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September 14, 2006

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

ATTN: FILE CODE CMS-1321-P

Re: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007; DRA Proposals

Dear Administrator McClellan:

The Academy of Molecular Imaging (AMI) is pleased to have the opportunity to comment on the proposed rule, CMS-13210P, Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007, published in the Federal Register on August 22, 2006. The AMI is comprised of academicians, researchers and nuclear medicine physicians utilizing Positron Emission Tomography (PET) technology. AMI serves as the focal point for PET education, training, research and clinical practice through its annual scientific meeting, educational programs, and its Journal, *Molecular Imaging & Biology*. AMI speaks for thousands of physicians, scientists, and patients with regard to this lifesaving technology.

AMI is concerned that, as the result of the proposed reductions under the Deficit Reduction Act of 2005 (DRA), the provision of PET with computed tomography (PET/CT) will no longer be economically viable for many independent diagnostic testing facilities (IDTFs)—a result that would significantly limit beneficiary access to this vital technology. The scope of the proposed DRA cuts is deep and far reaching, and applies to both diagnostic and therapeutic imaging. AMI believes that the proposed reductions in the payment rate for PET/CT are not supported by the language of the statute. In addition, because there is no statutory basis on which to conclude that Congress intended to cut payments for therapeutic imaging in particular, AMI respectfully requests that the Centers for Medicare & Medicaid Services (CMS) clarify that PET/CT scans provided for the purpose monitoring cancer therapy are not subject to the payment limitation imposed by Section 5102 of the DRA.

Background on PET/CT

PET is a highly sensitive imaging technique for the detection of actively growing cancer cells. The key to PET's effectiveness is its ability to provide physicians with information about the body's chemistry, cell function and tissue metabolism that traditional anatomic imaging modalities do not offer. With anatomic imaging, the detection of a malignancy requires the use of successive scans to measure a lesion's rate of growth. By contrast, PET identifies the presence of malignancy by detecting abnormal tissue metabolism, often at a point in time when anatomic imaging scans still appear normal.

The fusion of PET and CT into a single imaging modality, known as PET/CT, offers the most complete non-invasive information available on cancer location and metabolism. By seamlessly merging PET and CT images, PET/CT can identify and localize tumors more accurately than either of the component modalities taken alone. PET/CT distinguishes between malignant and benign processes and reveals tumors that may otherwise be obscured by the scarring that often results from surgery, radiation, and drug therapy. The benefits to patients are tremendous: earlier diagnosis, more accurate staging, more precise treatment planning, better monitoring of therapy, and a reduction in the number of invasive procedures, such as biopsies.

PET/CT is an integral and vital component of cancer therapy. Cancerous tumors frequently change shape or move slightly during the course of treatment. Oncologists often adjust their initial treatment regimen based on the results of periodic PET/CT scans. Scans conducted for therapeutic monitoring thus enable oncologists to better target the cancer and to spare non-cancerous tissue from unnecessary and potentially harmful radiation. This integration of routine imaging into patients' therapeutic regimens has significantly enhanced the quality and precision of cancer treatment.

The Deficit Reduction Act of 2005

The Physician Fee Schedule (PFS) uses a resource-based relative value scale to calculate payments to physicians. That scale incorporates values for physician work, practice expense, and malpractice. The value assigned to imaging services performed in a physician's office under the PFS is generally significantly higher that the value assigned to the same services under the Hospital Outpatient Prospective Payment System (HOPPS).

Section 5102 of the DRA includes two provisions that reduce Medicare payments for imaging services. First, it caps the Medicare payment rate for the "technical" component (as distinguished from the "professional," or interpretive, component) for imaging procedures performed in a physician's office at the rate paid to hospital outpatient departments under the HOPPS.[1] Our comment focuses on this provision. Second, the

[1] DRA, § 5102(b)(1), Pub. L. 109-171 (Feb. 8, 2006).

DRA exempts from Medicare budget neutrality requirements scheduled reductions for imaging services performed on contiguous body parts during the same procedure.[2] The DRA defines imaging services to include "X-ray, ultrasound (including echocardiography), nuclear medicine (including position emission tomography), magnetic resonance imaging, computed tomography, and fluoroscopy, but excluding diagnostic and screening mammography."[3]

Neither the original House nor Senate version of the DRA included any provision reducing Medicare payments for imaging services. In fact, cuts to imaging services were never directly addressed by either chamber, and Section 5102 was added to the bill only by the conference committee.[4] Because the legislative record is silent with respect to Congress' intent, CMS should construe the provisions relating to imaging narrowly and with particular caution. AMI is working with professional societies, patients' advocates, and other stakeholders to develop legislation that would delay the implementation of the DRA for two years, until the issue can be further studied and the consequences for Medicare beneficiaries better known.

The DRA-Imposed Cap on Medicare Payment for Imaging Services Does not Apply to PET/CT

Section 5102 of the DRA, which caps Medicare payment for imaging services paid under the PFS at the rate paid to hospital outpatient departments, does not apply to PET/CT. The DRA reduces payment only for imaging services that are paid under the PFS. Section 5102 clearly states that imaging cuts apply to "*the technical component (including the technical component portion of a global fee) of the service established for a year under the fee schedule*." However, PET/CT is one of the few imaging services for which the Medicare payment rate is not established by the PFS. Rather, in 2006 and previous years, rates were set by Medicare regional carriers. The flexibility of this policy allowed carriers to account for regional variations in the cost of providing PET/CT.

In the proposed rule CMS notes that the agency *"included carrier priced services since these services are within the statutory definition of imaging services and are also within the statutory definition of PFS services (that is, carrier-priced TCs of PET scans)*." In fact, CMS provides no compelling statutory basis for its decision to extend Section 5102 beyond the scope of services defined in Section 5102, to carrier-priced imaging services such as PET/CT. To the contrary, as we discuss below, the exclusion of carrier-priced services from the DRA-imposed payment cap is strongly supported by both the unique severity of such cuts for PET/CT services relative to other imaging services, as well as the devastating impact that such cuts would have on IDTFs.

The Proposed Payment Rate Reductions for PET/CT Will Have a Devastating Financial Impact on IDTFs

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[2] DRA, § 5102(a)(3)(v)(I), Pub. L. 109-171 (Feb. 8, 2006).
[3] DRA, § 5102(b)(1), Pub. L. 109-171 (Feb. 8, 2006).
[4] *See* Conference Report on S. 1932, Deficit Reduction Act of 2005 (House or Representatives, December 18, 2005).

As we noted above, Section 5102 of the DRA capped Medicare payment under the PFS for the technical component of imaging services at the rate paid to hospital outpatient departments. Medicare typically has reimbursed PET/CT at a substantially higher rate under the PFS than under the HOPPS, because the cost to IDTFs of providing those services is significantly higher than the cost to hospital outpatient departments. The current HOPPS rate for PET/CT (APC 1514) is $1,250. The current allowable reimbursement rate under the PFS ranges from $1,900 to $2,850 for PET/CT. A recent survey of 40 IDTFs demonstrated that the average cost of providing PET/CT was $1,923. The weighted average was somewhat lower due to the presence in the survey of a small number of very high-volume providers, but even that number—$1,646—is substantially higher than the current HOPPS rates.

Moreover, CMS has proposed to reduce the HOPPS payment rate for both PET/CT to $865 for CY 2007. If CMS ultimately adopts this proposal, IDTFs will face rate reductions as high as 70%. Even if CMS retains its current HOPPS rate for PET/CT, IDTFs will see rate reductions between 30% and 50%. Indeed, of the 40 facilities surveyed, only three reported an average cost per PET/CT scan lower than the current HOPPS rate of $1,250, and only two reported an average cost per scan lower than the proposed rate of $865.

The magnitude of the proposed reductions means that the provision of PET/CT services will no longer be viable for many IDTFs. As a result, many will be forced out of business. The result will be to limit beneficiary to these lifesaving technologies.

The DRA Should not Apply to PET/CT for Therapeutic Monitoring

CMS's proposal to construe Section 5102 very broadly, to include therapeutic as well as diagnostic imaging, lacks support in the statute, and would compromise patient access to quality cancer care.

When Congress enacted the DRA, it did not intend to cap Medicare payment for the technical component of PET/CT used to monitor cancer patients' response to treatment. There is no suggestion in the text or legislative history of Section 5102 that Congress intended the payment cap to extend beyond imaging provided for diagnostic purposes. Indeed, it does not appear that Congress specifically contemplated the status of PET/CT scans conducted for monitoring therapeutic response. It therefore lies within CMS's discretion to determine that the cap does not apply to this distinct class of scans.

PET/CT scans have great value in guiding cancer therapy. The information provided by PET/CT can spare a patient from unnecessary surgery or chemotherapy. In fact, in conjunction with CMS, AMI and the American College of Radiology are currently administering the National Oncologic PET Registry (NOPR). By linking Medicare coverage of PET/CT to the collection of clinical data, the NOPR will make possible a more accurate assessment of PET/CT's actual influence on patient management across a

wide spectrum of cancer indications. CMS's proposed extension of the DRA reductions to include therapeutic imaging would thus undermine one of the key goals of the NOPR.

AMI therefore requests that CMS clarify that imaging that is undertaken as part of a cancer treatment regime is exempt from the DRA-imposed cap on Medicare payment for the technical component of diagnostic imaging. This is exactly the approach that CMS has taken in the proposed rule with respect to other the therapeutic oncology codes, such as those for radiation therapy. Just as CMS has proposed to exclude radiation therapy from the list of radiology services subject to the DRA reductions, so should the agency exclude PET/CT for therapeutic monitoring.

AMI also requests that CMS consider the proposed cuts in light of the substantial payment reduction that the agency has proposed in the hospital outpatient context. Independent of the proposed PFS adjustments, CMS intends to reduce the HOPPS rate for PET/CT by approximately 31%.

AMI greatly appreciates the time and attention that CMS has devoted to ensuring that PET/CT remains available to Medicare beneficiaries, and would welcome the opportunity to meet with CMS regarding this important matter.

Sincerely,

Johannes Czernin, M.D.
President
Academy of Molecular Imaging