September 15, 2005

Administrator Mark McClellan M.D. PhD
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; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates; Proposed Rule

Dear Administrator McClellan:

We are writing in response to the proposed 2006 Hospital Outpatient Prospective Payment System (HOPPS) Rule, 70 Fed. Reg. 42673, July 25, 2005. The Society of Nuclear Medicine (SNM) representing more than 14,000 physicians, scientists, pharmacists and nuclear medicine technologists appreciates the opportunity to provide comments to assist the Centers for Medicare and Medicaid Services (CMS) in further refining the HOPPS. The SNM is committed to carefully reviewing and providing manageable options for all stakeholders. We appreciate CMS willingness to understand and account for the unique and varying attributes of radiopharmaceuticals and processes used in Nuclear Medicine procedures provided to Medicare beneficiaries. We look forward to working with the CMS collaboratively as you respond to our concerns and recommendations herein.

Additionally, we appreciated the opportunity to recently meet with CMS, along with the ACR and AMI, regarding appropriate reimbursement for diagnostic CT when performed in conjunction with PET/CT (CPT 78814-16). The issue is summarized in our letter to Dr. Simon dated July 11, 2005 which is attached (Addendum A). Our specific concern is appropriate reimbursement for a diagnostic CT study when acquired as part of the same data set as for the PET/CT study itself (what we have referred to as a “single CT acquisition”). Oncology practice is changing as the clinical usefulness of PET/CT technology is learned and applied. Although not yet widely adopted, increasing numbers of facilities are capable and currently performing single CT acquisition when their referring physicians order diagnostic CT (S) and PET/CT. At that meeting, we agreed that most of the technical resources for acquiring diagnostic CT data were the same as for the CT for attenuation correction and anatomical localization of the PET/CT, when only a single CT acquisition is performed. However, there are added costs for acquiring the diagnostic CT data such as for the contrast agent and appropriate nursing and technical personnel. These were not assumed for any previous cost determination, such as for the PEAC, for doing a PET/CT. These costs should be reflected in any new payment scheme proposed. Further, there should be consideration given on
how to properly code for a diagnostic CT when performed as single acquisition with a PET/CT. The Society will work with CMS and our colleagues from AMI and ACR on this issue.

Our comments on the Rule will address proposed changes to radiopharmaceuticals, radiopharmaceuticals handling costs, APC assignment of PET/CT CPT code 78814-6, Packaging issues and CPT relocation issues.

**Non-Pass Through Radiopharmaceuticals**

**Proposed Changes to Radiopharmaceutical (RP) Payment Policy in 2006**

CMS intends to implement “a temporary 1-year policy for CY2006 to pay for radiopharmaceutical agents that are separately payable in CY 2006 based on the hospital’s charge for each radiopharmaceutical agent adjusted to cost.” The SNM agrees with the implementation in CY2006 of this one-year temporary policy, with the understanding that the CMS intends to use the hospital general cost to charge ratio (CCR) and not a department specific CCR to make this adjustment. Radiopharmaceutical revenue codes 0343 and 0344 were implemented by the American Hospital Association effective October 2004. We intend to review the effect these codes could have on the department specific cost to charge ratios in the future. However, at present we would not support use of the department specific CCR for radiopharmaceuticals until we can analyze adoption and impact, which we would not expect to be fully realized for at least two years from implementation date.

We are also concerned about the effect of cost compression using the CCR. This will result in under payment for more expensive radiopharmaceuticals. Table 1 is a comparison of CMS hospital median cost, which CMS would believe is representative of hospital charges reduced to cost, and the GAO Acquisition Cost Survey from the same time period. As radiopharmaceutical costs increase, the differences between actual cost and CMS derived cost increase exponentially. We believe this is from cost (really charge) compression. We ask that CMS recognize this and consider measures to address this phenomenon. As an extreme example, if the general CCR for a hospital is .389 and acquisition cost alone for a therapeutic radiopharmaceutical such as Zevalin or Bexxar is $22,000, it is not likely that hospitals will set their charges at $56,555 for a single radiopharmaceutical. If hospitals charge what we believe is an average charge of $39,000 or less, this same hospital would receive only $15,171, which would be substantially less than for their acquisition costs alone.
Table 1 CMS median cost compared to GAO acquisition median cost

<table>
<thead>
<tr>
<th>HCPCS</th>
<th>Description</th>
<th>2004 CMS Median Unit Cost‡</th>
<th>2004 GAO Median Purchase Price†</th>
<th>% Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>A9500</td>
<td>Technetium Tc 99m Sestamibi, per dose</td>
<td>$70.61</td>
<td>$76.47</td>
<td>-8%</td>
</tr>
<tr>
<td>A9502</td>
<td>Technetium Tc 99m Tetrofosmin, per dose</td>
<td>$63.89</td>
<td>$67.59</td>
<td>-5%</td>
</tr>
<tr>
<td>A9505</td>
<td>Thallous Chloride Tl 201 per mCi</td>
<td>$21.82</td>
<td>$15.49</td>
<td>41%</td>
</tr>
<tr>
<td>A9507</td>
<td>Indium In 111 Capromab Pendetide, per dose</td>
<td>$747.47</td>
<td>$1,841.23</td>
<td>-59%</td>
</tr>
<tr>
<td>A9521</td>
<td>Technetium Tc 99m Exametazime, per dose</td>
<td>$236.06</td>
<td>$456.30</td>
<td>-48%</td>
</tr>
<tr>
<td>C1083</td>
<td>Yttrium 90 Ibritumomab Tiuxetan, per dose</td>
<td>$11,372.45</td>
<td>$19,516.70</td>
<td>-42%</td>
</tr>
<tr>
<td>C1775</td>
<td>Fluorodeoxyglucose (FDG) F-18, per dose (4-40 mCi)</td>
<td>$210.96</td>
<td>$272.80</td>
<td>-23%</td>
</tr>
</tbody>
</table>

†Table 1: Purchase Prices for Radiopharmaceuticals Accounting for 9% of Medicare Spending on SCODs Unit Dose

The SNM supports the use of the hospital general CCR for 2006 for the determination of most radiopharmaceuticals. However, we ask that CMS recognize the general reasonable concern using the general CCR methodology for highly expensive radiopharmaceuticals due to cost compression for those radiopharmaceuticals greater than $500 in acquisition costs per patient study. For these identified radiopharmaceuticals we recommend CMS use external data to verify and pay based on invoice acquisition costs plus handling fees, and/or freeze the CY 2005 payment rates for these radiopharmaceuticals listed in Table 2 that we have identified through our members to be greater than $500 in hospital acquisition costs.
### Table 2. SNM Member Identified Radiopharmaceuticals greater than $500 per dose

<table>
<thead>
<tr>
<th>HCPCS</th>
<th>Description</th>
<th>HOPPS 2005 CY Rates</th>
</tr>
</thead>
<tbody>
<tr>
<td>A4642</td>
<td>Satumomab pendetide per dose</td>
<td>$1,390.25</td>
</tr>
<tr>
<td>A9507</td>
<td>Indium In 111 Capromab Pendetide, per dose</td>
<td>$1,915.23</td>
</tr>
<tr>
<td>A9508</td>
<td>Iobenguane Sulfate I-131, per 0.5 mCi</td>
<td>$996.00</td>
</tr>
<tr>
<td>A9517</td>
<td>Th I131 so iodide cap mCi</td>
<td>$6.57</td>
</tr>
<tr>
<td>A9521</td>
<td>Technetium Tc 99m Exametazime, per dose</td>
<td>$778.13</td>
</tr>
<tr>
<td>A9522</td>
<td>Indium-111 Ibritumonomabtiuxetan per mCi</td>
<td>N/A</td>
</tr>
<tr>
<td>A9523</td>
<td>Yttrium-90 Ibrituminomonabtiuxetan per mCi</td>
<td>N/A</td>
</tr>
<tr>
<td>A9530</td>
<td>Th I-131 so iodide sol mCi</td>
<td>$9.73</td>
</tr>
<tr>
<td>A9533</td>
<td>I-131 tositumomab diagnostic per mCi</td>
<td>N/A</td>
</tr>
<tr>
<td>A9534</td>
<td>I-131 tositumomab therapeut per mCi</td>
<td>N/A</td>
</tr>
<tr>
<td>A9600</td>
<td>Strontium-89 chloride, per mCi</td>
<td>$406.16</td>
</tr>
<tr>
<td>A9605</td>
<td>Samarium Sm153 Lexidronamm, per 50 mCi</td>
<td>$907.33</td>
</tr>
<tr>
<td>C1080</td>
<td>I-131 tositumomab, dx, per dose</td>
<td>$2,241.00</td>
</tr>
<tr>
<td>C1081</td>
<td>I-131 tositumomab, tx, per dose</td>
<td>$19,422.00</td>
</tr>
<tr>
<td>C1082</td>
<td>In-111 ibritumomab tiuxetan, per dose</td>
<td>$2,419.78</td>
</tr>
<tr>
<td>C1083</td>
<td>Yttrium 90 Ibritumomab Tiuxetan, per dose</td>
<td>$20,948.20</td>
</tr>
<tr>
<td>C1093</td>
<td>TC99m fanolesomab per dose</td>
<td>$1,045.80</td>
</tr>
<tr>
<td>C1122</td>
<td>Tc99m Arcitumomab, per vial</td>
<td>$1,079.00</td>
</tr>
<tr>
<td>Q3008</td>
<td>Indium 111 Pentetreotide per 3 mCi</td>
<td>$1,079.00</td>
</tr>
</tbody>
</table>

**Proposed Changes to Radiopharmaceutical (RP) Payment Policy in 2007**

For 2007, clearly CMS is trying to come forth with an equitable solution for all radiopharmaceuticals based on cost of acquisition. We recognize that there are many factors that complicate an easy solution. We were impressed that the GAO survey acquisition cost data seemed to reflect the general experience of our members. Therefore, we believe that the GAO survey model could, in fact, be one basis for acquiring information on which a national rate setting could be established. Alternatively, recognizing the problems that manufactures may have providing certified ASP data, we ask that CMS consider and evaluate using ASP data directly from central radiopharmacies (distributors of radiopharmaceuticals.
Radiopharmaceutical Handling Costs

CMS states in this proposed rule, “We expect that hospitals’ different purchasing and preparation and handling practices for radiopharmaceuticals would be reflected in their charges, which would be converted to costs using hospital specific cost-to-charge ratios”. CMS should not assume that the hospitals have incorporated handling costs in their hospital charges for radiopharmaceuticals. Please refer to Table 1. For all but one radiopharmaceutical, CMS median costs are less than the GAO data for hospital purchase prices that specifically excluded handling fees.

There has been some ambiguity about what costs should be included for radiopharmaceutical charges as opposed to procedure charges. This is complicated by the difference in policy for physician offices as compared to the hospital outpatient. Differing payment policies and lack of clear instructions in the different settings contribute to the uncertainty of where, if anywhere, radiopharmaceutical handling costs are reported by hospitals. We ask that CMS specifically declare where the costs for handling should reside for all settings and give clear direction to providers. We believe due to the variety of radiopharmaceuticals that can be used with the same procedure such as CPT 78802 Radiopharmaceutical localization of tumor or distribution of radiopharmaceutical agent(s); whole body, single day imaging, it is best to incorporate radiopharmaceutical handling costs in the charge for the radiopharmaceutical rather than in the nuclear medicine procedure.

CMS takes a very nice first step to giving hospitals some clarification in this proposed rule on page 42731, CMS states some of the elements to consider including in the hospital radiopharmaceutical charges, “handling cost categories should include all aspects of radiopharmaceuticals handling and preparation, including transportation, storage, compounding, required shielding, inventory management, revision of dosages based on patient conditions, documentation, disposal, and regulatory compliance.” We would add that missing from this list would be time and cost for specially trained personal handling and compounding radiopharmaceuticals, as well as waste and spoilage.

Additionally, CMS should make clear where the radiopharmaceutical handling costs (transportation) costs should reside; that is i.e with acquisition costs or with the handling costs. For CMS information, at present, many radiopharmaceutical invoice acquisition costs could include the “transportation” costs, so we caution CMS regarding the potential for double counting. CMS should be very specific in future communications to providers regarding the components and to which portion CMS believes those cost should be attributed and specifically the transportation costs.

Some additional comments and concerns are also attached in addendum B in a letter addressed to Dr. Miller at MedPAC refuting their statement that handling costs are included in charges for radiopharmaceuticals. CMS states, “we are not proposing to create separate handling categories for radiopharmaceuticals for CY 2006.” The SNM is pleased that CMS does not intend to create codes for CY 2006 as we are concerned about creation of additional C or Q codes for hospitals to report their radiopharmaceutical
handling costs in 2006 for use in 2007 at no reimbursement to the hospital for this additional work. We believe this process will place an undue administrative burden on hospitals. CMS should consider working with medical specialty societies and industry to collect this data and incorporate these added handling costs directly into the final payment rates for radiopharmaceuticals by individual HCPCS code.

To assist CMS, as requested, “we are seeking specific categories for potentially capturing radiopharmaceutical handling costs,” below are some potential radiopharmaceutical handling categories;

IA    Single Photon Emitting Diagnostic Radiopharmaceutical for a nuclear medicine procedure, supplied as a unit dose
IB    Single Photon Emitting Diagnostic Radiopharmaceutical for a nuclear medicine procedure, compounded on-site
IIA   Radiopharmaceutical for a Therapeutic nuclear medicine procedure, supplied as a unit dose
IIB   Radiopharmaceutical for a Therapeutic nuclear medicine procedure, compounded on-site
IIIA  Positron Emitting Diagnostic Radiopharmaceutical for a nuclear medicine procedure, supplied as a unit dose
IIIB  Positron Emitting Diagnostic Radiopharmaceutical for a nuclear medicine procedure, compounded on-site
IV    Add-on Handling Costs associated with a Radiopharmaceutical compounded off-site, not included in acquisition costs or handling costs in categories I-III. (Use in addition to I-III above.)

New Technology

Assignment of Concurrent PET/CT for anatomic Localization

We appreciate CMS responsiveness in correcting payment rates for 78814, 78815, 78816 to restore APC placement and payments to 2005 rates in this proposed 2006 rule. As we have stated in the past, the differential in reimbursement for PET/CT and PET does not reflect the resources required to perform PET/CT. We are aware that the Academy of Molecular Imaging AMI is submitting external data in support of higher payment and reclassification for PET/CT. We support this proposal because of the higher capital and personnel costs in performing PET/CT. We ask that the data submitted be used to adjust PET/CT payment rates accordingly.
CMS Commitment to New Technologies

CMS is proposing to change the application and review process for assignment of new services to New Technology APCs. CMS proposes to require that an application for a code for new technology service be submitted to the American Medical Association (AMA) CPT Editorial Panel before CMS will accept a New Technology APC application for review. The SNM is somewhat concerned with the proposed requirement for submission of a CPT application for a Category I or III code, prior to accepting an application for a new technology APC for review.

We appreciate the reasons for this proposal. We ask that this new criteria remain as stated, that is, that an application has been submitted to CPT but not necessarily yet reviewed and processed by the AMA CPT Panel.

Relative Weights

Packaging Issues – Dipyridamole J1245

There are currently three major pharmacological stress agents used with cardiovascular nuclear medicine procedures, Adenosine (J0152 & C9223), Dipyridamole (J1245) and Dobutamine (J1250). Dobutamine is a low cost stress agent, which is used under very specific clinical indications in nuclear medicine. Adenosine and Dipyridamole are currently commonly used stress agents in nuclear medicine currently with a K status indicator, paid for separately.

We are concerned with the CMS proposal to bundle dipyridamole into the procedure in 2006, when the reported median cost is just under $50. (The median data file on the CMS web site cost per procedure for dipyridamole is $48.85.) There are clinical situations where the physician would prefer to utilize a particular pharmaceutical stress agent. We would not want payment rules to affect a patient access to a stress agent which may be clinically most effective for him/her.

The SNM recommends CMS maintain a status indicator of K for J1245 Dipyridamole.

Packaging Issues – CMS Clarification to Hospitals

The SNM commends CMS for the clarification and education to hospitals regarding the importance of coding and reporting charges for radiopharmaceuticals. We have seen several statements in transmittals and in federal register publications over the past year and we believe this persistent education has resulted in better data to CMS from hospitals. We believe that the CMS clarifications plus some stabilized HCPCS appropriate description codes, coupled with professional society intense education programs has lead to more accurately identified and separately paid radiopharmaceuticals as shown in the Table 3 below (Radiopharmaceutical changes in status indicator from N to K in this proposed rule).
We support these changes and encourage CMS to continue to remind hospitals to report charges regardless of N, K or H status indicators, as these charges plays a key role in setting future APC rates and assignment of appropriate status indicators.

Table 3 Radiopharmaceutical changes in status indicators “N” to “H”

<table>
<thead>
<tr>
<th>HCPCS</th>
<th>Description</th>
<th>Payment Status 2005</th>
<th>Payment Status 2006</th>
</tr>
</thead>
<tbody>
<tr>
<td>A9516</td>
<td>Supply of Radiopharmaceutical Diagnostic Imaging Agent, I-123 Sodium Iodide Capsule, per 100 uCi</td>
<td>N</td>
<td>H</td>
</tr>
<tr>
<td>A9524</td>
<td>Supply of Radiopharmaceutical Diagnostic Imaging Agent, Iodinated I-131 Albumin, per 5 uCi</td>
<td>N</td>
<td>H</td>
</tr>
<tr>
<td>A9531</td>
<td>Supply of Radiopharmaceutical Diagnostic Agent, I-131 sodium iodide, per uCi (up to 100 microcuries)</td>
<td>N</td>
<td>H</td>
</tr>
<tr>
<td>A9532</td>
<td>Supply of Radiopharmaceutical Therapeutic Agent, iodinated I-125, serum albumin, 5 microcuries</td>
<td>N</td>
<td>H</td>
</tr>
<tr>
<td>C9000</td>
<td>Injection, Sodium Chromate Cr51, per 0.25 mCi</td>
<td>N</td>
<td>H</td>
</tr>
<tr>
<td>C9102</td>
<td>Supply of Radiopharmaceutical Diagnostic Imaging Agent, 51 Sodium Chromate, per 50 mCi</td>
<td>N</td>
<td>H</td>
</tr>
<tr>
<td>C9103</td>
<td>Supply of Radiopharmaceutical Diagnostic Imaging Agent, Sodium Iothalmate I-125 Injection, per 10 uCi</td>
<td>N</td>
<td>H</td>
</tr>
<tr>
<td>Q3006</td>
<td>Supply of Radiopharmaceutical Diagnostic Imaging Agent, Technetium Tc99m Glucepatate, per 5 mCi</td>
<td>N</td>
<td>H</td>
</tr>
<tr>
<td>Q3010</td>
<td>Supply of Radiopharmaceutical Diagnostic Imaging Agent, Technetium Tc99m Labeled Red Blood Cells, per mCi</td>
<td>N</td>
<td>H</td>
</tr>
</tbody>
</table>

Packaging Issues – CPT 38792

We recognize CMS and the APC Panel are not concerned with cost allocations within hospitals. If nuclear medicine costs are inappropriately bundled into surgical procedures, CMS and others believe these costs are accounted for and paid to the hospitals. CMS believes the hospital is responsible for cost accounting to get the dollars back to the appropriate department.

However, we would like to call your attention that hospitals are performing injection-only procedures for external sites such as surgical centers. Many surgical centers do not have the proper licenses or personnel to purchase, handle and administer radiopharmaceuticals. In these cases both the Sentinel Node injection procedure CPT 38792, and any one of the three radiopharmaceuticals listed in Table 4 are currently bundled with status indicator N. Hospitals currently have no mechanism to code and bill for this as they are not allowed to bill two bundled codes on a claim alone.

We note CMS recognized and corrected similar situations for the bladder catheterization codes CPT 51701, 51702, 51703 as well as the injection codes CPT 90783, 90784, 90788 and 90799. We agree that
The SNM recommends CMS change the status indicator for CPT 38792 from N to X and place in APC 0359 in 2006.

**APC Assignments**

**Relocation Issues – CPT 78730**

Last year we brought to the attention of CMS that CPT 78730 is a nuclear medicine imaging procedure. We also brought to your attention that the high volume and low median cost data was due to inappropriate use by other specialties. Since that time, the SNM has notified AdminaStar Federal of the need for CCI edits.

At the February 2005 APC panel meeting the, The Panel recommends that CMS move CPT code 78730, urinary bladder residual study, to APC 404, assuming that new data confirmed that previous data were derived from incorrectly coded hospital claims.

However, CMS has failed to restore CPT 78730 to APC 404 as requested in our October 2004 and the January 2005 comments. CMS further suggested that a nuclear medicine technologist is not needed to perform this procedure; we continue to disagree with this CMS statement. This procedure is a nuclear medicine imaging procedure, which we believe has been historically miscoded in combination with non-imaging urological procedures. Placement of CPT 78730 Urinary bladder last year resulted in a 30.58% reduction in payment. While we recognize CMS made these decisions based on miscoded claims, this issue of miscoded claims should be resolved for 2006 and therefore CMS should restore CPT 78730 to its correct APC grouping 0404.

The SNM recommends CMS restore 78730 to APC 0404.
Relocation Issues – CPT 78700

The SNM has identified another procedure, CPT 78700 (Kidney imaging, static) which the CMS proposes to move from APC 0404 to 0267 Level III Diagnostic ultrasound. This change represents a 30.58% reduction in payment from 2005. The SNM is concerned with the CMS process and rational for moving APCs from clinically similar APCs to an unrelated non-clinically homogenous APC. CMS appears to make these decisions strictly on hospital costs reduced to charges and not aligning the procedures in APCs that are clinically similar.

At this time, we are unsure why CMS data has shown a shift in the costs of CPT 78700 Kidney imaging; static only. This procedure has NOT clinically or economically changed. We suggest that when CMS moves a CPT from one APC to another and the payment is increased or decreased by more than 10%, CMS should provide rational for why the move was necessary and why they choose the particular placement. This would allow the community opportunity to comment on the CMS rational as well as the placement.

▶ The SNM recommends CMS restore 78700 to APC 0404.

We thank you for your attention and consideration of these recommendations and comments. We look forward to continue working with CMS as we refine the Nuclear Medicine Procedure and Radiopharmaceutical APCs. If you need additional information, please contact the SNM staff, Denise Merlino at 781-435-1124 or dmerlino@snm.org.

Respectfully Submitted,

Gary Dillehay, M.D., FACR, FACNP
Chairman, Coding & Reimbursement Committee

Kenneth McKusick, M.D., FACR, FACNP
SNM Coding Advisor

cc: Herb Kuhn, CMS
    Kenneth Simon, MD, CMS
    Edith Hambrick, MD, CMS
    James Hart, CMS
    Joan Sanow, CMS
    SNM Coding & Reimbursement Committee
    Nuclear Medicine APC Task Force
Addendum A

July 11, 2005

To: Kenneth Simon M.D.
Re: Coding for PET/CT plus Diagnostic CT

CPT codes 78814-16 were first published in CPT 2005 to report tumor PET functional imaging in CT anatomical space. Over two years ago, when the Society of Nuclear Medicine Inc and American College of Radiology applied for those new codes, Tumor PET combined with concurrent CT for both attenuation correction and anatomical localization: limited, torso, or whole body, it was not thought that diagnostic quality CT data could or would be acquired during the CT phase of the study. Now, however, state of the art PET/CT integrated systems can acquire CT data for attenuation correction, anatomical localization and CT diagnosis simultaneously.

This was not anticipated. Although CPT does instruct users to add modifier 59 to a CT study done in addition to a PET/CT study, it was our general understanding at the time, that this would be for those uncommon occurrences that a separate CT study might be indicated on the same day as the PET/CT study (e.g. a chest CT for possible pulmonary embolism on the same say as a PT/CT done for neoplasm restaging).

Diagnostic CT studies are being requested by referring physicians and done not uncommonly with PET/CT studies on the same day. There are several possible acquisition scenarios:

1. Separate diagnostic CT(s) done on a CT device separate from the PET/CT.
2. Separate diagnostic CT(s) acquisition done after the PET/CT study (where the first CT data acquisition, done without contrast and as part of the PET/CT study, may be done at less than state of the art diagnostic quality using low maS for attenuation correction and anatomical localization, on the same device.
3. Diagnostic CT(s) done as part of the attenuation correction and anatomical phase of the PET/CT study.

The technical resources required to obtain the imaging data would not be the same for all three, even though the final product would be the same: a PET/CT study with anatomical localization and one or more diagnostic CTs, (e.g. chest, abdomen and/or pelvis.

#1 requires a minimum three imaging acquisitions (one PET and two CT) on two devices, #2 requires these three imaging acquisition on one device, and #3 requires a minimum of two imaging acquisitions (one PET and one CT) on one device.

As discussed with you, we would like to meet with CMS to discuss the current state of PET/CT imaging in oncology, and to develop a common understanding of the possible resource costs associated with the various imaging algorithms. The American College of Radiology, the Academy of Molecular Imaging and the Society of Nuclear Medicine, Inc would attend.

Ken McKusick M.D
Society of Nuclear Medicine
Addendum B

Aug 2, 2005

Via email

Mark Miller, Ph.D.
Executive Director, MedPAC
601 New Jersey Ave. N.W.
Suite 9000
Washington, DC 20001

RE: Request for Clarification: June 2005 MedPAC Report – Pharmacy Handling Costs in Hospital Outpatient Departments for Radiopharmaceuticals

Dear Dr. Miller:

On behalf of the Nuclear Medicine APC Task Force (NM APC TF), I thank you and your staff for taking the time on the conference call last May 25th, as well as the in person meeting on November 3, 2004 to discuss your report to Congress on the handling costs for radiopharmaceuticals and other products in the hospital outpatient department. Since then, your June 2005 Report to Congress was released which captured many of the unique overhead and handling costs related to radionuclides and radiopharmaceuticals (“RPs”). This letter provides additional clarification and follow-up on an issue important to any policy making on Medicare payment for radiopharmaceuticals.

The NM APC TF agrees with your primary finding that among the categories of products, RPs require unique resources including special equipment and protection for patients and staff during storage, preparation, and disposal, which, in turn, lead to higher costs. Further, hospitals must ensure and document compliance with federal and state requirements.

The NM APC TF is troubled by the MedPAC statement referring to commercially prepared patient unit doses that “the invoices for the product combines handling costs with acquisition costs and delivery fees” (June 2005 Report, Ch. 6, page 147). Although this statement is true regarding some handling costs in preparation that would otherwise be done “in-house”, we believe this is misleading to CMS and others should MedPAC’s choice of words be taken literally. Simply stated, a minor part of the routine handling costs are covered by invoices for commercially prepared unit doses. A more accurate statement might be that “invoices for the product may combine some of the handling costs etc. We support CORAR’s comment in their recent letter to you, that “all hospital outpatient departments (both “make” and “buy” models) that furnish radiopharmaceuticals (unit dose or components) must purchase special shielding equipment and dose calibrators, monitor employee exposure to radiation, employ radiation safety officers, and comply with specific regulations regarding radioactive material, waste, storage, and disposal, licensure, quality assurance and safety. Freestanding independent radiopharmacies that distribute and sell unit-dose radiopharmaceuticals do not factor in on an invoice the unique hospital handling costs related to, among other things, licensure, safety, employee monitoring, and quality
assurance. Therefore, it would be incorrect to imply all pharmacy handling costs for unit-dose radiopharmaceuticals are included on an invoice from an outside vendor.”

The MedPAC study on pharmacy costs associated with RPs may be the first to specifically analyze the handling and overhead costs and resources associated with RPs. Thus, your report may be accorded great weight in decisions regarding payment for RPs. The NM APC TF would appreciate a statement from MedPAC that qualifies the original statement. Specifically, we ask that MedPAC write to CMS and clarify that invoices for unit dose preparations do not include all the hospitals’ handling costs such as those associated with receiving the RP, dose measurements and quality assurance tests prior to administration, storage, disposal, regulatory compliance, and safety.

The NM APC TF would be pleased to discuss this further with MedPAC. In light of the published proposed HOPPS rule, the NM APC TF also intends to meet with CMS to help clarify and assist in the development of HOPPS payment policy that accurately reflects overhead costs for radiopharmaceuticals.

We thank you for your attention and consideration of these recommendations and comments. If you need additional information, please contact the NM APC TF staff, Denise Merlino at 781-435-1124 or dmerlino@snm.org.

Sincerely,

Kenneth A. McKusick, MD FACR FACNP
Chair, Nuclear Medicine APC Task Force

cc: Rachel Schmidt, Ph.D., MedPAC (via email)  
    Sarah Thomas, M.S.; MedPAC (via email)  
    Don Thompson, Director, Hospital and Ambulatory Policy Group, CMS (via email)  
    Edith Hambrick, M.D., J.D., Chair, APC Panel (via email)  
    NM APC TF members (via email)