already accounts for any cost-efficiencies incurred when contiguous body parts are examined.



## **B. Reduction in TC for Imaging Services Under the Physician Fee Schedule (PFS) to Outpatient Department (OPD) Payment Amount**

As required by the DRA, CMS proposes to cap Medicare payment amounts for certain imaging services at the amount paid to hospitals under the OPDS. ACR views this policy as ill-advised and inappropriate, and believes it will lead to inequitable payment amounts and compromise Medicare beneficiaries access to high quality imaging services. However, we recognize that CMS is simply attempting to implement a statutory requirement. Nevertheless, we believe that CMS should use its discretionary authority to the greatest extent possible to limit the potential disruption to patient access. This could be done by tightly circumscribing the list of affected services as noted below.

### **Definition of Diagnostic Imaging**

In the Deficit Reduction Act of 2005, section 5102 (B) describes imaging as follows:

“(B) Imaging Services Described. For purposes of subparagraph (A), imaging services described in this subparagraph are imaging and computer-assisted imaging services, including X-ray, ultrasound (including echocardiography), nuclear medicine (including positron emission tomography), magnetic resonance imaging, computed tomography, and fluoroscopy, but excluding diagnostic and screening mammography.”

In the proposed rule, CMS defines imaging as services that provide visual information regarding areas of the body that are not normally visible, thereby assisting in the diagnosis or treatment of illness or injury. CMS considered the CPT® 7XXXX series codes for radiology services and added other CPT codes and alpha-numeric HCPCS codes that describe imaging services. The ACR believes that the list of procedures affected by the DRA should not include imaging guidance for interventional procedures. While supervision and interpretation codes for diagnostic angiography may meet the definition of an imaging procedure, the ACR believes that supervision and interpretation for endovascular procedures such as angioplasty, stent placement, and imaging guidance for biopsy, injections or drainage do not.

Recently, imaging guidance has been incorporated into new CPT codes for surgical procedures to include cryoablation of the prostate, endovascular stent placement in the carotid artery and bone ablation. These codes are not affected by the DRA and for consistency, when imaging guidance is used to facilitate a surgical procedure, those codes should not be defined as diagnostic imaging nor included on the list of codes subject to the DRA provisions.

**Based on the definition above, the ACR believes that the DRA list needs to be further refined to exclude interventional radiology codes as we believe that the DRA was not intended to include imaging guidance that is integral to the performance of interventional treatment or diagnostic procedures.**

### **Exclusion of Carrier-Priced Services**

The ACR believes that a case can be made for excluding carrier-priced services, such as PET, from the list of services subject to the payment limitations required under section 5102 of the DRA. While the proposed rule argues that such carrier-priced services are “within the statutory definition of imaging services and are also within the statutory definition of PFS services,” we believe there are other factors



that need to be taken into account in determining whether carrier-priced services should be subjected to the DRA-mandated payment limitations. To begin with, section 5102 of the DRA speaks of the technical component established under the physician fee schedule, and by definition, carrier-priced services do not have a technical component calculated in the usual manner or published in the *Federal Register*. Further, the DRA provision in question speaks specifically about the technical component prior to the application of the relevant geographic adjustment factor. Once again, it may not be possible to tease apart the various components of a carrier-priced payment amount for a service or to assure oneself that the portion of the fee in question has not been adjusted for geographic considerations by the carrier. By making these points, we do not wish in any way to imply that we believe that some imaging services somehow “deserve” to experience a payment limitation while others do not. We are simply urging CMS to exercise its discretion to limit the application of what the ACR considers to be an inappropriate payment policy, particularly when it involves procedures that do not have a specific technical component value published in the Federal Register.

### **Effects of Professional Liability Insurance (PLI) Payments as a Result of DRA**

Since 1999, the ACR has been expressing concern to CMS that the malpractice relative values (MPRVUS) are inappropriately assigned between the professional component (PC) and technical component (TC). The ACR advocates that physicians incur the highest costs for malpractice insurance and are ultimately responsible when a study is in question in a malpractice case. Therefore, the ACR has taken the longstanding position that the MPRVUS assigned to the TC should more appropriately be placed in the PC and vice versa. Although CMS’ methodology did not allow for this change in the past, it was felt that medical practices who bill globally would still benefit from the global malpractice values. Now that the Deficit Reduction Act will cause severe cuts in the technical component of many imaging codes, this will also significantly cut the total malpractice value paid and malpractice funding available in the Medicare Trust Fund.

**The ACR requests that CMS consider implementing ACR’s previous requests to simply reverse the malpractice rate paid in the TC and PC to more accurately reflect where the liability risks and costs exist.**

### **Provisions**

#### **A. Practice Expense Review Committee**

CMS proposes to accept Practice Expense Review Committee (PERC) recommendations for all new codes that went through the Relative Value Update Committee from September 2005 through April 2006. ACR welcomes this decision.

However, the ACR believes that the new CMS practice expense methodology has caused inappropriate reductions in payment for certain procedures. The ACR believes that as we review the causes for these reductions that further refinement of direct inputs may be appropriate and requests that CMS support a society's ability to take these codes back to the PERC for review if necessary to insure accurate inputs and equipment costs.



## **B. Low and High Osmolar Contrast Media**

The ACR agrees with CMS's proposal to delete low osmolar and high osmolar contrast media from the practice expense database because they are separately reimbursed under the fee schedule.

## **C. Medical Supplies, Equipment, Imaging Rooms**

The ACR appreciates CMS's proposal to accept and implement updates to the various imaging rooms, the pricing for certain radiology equipment as submitted, and the updated cost information for the vertebroplasty kit.

## **D. Supply for code 50384**

The ACR agrees with CMS's proposal to delete a ureteral stent from the practice expenses for code 50384 (Removal (via snare/capture) of internally dwelling ureteral stent via percutaneous approach, including radiological supervision and interpretation). The ACR agrees that this supply item was submitted in error.

## **E. Table 2: Equipment Items Needing Specialty Input for Pricing and Proposed Deletions**

The ACR supports CMS's efforts to keep pricing information updated in the practice expense database. The ACR appreciates CMS's decision to accept the cost information submitted on the film alternator.

## **Miscellaneous Coding Issues**

### **A. Global Period for Remote Afterloading High Intensity Brachytherapy Global Procedures**

High intensity brachytherapy codes 77781, 77782, 77783 and 77784 are currently assigned a 90 day global period. In the proposed rule, CMS proposes to assign a global period of XXX for these codes to permit separate payment each time the services are provided and allow payment to be based on the actual service provided. CMS states that it is difficult to assign a relative value for a "typical" patient based on a global period of 90 days due to increasing variability in treatment regimens. The ACR supports this proposal and recommends that CMS change the global period for codes 77781, 77782, 77783 and 77784 from a 90 day to XXX global period.

## **Independent Diagnostic Testing Facility (IDTF) Issues**

The Office of Inspector General (OIG) found a potential \$71 million in improper payments made to IDTFs and as a result, CMS proposes that each IDTF be required to meet 14 standards, which resemble those that currently apply to suppliers of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS), in order to obtain or retain enrollment in the Medicare program. In addition to the following comments on the specific elements of this proposal, the ACR recommends that CMS consider a requirement for all non-facility diagnostic testing to comply with IDTF rules.



1. Operate in compliance with all applicable licensure and regulatory requirements;

The ACR believes that this proposed standard is too broad. Specifically, which licensure and regulatory requirements would CMS require? Would they be state requirements or new federal requirements? Since there is no uniformity among current state requirements, the ACR recommends that CMS draft minimum federal requirements that all IDTFs must adhere to.

2. Provide complete and accurate information on its enrollment application;

The ACR believes that this standard is very basic and should already be in place under the current IDTF and enrollment rules.

3. Maintain a physical facility (not a post office box or commercial mailbox);

The ACR supports this standard as it will be useful, especially with regard to conducting inspections as suggested in proposed standard 14.

4. Have all applicable testing equipment available at the physical site, excluding portable equipment;

The ACR has no comments as this standard seems to be a logical follow-up to the proposed standard 3.

5. Maintain a primary business phone under the name of the business;

The ACR believes that this standard should already be in place under the current IDTF rule.

6. Have a comprehensive liability insurance policy of at least \$300,000 or 20 percent of its average annual Medicare billings, whichever is greater, that covers both the place of business and all customers and employees;

The ACR recommends that CMS explain how insurance for IDTFs advances the stated purpose of protecting beneficiaries and the Trust Fund. The ACR also recommends that CMS more precisely define the type of insurance an IDTF should carry, and boost the minimum threshold of comprehensive liability coverage to \$1 million individual or \$3 million in aggregate liability limit.

7. Agree not to directly solicit patients;

The ACR agrees strongly with this proposed standard, although CMS must be very specific on what is the definition of "solicit". For instance, if an orthopedic surgeon has a long-time patient that may need an MRI on a particular visit and the surgeon offers an MRI at his facility, is that soliciting? Also, would this standard mean that an imaging-only facility could not advertise to the general public or work with physicians who do not have a financial interest in the facility to arrange a referral relationship?

8. Answer beneficiaries' questions and respond to their complaints;



This standard, as written, is fairly basic and subject to wide variation in compliance. The ACR would prefer a standard that requires an IDTF to have a written standard operating procedure for response to patient questions and complaints and a requirement to keep such questions and complaints on file.

9. Openly post these standards for review by patients and the public;

The ACR supports this standard.

10. Disclose to the government any person having ownership, financial or control interest, or any other legal interest in the supplier;

The ACR supports this standard.

11. Have its testing equipment calibrated per equipment instructions and in compliance with applicable national standards;

The ACR supports this standard, but recommends that it be modified to state that equipment must be evaluated by a qualified medical physicist or other appropriate expert (depending upon the type of equipment being used by a given IDTF).

12. Have a technical staff on duty with the appropriate credentials to perform tests;

The ACR supports this standard.

13. Have proper medical record storage and retrieval capabilities;

The ACR supports this standard, but, considering the rapid evolution but sporadic prevalence of digital image storage capacity, would like to have significant input into what would constitute “proper medical record storage and retrieval capabilities.”

14. Permit CMS or its agent/contractor to conduct unannounced on-site inspections.

The ACR supports this standard.

### ***Supervision***

The ACR supports the proposal to limit the number of IDTF’s a physician can supervise to no more than three sites.

### ***Place of Service***

CMS proposes to define the “point of the actual delivery of service” as the correct “Place of Service” for the claim form in the case of diagnostic testing performed outside the IDTF’s physical location.



For reasons of patient safety, quality of examination, and potential environmental hazard, the ACR believes that there should be limited medically necessary reasons to perform radiological or other medical imaging procedures at a beneficiary's residence.

### **Reassignment Rule and Physician Self-Referral**

The ACR shares the CMS concern “that allowing physician group practices or other suppliers to purchase or otherwise contract for the provision of diagnostic tests and then to realize a profit when billing Medicare may lead to patient and program abuse.” We strongly support the intent of CMS to address this issue in the proposals it has made in this rule. Specifically, the ACR agrees completely with the language proposed by CMS to amend § 424.80 of its regulations. **The ACR also believes that “diagnostic tests in the Designated Health Services (DHS) category of radiology and certain other imaging services” should not be excepted from CMS’s proposed reassignment changes.** Published evidence has shown that diagnostic test volume has increased dramatically in recent years, causing higher costs for federal and private payers.

The Medicare Payment Advisory Commission and the Blue Cross and Blue Shield Association reported in 2003 that diagnostic imaging was the fastest growing type of medical expenditure in the United States, with an annual growth rate of nine percent that more than doubles general medical procedures.<sup>1</sup> Blue Cross data in 2005 confirms that diagnostic imaging continues to accelerate in the United States.<sup>2</sup> More importantly, this development has resulted in medically unnecessary diagnostic tests being performed on patients.<sup>3</sup>

The ACR has advocated that Congress and CMS adopt quality standards to reverse this disturbing trend, ensure program integrity and safeguard against patient abuse. Consequently, we believe that the proposed reassignment changes could advance those critical objectives by influencing many physicians, medical groups and other entities to separately bill the technical and professional components of diagnostic studies. Although CMS focuses on suspect “pod lab” pathology arrangements that apparently involved potential fee-splitting and anti-kickback violations, the ACR maintains that those fraud and abuse concerns also apply in certain diagnostic test arrangements within the Designated Health Services (DHS) category of “radiology and certain other imaging services.” For example, the ACR has learned of arrangements where the technical component (TC) for MRI procedures performed under a lease arrangement is billed to Medicare at a significant markup to the supplier’s actual charge to the billing entity.

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<sup>1</sup> Hackbarth GM, Reischauer RD, Miller ME. Assessing payment adequacy and updating payments for physician services. *Medicare Payment Advisory Commission Report to Congress*, March 2003. BlueCross BlueShield Association, *Medical Technology as a Driver of Healthcare Costs: Diagnostic Imaging* (2003).

<sup>2</sup> Blue Cross and Blue Shield Association, *Medical Cost Reference Guide, Section 4, Projected Growth in Imaging Procedures, U.S. Market 1998-2008* (2006).

<sup>3</sup> Moskowitz H, Sunshine J, Grossman D, Adams L, Gelinis L. The effect of imaging guidelines on the number and quality of outpatient radiographic examinations. *AJR* 2000; 175:9-15. See also Litt AW, Ryan DR, Batista BA, et al., Relative Procedure Intensity with Self-Referral and Radiologist Referral: Extremity Radiography. *Radiology* 2005;235:142-147.



**The ACR also strongly supports adoption of further amendments to § 424.80(d) that CMS is considering in regard to when a physician or medical group can bill for a reassigned professional component (PC) of a diagnostic test, and recommends that diagnostic tests in the DHS category of radiology and certain other imaging procedures not be excepted from those amendments.** The amendments under consideration, if included in the final rule, would serve as a logical and supportive corollary to the proposed amendments regarding the TC.

The ACR is aware of arrangements in which the billing entity reportedly does not pay an independent contractor physician the full professional component fee, yet bills Medicare for the entire PC while retaining an amount that cannot be attributable to legitimate billing or other administrative expenses.

**Therefore, the ACR firmly believes that an anti-markup provision should apply to the reassignment of the PC of diagnostic tests performed under a contractual arrangement.** In response to the request for comments on “how to determine the correct amount that should be billed to the Medicare program”, the ACR suggests that CMS use the same language it has proposed for the TC anti-markup provision, i.e. “the amount billed to Medicare by the billing entity, less the applicable deductibles and coinsurance may not exceed the lowest of the following amounts:

- The physician or other supplier’s net charge to the billing physician or medical group
- The billing physician’s or medical group’s actual charge
- The fee schedule amount for the service that would be allowed if the physician or other supplier billed directly.”

The ACR also supports CMS’s efforts to change the definition of “centralized building” in the regulations to address certain space ownership or leasing arrangements that seek to meet the “physician services” or “in-office ancillary services” exceptions. However, we are concerned that inclusion of a minimum 350 square feet in the definition of “centralized building” would not effectively curtail potential program or patient abuse that could occur through provision of diagnostic tests in the DHS category of radiology and certain other imaging services. **The ACR therefore suggests that CMS consider a larger and more appropriate minimum square footage in the definition of “centralized building” for those specific DHS.**

**Alternatively, the ACR would more strongly recommend that CMS require that all “non-facility” provision of diagnostic tests in the DHS category of radiology and certain other imaging services be subject to the rules for Independent Diagnostic Testing Facilities (IDTF).** The ACR agrees with the proposal that the “centralized building” permanently contain the necessary equipment. We also believe that the potential for “pod” type abuse for radiology and imaging services would be minimized by requiring the group practice using the “centralized building” under the physician services exception or the in-office ancillary services exception to employ, in that space, a nonphysician employee or independent contractor who will perform services exclusively for the group for at least 35 hours per week. CMS is considering such a policy (at least in the case of pod labs) and we believe that it is reasonable and should be applied more broadly.

Finally, the ACR also supports amending the regulation to allow the reassigning supplier to have unrestricted access to claims information submitted to Medicare by the billing entity, irrespective of whether the supplier is an employee or an independent contractor of the billing entity.

## **Geographic Practice Cost Indices (GPCI)**



Effective January 1, 2007, CMS is mandated to drop the current floor of 1.00 for the work GPCI. CMS seeks suggestions on alternative ways that CMS could administratively reconfigure payment localities that could be developed and proposed in future rulemaking. In this regard, the ACR remains concerned that the current GPCI for Puerto Rico is making it difficult for physician practices to retain professional and technical staff, who are being recruited away by physician offices from locales with much higher GPICs, particularly in the State of Florida. We, therefore, urge CMS to examine more carefully the reasonableness of the data for Puerto Rico that are used in constructing the applicable GPCI and to consider alternative data sources or ways to configure payment localities that would address these concerns.

### **Conclusion**

Thank you for the opportunity to comment on this proposed notice. 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 with respect to radiology, please contact Angela Choe at 800-227-5463 ext. 4556 or via email at [achoe@acr.org](mailto:achoe@acr.org).

Respectfully Submitted,

A handwritten signature in black ink that reads "Harvey L. Neiman, MD". The signature is written in a cursive style.

Harvey L. Neiman, MD, FACR  
Executive Director

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