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September 15, 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, DC 20201

ATTN: FILE CODE CMS-1501-P

**Re: Medicare Program; Changes to the Hospital Outpatient
Prospective Payment System and Calendar Year 2006
Payment Rates**

Dear Administrator McClellan:

The Academy of Molecular Imaging (AMI) is pleased to have the opportunity to comment on the proposed rule, CMS-1501-P, Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates, published in the Federal Register on July 25, 2005. The AMI is comprised of academicians, researchers and nuclear medicine physicians utilizing Positron Emission Tomography (PET) technology, and serves as the focal point for PET education, training, research and clinical practice through its annual scientific meeting, its educational programs, and its Journal, *Molecular Imaging & Biology*. AMI also speaks for thousands of physicians, scientists and patients with regard to this lifesaving technology. The AMI greatly appreciates the time and attention that you and your staff have devoted to making PET and PET/CT technology accessible to Medicare beneficiaries.

Summary

PET/CT is one of the leading imaging technologies used for the management of cancer patients. This new imaging technology was first introduced in 2000, and thus had limited hospital utilization in 2001 and 2002. PET/CT is now more widely used in hospitals, and because it provides to physicians numerous clinical benefits beyond conventional PET, and provides to patients more precise treatment planning, it will eventually replace the use of PET-only scanners in the United States.

Hospitals incur more capital and maintenance costs with a PET/CT scanner than with a conventional PET scanner.

In the 2006 Proposed Hospital Outpatient payment rule, CMS proposed to assign the PET/CT New Technology classification payment rate to New Technology APC 1514 (\$1250). This payment rate is far below the true cost of PET/CT, and it significantly underpays hospitals. This rate also does not recognize the additional diagnostic benefits provided by PET/CT over traditional diagnostic PET and computed tomography (CT) scans.

AMI recommends that in the final hospital outpatient rule, CMS reimburse PET/CT in a New Technology Ambulatory Payment Classification (APC) and, because there is no available claims data for PET/CT, that it base the payment rate on external data. For the reasons set forth below, we respectfully recommend that CMS assign CPT codes 78814¹, 78815², and 78816³ to APC 1519, with a payment rate of \$1,750.

This recommendation is consistent with the New Technology payment policy for new products where no claims data exist, and will make PET/CT available to Medicare beneficiaries in hospitals. This payment rate also reflects the clinical and cost differences between PET and PET/CT.

Clinical Differences Between PET and PET/CT

PET is a highly sensitive technique that detects the metabolic signal from actively growing cancer cells in the body. PET employs two scans to accurately identify the location of this signal. The first detects the metabolic signal; the second detects a radioactive source circulating throughout the body, and is used to correct the metabolic scan for radioactivity that is absorbed or attenuated by the body. The PET scan provides accurate metabolic information, but it does not determine the exact anatomic location of the signal in the body.

The key to PET's effectiveness is that it provides physicians with information about the body's chemistry, cell function, and metabolism that anatomic imaging modalities, such as CT and MRI, do not. Certain diseases cause abnormalities of blood flow or metabolism before anatomic changes become apparent. These abnormalities can be detected by PET at a stage when the anatomic imaging scans appear normal. Moreover, whereas anatomic imaging depends on the size and growth rate of lesions to determine the likelihood of malignancy, PET physicians can determine the presence or absence of malignancy through the evaluation of tissue metabolism.

¹ CPT code 78814 description: Tumor imaging, positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization; limited area (e.g. chest, head/neck).

² CPT code 78815 description: Tumor imaging, positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization; skull base to mid-thigh.

³ CPT code 78816 description: Tumor imaging, positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization; whole body.

CT is a standard imaging method that provides high-resolution anatomic information by detecting differences in the density of various tissues. The combination of PET and CT into a single device, known as a PET/CT, is a breakthrough in imaging because the images from a PET scan and a CT scan can be seamlessly merged into an image that more accurately identifies and localizes tumors in the body.

When the results of the scans are fused together, they provide the most complete non-invasive information available on cancer location and metabolism. In addition, PET/CT allows both tests to be performed without moving the patient, and the resulting images leave less room for error in interpretation due to the more accurate picture of the cancer provided by the scan.

The benefits to the patient are tremendous: **earlier diagnosis, more accurate staging, more precise treatment planning, and better monitoring of therapy.** A PET/CT image separates malignant from benign processes and reveals tumors that may otherwise be obscured by the scars and swelling that result from therapies such as surgery, radiation, and drug administration. PET/CT images often reduce the number of invasive procedures required during follow-up care, including biopsies, and may reduce the number of anatomical scans needed to assess therapeutic response. In some cases, the images are so precise that they can locate an otherwise undetectable tumor.

Background on FY 2005 and FY 2006 Hospital Outpatient Payment for PET/CT

During the 2005 rulemaking process for the Hospital Outpatient Prospective Payment System (HOPPS), PET/CT was a new technology with no identifiable Medicare claims data. Because PET/CT did not yet have an established CPT code when HOPPS rates were set, CMS did not set a payment rate for PET/CT when it published the final hospital outpatient rule on November 15, 2004.

The American Medical Association (AMA) granted three new CPT codes (78814, 78815, and 78816), which were implemented in January 2005, to describe PET with concurrent CT when CT is used solely for attenuation correction and anatomical localization (rather than for diagnostic purposes).

In March 2005, with no discussion and without soliciting public comment, CMS assigned these three new codes to New Technology APC 1514, in the Hospital Outpatient Quarterly Update Transmittal 514. CMS established the payment rate of \$1,250, which is \$100 higher than the payment rate for PET scans in APC 1513. CMS correctly assigned PET/CT to a different APC from PET. This is consistent with the Food and Drug Administration's (FDA) conclusion in both its premarket approvals and regulations that PET/CT is a different medical device from PET. For example, PET/CT devices are specifically cleared by the FDA for marketing under the 510(k) process on the basis of marketed (or predicate) PET/CT devices, not PET devices.

However, it is unclear how CMS arrived at the payment rate established in the Quarterly Update. CMS provided no rationale for the rate, and because no code for PET/CT then existed (codes for

PET/CT were first implemented in January 2005), there was no identifiable claims data for PET/CT.

In the 2006 Proposed Hospital Outpatient payment rule, CMS proposed to continue its assignment of PET/CT codes to New Technology APC 1514 with a payment rate of \$1,250.⁴ Although AMI agrees with CMS that PET/CT should remain in the New Technology classification for 2006, we believe the current and proposed payment rates are too low and, due to the lack of claims data, should be modified on the basis of external data.

Recommendation for the Final Hospital Outpatient Rule for PET/CT

AMI greatly appreciates the hard work and careful consideration CMS put into developing the proposed rule. We are concerned, however, that the proposed payment rate for PET/CT does not adequately cover hospitals' costs for providing PET/CT services. The costs and resource use involved in a PET/CT scan are more substantial than those involved in a PET-only scan. For example, hospitals incur more capital and maintenance costs with PET/CT than with conventional PET. A new PET/CT scanner costs approximately \$1.8 million dollars, compared to \$1.2 million for a conventional PET scanner. Further, a PET/CT scanner carries twice the operating cost of a conventional PET scanner, with an annual maintenance contract of approximately \$240,000, compared to \$120,000 for a PET-only scanner.

AMI is also concerned that the proposed payment rate for PET/CT does not reflect that the CT scan performed during a PET/CT is not limited to one part of the body but includes the entire area imaged by the PET scan. When a physician orders a PET/CT and a diagnostic CT the nuclear medicine physician can in some cases perform both a CT scan for attenuation correction and a diagnostic CT scan with contrast with a single PET/CT scan. For example, CPT code 78815 could include a CT scan from the skull base to the mid-thigh, which is equivalent in area to a CT scan of the neck, chest, abdomen, pelvis, and part of the lower extremity. The CT portion of a PET/CT may be equivalent to multiple diagnostic CT scans and is performed with or without contrast. This is more efficient than performing one PET scan plus several separate CT scans for different regions of the body. An individual regional CT scan with contrasts is reimbursed by Medicare at approximately \$300.

In some instances a nuclear medicine physician needs to order both a PET/CT and a diagnostic CT scan. For example, the clinical protocol for diagnosing a small lung nodule calls for the patient to hold their breath during the scan. Because PET/CT requires a longer period of time for image acquisition, it is not possible to perform the PET/CT scan and diagnostic CT scan simultaneously. In that case, the physician must perform a separate diagnostic CT scan.

Because the PET/CT CPT codes and payment rate were first implemented in April 2005, there is no available Medicare claims data for PET/CT. Therefore, for the final hospital outpatient rule

⁴ We appreciate that CMS corrected its technical error with respect to the PET/CT rate, published in the proposed rule as \$1150.

for FY 2006, CMS should base the New Technology payment rate for PET/CT on external data and economic analysis. The attached paper shows the hospital cost of providing a PET/CT scan, based on the extrapolation of a published economic cost model. According to its authors, the model is based on average national utilization rates in the hospital outpatient department, and is adjusted for PET/CT equipment and operational requirements. Based on this economic analysis, the costs for a PET/CT scan are approximately **\$1,717**. The present PET/CT payment rate is therefore far below the true costs of providing the service in hospital outpatient departments. CMS should use this published economic model cost analysis to set the New Technology rate for 2006.

Based on this external analysis, we recommend that CMS assign CPT codes 78814, 78815, and 78816 to APC 1519 with a payment rate of \$1,750. This recommendation is consistent with the attached data, with the clinical use of PET/CT, and with the greater relative resource use associated with PET/CT than with conventional PET.

AMI Supports the Proposed Payment Classification for PET Scans

We strongly support the proposal in the rule to maintain covered FDG PET procedures in New Technology APC 1513. This decision reflects the fact that the hospital outpatient claims data used to set the 2006 proposed payment rates do not accurately reflect the costs of providing these services. Adequate payment for these services is essential to ensure patient access to this important technology. AMI will continue to work with CMS and providers on issues relating to PET claims data.

Payment for Radiopharmaceutical Fluorodeoxyglucose (FDG)

The proposed rule makes significant changes to hospital outpatient payments for radiopharmaceuticals in 2006 and subsequent years. The rule proposes to pay for FDG and other radiopharmaceuticals based on hospital charges reduced to costs by the hospital cost to charge ratio (CCR). AMI supports this proposal but has concerns about its implementation. AMI is committed to working with CMS and other stakeholders on payment issues for nuclear medicine therapies and isotopes, including how to implement CMS's proposed payment methodology appropriately in FY 2006.

AMI recommends that the hospital-wide CCR be used, as this is the appropriate hospital cost center for FDG. Hospitals have a wide variety of mark-up policies for drugs and radionuclides. It will be critical that hospitals charge appropriately and that CMS and contractors apply the correct CCR. AMI will work with providers to educate them regarding the proposed new payment methodology for FDG.

AMI is interested in working with CMS on establishing appropriate payments for FDG and other radiopharmaceuticals in subsequent years. In the proposed rule CMS asks for comments on whether radiopharmaceuticals should be paid based on average sales price (ASP) starting in 2007. Due to the difficulties with reporting ASP for FDG and other radiopharmaceuticals, AMI believes that CMS should study this issue further in the context of a public process that allows

The Honorable Mark McClellan

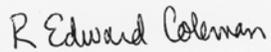
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for significant stakeholder input. AMI stands ready to work with CMS and other stakeholders on payment for FDG in 2007 and subsequent years.

AMI appreciates the opportunity to submit these comments, and looks forward to an ongoing dialogue with CMS on these important issues.

Sincerely,

A handwritten signature in black ink that reads "R. Edward Coleman". The signature is written in a cursive style and is centered within a light gray rectangular box.

Dr. R. Edward Coleman
Immediate Past President
Academy of Molecular Imaging