

September 19, 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-1506-P**

**Re: Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2007 Payment Rates; Payment for PET/CT**

Dear Administrator McClellan:

The Academy of Molecular Imaging (AMI) is pleased to have the opportunity to comment on the proposed rule, CMS-1506-P, Hospital Outpatient Payment System and CY 2007 Payment Rates, published in the Federal Register on August 23, 2006. AMI is comprised of academicians, researchers and nuclear medicine providers utilizing positron emission tomography (PET) technology. AMI serves as the focal point for molecular imaging education, training, research and clinical practice through its annual scientific meeting, its educational programs, and its Journal, *Molecular Imaging & Biology*. AMI speaks for thousands of physicians, providers, and patients with regard to this lifesaving technology, and has worked closely with CMS over the past two years to increase beneficiary access to both standard PET and PET with computed tomography (PET/CT) through the development of the National Oncology PET Registry (NOPR).

### **Summary**

AMI believes that CMS's proposal to reassign PET/CT from a new technology Ambulatory Payment Classification (APC) to APC 308 is premature and unsupported by reliable cost data. The proposed payment rate of \$865 represents a decrease of over 30% from the 2006 rate; moreover, is far below the true costs of providing PET/CT, and fails to recognize either the unique clinical benefits of PET/CT or that PET/CT is associated with substantially higher costs than conventional PET. The proposed reassignment of PET/CT would seriously underpay hospitals, and risk limiting beneficiary access to a service that now represents the standard of care for most oncology patients.

This comment focuses on two crucial points. First, PET/CT is a clinically distinct technology from conventional PET, and entails substantially higher capital, maintenance, and operational costs. Second, the CPT codes for PET/CT were only implemented for

Medicare payment in April 2005. Because hospitals typically do not update their charge masters more than once every year, hospital claims data from the last nine months of 2005—the period cited by CMS as its evidentiary basis for the proposed rule—does not accurately reflect the true cost to hospitals of providing PET/CT. For these reasons, PET/CT should remain in New Technology APC 1514 (Level XIV) at a rate of \$1,250 for one more year.

On August 23, 2006, the APC Advisory Panel heard presentations on PET/CT from CMS and from outside groups, including AMI. The APC Advisory Panel voted in favor of maintaining PET/CT in its current New Technology APC at a rate of \$1,250. AMI supports the recommendation of the APC Advisory Panel. AMI has engaged in an extensive provider education effort with CMS as part of the implementation of the NOPR, and is committed to working with CMS to educate hospitals about PET/CT.

### **PET/CT Should Be Paid Under a Separate APC from PET**

The proposed CY 2007 rule would assign conventional PET and PET/CT to the same APC classification for the first time. The assignment of PET and PET/CT to the same APC is inconsistent with Medicare regulations. As the proposed rule states, all of the items and services within a given APC group must be “comparable clinically and with respect to resource use.” With regard to CMS’s determination of a clinically appropriate APC, the agency has stated:

After we gain information about actual hospital costs incurred to furnish a new technology service, *we will move it to a clinically-related APC group with comparable resource costs.* If we cannot move the new technology service to an existing APC because it is dissimilar clinically and with respect to resource costs from all other APCs, we will create a separate APC for such service. (65 FR 18476, 18478 (April 7, 2000))

The combination of PET and CT into a single device, known as a PET/CT, represents a clinical breakthrough in imaging. The integration of the two scans provides the most complete non-invasive information available about cancer location and metabolism. PET/CT identifies and localizes tumors more accurately than either of the component images taken alone. In addition, PET/CT technicians can perform both scans without having to move the patient. The resulting images thus leave less room for error in interpretation.

The benefits of PET/CT to the patient are tremendous: **earlier diagnosis, more accurate staging, more precise treatment planning, and better monitoring of therapy.** A PET/CT image can distinguish between malignant and benign processes, and reveal 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. For all of these reasons, PET/CT now represents the standard of care for most oncology patients.

FDA has consistently concluded in both premarket approvals and its regulations that PET/CT is a distinct medical device from PET. New PET/CT devices are specifically cleared by FDA for marketing under the 510(k) process on the basis of currently marketed (or predicate) PET/CT devices, not PET devices. Moreover, as we have explained, PET/CT is technologically and clinically unique and entails substantially higher capital, maintenance, and operational costs than conventional PET. Due to these highly relevant dissimilarities, PET/CT should not be assigned to the same APC as conventional PET.

### **Background on Medicare Payment for PET/CT**

During the rulemaking process for the CY 2005 Hospital Outpatient Prospective Payment System, PET/CT was a new technology with no identifiable Medicare claims data. At the time CMS set payment rates for CY 2005, PET/CT did not have an established CPT code. In the final hospital outpatient rule, published on November 15, 2004, CMS referred to PET/CT in its comments, but did not set a payment rate. CMS stated in the final rule:

The current G code descriptors do not describe PET/CT scan technology, and should not be reported to reflect the costs of a PET/CT scan. At present, we have decided not to recognize the CPT codes for PET/CT scans that the AMA intends to make effective January 1, 2005, because we believe the existing codes for billing a PET scan along with an appropriate CT scan, when provided, preserve the scope of coverage intent of the PET G-codes as well as allow for the continued tracking of the utilization of PET scans for various indications. (69 FR 65682, 65717 (November 15, 2004))

The American Medical Association (AMA) subsequently granted three new CPT codes (78814, 78815, and 78816) to describe PET with concurrent CT when it is used solely for attenuation correction and anatomical localization, rather than for diagnostic purposes. In March 2005, in the Hospital Outpatient Quarterly Update Transmittal 514, CMS assigned these three new codes to New Technology APC 1514, at a payment rate of \$1,250. PET/CT remained in New Technology APC 1514, at a payment rate of \$1,250, for CY 2006.

### **Medicare Claims Data Under-represents the Costs of Providing PET and PET/CT**

In anticipation of the 2007 hospital outpatient rule, AMI contracted with a leading hospital network, Premier Inc., to collect external hospital cost data for PET and PET/CT. The Premier data obtained by AMI for conventional PET indicates an average cost to hospitals significantly higher than the proposed payment rate of \$865. The 14 Premier hospitals that calculate costs according to the ratio-of-costs-to-charges (RCC) method reported an average cost for PET CPT 78812—the PET code most commonly paid by Medicare—of \$1,336. The 19 Premier hospitals that use the relative value unit (RVU) method reported an average cost of \$1,143.

The data for PET/CT showed improbably wide variation in hospitals' reported "average costs" of providing PET/CT, ranging from as low as \$400 per scan to more than \$2,400 per scan for PET/CT CPT 78815—the PET/CT CPT code most commonly paid by Medicare. The "average cost" of administering PET/CT also varied substantially depending on the method of cost accounting employed by the hospital. The reported average cost to RCC hospitals of \$1147 is significantly higher than the proposed rate. The results of the Premier analysis are included with this comment as Attachment A.

AMI has asked Premier to audit the hospitals to determine the reason for the dramatic variability in reported costs. It is highly likely, however, that many hospitals have not yet properly updated their charge masters since the PET/CT CPT codes were introduced for Medicare payment in April 2005. Hospitals typically update their charge masters at most once per year, and sometimes less frequently than that. Contracts with private payers often limit a hospital's ability to change its charge master during a fiscal year. Accordingly, it is not uncommon for it to take two to three years after the implementation of a CPT code for a new technology until the new code is reflected in hospital costs data. Vanguard Health Systems testified at the August 23 APC Advisory Panel meeting that hospitals typically do not update charge masters for new technologies for two to three years. This is precisely the rationale behind the New Technology classification, which affords hospitals two to three years to obtain reliable cost data for new technologies. This fact strongly supports leaving PET/CT in New Technology APC 1514, with a payment rate of \$1,250, for at least one more year.

### **Hospital Costs are Higher for PET/CT than for Conventional PET**

The proposed rate reduction, and particularly CMS's intention to pay PET and PET/CT at the same rate, ignores the fact that it is significantly more expensive for hospitals to provide PET/CT services than conventional PET. AMI believes that the respective payment rates should reflect the relatively higher cost to hospitals of acquiring, maintaining, and operating a PET/CT scanner than a conventional PET scanner. AMI has undertaken a cost analysis of PET/CT using a published, peer-reviewed cost model.<sup>1</sup>

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<sup>1</sup> See Keppler JS and Conti PS, A Cost Analysis of Positron Emission Tomography, Am. J. Radiology: 177, July 2001.

AMI contracted with Jennifer Keppler to develop an external analysis of the cost to hospitals of providing PET/CT. The study is based on fixed capital and operating costs, and incorporates national averages to account for scan volume. The study, which is included as Attachment B for your review, places the average cost of furnishing PET/CT at \$1,368.

Hospitals incur significantly higher capital, maintenance, and operating costs with PET/CT than with conventional PET. The current price for a new PET/CT scanner is approximately \$1.8 million, compared to \$1 million for a conventional PET scanner. Further, a PET/CT scanner entails an annual maintenance cost of approximately \$216,000, compared to \$100,000 for a conventional PET scanner. Finally, the average salary for a technologist qualified to operate a PET/CT scanner is \$70,000, compared to \$45,000 for the operation of a conventional PET scanner.

In the final rule for CY 2006, CMS acknowledged that “*PET/CT scanners may be more costly to purchase and maintain than dedicated PET scanners,*” but suggested that “*a PET/CT scanner is versatile and may also be used to perform individual CT scans [in the event that] PET/CT scan demand is limited.*” (70 Fed. Reg. 68516, 68581 (November 10, 2005)). The proposed rule for CY 2007 appears to reiterate a similar rationale when it attributes claims data suggesting an apparent similarity between the median cost of PET and PET/CT to the fact that “*many newer PET scanners also have the capability of rapidly acquiring CT images for attenuation correction and anatomical localization . . .*” The implication appears to be that the high capital and maintenance costs associated with PET/CT scanners can be offset by their supplemental performance of CT-only scans.

However, CMS has provided no data on the actual utilization of PET/CT scanners to support this assertion. In fact, a survey of AMI member PET/CT providers indicates that a solid majority do not use their PET/CT scanners to provide CT-only scans. Keppler’s cost analysis nevertheless assumes that each PET/CT scanner is used to perform an average of 4.5 stand-alone diagnostic CT scans per day. Even after incorporating this conservative assumption, Keppler calculated a cost estimate of \$1,368 per PET/CT scan.

### **CMS Should Continue to Pay PET/CT In a New Technology APC in 2007**

The New Technology APCs were created specifically because it takes several years for hospital charges to reflect the costs of new transformative products. CMS has stated that it expects to assign an item or service to a new technology APC for at least two years, or until the agency can obtain sufficient hospital claims data to justify reassigning the item or service to an existing APC. As we noted above, CMS first implemented New Technology APC 1514 for PET/CT in April 2005. CMS now proposes to reassign PET/CT from a new technology APC to an existing APC after only 21 months, based on the agency’s analysis of Medicare claims data *from nine months in CY 2005*.

This proposal is at odds with the common hospital practice of updating their charge master once per year, if not less frequently. A hospital that updated its charge master at the end of CY 2005 would not have reported cost data specific to PET/CT until *after* the period on which CMS proposes to base the reassignment of PET/CT. The “close relationship between median costs of PET and PET/CT” that CMS discovered in the claims data of 362 providers reflects not the cost similarity between PET and PET/CT, but rather the fact that hospitals generally do not update their charge masters frequently enough to account for new CPT codes that are implemented mid-way through a calendar year. Nine months worth of cost data is not a sufficient basis for terminating a new technology classification.

As the proposed rule explains, CMS will “retain a service within a new technology APC until we acquire sufficient data to assign it to a clinically appropriate APC group.” The decision to remove PET from a new technology classification is based on a review of five years worth of claims data. By contrast, because the PET/CT CPT codes and payment rate were only implemented in April 2005, sufficient Medicare claims data for PET/CT is not yet available. In light of CMS’s own new technology guidelines, both the newness of the PET/CT CPT codes and the absence of accurate and reliable claims data militate heavily in favor of maintaining PET/CT’s new technology status for CY 2007.

### **Payment for Myocardial PET**

Finally, AMI believes that CMS’s proposal to assign HCPCS code 78492, for multiple myocardial PET scans, to the same APC as the HCPCS codes describing single myocardial PET will significantly underpay providers for multiple scanning procedures. Multiple scans require greater hospital resources, as well as longer scan times, than single scans. The current two-tiered APC structure, under which single and multiple scanning procedures are paid at \$800.55 and \$2,484.88, respectively, reflects this fact.

CMS speculates that, as myocardial PET scans “are being provided more frequently at a greater number of hospitals than in the past, it is possible that most hospitals performing multiple PET scans are particularly efficient in their delivery of higher volumes of these services and, therefore, incur hospital costs that are similar to those of single scans, which are provided less commonly.” However, CMS provides no data to support this assertion. Further, the hospital claims data relied upon by CMS to justify consolidating single and multiple scanning procedures into one unified APC (APC 0307) with a payment rate of \$721.26 show an improbably dramatic reduction over the course of a single year—CY 2005—in the cost to hospitals of providing multiple myocardial PET. Stakeholders and CMS require additional time to gather data and to study the reasons that the 2005 claims data shows such precipitous decline in hospital costs.

AMI appreciates the serious attention that CMS has afforded this important issue, and looks forward to working with the agency to ensure that Medicare beneficiaries retain access to this breakthrough technology.

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Sincerely,

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President  
Academy of Molecular Imaging