

August 30, 2012

Marilyn B. Tavenner
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare Program: Changes to the Hospital Outpatient Prospective Payment System and CY 2013 Payment Rates; Proposed Rule CMS-1589-P

Dear Acting Administrator Tavenner:

We are writing in response to the Calendar Year (CY) 2013 Hospital Outpatient Prospective Payment System (HOPPS) Proposed Rule, published July 30, 2012 *Federal Register* Vol. 77 No. 146 p. 45061. The Society of Nuclear Medicine and Molecular Imaging's (SNMMI) more than 18,000 members set the standard for molecular imaging and nuclear medicine practice by creating guidelines, sharing information through journals and meetings, and leading advocacy on key issues that affect molecular imaging and therapy research and practice. We appreciate the opportunity to provide comments to assist the Centers for Medicare & Medicaid Services (CMS) in further refining the HOPPS.

We offer comments and recommendations on the following topics addressed in this proposed rule:

- Add-On Payment Adjustment Policy for Radioisotopes Derived from non-Highly Enriched Uranium (non-HEU) Sources
 - Authority, Transparency in Methodology
 - Code Description Modification & Unit Clarification
 - Other Clarifications
- Separately Payable Drugs Without Pass-Through Status
- Increase in Threshold for Drugs, Biologicals, and Tx RPs That Are Paid Separately
- Therapeutic Radiopharmaceuticals (Tx RPs)

**Add-on Payment Adjustment Policy for Radioisotopes Derived from non-HEU Sources
Authority, Transparency in Methodology**

CMS included a proposal regarding non-HEU sources in response to the White House Administration's agenda to eliminate domestic reliance on reactors outside of the United States that produce highly enriched uranium (HEU), and to promote the conversion of all medical isotope production to non-HEU sources. Specifically, the CMS is proposing to exercise their statutory authority to make payment adjustments necessary to ensure equitable payments, to provide an adjustment for CY 2013 and in

future years, to cover the costs of hospital conversion to use of non-HEU sources to obtain radioisotopes used in medical imaging. **The SNMMI agrees with the CMS assertion that the current 2012 HOPPS diagnostic radiopharmaceutical packaging policy does not support the hospital nuclear medicine community adoption of increased costs, as would be imposed, in moving to non-HEU sources.**

We appreciate the efforts of CMS to implement this non-HEU policy change with a goal to achieve full cost recovery supporting the conversion to use of non-HEU sources to obtain diagnostic radiopharmaceuticals. However, we believe there are many unknowns and moving parts which complicate implementation of this policy by CMS, hospitals and other nuclear medicine industry stakeholders. In order to avoid placing undue burden on the patient or hospital, we urge CMS to continue to work with all stakeholders to help provide offset payments that flow to the supply chain. While this proposed policy focuses on technetium based non-HEU products, it should not exclude other byproduct produced non-HEU radiopharmaceuticals (e.g. I-131).

The SNMMI agrees that CMS does have the statutory authority to make adjustments, to ensure equitable payments in HOPPS. However, what is less clear at this time is the amount of the increased costs that will be passed on to the hospitals for the purchase of non-HEU diagnostic radiopharmaceuticals and hence the CMS estimate of \$10 per dose. In the proposed rule CMS states, “We are proposing to base this payment on the best available estimations of the marginal costs associated with non-HEU radioisotope production,” yet in the proposed rule there is no mention of how the \$10 was derived by CMS. Therefore, of most importance, we believe CMS should be transparent in any methodology to calculate or adjust this non-HEU add-on payment. The SNMMI is concerned that CMS did not disclose for public input, in the proposed rule, a clear methodology for the establishment of the \$10 per dose rate nor does CMS specify how future adjustments would be made. **We strongly urge CMS to publish the methodology used to establish the \$10 amount (or modified in the final rule) add-on payment, as well as, publish the methodology for necessary future adjustments.**

We believe that CMS could consider the current average sales price (ASP) methodology as a model specifically as it is applied to the therapeutic radiopharmaceuticals in establishing a voluntarily standardized transparent methodology for the add-on payment adjustment. We recognize the ASP standard methodology is imperfect for some diagnostic radiopharmaceuticals; however there are elements which are desirable for this add on payment methodology. Elements of the standard drug ASP methodology which we believe CMS should consider are the following: transparency, the publication of aggregate data, and quarterly updates of data to allow for quarterly updated payments. Elements of the therapeutic radiopharmaceutical ASP methodology which are desirable are that they are voluntarily submitted and account for the unique aspects of radiopharmaceuticals. We believe that CMS should be transparent in rate setting so that hospitals can maintain some measurable level of predictability. Absent data and review of the methodology, we are unclear if the \$10 per study dose is adequate and or appropriate for this add-on payment.

QXXXX Code Description Modification & Unit Clarification

CMS states, “We are proposing to establish a new HCPCS code, QXXXX (Tc-99m from non-HEU source, full cost recovery add-on, **per dose**) to describe the Tc-99m radioisotope produced by non-HEU methods and used in a diagnostic procedure.” The SNMMI, as stated earlier, would prefer a method which did not require the implementation of a code; however, if tracking and documentation are necessary for a CMS add-on policy, the SNMMI agrees that a single code to report the Tc-99m from non-HEU source is likely the least burdensome to implement. Therefore, if CMS maintains the voluntary nature of the reporting, we would support the CMS creation of a single HCPCS level II code, with one minor modification; add the word “study” prior to the word dose. This change would better clarify appropriate units and mirror other existing diagnostic radiopharmaceutical HCPCS Level II code descriptions. In addition it would account for CPT procedure codes that report multiple procedure studies, therefore multiple doses in one CPT code. Specifically, ***the SNMMI requests the CMS modify the proposed description of the QXXXX code, by adding the word “study”. Therefore the code description would be QXXXX (Tc-99m from non-HEU source, full cost recovery add-on, per study dose***. We have supplied a list of HCPCS Level II diagnostic radiopharmaceutical codes at the end of this letter in Table 1 that shows that 100 percent of the time a description is labeled per dose, the description is “per study dose”.

The rationale for adding the word “study” is that several nuclear medicine procedures could require multiple Tc99m doses being administered along with one CPT procedure code. Providers would purchase 1-3 study doses and CMS must make clear that the add-on payment would apply to each per study dose of the complete service as described by the CPT procedure code. Examples of nuclear medicine procedures which **could have more than (1) study dose** with a non-HEU sources are as follows:

- 78452: Myocardial perfusion imaging, tomographic (SPECT) (including attenuation correction, qualitative or quantitative wall motion, ejection fraction by first pass or gated technique, additional quantification, when performed); **multiple studies**, at rest and/or stress (exercise or pharmacologic) and/or redistribution and/or rest reinjection
- 78454: Myocardial perfusion imaging, planar (including qualitative or quantitative wall motion, ejection fraction by first pass or gated technique, additional quantification, when performed); **multiple studies**, at rest and/or stress (exercise or pharmacologic) and/or redistribution and/or rest reinjection
- 78483: Cardiac blood pool imaging (planar), first pass technique; **multiple studies**, at rest and with stress (exercise and/or pharmacologic), wall motion study plus ejection fraction, with or without quantification

- 78709: Kidney imaging morphology with vascular flow and function, **multiple studies**, with and without pharmacological intervention (eg, angiotensin converting enzyme inhibitor and/or diuretic)
- 78582: Pulmonary **ventilation** imaging (eg, aerosol or gas) and **perfusion** imaging
- 78598: Quantitative differential pulmonary **perfusion** and **ventilation** (eg, aerosol or gas), including imaging when performed

Additionally, the **SNMMI requests CMS clarify in the final rule the intent for multiple study dose procedures. Providers may bill the QXXXX code with multiple units and be paid (\$10) per the number of study doses provided during the procedure CPT code, as appropriate.**

Other Clarifications to the non-HEU Policy

Current language within the proposed rule states “if the industry should implement labeling of generators and/or doses with **labels attesting** to 100 percent non-HEU sources prices at Full Cost Recovery, documentation of labeled isotope usage using either the specific dose approach or the 100 percent hospital usage approach could provide evidence of hospital compliance.” **The SNMMI requests official CMS clarification in the final rule regarding the adequate documentation necessary to confirm that the provider obtained a dose for a particular patient is 100 percent non-HEU.** The term “attesting” in the ASP model is significantly different from what we believe the intent of this CMS policy is stating. Therefore, CMS must further clarify what constitutes an adequate and appropriate documentation of the percent of non-HEU for the hospital community. We do not believe CMS intended nor should CMS place significant administrative burden on the hospital or nuclear medicine industry to achieve this goal.

Further language states that CMS will “continue to calculate the total costs of radionuclide scans using claims data, and would periodically recalculate the estimated marginal cost of non-HEU Full Cost Recovery sources using models relying on the best available industry reports and projections, and would adjust the payment for HCPCS QXXXX code accordingly, reducing the payment for the scans by the amount of cost paid through HCPCS QXXXX code payment.” **The SNMMI requests clarification on the proposed implementation date and methodology of this section.** It is our understanding that this would not occur in 2013 or 2014 as data would not yet be available, and the intent is to ensure that there is no double counting for the rate setting for 2015 and beyond. Additionally, as stated earlier in these comments, we believe that CMS should clearly define in proposed rules open to comment period, any payment methodology calculation in the establishment or modifications of this add-on payment or effects of future APC payment rates.

Additionally, the SNMMI has reservations regarding the ability of hospitals and industry to transition to 100% non-HEU in 2013 or 2014. The SNMMI fears that this proposed CMS goal might be unattainable due to the lack of availability of the supply at 100 percent. While conversion to LEU remains an

important goal for us all, too many unknowns remain. We have concerns from past years fragile supply of diagnostic radiopharmaceuticals, which could be carried into the future if the supply chain is fragmented potentially putting patients' diagnostic procedures at risk. Nevertheless, we support this proposed 100 percent goal for future years and believe it will be a more realistic to achieve by a larger percentage of hospitals with a phase in approach. Therefore, **the SNMMI recommends that CMS consider options for a phase in approach to the percentage utilization of non-HEU that would be less than 100 percent for 2013. CMS should continue to work with industry stakeholders and remain flexible as we see this process and availability of the product evolving.**

Separately Payable Drugs without Pass-Through Status

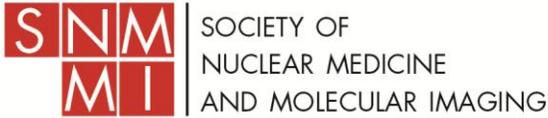
The SNMMI appreciates CMS's recommendation that separately payable drugs and biological without pass-through status should be paid at 106 percent of the ASP in place of the current rate of 104 percent of ASP in 2012. We agree that the statutory default of ASP+6 percent is appropriate as it yields increased predictability in payment for separately payable drugs and biologicals under the OPPI and is consistent with payment amounts yielded by drug payment methodologies in recent years.

Increase in Threshold for Drugs, Biologicals, and Radiopharmaceuticals That Are Paid Separately

The SNMMI has concerns with the increase of \$5 in the threshold for drugs, biologicals, and radiopharmaceuticals that are paid separately. The CY2012 Final Rule set the threshold for establishing separate APCs for drugs and biologicals at \$75 per day, a \$5 increase from CY2011. *Regardless of the formula CMS has used in previous years, the SNMMI has apprehensions with the steep escalating of cost per day threshold from \$50 in CY 2006 to the current proposed amount of \$80. **Therefore, the SNMMI strongly urges CMS to reconsider the APC Panel's recommendation to freeze the packaging threshold at \$75.***

Therapeutic Radiopharmaceuticals (Tx RPs)

The SNMMI appreciates the continuation of the CMS policy for separately payable therapeutic (Tx) radiopharmaceuticals (RPs) in 2013, setting the prospective payment rate on voluntary manufacturer-submitted average sales price (ASP) data when available or, if not available, using CMS claims data. The SNMMI supports the ASP methodology, as we believe it is the most reflective of the actual costs incurred by hospitals.



The SNMMI appreciates the opportunity to comment on this HOPPS 2013 Proposed Rule to the CMS. As always, the SNMMI is ready to discuss any of its comments or meet with CMS on the above issues. In this regard, please contact Susan Bunning, Vice President, Government Affairs, by email at sbunning@snmmi.org or by phone at 703-326-1182.

Respectfully Submitted,

A handwritten signature in black ink, appearing to read 'Frederic H. Fahey'.

Frederic H. Fahey, DSc
President, SNMMI

CC:

John McInnes, MD, JD
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SNM Coding & Reimbursement Committee

Table 1 Diagnostic Radiopharmaceuticals (dx RP)

39 of 54 dx RP code descriptions contain the description **Per Study Dose** (PSD); the other 15 are not per dose descriptions.

HCPCS Level II 2012 Code	Short & Long Description
A4642	In111 satumomab INDIUM IN-111 SATUMOMAB PENDETIDE, DIAGNOSTIC, <u>PER STUDY DOSE</u> , UP TO 6 MILLICURIES
A9500	Tc99m sestamibi TECHNETIUM TC-99M SESTAMIBI, DIAGNOSTIC, <u>PER STUDY DOSE</u> , UP TO 40 MILLICURIES
A9501	Technetium TC-99m teboroxime TECHNETIUM TC-99M TEBOROXIME, DIAGNOSTIC, <u>PER STUDY DOSE</u>
A9502	Tc99m tetrofosmin TECHNETIUM TC-99M TETROFOSMIN, DIAGNOSTIC, <u>PER STUDY DOSE</u>
A9503	Tc99m medronate TECHNETIUM TC-99M MEDRONATE, DIAGNOSTIC, <u>PER STUDY DOSE</u> , UP TO 30 MILLICURIES
A9504	Tc99m apcitide TECHNETIUM TC-99M APCITIDE, DIAGNOSTIC, <u>PER STUDY DOSE</u> , UP TO 20 MILLICURIES
A9505	TL201 thallium THALLIUM TL-201 THALLOUS CHLORIDE, DIAGNOSTIC, PER MILLICURIE
A9507	In111 capromab INDIUM IN-111 CAPROMAB PENDETIDE, DIAGNOSTIC, <u>PER</u>



	<u>STUDY DOSE</u> , UP TO 10 MILLICURIES	
A9508	I131 iodobenguante, dx IODINE I-131 IOBENGUANE SULFATE, DIAGNOSTIC, PER 0.5 MILLICURIE	
A9509	Iodine I-123 sod iodide mil IODINE I-123 SODIUM IODIDE, DIAGNOSTIC, PER MILLICURIE	
A9510	Tc99m disofenin TECHNETIUM TC-99M DISOFENIN, DIAGNOSTIC, <u>PER STUDY DOSE</u> , UP TO 15 MILLICURIES	
A9512	Tc99m pertechnetate PERTECHNETATE, DIAGNOSTIC, PER MILLICURIE	TECHNETIUM TC-99M
A9516	Iodine I-123 sod iodide mCi IODINE I-123 SODIUM IODIDE, DIAGNOSTIC, PER 100 MICROCURIES, UP TO 999 MICROCURIES	
A9521	Tc99m exametazime TECHNETIUM TC-99M EXAMETAZIME, DIAGNOSTIC, <u>PER STUDY DOSE</u> , UP TO 25 MILLICURIES	
A9524	I131 serum albumin, dx SERUM ALBUMIN, DIAGNOSTIC, PER 5 MICROCURIES	IODINE I-131 IODINATED
A9526	Nitrogen N-13 ammonia NITROGEN N-13 AMMONIA, DIAGNOSTIC, <u>PER STUDY DOSE</u> , UP TO 40 MILLICURIES	
A9528	Iodine I-131 iodide cap, dx IODINE I-131 SODIUM IODIDE CAPSULE(S), DIAGNOSTIC, PER MILLICURIE	
A9529	I131 iodide sol, dx IODINE I-131 SODIUM IODIDE SOLUTION, DIAGNOSTIC, PER MILLICURIE	



A9531	I131 max 100uCi IODINE I-131 SODIUM IODIDE, DIAGNOSTIC, PER MICROCURIE (UP TO 100 MICROCURIES)
A9532	I125 serum albumin, dx IODINE I-125 SERUM ALBUMIN, DIAGNOSTIC, PER 5 MICROCURIES
A9536	Tc99m depreotide TECHNETIUM TC-99M DEPTEOTIDE, DIAGNOSTIC, <u>PER STUDY DOSE</u> , UP TO 35 MILLICURIES
A9537	Tc99m mebrofenin TECHNETIUM TC-99M MEBROFENIN, DIAGNOSTIC, <u>PER STUDY DOSE</u> , UP TO 15 MILLICURIES
A9538	Tc99m pyrophosphate TECHNETIUM TC-99M PYROPHOSPHATE, DIAGNOSTIC, <u>PER STUDY DOSE</u> , UP TO 25 MILLICURIES
A9539	Tc99m pentetate TECHNETIUM TC-99M PENTETATE, DIAGNOSTIC, <u>PER STUDY DOSE</u> , UP TO 25 MILLICURIES
A9540	Tc99m MAA TECHNETIUM TC-99M MACROAGGREGATED ALBUMIN, DIAGNOSTIC, PER STUDY DOSE, UP TO 10 MILLICURIES
A9541	Tc99m sulfur colloid TECHNETIUM TC-99M SULFUR COLLOID, DIAGNOSTIC, <u>PER STUDY DOSE</u> , UP TO 20 MILLICURIES
A9542	In111 ibritumomab, dx INDIUM IN-111 IBRITUMOMAB TIUXETAN, DIAGNOSTIC, <u>PER STUDY DOSE</u> , UP TO 5 MILLICURIES
A9544	I131 tositumomab, dx IODINE I-131 TOSITUMOMAB, DIAGNOSTIC, <u>PER STUDY DOSE</u>



A9546	Co57/58 COBALT CO-57/58, CYANOCOBALAMIN, DIAGNOSTIC, <u>PER STUDY DOSE</u> , UP TO 1 MICROCURIE
A9547	In111 oxyquinoline INDIUM IN-111 OXYQUINOLINE, DIAGNOSTIC, PER 0.5 MILLICURIE
A9548	In111 pentetate INDIUM IN-111 PENTETATE, DIAGNOSTIC, PER 0.5 MILLICURIE
A9550	Tc99m gluceptate TECHNETIUM TC-99M SODIUM GLUCEPTATE, DIAGNOSTIC, <u>PER STUDY DOSE</u> , UP TO 25 MILLICURIES
A9551	Tc99m succimer TECHNETIUM TC-99M SUCCIMER, DIAGNOSTIC, <u>PER STUDY DOSE</u> , UP TO 10 MILLICURIES
A9552	F18 fdg FLUORODEOXYGLUCOSE F-18 FDG, DIAGNOSTIC, <u>PER STUDY DOSE</u> , UP TO 45 MILLICURIES
A9553	Cr51 chromate CHROMIUM CR-51 SODIUM CHROMATE, DIAGNOSTIC, <u>PER STUDY DOSE</u> , UP TO 250 MICROCURIES
A9554	I125 iothalamate, dx IODINE I-125 SODIUM IOTHALAMATE, DIAGNOSTIC, <u>PER STUDY DOSE</u> , UP TO 10 MICROCURIES
A9555	Rb82 rubidium RUBIDIUM RB-82, DIAGNOSTIC, <u>PER STUDY DOSE</u> , UP TO 60 MILLICURIES
A9556	Ga67 gallium GALLIUM GA-67 CITRATE, DIAGNOSTIC, PER MILLICURIE



A9557	Tc99m bicisate TECHNETIUM TC-99M BICISATE, DIAGNOSTIC, <u>PER STUDY DOSE</u> , UP TO 25 MILLICURIES
A9558	Xe133 xenon 10mci XENON XE-133 GAS, DIAGNOSTIC, PER 10 MILLICURIES
A9559	Co57 cyano COBALT CO-57 CYANOCOBALAMIN, ORAL, DIAGNOSTIC, <u>PER STUDY DOSE</u> , UP TO 1 MICROCURIE
A9560	Tc99m labeled rbc TECHNETIUM TC-99M LABELED RED BLOOD CELLS, DIAGNOSTIC, <u>PER STUDY DOSE</u> , UP TO 30 MILLICURIES
A9561	Tc99m oxidronate TECHNETIUM TC-99M OXIDRONATE, DIAGNOSTIC, <u>PER STUDY DOSE</u> , UP TO 30 MILLICURIES
A9562	Tc99m mertiatide TECHNETIUM TC-99M MERTIATIDE, DIAGNOSTIC, <u>PER STUDY DOSE</u> , UP TO 15 MILLICURIES
A9563	P32 Na phosphate SODIUM PHOSPHATE P-32, THERAPEUTIC, PER MILLICURIE
A9564	P32 chromic phosphate CHROMIC PHOSPHATE P-32 SUSPENSION, THERAPEUTIC, PER MILLICURIE
A9566	Tc99m fanolesomab TECHNETIUM TC-99M FANOLESOMAB, DIAGNOSTIC, <u>PER STUDY DOSE</u> , UP TO 25 MILLICURIES
A9567	Technetium TC-99m aerosol TECHNETIUM TC-99M PENTETATE, DIAGNOSTIC, AEROSOL, <u>PER STUDY DOSE</u> , UP TO 75 MILLICURIES



A9568	Technetium tc99m arcitumomab TECHNETIUM TC-99M ARCITUMOMAB, DIAGNOSTIC, <u>PER STUDY DOSE</u> , UP TO 45 MILLICURIES
A9569	Technetium TC-99m auto WBC TECHNETIUM TC-99M EXAMETAZIME LABELED AUTOLOGOUS WHITE BLOOD CELLS, DIAGNOSTIC, <u>PER STUDY DOSE</u>
A9570	Indium In-111 auto WBC 'INDIUM IN-111 LABELED AUTOLOGOUS WHITE BLOOD CELLS, DIAGNOSTIC, <u>PER STUDY DOSE</u>
A9571	Indium IN-111 auto platelet INDIUM IN-111 LABELED AUTOLOGOUS PLATELETS, DIAGNOSTIC, <u>PER STUDY DOSE</u>
A9572 CMS deleted A9565	Indium In-111 pentetretotide 'INDIUM IN-111 PENTETREOTIDE, DIAGNOSTIC, <u>PER STUDY DOSE</u> , UP TO 6 MILLICURIES
A9580	Sodium Fluoride F-18, Sodium Fluoride F-18, diagnostic, <u>per study dose</u> , up to 30 millicuries
A9582	lobenguane, I-123, diagnostic, <u>per study dose</u> , up to 15 millicuries
A9584	Iodine I-123 ioflupane, diagnostic, <u>per study dose</u> , (up to 5 millicuries)