ACADEMY OF MOLECULAR IMAGING
www.ami-imaging.org ami@mednet.ucla.edu

Box 951735
Los Angeles, CA
90095-1735
310.267.2614
Fax: 310.267.2617

September 7, 2005

The Honorable Mark McClellan
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
Room 445-G
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: File Code CMS-1502-P

Proposed rule for the Medicare Program regarding Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006 -- NUCLEAR MEDICINE SERVICES

Dear Administrator McClellan:

The Academy of Molecular Imaging (AMI)[1] appreciates the opportunity to comment on the proposed Physician Fee Schedule rule, as published in the Federal Register on August 8, 2005 by the Centers for Medicare and Medicaid Services (CMS). AMI comments specifically on the provision relating to physician referrals for nuclear medicine services with which they have financial relationships. Under the proposed rule, CMS would reclassify nuclear medicine services as Designated Health Services (DHS), thereby bringing them within the category of services covered by the physician self-referral law. AMI believes that this change would significantly limit beneficiary access to nuclear medicine services. Of special concern is its potential impact on the availability of positron emission tomography (PET) scans, which constitute an important share of Medicare-covered nuclear imaging. AMI respectfully requests that this proposed change not be included in the final rule for two reasons. First, Congress did not intend for the physician self-referral law to apply to nuclear medicine services because it recognized, as has CMS, that nuclear medicine is a distinct medical specialty from radiology. Second, nuclear medicine services are not at risk for the kind of over-utilization that the physician self-referral rules are designed to prevent.

[1] The AMI is a professional organization committed to advancing the field of molecular imaging. In addition to its annual conference, the AMI holds programs designed to educate clinicians, government agencies and the public about molecular imaging, and publishes a journal, *Molecular Imaging and Biology*.

However, in the event that CMS disagrees with AMI's recommendations and does reclassify nuclear medicine services as DHS, AMI requests that the final rule exempt from the prohibition on self-referrals physician ownership arrangements that have been formed in good-faith reliance on the existing regulations.

I. Nuclear Medicine Services are not DHS Under the Physician Self-Referral Statute

The statutory text, legislative history, and CMS's own long-standing interpretation of the physician self-referral law clearly support the exclusion of nuclear medicine from the definition of DHS. Congress specifically elected not to classify nuclear medicine services as DHS. Under Section 1877(h)(6) of the Social Security Act, DHS encompass only certain enumerated services, which do not include nuclear medicine. The statute specifically lists the following services:

> *clinical laboratory services; physical therapy services; occupational therapy services;* ***radiology services, including magnetic resonance imaging, computerized axial tomography, and ultrasound services****; radiation therapy services and supplies; durable medical equipment and supplies; parenteral and enteral nutrients, equipment, and supplies; prosthetics, orthotics, and prosthetic devices and supplies; home health services; outpatient prescription drugs; and inpatient and outpatient hospital services.*[2]

The proposed rule acknowledges that the statute does not mention nuclear medicine. In order to bring nuclear medicine within the scope of the statutory limitations on physician self-referral, the proposed rule must therefore argue somehow that nuclear medicine is encompassed in one of the congressionally enumerated categories. CMS proposes to accomplish this by re-designating nuclear medicine procedures under what it calls "*radiology and certain other imaging services*."[3] However, this phrase is not included in the applicable statutory provision and is clearly beyond the scope of the statutory language.

Specifically, the words *"certain other imaging services"* do not even appear in Section 1877(h)(6). In fact, Congress has expressly rejected virtually identical statutory phrasing. The original provision included the extremely broad category "*radiology, and other diagnostic services*" as DHS in Section 1877(h)(6)(D) of the Omnibus Budget Reconciliation Act of 1993.[4] The following year, however, in the Social Security Act Amendments of 1994, Congress narrowed that broad language by striking the phrase "*other diagnostic services,*" and replacing it with a far more precise description of the covered services. The new, narrowly drawn category of DHS consisted of "*radiology services, including magnetic resonance imaging, computerized axial tomography, and ultrasound services*."[5] This provision does not mention nuclear medicine or particular nuclear medicine technologies, such as PET.

The proposed rule now seeks to rely on language that Congress has previously rejected. If Congress had intended to broaden the scope of the statute to include nuclear medicine services it would have retained the earlier, broadly drawn category. Alternatively, Congress could have listed nuclear medicine services, such as PET, alongside of MRI, CT, and ultrasound. Instead,

[2] 42 U.S.C. § 1395nn(h)(6) (2005).
[3] 70 Fed. Reg. 151 (Aug. 8, 2005).
[4] Public Law 103-66, Sec. 13,562 (Aug. 10, 1993).
[5] Public Law 103-432, Sec. 152 (Oct. 31, 1994).

when Congress amended the statute, it affirmatively defined the scope of radiology services to omit nuclear medicine.

Moreover, this interpretation of Section 1877(h)(6)(D) conforms to CMS's own long-standing and well-considered view that nuclear medicine is not a radiology service for the purpose of the physician self-referral law. After carefully considering the statutory text and legislative record, CMS concluded in its January 4, 2001 final rule to "*exclude[] nuclear medicine [from DHS] because those services are not commonly considered to be radiology*."[6] It bears emphasis that this judgment was based on a specific factual finding with respect to the proper classification of nuclear medicine.

As will be discussed below, the proposed rule offers no evidence to support reversing the factual and regulatory conclusion that it reached less than five years ago. As the Supreme Court has observed, a "settled course of behavior embodies [an] agency's informed judgment that, by pursuing that course, it will carry out the policies committed to it by Congress." Because agencies and reviewing courts alike operate under "a presumption that those policies will be carried out best if the settled rule is adhered to," an agency that departs from such a rule "is obligated to supply a reasoned analysis for the change beyond that which may be required when an agency does not act in the first instance."[7] The proposed rule does not satisfy this obligation. For CMS to reclassify nuclear medicine in the manner indicated would be to allow its preferred regulatory application to dictate its factual findings, rather than the reverse.

II. Nuclear Medicine Is a Distinct Medical Specialty from Radiology

Nuclear medicine services are clinically and technically distinct from the services that Congress enumerated when it defined the scope of "radiology services" in Section 1877(h)(6)(D). The American Board of Nuclear Medicine (ABNM), the primary certifying organization for the practice of nuclear medicine in the United States, defines nuclear medicine as "*the medical specialty that employs radionuclides to evaluate metabolic, physiologic and pathologic conditions of the body for the purposes of diagnosis, therapy and research*."[8] In a typical procedure, a physician trained as a nuclear medicine specialist supervises the administration of a radioactive material into a patient. The subsequent distribution of this material within the body is then determined by a special device that detects the radioactivity coming from the patient. The nuclear medicine physician makes a diagnosis based on that distribution.[9] The introduction of radiolabeled, biologically active compounds into patients distinguishes nuclear medicine from radiology. Although radiologists sometimes do administer "contrast agents," such as barium sulfate or iodine (X-ray), or gadolinium (MRI), these agents are biologically inert, and their function is entirely different from that of radioisotopes in a nuclear medicine procedure.

---

[6] 66 Fed. Reg. 927 (Jan. 4, 2001). More recently, CMS confirmed its practice of construing the scope of "radiology services" narrowly with respect to other (non-nuclear) procedures, finding that "angiographies, angiograms, cardiac catheterizations, and endoscopies . . . are not fundamentally radiological in nature because they do not involve an imaging service that is described in 1877(h)(6)(D) of the Act." 69 Fed. Reg. 16,104 (Mar. 26, 2004).

[7] *Motor Vehicle Manufacturers Ass'n of the U.S., Inc. v. State Farm Mutual Automobile Ins. Co.*, 463 U.S. 29, 42-43 (1983) (quoting *Atchison, Topeka & Santa Fe Ry. v. Wichita Bd. of Trade*, 412 U.S. 800, 807 (1973) (internal citations omitted)).

[8] http://www.abnm.org/index.html (accessed June 28, 2005).

[9] *See, e.g.*, http://www.radiochemistry.org/nuclearmedicine/definition.htm. Through PET, for example, the molecular errors that cause disease can be accurately identified and understood in terms of the specific nature of the disease. This separates PET from conventional anatomic imaging modalities such as X-ray films, CT and MRI. By assisting physicians in the diagnosis and management of tumors, cardiac disorders and neurological disorders, PET can eliminate unnecessary surgeries, reduce the number of diagnostic procedures, and otherwise help physicians to determine the best, most effective mode of treatment for a patient.

Additionally, some of the procedures performed in nuclear medicine are for therapeutic purposes, and specialized training, such as that obtained in programs leading to certification by the ABNM, is a prerequisite for clinically appropriate use.

The proposed rule provides little in the way of independent authority to controvert its earlier position that nuclear medicine services "are not commonly considered to be radiology." The proposed rule relies, first, on an excerpt from Dorland's Illustrated Medical Dictionary and a statement by the Society for Nuclear Medicine, confirming that nuclear medicine procedures involve the introduction into the body of tracers that emit small amounts of radiation. The proposed rule appears to imply that because nuclear medicine employs radioactive material, logically it must be a subspecialty of diagnostic radiology. This implication is not warranted. Radioactive materials are used in many other areas of clinical practice--for example, the performance of radioimmunoassays and irradiation of blood products. Importantly, these procedures are not considered radiological services merely because they involve radioactive material.[10]

The proposed rule also relies on a letter from the American College of Radiology (ACR), claiming that nuclear medicine is "a part of the specialty of radiology" and noting that the American Board of Radiology's (ABR) process of certifying diagnostic radiologists includes examination in nuclear medicine. This position is directly contradicted by the American Board of Medical Specialties (ABMS), the body that officially sanctions all medical residency training programs in the United States. It is physicians trained in ABMS-approved programs, rather than the ABR, that define the specialty of nuclear medicine. According the ABMS, Nuclear Medicine and Radiology each posses "primary" (that is, fundamental and independent) board status as medical specialties. Nuclear Medicine, like Radiology, is one of only 26 distinct medical disciplines subject to Primary Board Certification. Services such as CT and MRI, by contrast, have "affiliate" status, and are among the many subspecialty groups within radiology. Moreover, the ABMS oversees separate specialty training programs in both diagnostic radiology and nuclear medicine. Although some nuclear medicine training is incorporated into the diagnostic radiology training program, and the ABR does include questions on nuclear medicine in its certification examination, physicians become eligible to take the ABNM examination only after successfully completing a nuclear medicine residency program.[11]

The proposed rule further attempts to bolster its assertion that nuclear medicine is a subcategory of radiology by citing the fact that the Social Security Act "places nuclear medicine in the same category as diagnostic radiology for coverage and payment purposes." CMS points to Section 1833(t), providing payment for "outpatient hospital radiology services (including diagnostic and therapeutic radiology, nuclear medicine, CAT scan procedures, magnetic resonance imaging, and ultrasound and other imaging services, but excluding mammography)," as described in Section 1833(a)(2)(E)(i). CMS interprets this provision to mean that Congress considers nuclear medicine to be a subcategory of radiology services. In fact, Section 1833(t) is strictly a payment provision, and refers to the grouping of technologies in Section 1833(a)(2)(E)(i) exclusively for

[10] In addition, hospitals and clinics frequently house nuclear medicine departments that are separate from their radiology departments, whereas ultrasound, MRI and CT are virtually always performed in radiology departments.

[11] In addition, for a physician to be eligible for a dual certification in nuclear medicine and radiology under the ABNM program, she must first obtain separate approval for her proposed training program from both the ABNM and the ABR. After completing her training, she must then pass a certifying examination in radiology and a certifying examination in nuclear medicine, each administered by its respective certifying board.

the administrative purposes of providing for Medicare reimbursement.[12] Further, 1833(a)(2)(E) predates the enactment Section 1877, limiting physician self-referrals, by several years. If Congress had considered Section 1833(a)(2)(E) an authoritative description of the scope of radiology services, it could have imported that language directly into Section 1877(h)(6) when it amended the self-referral law in 1993 and 1994. The fact that Congress did not do so lends further support to the position that Congress has never considered nuclear medicine a subcategory of radiology for the purpose of Section 1877(h)(6).

Finally, the proposed rule suggests that the fact that nuclear medicine and radiological services are both paid under Section 1861(s)(3) evidences their clinical similarity. Again, the proposed rule supplies no basis for concluding that their common classification in this narrow context bears on the question of whether nuclear medicine is a subspecialty of radiology, or whether that classification represents anything more than administrative convenience. In fact, Section 1861(s)(3) applies to all diagnostic tests regardless of their clinical properties, and includes not only MRI, CT, and PET, but also diagnostic clinical laboratory tests.[13]

III. Nuclear Medicine Services are not Subject to Over-Utilization

The proposed rule offers no evidence that nuclear medicine services are abused or over-utilized. CMS maintains that any lingering doubt about whether "nuclear medicine services are radiology…within the meaning of section 1877(h)(6)" should be resolved in favor of the proposed rule, because such services "pose the same risk of abuse that the Congress intended to eliminate for other types of radiology, imaging, and radiation therapy services and supplies."[14]

The empirical support cited for this claim is particularly misleading and unreliable. The proposed rule relies on a number of studies of diagnostic imaging, but none that have reviewed the utilization of any nuclear medicine service, including PET. Although the proposed rule acknowledges that the principal study on which it relies excluded nuclear imaging, it insists that there is "[no] basis for assuming that physician behavior would be different for nuclear imaging than it is for other imaging services." Imaging services encompass an extremely wide variety of technologies and clinical uses, and it is not easy to extrapolate data from one service and apply it to another. Unlike most radiology services, nuclear medicine imaging introduces radioactive material directly into the body. This is an important factor in limiting clinical use of nuclear medicine imaging to medically useful and appropriate circumstances. Second, as is discussed below, limitations on Medicare coverage for PET likewise significantly constrain its use. Unlike CT and MRI, PET is subject to numerous national coverage determinations limiting coverage to certain tumor types and indications.[15]

The proposed rule also relies on the fact that since the publication of the Phase I final rule excluding nuclear medicine services from DHS, "many more nuclear medicine procedures have been performed in physician offices or in physician-owned freestanding facilities." The proposed rule reports that while physician services in general increased by 22 percent between

[12] Under CMS's reading of Section 1833(t), Congress' inclusion of the catch-all category of "other imaging services" in the parenthesis following "radiology services" would make *any* imaging service a subcategory of radiology.

[13] The Section covers "diagnostic X-ray tests (including tests under the supervision of a physician, furnished in a place of residence used as the patient's home, if the performance of such tests meets such conditions relating to health and safety as the Secretary may find necessary and including diagnostic mammography if conducted by a facility that has a certificate (or provisional certificate) issued under Section 354 of the Public Health Service Act), diagnostic laboratory tests, and other diagnostic tests."

[14] 70 Fed. Reg. 151 (Aug. 8, 2005).

[15] *See, e.g.*, Medicare National Coverage Determinations Manual § 220.6 (Rev 35, May 6, 2005).

1999 and 2003, imaging services increased by 45 percent, and nuclear medicine services increased by 85 percent. The implication appears to be that the absence of self-referral restrictions on nuclear medicine services has made such services increasingly, perhaps even especially, subject to over-utilization. This implication is unwarranted. Two particular considerations account for the relative growth of nuclear imaging services. First, nuclear medicine imaging still represents only a very small fraction of all diagnostic imaging. For this reason, even modest numerical growth can appear dramatic when it is presented in the form of a percentage increase. Despite PET's recent increase in utilization the total number of PET scans performed is dwarfed by the number of other imaging procedures performed, such as MRI and CT. In 2004, PET still accounted for less than one percent of Medicare reimbursement for diagnostic imaging.

Second, as the proposed rule notes, Medicare coverage of PET scans has expanded since December 2001, a change that reflects CMS's recognition of PET's utility in diagnosing and treating an increasing variety of cancers. In fact, expansion of coverage by Medicare, and not inappropriate referral, is likely the most important factor in increased utilization of PET scans. Unlike Medicare coverage of MRI and CT, coverage of PET initially was extremely limited and only applied to a handful of cancer indications and qualifying uses, such as staging. Although CMS has gradually extended PET coverage for cancer over the past four years, at present Medicare still only covers the 8 to 10 leading tumor types. Coverage also remains limited to certain functions, such as diagnosis and staging, and does not apply to the monitoring of therapeutic response. Further, many common cancers, such as prostrate, ovarian, and testicular remain ineligible, while others, such as breast and cervical, are covered but reimbursement is confined to clinically appropriate referrals. CMS has proposed to expand coverage to all cancers, but the decision has not yet been implemented. These tight coverage policies function as an intrinsic check on the risk of exactly the kinds of over-utilization and abuse that that the self-referral prohibitions are designed to prevent. In summary, the very specific criteria enumerated in the expansion of Medicare coverage for PET scans created a scenario where the increase in utilization, sanctioned by Medicare, is highly unlikely to include clinically unnecessary or inappropriate PET scans.

As part of its proposed expansion of PET coverage, CMS is working with AMI to establish a national data registry, which will be one of the first new coverage policies instituted under Coverage with Evidence Development (CED). Any new coverage of PET would require the referring physician to submit a case report form to a data registry. The data registry will provide CMS with accurate information on how PET impacts patient management and improves health outcomes. Such information will afford CMS an invaluable tool with which to evaluate PET's utility in improving the management of oncology patients.

The proposed rule further states that the "risk of abuse and anti-competitiveness" that exists with physician self-referrals in general "is exacerbated by the greater affordability of nuclear medicine equipment."[16] This statement misapprehends both the importance of many physician-owned nuclear medicine services to patient access, and the nature of most current physician ownership interests. Because the equipment in physician-owned PET centers is expensive, typically an individual physician owns only a small percentage interest, and, as a result, has a very modest stake in the center's profitability. These small stakeholders do not have a substantial incentive to over-utilize PET scans. By including nuclear medicine as a DHS, however, the proposed rule would encourage many individual and group physician-owners to acquire expensive PET equipment to operate in their own private offices, under the in-office ancillary service exception

[16] 70 Fed. Reg. 151 (Aug. 8, 2005).

to the self-referral rule. The proposed rule would thus result in many physicians acquiring a *more* substantial ownership interest in PET scanners than they now possess, and for that reason could exacerbate, rather than mitigate, the potential for over-utilization.

IV. Should CMS Reclassify Nuclear Medicine Services as DHS, Existing Physician Ownership Interests Should be Exempted from the Prohibition on Self-Referrals

If CMS does reclassify nuclear medicine as a DHS, contrary to the statutory language, it should take strong measures to protect current physician-stakeholders. CMS rightly acknowledges that the guidance it offered in the Phase I final rule has "*encouraged physician investment in nuclear medicine equipment and ventures, particularly PET scanners, which are very expensive and often require a substantial financial investment on the part of physician-owners.*"[17] Many physicians have entered into ownership arrangements in good-faith reliance on the existing regulations, not least CMS's express exclusion of nuclear imaging from DHS. Accordingly, the proposed rule recognizes that it may be necessary to extend special consideration to physicians who have pre-existing ownership interests. The rule specifically requests comments on whether to delay the new rule's effective date or to "grandfather" certain arrangements. As set out below, AMI respectfully requests that CMS minimize the impact of any change to the physician self-referral requirements on both beneficiary access and physician-investors by exempting existing physician-owned nuclear medicine services from reclassification as DHS.

When Congress established, in the Medicare Modernization Act, an 18-month moratorium on physician self-referrals to specialty hospitals, it concluded that as a matter of basic fairness it would be inappropriate to apply the new prohibition to physicians who had already made substantial investments in such hospitals.[18] Accordingly, Congress provided for the grandfathering of existing facilities and those under development as of the date that the specialty hospital bill was passed by both houses. The case for grandfathering is even more compelling with respect to nuclear medicine services, because physicians have relied on CMS's express declaration that nuclear medicine is not a subspecialty of radiology. AMI urges that a similar grandfathering exemption be adopted for physician-owned nuclear medicine services, and proposes the following language:

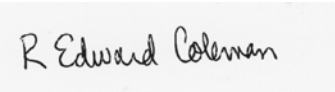
> Any nuclear medicine service provided at a facility in operation or under development on the effective date of the final rule, and for which
>
> > (i) the number of physician investors has not increased since that date;
> >
> > (ii) the specialized services furnished by the facility have not expanded beyond imaging since that date; and
> >
> > (iii) there has not been a substantial increase in the capacity of the facility due to the addition of capital equipment, except for capital equipment acquired for the purpose of replacing or upgrading existing equipment,
>
> is not a Designated Health Service.

[17] 70 Fed. Reg. 151 (Aug. 8, 2005).
[18] See CMS Transmittal No. 62, March 19, 2004, available at http://www.cms.hhs.gov/manuals/pm_trans/R62OTN.pdf.

Conclusion

AMI believes that compelling evidence of congressional intent, the clinical distinctiveness of nuclear medicine from radiology, strong inherent checks against over-utilization, and the specific structure of physician ownership interests all counsel strongly against subjecting nuclear medicine services to the prohibition against physician self-referral. For these reasons, AMI respectfully requests that CMS maintain its present policy that nuclear medicine services are not DHS. AMI would welcome the opportunity to meet with agency staff during the comment period in order to discuss these issues in more detail.

Very truly yours,



R. Ed Coleman