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Submitter : Dr. Donald Schon **Date:** 10/04/2006

Organization : AKDHC

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

SEE ATTACHMENT

CMS-1506-P-255-Attach-1.RTF

The American Society of Interventional Nephrology (otherwise referred to as ASDIN) is the society which represents over 95 % of the interventional nephrologists in the United States as well as many radiologists who specialize in interventional procedures for dialysis accesses. Because of this ASDIN represents major stake holders affected by proposal CMS1506P.

We support many aspects of this proposal by CMS. We are especially supportive of the intent to improve access for Medicare recipients to dialysis access maintenance procedures. The proposal to evolve from a list of allowed procedures to a list of disallowed procedures goes a long way towards achieving this goal. However there are several aspects of this proposal which we feel are counter productive and will have the effect of inhibiting access to appropriate care for end stage renal disease (ESRD) recipients of Medicare.

Currently access procedures are reimbursable in either the office setting or the hospital setting and, to a markedly lesser extent, in the ASC setting. Adequately and appropriately reimbursing these procedures in an ASC setting will not change the frequency of these procedures. It will however, improve patient access to care. By shifting procedures out of the hospital it will provide a net savings to the Medicare system and should rightly be encouraged.

As CMS is well aware, the state of vascular access for dialysis in the United States is such that marked improvement is necessary. To this end, the KDOQI (Kidney Disease Outcome Quality Initiative) practice guidelines were developed as a joint effort of multiple organizations and then embraced by the nephrology community. Supporting organizations include the National Kidney Foundation, the American Society of Nephrology and the Renal Physicians Association. As documented in the USRDS database, vascular access in the United States has been improving since implementation of these guidelines. KDOQI mandates the development of facilities and mechanisms to improve timely access to dialysis access maintenance procedures. In addition it was recommended that these procedures be moved to the outpatient setting. To further these goals, effective January 1, 2005 CMS changed the reimbursement guidelines for procedures done in place of service 11 (POS 11) or an extension of a physician's office setting. Since the reimbursement changes have been implemented, over 30 freestanding centers for the performance of vascular access procedures have been built by physician practices throughout the United States. These centers perform more than 50,000 access related procedures annually. All of these procedures have been moved from the hospital setting. Many more centers are currently planned. Currently, the vast majority will function in POS 11. The current proposal has the intent of similarly improving access to procedures performed in the ASC setting.

Because of the nature of dialysis access procedures, specialized radiology equipment and supplies are necessary. This equipment must be provided in an ASC dedicated to dialysis vascular access procedures. The specialized equipment and supplies are not easily transferable to other uses if dialysis access procedures are to continue to be the main focus of the ASC. This focus is necessary to achieve the desired improved access to care for ESRD patients with dialysis access problems discussed below. Because of this, these centers cannot "blend" in other procedures to counter a 38 percent decrease in reimbursement per procedure. In addition, the cost per procedure does not go down 38 percent with an increasing volume of access procedures. Also, CMS has proposed a reduction in reimbursement for multiple radiology procedures done on the same day. CMS already imposes a 50 % reduced reimbursement for multiple surgical procedures performed on the same day. If in addition to this, if the proposed reduction in reimbursement for multiple radiology procedure is superimposed the combined effect would be prohibitive.

KDOQI and the Fistula First initiative have set as goals an increase in fistula prevalence in ESRD patients to greater than 65%. To facilitate this effort the National Kidney Foundation, American Society of Nephrology, Renal Physicians

Association and Fistula First Initiative have advocated making interventional procedures more available to patients, especially in the outpatient setting. The proposed cuts will make performing access related procedures in an ASC a financially marginal endeavor from the perspective of operating revenues. This will have the effect of retarding the shift of access related procedures to the outpatient departments from the inpatient settings. It will also have the effect of reducing access to care for Medicare recipients who suffer from ESRD. Since the hospital setting is both less efficient and more expensive, the result will be an increase in Medicare expenditures.

The proposed list of procedures prohibited from reimbursement in an ASC includes 35475 and 37206. 35475 is the code used by interventional physicians performing procedures (i.e. balloon angioplasty or PTA) at the arterial anastomosis of a fistula or graft and the proximate feeding artery. When applied to the repair and maintenance of vascular access for dialysis, these procedures are very safely performed in an ASC. Indeed, they are currently frequently performed safely in POS 11. Data from three sources is provided. The first is an ASC setting with low volume of procedures coding 35475. The second is a single Access Center which performs greater than 3,000 procedures per year all on dialysis vascular access. The third is a large number of procedures from multiple access centers all functioning as POS 11 and managed by a common entity.

no. proc.% major complications 140 %4550 %1,968< 0.3 %

In each case the number of major complications is miniscule and well within the professional guidelines for each center and the national guidelines published by the Society for Interventional Radiology. Thus, excluding procedures performed on dialysis vascular access which would be coded as 35475 would be inappropriate as well as counterproductive. These procedures can be safely and effectively performed in an outpatient setting. Prohibiting this code would also have the affect of limiting access to care for ESRD patients as these patients would have to have a second procedure and anesthesia to open these lesions at a separate time. Since they would need a way to achieve dialysis access in the meantime, a large number of otherwise unnecessary catheter insertion procedures would be necessitated and the cost to the Medicare program from both additional procedures would go up significantly.

37206 is the code utilized by interventional physicians for placement of additional vascular stents in the venous system. These procedures have been safely performed in the outpatient setting for years. In addition, the initial placement of a stent in the venous system, coded 37205, is not on the list of excluded procedures. In our opinion, this prohibition is logically inconsistent, not medically indicated and would necessitate repeat and additional procedures which could otherwise be avoided.

We recommend and request that 35475 and 37206 both be removed from the list of excluded services when applied to dialysis access.

Lastly is the issue of frequent procedures and budget neutrality.

Interventional access procedures are a very cost effective means of treatment for dysfunctional dialysis accesses. They are much less costly than equivalent surgical procedures. Thus, increasing access procedures and reducing surgical and hospital based procedures will not increase overall Medicare expenditures. Therefore, reducing ASC reimbursement in the name of budget neutrality is neither appropriate nor fair. For every ASC performed procedure there is a net savings to the ESRD system as opposed to the procedure being performed within a hospital setting.

We feel that the intent of the CMS proposal CMS1506P is excellent. However, certain features of the proposed implementation will make the proposed goals elusive or impossible to achieve. To this end we have tried to make positive suggestions to further the common goal of achieving better care and better access to care for Medicare recipients with ESRD.

In summary, ASDIN respectfully suggests and requests the following.
1. We support the proposed shift from a list of approved procedures to a list of disallowed procedures.
2. We support improving access to outpatient vascular access procedures in the ASC setting for ESRD patients.
3. We maintain that shifting procedures to the ASC from the inpatient setting will not change the absolute number of procedures performed as these are essential procedures to sustain life on dialysis.
4. There will be a major savings to the Medicare system from this shift. Therefore, reducing reimbursement for budget neutrality is not logical. There will result a net savings without the reduction.
5. ASC access centers are of necessity highly specialized facilities dedicated to a specific purpose. The equipment and set up are not routinely useful to other procedures performed in the ASC setting. Thus, these centers will feel an effect from the proposed reimbursement cuts which cannot be mitigated by "blending" in other procedures.
6. CMS has also proposed reimbursement cuts for multiple radiology procedures. The combined effect, if implemented, of both the 38 % reduction in ASC reimbursement and reduction for multiple radiology procedures will severely and disproportionately penalize ASC facilities dedicated to dialysis vascular access.
7. The above proposals will retard the shift in dialysis access procedures to the outpatient setting. This will result in lost opportunity for savings to the Medicare system and reduce access to care for Medicare recipients.
8. We request the removal of codes 37206 from the list of disapproved procedures on the basis of safety and consistency. We request the removal of code 35475 from the list of disapproved procedures when applied to dialysis vascular access. Data documenting the safety of such procedures in the outpatient setting is supplied for low and high volume facilities.
9. Maintaining 37206 and 35475 on the list of disapproved procedures would result in multiple procedures which could otherwise be avoided.

Donald Schon, MD, FACP
Councilor for Regulatory Affairs
Ted Saad, MD, FACP
President ASDIN
The Committee of Officers and Councilors of ASDIN on behalf of the membership:
Arif Asif, MD
Timothy Pflederer, MD
Jack Work, MD
Gerald Beathard, MD
Michael Levine, MD
Kenneth Abreo, MD
Tom Vessely, MD
Tony Besarab, MD
Linda Francisco, MD
Rick Mishler, MD
Stephen Ash, MD
Terry Litchfield

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4 ASDIN response to CMS 1506-P

5 ASDIN response to CMS 1506-P

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Submitter : Mrs. Dixie Calhoun **Date:** 10/05/2006

Organization : Endoscopy Center of Southeast Georgia, Inc.

Category : Ambulatory Surgical Center

Issue Areas/Comments

CY 2007 ASC Impact

CY 2007 ASC Impact

I am an Administrator and Clinical Nursing Director for an ASC in Southeast rural Georgia. Our ASC is a single specialty center that delivers GI endoscopy services. I would like to express my concern over the proposed changes in the ASC payment system for 2008. If implemented as proposed, the CMS rule could have a disastrous impact on single-specialty GI ASCs. The proposal is misguided, and if it were to be implemented as written, would almost certainly assure: 1) the closing of many GI ASCs, 2) reduction in access for Medicare beneficiaries, 3) reduce the levels of colorectal cancer screening, and 4) higher total costs to the Medicare program. We are totally commited to the delivery of quality care to our patients. This commitment does require adequate compensation in order to maintain the level of service that Medicare beneficiaries deserve. Medicare beneficiaries comprise 47% of out patients. The out of pocket expense will be greater and there will be a delay in their care because our local hospitals do not have the capacity, nor adequate number the qualified physicians, to accommodate the additional case load in a timely manner. We serve a 8-9 county area and perfom over 2500 procedures annually. The county, in which our ASC is located, is proud to be in the lowest 10% in Georgia and the nation, in the occurence of deaths due to colorectal cancer. This is a result of our commitment to and passion for colorectal cancer prevention. We sponsor a weekly local TV program that reaches out to the 8-9 county area we serve, with an emphasis on colorectal cancer prevention and present many educational programs for our communities. These programs also come at a cost to our Center. Research has proven that lack of public education is a strong contibutor to non-compliance in colorectal cancer screening recommendations. The proposed 62% of HOPD, for the SAME service, is not acceptable or reasonable. The elderly population is more prone to be compliant with the national recommendations for colorectal cancer screening if they do not have to go through all the "red tape" that occurs regularly in the hospital environment. I find it ironic that CMS approved colorectal cancer screening as a covered service and now are attempting to implement changes that will discourage the beneficiaries from seeking adequate screening and continued surveillance. I would like to strongly request reconsideration of CMS-1506-P to identify and document the potential devasting effects if the proposal is implemented as written now. The issue is not just "money". The real issus is Medicare beneficiaries being able to obtain quick access to high quality, cost efficient healthcare and the proposed changes will definitely effect this in a negative manner. Again, I strongly urge the powers that be to relook and rethink this proposal and adjust according to the real needs!!! Thank you for your time and consideration of this request.

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Submitter : Dr. Ronnie Smith **Date:** 10/05/2006

Organization : Endoscopy Center of Southeast Georgia

Category : Ambulatory Surgical Center

Issue Areas/Comments

CY 2007 ASC Impact

CY 2007 ASC Impact

October 5, 2006

I am a practicing physician in Vidalia, Georgia. I am writing to express my deep concern over Medicare s proposed rule to change the payment system for ambulatory surgery centers (ASC). Approximately 47% of the procedures that I perform every year are Medicare patients.

The Endoscopy Center of Southeast, Inc., of which I am part owner and where I perform over 2,300 endoscopy procedures every year, takes great pride promoting Colorectal Cancer Prevention. Our facility complies with the Colorectal Screening guidelines recommended by the American Cancer Society, the Center for Disease Control and Prevention (CD), the National Institute of Health, and the American Society of Gastrointestinal Endoscopy. Not only do we comply with their recommended guidelines but we also conform to the payment guidelines as set fourth by Medicare, BC/BS, United Healthcare and other major reputable insurance companies for cancer screening.

Considerable time, effort, and cost are invested not only by me but by the competent staff that makes the Endoscopy Center of Southeast Georgia successful. Great pride is taken in the fact that Toombs County s death rate from colorectal cancer has declined substantially. The CDC reported that the colorectal cancer death rate for Toombs County is among the lowest 10% in the state and nation.

One would think that a facility of this description would be located in a metropolitan area, but the fact is this facility is located in rural Toombs County. Services of this type cannot be found without leaving the area and traveling to a large city. Medicare patients tend to be older and traveling out of town for this type of medical care would be a major inconvenience.

Medicare is proposing to reduce its ASC payment for endoscopy more than 25% by 2008. The rates Medicare is currently allowing ($424.41) is already well below our cost of performing these endoscopy procedures, including screening for cancer. Our practice will lose money on every Medicare patient that comes to our ASC. The facility fees of the Endoscopy Center of Southeast Georgia are affordable and reasonable. The fee is less than 20% of the local hospitals. As an ASC we are able to provide patients with the safest, highest quality of care available.

Congress needs to change its instructions on budget neutrality to avoid cuts in payment reimbursement to ASC s. I know we can continue to provide services to Medicare patients in the ASC and save Medicare money if the reimbursement rules make sense. This proposal, however, does not pass that test.

Thank you for your careful consideration of this request. As a passionate physician in preventing Colorectal Cancer I urge you to convey these concerns to the leadership of the Committees that handle Medicare and to encourage action this year to correct this problem.

Sincerely,
Ronnie R. Smith, M.D.

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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

APC
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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.[1]

[1] *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 that 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.

Sincerely,

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

Attachment A

PREMIER

Table 2: Average Cost and Charges by [illegible] Hospitals

Indication: Procedure Code 78812, Outpatient only, Defined by Premier Standard Charge Code only

Time Period: July 2005 - December 2005

	PET SCAN				IMAGING AGENT			
	N*	%	Average Cost	Average Charges	N*	%	Average Cost	Average Charges
Sample Discharges	**765**	**100.00%**	**$1,336**	**$2,824**	**761**	**100.00%**	**$277**	**$662**
Number of Hospitals	14				13			
Hospital Detail								
HOSPITAL 613009	5	0.65%	$1,135	$3,975	5	0.66%	$127	$445
HOSPITAL 623328	30	3.92%	$1,568	$3,323	30	3.94%	$198	$420
HOSPITAL 623332	56	7.32%	$1,509	$3,323	54	7.10%	$193	$420
HOSPITAL 623333	101	13.20%	$1,890	$3,226	101	13.27%	$160	$494
HOSPITAL 623336	42	5.49%	$1,668	$3,323	42	5.52%	$211	$420
HOSPITAL AL0122	104	13.59%	$808	$2,535	104	13.67%	$242	$758
HOSPITAL IL2028	267	34.90%	$1,533	$2,501	267	35.09%	$364	$593
HOSPITAL MD0048	1	0.13%	$1,582	$2,065				
HOSPITAL MS0028	5	0.65%	$1,243	$3,323	4	0.53%	$156	$420
HOSPITAL MS0057	37	4.84%	$557	$3,184	37	4.86%	$105	$602
HOSPITAL OH2278	21	2.75%	$704	$3,292	21	2.76%	$419	$1,959
HOSPITAL PA2006	56	7.32%	$856	$1,820	56	7.36%	$311	$662
HOSPITAL VA0001	1	0.13%	$1,025	$3,115	1	0.13%	$207	$629
HOSPITAL WV0036	39	5.10%	$984	$3,786	39	5.12%	$383	$1,473

* Represents discharges with cost and charges > 0.

PREMIER

Table 2: Average Cost and Charges by EVU Hospital

Indication: Procedure Code 78812, Outpatient only, Defined by Premier Standard Charge Code only

Time Period: July 2005 - December 2005

	PET SCAN				IMAGING AGENT			
	N*	%	Average Cost	Average Charges	N*	%	Average Cost	Average Charges
Sample Discharges	**1,426**	**100.00%**	**$1,143**	**$3,502**	**1,340**	**100.00%**	**$236**	**$933**
Number of Hospitals	19				19			
Hospital Detail								
HOSPITAL 600501	2	0.14%	$392	$3,149	2	0.15%	$349	$822
HOSPITAL CA2011	8	0.56%	$348	$4,457	8	0.60%	$491	$1,681
HOSPITAL FL0287	101	7.08%	$732	$3,600	100	7.46%	$544	$1,147
HOSPITAL FL9120	173	12.13%	$2,214	$3,787	166	12.39%	$228	$1,147
HOSPITAL GA0126	124	8.70%	$1,103	$5,589	124	9.25%	$103	$525
HOSPITAL KS2072	141	9.89%	$915	$3,109	141	10.52%	$233	$791
HOSPITAL MO2190	1	0.07%	$1,178	$2,247	1	0.07%	$300	$600
HOSPITAL MT2001	8	0.56%	$1,290	$3,469	8	0.60%	$322	$867
HOSPITAL MT2003	85	5.96%	$1,503	$3,872	85	6.34%	$487	$802
HOSPITAL NC0153	1	0.07%	$2,026	$3,411	1	0.07%	$541	$910
HOSPITAL NC0302	1	0.07%	$1,544	$2,625	1	0.07%	$463	$788
HOSPITAL NE2001	16	1.12%	$992	$3,032	16	1.19%	$334	$1,021
HOSPITAL OH2004	192	13.46%	$2,444	$3,894	192	14.33%	$32	$1,306
HOSPITAL SC0053	106	7.43%	$1,695	$2,379	105	7.84%	$366	$564
HOSPITAL SC0074	1	0.07%	$367	$2,900	1	0.07%	$246	$1,034
HOSPITAL WI2004	6	0.42%	$1,115	$3,737	6	0.45%	$763	$761
HOSPITAL WI2007	4	0.28%	$490	$4,093	4	0.30%	$388	$693
HOSPITAL WI2033	1	0.07%	$1,426	$3,000	1	0.07%	$561	$641
HOSPITAL WV0013	455	31.91%	$189	$2,954	378	28.21%	$189	$895

* Represents discharges with cost and charges > 0.

PREMIER

Table 2: Average Cost and Charges Reported by Each Hospital

Indication: Procedure Code 78815 Outpatient only, Defined by Premier Standard Charge Code only

Time Period: July 2005 - December 2005

	PET/CT SCAN				IMAGING AGENT			
	N*	%	Average Cost	Average Charges	N*	%	Average Cost	Average Charges
Sample Discharges	**1,688**	**100.00%**	**$1,147**	**$3,248**	**1,315**	**100.00%**	**$211**	**$748**
Number of Hospitals	14				13			
Hospital Detail								
HOSPITAL 626723	133	7.88%	$726	$2,186	133	10.11%	$287	$863
HOSPITAL CO2087	365	21.62%	$2,321	$4,866				
HOSPITAL FL0091	93	5.51%	$771	$2,900	93	7.07%	$153	$577
HOSPITAL FL0161	322	19.08%	$699	$3,125	322	24.49%	$307	$1,375
HOSPITAL GA2039	2	0.12%	$1,792	$4,901	2	0.15%	$272	$745
HOSPITAL KY0106	74	4.38%	$1,029	$3,429	71	5.40%	$282	$939
HOSPITAL MS0052	3	0.18%	$1,366	$3,650	3	0.23%	$178	$475
HOSPITAL NC0001	379	22.45%	$690	$2,011	376	28.59%	$59	$171
HOSPITAL NE2008	28	1.66%	$1,393	$3,032	28	2.13%	$604	$1,021
HOSPITAL NE2033	1	0.06%	$700	$2,917	1	0.08%	$133	$556
HOSPITAL OH2017	25	1.48%	$720	$3,320	25	1.90%	$102	$416
HOSPITAL PA2006	10	0.59%	$834	$1,789	10	0.76%	$309	$662
HOSPITAL VA0001	222	13.15%	$1,171	$3,685	220	16.73%	$237	$744
HOSPITAL VA0095	31	1.84%	$831	$3,115	31	2.36%	$195	$706

* Represents discharges with cost and charges > 0.

PREMIER

Table 2: Average Cost and Charges by [illegible] Hospital

Indication: Procedure Code 78815, Outpatient only, Defined by Premier Standard Charge Code only

Time Period: July 2005 - December 2005

	PET/CT SCAN				IMAGING AGENT			
	N*	%	Average Cost	Average Charges	N*	%	Average Cost	Average Charges
Sample Discharges	**3,607**	**100.00%**	**$846**	**$4,027**	**3,545**	**100.00%**	**$403**	**$769**
Number of Hospitals	23				23			
Hospital Detail								
HOSPITAL 600501	166	4.60%	$401	$3,155	166	4.68%	$347	$824
HOSPITAL 609531	61	1.69%	$1,024	$3,143	61	1.72%	$228	$625
HOSPITAL 620028	184	5.10%	$1,202	$6,064	177	4.99%	$198	$1,000
HOSPITAL AL0051	309	8.57%	$1,521	$2,884	309	8.72%	$512	$585
HOSPITAL CA2013	411	11.39%	$760	$4,426	406	11.45%	$382	$779
HOSPITAL FL0287	420	11.64%	$753	$3,800	412	11.62%	$545	$1,147
HOSPITAL GA0126	78	2.16%	$906	$4,493	74	2.09%	$103	$500
HOSPITAL GA0178	16	0.44%	$1,896	$3,946	16	0.45%	$433	$901
HOSPITAL KY0022	9	0.25%	$445	$2,127	9	0.25%	$138	$662
HOSPITAL MO2190	6	0.17%	$1,311	$2,247	6	0.17%	$300	$600
HOSPITAL NE2001	69	1.91%	$1,004	$3,032	69	1.95%	$338	$1,021
HOSPITAL OH2004	78	2.16%	$2,404	$3,894	78	2.20%	$32	$1,306
HOSPITAL SD2018	59	1.64%	$731	$2,377	59	1.66%	$296	$1,155
HOSPITAL TX0083	198	5.49%	$851	$3,916	198	5.59%	$846	$806
HOSPITAL TX0393	246	6.82%	$446	$4,379	208	5.87%	$33	$324
HOSPITAL VA0106	6	0.17%	$1,023	$5,182	6	0.17%	$1,023	$410
HOSPITAL VA0112	177	4.91%	$677	$5,182	177	4.99%	$215	$410
HOSPITAL VA2038	108	2.99%	$1,414	$5,182	108	3.05%	$222	$410
HOSPITAL WA2005	41	1.14%	$873	$3,497	41	1.16%	$873	$827
HOSPITAL WI2004	89	2.47%	$1,130	$3,734	89	2.51%	$756	$761
HOSPITAL WI2007	841	23.32%	$481	$4,093	841	23.72%	$388	$693
HOSPITAL WI2008	1	0.03%	$465	$4,093	1	0.03%	$388	$693
HOSPITAL WI2009	34	0.94%	$875	$3,221	34	0.96%	$90	$528

* Represents discharges with cost and charges > 0.

Attachment B