

January 27, 2014

Marilyn B. Tavenner  
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 2014 Payment Rates; Final Rule CMS-1601-FC**

Dear Administrator Tavenner:

We are writing in response to the Calendar Year (CY) 2014 Hospital Outpatient Prospective Payment System (HOPPS) Final Rule, published December 10, 2013, *Federal Register* Vol. 78 No. 237 p. 74826. 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:

- New/Expanded Packaging Categories
- New or Revised APC Placements
  - APC placement of two new CPT Category III codes
  - Discontinuing the diagnostic radiopharmaceutical to procedure edits
- Add-On Payment Adjustment Policy for Radionuclides Derived from non-Highly Enriched Uranium (non-HEU) Sources

### **New/Expanded Packaging Categories**

Beginning in CY 2014, CMS will unconditionally or conditionally package five items and services, which will be added to the list of OPPTS packaged items and services in 42 CFR 419.2(b) (Drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure; Drugs and biologicals that function as supplies when used in a surgical procedure; Certain clinical diagnostic laboratory tests; Certain procedures described by add-on codes; and Device removal procedures.) Earlier in the proposed rule, CMS had suggested unconditionally or conditionally packaging seven items and services. SNMMI appreciates that you did not finalize all seven, but remain concerned about the packaging of stress agents and codes into the procedure. **SNMMI cannot support these updated packaging policies without sufficient analysis of the data to allow us to make meaningful comments. SNMMI respectfully requests that CMS reevaluate this policy in the future. Additionally, CMS should consider alternative packaging options for diagnostic radiopharmaceuticals as they become available. SNMMI remains concerned that some nuclear medicine**

services are not adequately reimbursed, especially low volume or high cost diagnostic radiopharmaceuticals, and CMS packaging policies now appear to be limiting access to some of these services.

## New or Revised APC Placements

### *APC placement of two new CPT Category III codes*

SNMMI would like to thank CMS for moving two CPT Category III codes from APC 0398 to 0377: CPT 0331T Myocardial sympathetic innervation, imaging, planar qualitative and quantitative assessment; and 0332T Myocardial sympathetic innervation, imaging, planar qualitative and quantitative assessment; with tomographic SPECT. Originally, these codes had placed in APC 0398 at a July 1, 2013 rate of \$308.99 and a proposed CY 2014 rate \$397.32. However, these rates were substantially lower than the cost of the diagnostic radiopharmaceutical alone and we had been concerned that this placement will hinder Medicare beneficiaries' access to this new service. **SNMMI greatly appreciates the placement of these codes in APC 0377, while not covering the full cost, does provide a closer payment rate of \$1,153.62 to hospitals costs.**

### *Discontinuing the diagnostic radiopharmaceutical to procedure edits*

CMS will discontinue the diagnostic radiopharmaceutical to procedure edits that are in place for CY 2013. CMS has stated that they believe that since hospitals now have enough time and experience with billing services, they are no longer required. As a result, claims for services that would require a diagnostic procedure will no longer be returned to providers to ensure expensive services are on the claim and it will be the responsibility of the hospital to submit claims correctly to provide CMS with the necessary data for appropriate rate setting. **SNMMI believes that in this situation, these claims could possibly fall off of the charge master and no longer be billed by the hospital. We respectfully disagree with this decision and ask CMS to reconsider this discontinuation. We appreciate CMS's continuation of the offset file, which will allow providers to continue to monitor the proportions of diagnostic radiopharmaceuticals and drugs as part of the packaged service and is necessary for ongoing publications by CMS in future rules.**

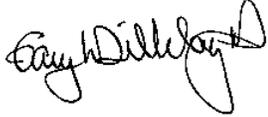
## Add-on Payment Adjustment Policy for Radionuclides Derived from non-HEU Sources

CMS has continued with their policy regarding add-on payment adjustment for radionuclides derived from non-HEU sources. As a result, we have continued concerns on this policy. 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 continue to believe there are many unknowns and moving parts which complicate implementation of this policy by CMS, hospitals and other nuclear medicine industry stakeholders. We urge CMS to continue to work with all stakeholders in further refinements to this new policy. **Additionally, we reaffirm our request and respectfully ask that CMS consider applying this non-HEU add-on policy to other appropriate non-HEU sourced radiopharmaceuticals in future rulemaking.**

While SNMMI welcomes the add-on payment, we feel that \$10 per study dose is too low and insufficient for radioisotopes derived from non-highly enriched uranium. Additionally, we strongly disagree with \$2 of this payment being paid by the patient under a co-insurance. **SNMMI believes CMS should reconsider the amount of this add-on payment and raise it to a more appropriate price while not putting any of the cost onto the patient. We believe that this add-on payment should be exempt from applying the co-insurance to the patient as are add-on pass through products.**

SNMMI appreciates the opportunity to comment on this HOPPS CY 2014 Final Rule to CMS. As always, 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](mailto:sbunning@snmmi.org) or by phone at 703-326-1182.

Respectfully Submitted,



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President, SNMMI