

August 30, 2007

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Herb Kuhn  
Acting Deputy Administrator  
Centers for Medicare & Medicaid Services  
U.S. Department of Health and Human Services  
Attention: CMS-1385-P  
7500 Security Boulevard  
Baltimore, MD 21244-1850

**Re: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2008; Proposed Rule**

Dear Mr. Kuhn:

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 2008” published in the Federal Register on July 12, 2007. We will address malpractice; budget neutrality; resource-based practice expense (PE) relative value units (RVUs); practice expense per hour; Relative Value Update Committee (RUC) recommendations; additional codes from the five year review; the 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].

**Malpractice**

The ACR has suggested in the past that there is disproportionate allocation of the malpractice values between the professional component (PC) and the technical component (TC). The ACR’s recommendation was to flip the malpractice values associated with each of the component parts so the technical component malpractice values are assigned to the professional component and the professional component malpractice values are assigned to the technical component. This is because physicians incur the higher costs for malpractice insurance.

In the past, the RUC also provided comments to Centers for Medicare and Medicaid Services (CMS) and they recommended that the CMS: 1) Flip the malpractice values associated with each of the component parts so the technical component malpractice values are assigned to the professional component and the professional component malpractice values are assigned to the technical component or 2) Make the malpractice values of the technical component equal to the malpractice values of the professional component. The ACR is aware that the AMA RUC comments being submitted in response to this proposed rule may reference a RUC Professional Liability Insurance (PLI) workgroup recommendation that the malpractice values in the technical component should be zero as there are no identifiable professional liability costs associated with providing the TC. CMS should be aware that this position has not been vetted and approved by the full RUC, and that the ACR disagrees with the conclusions of the PLI workgroup. Although

the ACR believes that the PC malpractice values should be higher, **the ACR does not believe that the malpractice values in the technical component should be zero.**

The ACR is aware that CMS is requiring independent diagnostic testing facilities to purchase a certain level of liability insurance. CMS is, therefore, acknowledging that some liability costs do exist in the TC and the ACR supports CMS' comments on this issue in past final rules. Also, other clinical staff such as radiology technologists and medical physicists purchase professional liability insurance and are represented in the TC. According to the American Association of Medical Physicists, "Medical physicists, due to their key role in the design and quality assurance of high-risk radiation therapy procedures, have a significant liability exposure, and so liability insurance is normally carried by the medical physicist's employer or by the medical physicist if self-employed. Typical policies are valued at \$1Million Individual / \$3Million Aggregate coverage."

### **Budget Neutrality**

The ACR is again disappointed that the CMS decided to apply the budget neutrality adjustment by way of a physician work adjustment factor as a result of the increase in anesthesia physician work under the third five year review. The CMS decision is contrary to the views of almost the entire medical community that are expressed in numerous comments. 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.

The ACR believes that being consistent with previous adjustments to the conversion factor is a more fair and equitable application of budget neutrality adjustments. In addition to its objection on a methodological basis, the ACR is opposed to the CMS decision because it places a disproportionate burden on hospital-based physicians whose compensation for medical services is derived only from the PC and is thus heavily dependent on the work RVU.

**The ACR again strongly recommends that CMS reconsider applying the budget neutrality adjustment to the conversion factor and not to the physician work RVU.**

Also, it appears that CMS has used the adjusted work RVUs as the allocator of indirect practice expense in its calculations for the proposed 2008 Medicare Physician Fee Schedule (MPFS). The work RVUs were adjusted solely to meet Medicare's statutory requirement to maintain budget neutrality. In fact, CMS does not even publish the adjusted work RVUs in the *Federal Register*. We believe the use of reduced work RVUs to calculate indirect practice expense costs results in incorrectly reduced PE RVUs and distorts the relativity of the fee schedule. **The ACR strongly recommends that CMS use unadjusted work relative values as the allocator of indirect practice expenses.**

## **Resource-based PE RVUs**

### *Interest Rate*

The ACR supports CMS' decision not to change the interest rate in the practice expense equipment cost calculation of 11 percent. Analysis of the 2007 Small Business Administration (SBA) data on loans and applicable interest rates seems appropriate.

### *Equipment Usage Percentage*

The ACR supports the CMS decision not to change the equipment utilization rate of 50 percent until there is better data to show the correct percentage. Arbitrarily setting high utilization rates on higher priced equipment may not always be accurate. It should not simply be concluded that higher priced equipment is utilized at a higher rate. There are higher priced technologies such as proton beam radiation therapy or magnetoencephalography (MEG) that are highly beneficial to a select population but are not necessarily utilized at the same rate as other higher cost technologies. In addition, there is no standard definition of a work day among medical practices. Some medical practices are open 8 hours a day, but many others may be open longer or shorter hours. Those that are open longer hours may only be operating certain pieces of equipment on select days such as Mondays, Wednesdays and Fridays.

The ACR agrees that there is not sufficient evidence to justify an alternative proposal on this issue. We support the concept of data collection through extensive survey to accurately determine the utilization rate for **all** medical equipment, using a prospective evidence-based methodology. **The ACR disagrees with others who might propose that CMS arbitrarily choose a rate higher than 50 percent and then allow exceptions based on individual petition.** The ACR is willing and ready to work with CMS to ensure the appropriate equipment utilization rates are captured for the great variety of equipment used in our field.

## **Practice Expense Per Hour**

The ACR appreciates CMS' and the Lewin Group's conclusion that weighing the ACR's supplemental survey data by practice size more appropriately accounts for the small, high-cost entities in the final PE/HR for radiology. The ACR has discussed extensively with the Lewin Group from the beginning of the survey process about how to weight the practice level survey data to be representative of all radiology practices, large and small, in the U.S., and is pleased that CMS agrees that ACR's approach more appropriately identifies the PE/HR for radiology.

## **RUC Recommendations for Direct PE Inputs and Other PE Input Issues**

### *RUC Recommendations for DXA, CAD and Nuclear Medicine*

The ACR appreciates CMS' decision with respect to the direct practice expense inputs for dual energy x-ray absorptiometry (DXA), computer-aided detection (CAD) and nuclear medicine services.

***Table 5: Supply Items Needing Specialty Input for Pricing***

The ACR supports the cost documentation being submitted by the Society of Interventional Radiology (SIR) for the vascular stent deployment system.

***Table 6: Equipment Items Needing Specialty Input for Pricing and Proposed Deletions***

The ACR supports information being submitted by the SIR on the plasma pheresis machine with an ultraviolet light source.

***Coding – Additional Codes From Five -Year Review***

CMS proposes to bundle code 93325 (Doppler echocardiography color flow velocity mapping (List separately in addition to codes for echocardiography) into codes 76825, 76826, 76827, 76828, 93303, 93304, 93307, 93308, 93312, 93314, 93315, 93317, 93320, 93321, and 93350, apparently without adjusting the work values for these codes. The ACR opposes bundling when reporting of multiple codes is required to accurately describe the services performed. The ACR also believes that CMS should rely on the CPT® Editorial Panel and RUC processes to address issues relating to CPT code 93325 and should not rebundle any CPT codes independent of those processes. **The ACR requests that CMS withdraw its proposal to reject the RUC recommendation and to refer CPT code 93325 to the CPT Editorial Panel.**

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

***Revised Standard Number 6***

CMS proposes to change standard 6 to read “Has a comprehensive liability insurance policy in the amount of at least \$300,000 per incident that covers both the supplier’s place of business and all customers and employees of the supplier and ensures that this insurance policy must remain in force at all times. The policy must be carried by a nonrelative-owned company. The IDTF must list the Medicare contractor as a Certificate Holder on the policy and promptly notify the Medicare contractor in writing of any policy changes or cancellations.”

The ACR supports the requirement for an IDTF to have comprehensive liability insurance but is concerned that requiring a Medicare contractor to be listed as a Certificate Holder will create reluctance of insurance underwriters to issue such policies, since listing a Medicare carrier as a Certificate Holder could, theoretically, provide the government with contractual rights to indemnification or payment that it would not otherwise have.

***New Performance Standard***

CMS proposes to prohibit IDTFs from sharing space, equipment or staff with, or subleasing its operations to, another individual or organization. CMS would have prohibited IDTFs from entering into part-time leases, even if those complied with the anti-kickback and Stark exceptions. Many IDTFs lease space and technologists part-time to radiology groups. Alternatively, many radiology groups have limited liability corporations that own and operate IDTFs, employing the same technologists that work for the IDTF. As the government has recognized historically,

radiologists are not in a position to create abusive self-referral arrangements with IDTFs or other entities.<sup>1</sup>

**The ACR, therefore, recommends that in its final rule, CMS amend the language of its proposal to read: “a new performance standard at § 410.33(g)(15), which states, ‘Does not share space, equipment or staff or sublease its operations to another individual, organization, employee or contractor of such organization, that refers Medicare patients to the IDTF for designated health services (DHS).’”**

### *Supervision*

The ACR agrees with the CMS proposal to delete the requirement that the supervising physician is responsible for the overall operation and administration of an IDTF. CMS proposes to clarify the standard that a physician providing general supervision can oversee a maximum of three IDTF sites by noting that the term “sites” includes fixed as well as mobile sites. The ACR is concerned that the supervising physician list for each IDTF site may not be kept updated. Failure to keep these records up to date may result in the appearance that a particular physician is supervising more than the allowed number of sites when, in fact, this is not the case. **At this time, the ACR requests that CMS delay the implementation of limiting a physician to supervise more than 3 IDTF sites.** The ACR would like to work with CMS to provide information on various practice patterns and to determine ones that are problematic.

### **TRHCA-SECTION 101(b): Physician Quality Reporting Initiative (PQRI)**

#### *Proposed Quality Measures for the 2008*

In general, the ACR supports the PQRI as an important first step in moving towards a value-based reporting system for physicians. We also appreciate CMS’ support for allowing measures to be developed through the AMA Physicians Consortium for Performance Improvement (PCPI) process, and the consensus development and endorsement roles played, respectively, by the Ambulatory Care Quality Alliance (AQA) and the National Quality Forum (NQF).

The ACR’s membership has shown a good deal of interest in participating in the PQRI, based on feedback and questions received through our website. While the 2007 PQRI does contain measures which would allow diagnostic and interventional radiologists to report, as well as radiation oncologists, it is the ACR’s goal to expand the number of measures applicable to a wider range of radiologists in 2008. This includes measures now under development by the AMA Consortium’s Radiology workgroup relating to CT radiation dose reduction, mammography, exposure time reported for fluoroscopy, and expansion of reporting eligibility for two existing 2007 PQRI measures related to stroke/stroke rehabilitation imaging. While these proposed measures are not listed in Table 17 of the proposed rule as under AMA/PCPI development, it is the ACR’s expectation that these measures will likely advance and achieve

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<sup>1</sup> OIG Advisory Opinions 29 May, 2003 (03-12) and (97-5) 15 Oct, 1997 <<http://www.oig.hhs.gov/fraud/advisoryopinions/opinions.html>>

AQA approval prior to the final rule deadline of November 15, 2007 for inclusion in the 2008 PQRI.

The ACR supports CMS' proposal, Table 20, to include in the 2008 PQRI, those AQA starter set primary care prevention and screening clinical measures that were not included in the 2007 PQRI quality measures. The ACR also supports the two structural measures under Table 19, relating to adoption/use of e-prescribing and electronic health records, but would urge CMS to also consider expanding this list to include adoption/use of electronic Radiology Information Systems (RIS) and Picture Archiving and Communication Systems (PACS) which are vital ingredients of radiology patient safety and quality.

***Addressing a Mechanism for Submission of Quality Measures via a Medical Registry or Electronic Health Record***

The ACR supports the concept of allowing individual physician quality measures to be submitted directly through the vehicle of a medical registry, avoiding duplicate submission of the same data to CMS. We have reviewed the five options for registry-based reporting presented by CMS, and believe Option 3 to be the most feasible in terms of minimized burden on reporting physicians, and the fact that only aggregate individual physician reporting and performance rates must be reported out of the registry. Our major concern is the potential discoverability, under the Freedom of Information Act, of individual physician reporting and performance rates, and the counterproductive chilling effect this might have on physician registry participation. The ACR supports the pilot testing of registry-based reporting in 2008, but is unable to participate at this time as our registries are not collecting any PQRI data.

**TRHCA—Section 101(d): PAQI**

The following comments concern how CMS will use the \$1.35 billion Physician Assistance and Quality Initiative (PAQI) Fund. Under the Tax Relief and Health Care Act of 2006 (TRHCA), CMS has the option of using all of this money for continuing PQRI bonuses in calendar 2008, or applying these funds to buy down the negative update to the Medicare Physician Fee Schedule for calendar year 2008. CMS has stated its preference to use the PAQI funds to support PQRI bonuses in 2008. ACR believes it is vital that the momentum built under the 2007 PQRI be maintained by assuring the program continues to pay bonuses in 2008. However, the payment of bonuses should be funded as a supplement to Medicare physician reimbursement, and not at the expense of lowering overall physician payments under the 2008 Medicare Physician Fee Schedule.

Speakers at a major pay for performance conference held in Boston in August frequently pointed to a performance bonus in the 5 to 10 percent range as the minimum necessary to effectively gain the attention of providers; a PQRI devoid of a bonus payment would all but end interest in this valuable Federal effort to raise the bar on quality for Medicare beneficiaries. As such, **the ACR recommends that PQRI bonus funding be independent, and not at the expense of, the 2008 Medicare Physician Fee Schedule update.**

## Physician Self-Referral Provisions

### General

CMS acknowledges that the medical landscape has evolved since Congress extended the Stark law in 1993 to reach radiology and radiation oncology services. There has been unanticipated and significant growth in the use of medical imaging services, particularly MRI, CT and PET. The ACR believes that much of the growth of medical imaging can be explained by the shift from the use of invasive surgical and diagnostic procedures to the use of non-invasive medical imaging studies; the maturation of technologies and the dissemination of their capabilities to practicing physicians; and the overall benefit to patients to establish a timely and accurate diagnosis for the clinical problems.

However, because medical imaging is safe, non-invasive and well tolerated by patients, there is a high potential for inappropriate utilization of these services. At the same time, because these high end procedures are necessary to the care of many patients with both medical and surgical disease, many non-radiologist physicians and physician groups have purchased high-end imaging equipment not only to provide these services for their patients but to also increase the ancillary income for their practices. As this trend has evolved, CMS' recognition that more imaging services occur today under the protective umbrella of the in-office exception that "are often not as closely connected to the physician practice" is truly an understatement of the problem.

In addition to outright purchase of high-end imaging equipment, self-referring physicians have entered into leasing arrangements, purchasing of diagnostic tests and reassignment arrangements that circumvent and subvert the original intent of the Stark legislation's ban on inappropriate self-referral. In its comments to CMS on the CY 2007 MPFS proposed rule, the ACR strongly supported the CMS proposals to restrict abuse through tightening the rules on purchased diagnostic tests and reassigned claims. **We are pleased that CMS, in its CY 2008 MPFS proposed rule, has decided to augment its 2007 proposed restrictions and extend those restrictions to include potentially abusive leasing arrangements, percentage-based compensation arrangements, services furnished "under arrangements," as well as to invite comments on amending the in-office ancillary services exception.**

In general, the ACR does not believe these proposals to be confusing or unfair, nor does the ACR consider them to create uncertainty, ambiguity or create barriers to the delivery of care. **To the contrary, the ACR believes that barriers to the delivery of high quality care are inherent in the perverse effect on medical decision making that is engendered by the conflict of interest in self-referral of imaging.**

### *In-Office Ancillary Services Exception*

The ACR strongly supports CMS revisiting and changing the in-office ancillary exception. As explained below, the ACR believes that, due to their complex specialized nature, "advanced imaging studies" that involve CT, MR and PET, as well as radiation therapy, should never be defined as "ancillary" services and, therefore, should not qualify for the in-office ancillary services exception. **Additionally, the ACR recommends that CMS require that physicians provide in-office ancillary services within one hour after a patient's scheduled office visit.**

**We also recommend that CMS modify the definition of a “centralized building” to a location within five miles of the building where a physician or medical group furnishes designated health services.** We would support CMS implementing this definition only if it adopts the ACR’s recommendations to restrict the time and eliminate certain imaging services from those qualifying for the in-office medical exemption. **Finally, the ACR recommends that non-specialist physicians should not be able to use the in-office ancillary 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.**

The ACR believes that the in-office ancillary exception, as it is currently structured, has been counterproductive to what was originally proposed by Congress under the Stark laws. Congress intended to eliminate conflicts of interest for physicians in ordering imaging tests. Thus, while the laws preclude physicians from referring to an imaging center in which they have a financial interest under the in-office exemption, they do not preclude physicians from purchasing and owning the imaging equipment themselves. It was initially believed that the high cost of this equipment would deter most if not all physician practices from entering this market, but as the technology has matured and used imaging equipment became available, more and more self-referring physician practices have entered the market because they view imaging as a major ancillary revenue source. Unfortunately, these self-referring physicians now have significant financial incentives to order high-end imaging studies in order to get a return on their investment.<sup>2</sup> CMS has long recognized an inherent conflict of interest when physicians are allowed to provide pharmacy services to their patients by prescribing medications and then selling the prescribed medication to their patients. We believe it is time to recognize that the same type of conflict arises when physicians are permitted to order medical imaging and then sell that imaging to their patients.

The ACR agrees with CMS that the original intent of the Congress in establishing the in-office ancillary services exemption was to allow patients to receive a test or procedure at the time of the office visit that was truly ancillary to the office visit and necessary to the diagnosis and treatment of the condition that brought the patient to the physician’s office. Congress assumed that such testing would involve simple examinations such as laboratory tests and simple x-rays to visualize a fracture or a pneumonia. Congress simply could not have anticipated the expansion of this regulation beyond its original intended purpose and the subsequent abuse this expansion has permitted. Advanced imaging tests involving CT, MRI and PET clearly do not represent “ancillary” services. These tests are sophisticated imaging examinations, requiring the expertise of specialty physicians and technologists with advanced training in radiation safety, examination design and protocol and interpretation of complex image datasets sometimes involving thousands of images for a single patient. The argument that these tests are necessary to assist the physician at the time of the visit is spurious at best and deceitful at worst.

Likewise, radiation therapy services have no place in the referring physician’s office and should never be considered as “ancillary” services. Radiation therapy represents a clearly distinguishable consultative medical service that is provided only after thorough evaluation of the patient’s medical condition by many consultants. It is never provided as an ancillary service for

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<sup>2</sup> Oran Technologies. Association of Otolaryngology Administrators. *An Introduction to In-Office CT*.

the “convenience” of the patient, and to allow self-referring physicians to provide it under the in-office ancillary services exemption is indefensible.

In-office imaging and radiation therapy may also deprive patients of the significant peer-review benefit of independent interpretation of the diagnostic studies and independent evaluation of the appropriate method of radiation treatment for cancer patients, which in turn may lead to unnecessary surgery or other treatment. When a physician with a clear financial interest is permitted to refer, perform, interpret and act on the findings of a diagnostic examination or make a financially-motivated decision on a course of radiation treatment, the patient is deprived of an objective outside review of the process under medical practice standards, peer-review and case-by-case oversight.

Despite claims that patients receive more convenient service from undergoing a study in an MR or CT scanner in their office suite, physicians have taken advantage of the in-office ancillary services exception, using financial incentives to more frequently order medically questionable studies and then fail to have a trained imaging specialist interpret them. In the physician office setting, studies such as CT, MRI and PET seldom, if ever, occur within the hour for patients for their patient’s convenience. In fact, research shows that fewer than three percent of myocardial perfusion and PET nuclear medicine studies, along with MR and CT studies, even take place on the same day a patient visits a physician’s office. Such sophisticated imaging studies require separate scheduling and patient preparation (e.g., fasting before study, pre-ingestion of drugs and/or contrast media).

These separately scheduled studies can be provided at a location where there is no financial interest to the referring physician, just as easily as they can be provided in the referring physician’s office. Allowing these services to be performed in a “centralized building” is completely contradictory to the intent of Congress in creating this exception.

Congress and CMS have imposed laws and regulations that attempt to mitigate this problem by reducing the reimbursement for these high end examinations. Unfortunately, this only incentivizes those physicians who own or lease imaging equipment to order more studies in order to maintain the profitability of their equipment and inappropriately penalizes hospitals and independent imaging centers.

The ACR, historically, has opposed self-referral arrangements because they may improperly affect medical decision-making and may compromise quality patient care. There can be no question that self-referral in the United States, particularly in diagnostic imaging, has contributed to skyrocketing health care costs and frequently impeded quality of care. The BlueCross BlueShield Association in 2003 and the Medicare Payment Advisory Commission (MedPAC) in 2005 each reported 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>3</sup> Technology developments in magnetic resonance imaging (MRI),

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<sup>3</sup> Miller, Mark E., Ph.D. MedPAC recommendations on imaging services. Testimony to Subcommittee on Health Committee on Ways and Means. March 2005.

computed tomography (CT) and ultrasound, coupled with a regulatory vacuum, have created incentives for entrepreneurs and clinicians to increase imaging volume.<sup>4</sup>

Such accelerated volume has certainly led to many unnecessary imaging procedures performed by self-referring physicians.<sup>5</sup> As the MedPAC and BlueCross BlueShield data illustrate, more physicians are responding to financial and regulatory incentives to send their patients “where the money is.”<sup>6</sup> Even more importantly, inappropriate and unnecessary medical imaging may compromise patient safety by exposing those patients to excess radiation. The ACR maintains that appropriate use of imaging services, competently performed and interpreted, will maintain quality of care and decrease health care costs.

Fundamentally, in-office medical imaging has proliferated because of the acquisition of high-tech imaging equipment by physicians who were not trained as radiologists, or even to supervise the operation of equipment or oversee these specialized procedures. Radiologists are trained for at least 4 years and usually as many as 5 or 6 years to perform and interpret imaging studies. In their practices, they do not have the opportunity to self-refer. All their patients are referred to them by other physicians, for no other reason than that they desire information about their patients. Conversely, nonradiologist physicians who operate their own imaging equipment (or, through various indirect arrangements own equipment to which they refer) are almost always in a position to self-refer or to refer within their group (which is essentially the same thing as self-referral).

Recent data illustrate how self-referral has spurred imaging utilization. The Department of Radiology at Thomas Jefferson University Hospital years ago formed the Center for Research on Utilization of Imaging Services (CRUISE). David Levin, M.D., and his colleagues have studied utilization trends and practice patterns in imaging, primarily using the CMS Physician/Supplier Procedure Summary Master Files. Their data have corroborated other studies and that have shown quite clearly that self-referring physicians are a major contributor to the rapid growth the Medicare program is experiencing in imaging.

Notably, a recently completed CRUISE study by Dr. Levin, et al. compared utilization trends in MRI, CT, and nuclear scans done on units owned by radiologists or nonradiologist physicians in their private offices. Between 2000 and 2005, the MRI utilization rate per 1000 Medicare beneficiaries increased by 83 percent in radiologist offices, compared with 254 percent in nonradiologist offices. The CT utilization rate increased by 109 percent in radiologist offices, compared with 253 percent in nonradiologist offices. The nuclear scan rate increased 40 percent in radiologist offices, compared with 192 percent in cardiologist offices (cardiologists are the only other specialty having major activity in nuclear scanning). These data substantiate the

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<sup>4</sup> BlueCross BlueShield Association. (2003). *Medical Technology as a Driver of Healthcare Costs: Diagnostic Imaging*.

<sup>5</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.” *American Journal of Radiology*. 2000 : 175:9-15.

<sup>6</sup> Hoangmai H. Pham, Kelly J. Devers, Jessica H. May, and Robert Berenson  
“Financial Pressures Spur Physician Entrepreneurialism.” *Health Affairs*, March/April 2004; 23(2): 70-81.

concerns that CMS has raised and further solidify the evidence against continuation of the in-office ancillary services exemption as it is currently structured.

The ACR understands that there are situations where the in-office ancillary services exception continues to be appropriate and include ultrasound in an obstetrician-gynecologist's office; echocardiography that cardiologists perform and interpret; and simple imaging examinations that need to take place for acute conditions and can be provided immediately (i.e., x-rays for possible fracture or pneumonia). In these situations, patients should be advised that their physicians own this equipment and are performing the studies to provide immediate patient care.

**In response to the questions raised by CMS, the ACR firmly believes that changes to the in-office ancillary exemption are necessary.**

**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 restrictions should be placed 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 originally intended in this exception.**

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

CMS again proposes to apply the "anti-markup" provision on the technical and professional component of diagnostic tests. This proposal would prevent imaging providers from marking up the TC or PC of studies, whether or not a billing physician or medical group outright purchases the professional component or the technical component, or whether the TC or PC provider reassigns his or her right to bill to the billing physician or medical group (unless the performing supplier is a full-time employee of the billing entity).

CMS also seeks comments on whether to impose the anti-markup rule to TCs that occur in a "centralized building." The ACR recognizes that CMS wants to close a perceived loophole in

which a part-time or leased group employee performs the technical component of imaging in a “centralized building,” but the group neither gets a reassignment from the employee technician (one who cannot bill the TC or PC directly), nor buys the TC outright from the technician. **The ACR supports CMS applying the anti-markup provision to TCs that are performed in a “centralized building.”**

The ACR continues to share 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.”<sup>7</sup> 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. The billing entity (usually the self-referring physician or medical group) thus is essentially in the role of a “broker” of imaging services. They neither provide the actual service nor interpret the images. Nevertheless, they garner the lion’s share of the reimbursement for the simple process of “brokering” the transaction, in which their patient is captive and is not offered a choice of imaging provider.

Generally, the ACR agrees with the language proposed by CMS to amend § 424.50 and § 424.80 of its regulations. 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 purchased diagnostic test and 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.

The ACR supports CMS’ proposal to exempt from the anti-markup provision diagnostic tests that independent laboratories have not ordered themselves. **The ACR urges CMS to extend this exemption to radiologists’ offices.** However, we are concerned that the proposed anti-markup provisions include services performed by independent contractors and part-time employees of the billing physician or medical group. We believe that excluding only full-time employees of the billing physician or medical group from the anti-markup proposals could impair many legitimate, non-abusive arrangements where radiology practices engage exclusive contractors or employ exclusive part-time radiologists or in which radiologists independently contract with or are part-time employees of multiple radiology groups that do not engage in self-referral. The ACR offers the following alternative proposal. Since radiologists are not in a position to profit from abusive self-referral, CMS should extend the anti-markup exclusion to contractors and part-time employees of radiology physicians or radiology groups.

**The ACR recommends that CMS change the language in the first column on page 38180 of the proposed rule to read “(unless the performing supplier is a full-time employee of the billing entity or the billing entity is a radiologist or radiology group).”**

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<sup>7</sup> 2007 Medicare Physician Fee Schedule Proposed Rule. Federal Register. Vol. 71, No. 162. 22 August, 2006.

*Unit-of-Service (Per-Click) Payments in Space and Equipment Leases*

CMS proposes that the Stark regulatory exception for space and equipment leases may **not** include per click-based payments to a physician lessor for services rendered by an entity lessee to patients who are referred by the physician to the entity. The agency believes that such arrangements “are inherently susceptible to abuse” because the physician lessor would have a clear incentive to profit by referring more patients to the lessee. Imaging leases have boomed since CMS initially proposed the Stark space/equipment rental exception in 1998. Given the Congress’ and state attorneys general interest in lease transactions, ACR welcomes CMS focusing on per-click leases in the Rule. We strongly support banning time-based and unit-of-service based leases, with a one-year grace period to allow physicians who have these leases to unwind them.

The ACR maintains that per-unit or “per click” leases fuel an incentive to order unnecessary examinations that is essentially as potent as if the ordering physician is a partner in a joint venture. Additionally, incentives to order unnecessary examinations are just as strong for non-Medicare patients.<sup>8</sup> This further extends the waste of health care dollars.

Professor Jean Mitchell conducted a recent study, finding that almost half of all imaging done outside of the hospital setting was done in a self-referral situation by non-radiologists for CT, MR and PET. Among this group that billed for these procedures, 61 percent of MR, 64 percent of CT and 30 percent of PET billings were from groups that did not have equipment in their offices.<sup>9</sup> For MR and PET, the data showed that the share of statewide volume billed by the physicians has grown dramatically since 2000. Many self-referring physicians have made the argument that there is a need to have CTs, MRs and PET machines in their office for patient convenience. Mitchell believes, and the ACR agrees, that the large amount of billings of these leases or “per click” arrangements located outside of their offices undermines the convenience argument.

The ACR encourages CMS to use its authority under section 1877(e)(1) of the Act to prohibit time-based or unit-of-service-based payments to an entity lessor by a physician lessee, to the extent that such payments reflect services rendered to patients sent to the physician lessee by the entity lessor.

Perhaps the most abusive unit-of-service leasing arrangement is the scheme whereby a referring physician leases space on a unit-of-service or per diem basis from a MRI facility and then submits a claim to Medicare for the global fee.<sup>10,11</sup> Other provisions of this CY 2008 MPFS proposed rule

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<sup>8</sup> Mitchell, J., “The Prevalence of Physician Self-Referral Arrangements After Stark II: Evidence From Advanced Diagnostic Imaging”, Health Affairs, April 16, 2007.

<sup>9</sup> Mitchell, J., “The Prevalence of Physician Self-Referral Arrangements After Stark II: Evidence From Advanced Diagnostic Imaging”, Health Affairs, April 16, 2007.

<sup>10</sup> David Armstrong. WSJ May 2, 2005: “Own Image: MRI and CT Centers Offer Doctors Ways to Profit on Scans; Physicians Pay a Flat Fee For Procedures, Then Bill Insurers – at Higher Rate; Navigating Legal Landscape.” Wall Street Journal 2 May, 2005.

would restrict any abusive profit to the lessee physician or medical group under such an arrangement. However, since the marketplace has repeatedly created an “advisory industry” (see attachment) to find loopholes, the ACR believes CMS could firmly close the door on such abuses by prohibiting all such arrangements.

The ACR believes that most leasing arrangements are economically driven, do not contribute to patient convenience or any other attributes that promote better patient care and generally drive up utilization. **The ACR supports a ban on all time-based and unit-of-service-based leasing arrangements.**

**The ACR supports a one-year grace period to allow unwinding of such banned leasing arrangements.**

*“Set in Advance” or Percentage-Based Compensation Arrangements*

In a further attempt to curtail certain abusive arrangements, CMS would clarify its original intent that percentage compensation arrangements could be used only for compensating physicians for the services they perform by disallowing arrangements that pay for services and items, e.g., medical equipment and office space, on a percentage of revenues the equipment or space realizes. CMS only would allow percentage-based compensation to pay for physician services that a physician personally performs; and that must be derived directly from service-related revenues.

In 2002, the ACR commented to CMS that it supported the ability of physicians to receive compensation for their professional services on a percentage-basis. The ACR agrees with CMS’ decision to continue allowing such arrangements and proposed action to curtail potentially abusive percentage compensation arrangements to physicians for non-professional services.

*Stand in the Shoes*

The ACR shares the concern of CMS that inserting entities or contracts into a chain of financial relationships linking a DHS entity and a referring physician is a subterfuge that intends to circumvent Stark self-referral prohibitions. **Therefore, the ACR supports CMS’ proposal to amend § 411.354(c) to require a DHS entity to stand in the shoes of another entity it owns, to which physicians refer Medicare patients for DHS.**

*Under Arrangements*

CMS also proposes to restrict certain services furnished ‘under arrangements.’ CMS is trying to determine the best approach to prohibit certain arrangements under which physicians supply items and services to DHS entities. For instance, a group of radiologists and cardiologists form a joint venture to purchase a 64-slice CT scanner to establish a cardiac imaging center on an academic medical center’s campus. Instead of enrolling the venture as a supplier with Medicare and commercial payers, the venture enters into an “under arrangements” contract with the hospital. The venture would provide imaging services to registered hospital outpatients (some of whom the cardiologists would refer), while the hospital bills for the services rendered to

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<sup>11</sup> Bruce Jaspen. “Doctors’ MRI Deals a “Sham”, State Says.” Chicago Tribune 10 May, 2007.

Medicare beneficiaries under the HOPPS. In return, the hospital pays the venture a negotiated contract rate for each study it performs.

Current Stark rules do allow such referrals by the cardiologists to the joint venture for imaging because the cardiologists technically are not referring to the joint venture “entity,” but rather to the hospital. Only hospitals submit claims to Medicare in the “under arrangements” context. CMS proposes to curb the risk of imaging overutilization by expanding its definition of “entity,” so that a DHS entity includes both the person or entity that performs the DHS, and the person or entity that submits claims or causes claims to be submitted to Medicare for the DHS. CMS recognizes that independent diagnostic testing facilities (IDTFs), ambulatory surgical centers (ASCs) and other non-hospital settings have taken advantage of the “under arrangements” opportunity. Accordingly, CMS solicits comments on whether to adopt its approach; MedPAC’s recommendation of broadening the Stark definition of “physician ownership;” or a combination of both approaches. If CMS adopts any of these approaches, the U.S. imaging environment would change dramatically. Referring physicians apparently would not be able to participate in joint ventures that provide services to hospitals and others “under arrangements.”

The ACR historically opposes any financial arrangements that could harm patients, or give an economic incentive to perform unnecessary imaging. Therefore, we have supported federal legislative and regulatory action to prohibit self-referral or restrict its influence on patient care decisions.

CMS’ fundamental concern that many referring physicians have prospered from joint venturing with hospitals for imaging services via “under arrangements” is shared by the ACR. These arrangements are essentially thinly veiled substitutes for the imaging centers that were the original target of the Stark laws. Many of these deals do not appear to have any clinical value yet they may well increase costs to Medicare beneficiaries and the Medicare program. **Thus, the ACR believes the CMS proposal to tighten “under arrangements” services could benefit patient care and reduce undue financial incentives.**

However, the ACR is concerned that the proposal to change the definition of entity at §416.351 to include both the person or entity that performs the DHS as well as the person or entity that submits claims or causes claims to be submitted to Medicare for DHS may not have its desired effect due to potential ambiguity in the interpretation of the meaning of “performs.” **While the ACR supports this proposed change, we recommend that, in its Final Rule, CMS more specifically define the meaning of “performs” to avoid creation of future loopholes.**

The ACR is also concerned that the implementation of this “under arrangements’ proposal, as well as the preceding “stand in the shoes” proposal, if instituted without a comprehensive implementation of all other CMS proposals in this rule, as well as recommendations from ACR on the in-office ancillary services exception, could lead to formation of multi-specialty groups of referring physicians for the sole purpose of providing high-cost imaging under the umbrella of the in-office ancillary services exception. This subterfuge would result in no relief from the current abusive practices and could result in a severe revenue loss for already-besieged hospitals.

**The ACR, therefore, recommends that CMS not implement its proposed policies on self-referral on a piece-meal basis, but rather implement them in a comprehensive package that allows no escape for abusive practices.**

In an environment where there is no shortage of legal advice to individuals who desire to benefit from regulatory loopholes, the ACR believes that CMS should tighten the noose on potentially abusive self-referral by using all the tools at its disposal. **Therefore, the ACR supports including the MedPAC recommendation to expand the definition of physician ownership in the current CMS proposal on services furnished “under arrangements.”**

**Additionally, we would recommend changing the language of the MedPAC recommendation to state “...an entity that derives a substantial proportion of its revenue from a provider of designated health services or from the business of providing designated health services.” We would also recommend that, for this purpose, a “substantial” portion of revenue should constitute 50 percent or greater.**

As CMS noted in an earlier Stark II final rule (Phase I; January 4, 2001), restricting “under arrangements” could disrupt patient care and cause administrative burden to physician practices and hospitals. We are aware that certain physician groups who are party to “under arrangements” have negotiated termination clauses if the arrangements no longer comply with federal law or rules.

**However, should CMS adopt its proposal in the final MPFS rule effective January 1, 2008, we acknowledge that many physician-hospital ventures would need to be unwound. The ACR, therefore, recommends that CMS consider affording a one-year grace period to such ventures.**

#### **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 on radiology, please contact Angela Choe at 800-227-5463 ext. 4556 or via email at [achoe@acr.org](mailto:achoe@acr.org).

Respectfully Submitted,



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Attachments to be sent under separate cover via U.S. mail.

