

September 6, 2013

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; Proposed Rule CMS-1601-P**

Dear Administrator Tavenner:

We are writing in response to the Calendar Year (CY) 2014 Hospital Outpatient Prospective Payment System (HOPPS) Proposed Rule, published Jul 19, 2013, *Federal Register* Vol. 78 No. 139 p. 43534. The Society of Nuclear Medicine and Molecular Imaging's (SNMMI) more than 19,000 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
  - Nuclear Medicine APC changes
  - 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**

CMS is proposing to unconditionally package or conditionally package several items and services (Add-on codes; Ancillary Services; Device Removals; Diagnostic tests on the bypass list; Clinical diagnostic laboratory tests; Skin Substitutes; and Stress Agents) which would be added to the list of OPSS packaged items and services in § 419.2(b). CMS states, "Our packaging policies support our strategic goal of using larger payment bundles to maximize hospitals' incentives to provide care in the most efficient matter...In a budget neutral system, the monies previously paid for services that are now proposed to be packages are not lost, but are redistributed to all other services...However, we recognize that decisions about packaging payment involve a balance between ensuring that payment is adequate to enable the hospital to provide quality care while establishing incentives for efficiency through larger units of payment." **SNMMI cannot**

**support these updated packaging policies without sufficient data to allow us to make meaningful comments. SNMMI respectfully requests that CMS delay implementing this policy until adequate data is released so we can better understand the reason for these changes.**

## **New or Revised APC Placements**

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

CMS has proposed the APC placement of two new CPT Category III codes effective July 1, 2013: 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. Both of these codes are placed in APC 0398 at a July 1, 2013 rate of \$308.99 and a proposed CY 2014 rate \$397.32. Both of these rates are substantially lower than the cost of the radiopharmaceutical alone. Consequently, we have serious concerns that this placement will hinder Medicare beneficiaries' access to this new service. In the CMS drug median file, A9582 is listed at a mean cost \$1,319.97 and median cost \$1,178.52. The most recent OPSS posted rate is October 2011 with an ASP derived rate of \$2,636.16. **SNMMI strongly believes that at a minimum these CPT codes should be placed in APC 0377 and respectfully requests that CMS make these changes. Both SNMMI and the American Society of Nuclear Cardiology (ASNC) jointly presented and reaffirmed this position at the APC panel meeting August 26, 2013.**

### *Nuclear Medicine APC changes*

In recent years, CMS has moved several of the neurologic CPT codes back and forth between APC 0402 and 0403. It appears that CMS has moved these codes based on the line item CPT code geometric mean claim cost data. CPT 78605 Brain Imaging, minimum 4 static views and CPT 78601 Brain imaging, vascular flow moved from APC 0403 to 0402 with a 288 percent increase in payment from 2013 rates. Conversely, CPT 78647 Cerebrospinal fluid flow, imaging (not including introduction of material); tomographic (SPECT) moved from APC 0402 to 0403 with a 61 percent decrease from the 2013 payment rate. Additionally, CPT 78801 Radiopharmaceutical localization of tumor or distribution of radiopharmaceutical agent(s); multiple areas has also changed APCs from 0414 to 0406 with a decrease of 22 percent; if the service had remained in the CY 2013 APC, it would have an increase of 35 percent. The final significant payment shift identified outside of the packaging policies is the payment rate for A9517 Iodine I-131 sodium iodide capsule(s), therapeutic, per millicurie. This decreased by 54 percent, though it is unclear why this occurred or what has changed. **SNMMI has concerns about CMS moving these CPT codes back and forth between APCs without rationale and discussion in the proposed rule. Hospitals need stable and appropriate payment for services and budgeting purposes, wide shifts in payment year to year without logic and discussion is problematic. SNMMI asks that CMS supply further information as to why these CPT codes have been moved between APCs.**

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

CMS has proposed to 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 provider 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 in the hospital. We respectfully disagree with this decision and ask CMS to reconsider this discontinuation.**

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

While not discussed or modified in the Proposed Rule, it appears that 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 appreciates the add-on payment, we continue to feel that a \$10 per study dose is too low and insufficient for radionuclides derived from non-highly enriched uranium. Additionally, we still strongly disagree with \$2 of this payment being paid by the patient under a co-insurance. **SNMMI would like to reiterate our request that CMS 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.**

SNMMI appreciates the opportunity to comment on this HOPPS CY 2014 Proposed Rule to the 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,



Gary L. Dillehay, MD, FACNM, FACR  
President, SNMMI