SOCIETY OF NUCLEAR MEDICINE AND MOLECULAR IMAGING

August 31, 2016

Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1656-P
P.O. Box 8013
Baltimore, MD 21244-8013

Re: Medicare Program: Changes to the Hospital Outpatient Prospective Payment System and CY 2017 Payment Rates; Proposed Rule 1656-P

Dear Administrator Slavitt:

We are writing in response to the Calendar Year (CY) 2017 Hospital Outpatient Prospective Payment System (OPPS) Final Rule, published July 14, 2016 in *Federal Register* Vol. 81 No. 135 p. 45604. The Society of Nuclear Medicine and Molecular Imaging's (SNMMI) more than 17,000 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 and Medicaid Services (CMS) in further refining the HOPPS.

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

- Proposed OPPS APC-Specific Policies
- Annual Reclassification and Recalibration Related Changes
- Payment Modifier for X-ray Films
- Section 603 Off-Campus Provider-Based Department Proposals
- Proposal to Make the Transitional Pass-Through Payment Period 3 Years for All Pass-Through Drugs, Biologicals, and Radiopharmaceuticals and Expire Pass-Through Status on a Quarterly Rather than Annual Basis
- Non-HEU Q9969 Code

Proposed OPPS APC-Specific Policies

SNMMI has reviewed CMS's restructuring of nuclear medicine and diagnostic imaging ambulatory payment classifications (APCs) and commends CMS for maintaining the current 2016 APC categories for placement of nuclear medicine services. SNMMI supports the proposed policy to specifically exclude nuclear medicine from the diagnostic radiology restructure as nuclear medicine services require equipment, supplies, and resources which differ from radiology services. Additionally, there are distinct clinical differences in these services and would not meet the required homogeneity if combined. Therefore, CMS should finalize the proposed five APC categories for Nuclear Medicine services.

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While we appreciate the difficult job you have, and fully understand the complexity of nuclear medicine, we fear that the current bundled diagnostic radiopharmaceutical reimbursement structure will continue to contribute to the decline of a vital part of medicine. Ultimately, this will lead to further erosion of getting the patient the right test at the right time.

SNMMI respectfully requests that CMS reconsider separate payment for diagnostic radiopharmaceuticals either separately or APCs for groups of diagnostic radiopharmaceuticals (as proposed in our letter and meeting in February 2015) that will be paid separately from the nuclear medicine APC procedure groups.

As previously stated in our final rule comments to CMS, SNMMI created an APC Reconfiguration Task Force, which methodically evaluated, developed, and proposed a reconfiguration for nuclear medicine APC restructuring. The team comprised physicians, technologists, pharmacists, and coders who thoroughly reviewed society guidelines and hospital practices in nuclear medicine to provide a thoughtful proposal taking into account CMS's packaging preferences. SNMMI has accepted the CMS model for APC procedure groups, however, the society urges CMS to consider varying thresholds and establishment of APC groups for high cost, low volume diagnostic radiopharmaceuticals. SNMMI reiterates that SNMMI's APC proposal to develop diagnostic radiopharmaceutical groups is sound and has been developed with careful methodology to keep beneficiary access and innovations in mind for solutions. While we do believe that over time it is important to review and update all APCs periodically, we believe our proposal will provide hospitals the stability, and CMS the packaging, while serving our patients.

Annual Reclassification and Recalibration Related Changes

The society noticed that CMS has shifted some nuclear medicine CPT codes into different APC categories, based on CMS cost data. SNMMI has reviewed those and supports these changes as we believe the cost data supports the nuclear medicine changes, and has no issues at the present time. Specifically, SNMMI supports the placement of CPTs 78195, 78201, 78202, 780205, 78203, 78227, 78645, 78725, 78802, 78468, 78469, 78453, and 78457 (noted in table below).

However, we are concerned with a few placements of nuclear medicine drugs and diagnostic radiopharmaceuticals. We appreciate that CMS moved most of the non-imaging out of the NM therapy APC 5661 and placed them into other nuclear medicine APC groups (based on the hospital mean cost information). Still, we reaffirm our strong recommendation to remove non-nuclear medicine services from the nuclear medicine APCs as we do not believe these services are clinical or resource homogeneous.

SNMMI has reviewed the specific nuclear medicine APC changes for individual codes and believes it is premature to move PET CPT code 78811, as CMS lacks sufficient claims data. On March 2, 2016, the Imaging Dementia—Evidence for Amyloid Scanning (IDEAS) Study began and is currently underway. The study is following more than 18,000 Medicare beneficiaries to determine the clinical value of a brain positron emission tomography (PET) scan to detect the hallmark brain amyloid accumulation of Alzheimer's disease in diagnosing and managing treatment of patients age 65 and older with mild cognitive impairment (MCI) or dementia of uncertain cause. Information from this scan can help exclude

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underlying Alzheimer's disease, and may help guide patient management. As such, SNMMI recommends that CMS keep this CPT code as a category 4, and review again when there is sufficient data available.

78195	Lymphatics and lymph nodes imaging (For sentinel node identification without scintigraphy imaging, use 38792)	5591	5592	$332.65	$431.04
78201	Liver imaging; static only	5591	5593	$332.65	$1,142.71
78202	Liver imaging; with vascular flow	5591	5593	$332.65	$1,142.71
78205	Liver imaging (SPECT);	5591	5593	$332.65	$1,142.71
78206	Liver image (SPECT); with vascular flow	5591	5592	$332.65	$431.04
78227	Hepatobiliary system imaging, including gallbladder when present; with pharmacologic intervention, including quantitative measurement(s) when performed	5591	5592	$332.65	$431.04
78610	Brain imaging, vascular flow only	5591	5592	$332.65	$431.04
78645	Cerebrospinal fluid flow, imaging (not including introduction of material); shunt evaluation (For injection procedure, see 61000-61070, 62270-62294)	5591	5592	$332.65	$431.04
78725	Kidney function study, non-imaging radioisotopic study	5661	5591	$249.98	$334.19
78802	Radiopharmaceutical localization of tumor or distribution of radiopharmaceutical agent(s); whole body, single day imaging	5592	5593	$441.36	$1,142.71
78468	Myocardial imaging, infarct avid, planar; with ejection fraction by first pass technique	5591	5592	$332.65	$431.04
78469	Myocardial imaging, infarct avid, planar; tomographic SPECT with or without quantification	5592	5593	$441.36	$1,142.71
78453	Myocardial perfusion imaging, planar (including qualitative or quantitative wall motion, ejection fraction by first pass or gated technique, additional quantification, when performed);	5592	5593	$441.36	$1,142.71

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	single study, at rest or stress (exercise or pharmacologic)				
78457	Venous thrombosis imaging, venogram; unilateral	5592	5593	$441.36	$1,142.71

RECOMMENDATION: Therefore, the SNMMI recommends that CMS restore CPT 78811 and finalize placement into NM level 4 rather than moving it to NM level 3.

Payment Modifier for X-Ray Films

SNMMI understands that CMS has a statutory requirement from Section 502(b) of Division O, Title V of the Consolidated Appropriations Act, 2016 (Pub.L 114-113) amended section 1833(t)(16) of the Act by adding new subparagraph (F),that services furnished during 2017 or any subsequent year, the payment under the OPPS for imaging services that are X-rays taken using film (including the X-ray component of a packaged service) that would otherwise be made under the OPPS (without application of this paragraph and before application of any other adjustment) shall be reduced by 20 percent. However, we do not believe CMS have provided sufficient information on this proposed policy change. **SNMMI recommends that CMS clarify the intent of this law. Specifically, CMS should state that the law only applies (and requires use of a modifier) to sites that use X-ray as a single method for image capture. CMS should clarify that if a site uses both X-Ray film and electronic capture of images and maintains digital archives, by a picture archiving communication system or other electronic method, that the site is not required to report the modifier.**

Section 603 Off-Campus Provider-Based Department Proposals

SNMMI remains concerned about the timeline of this policy and requests a delay on site neutral implementation. The society recommends that CMS provide details clarifying which hospital claims will need to contain this modifier, as many sites have told us they are unclear if this new modifier would apply to their campus or not. Additionally, it would be helpful if CMS defined a list of services by CPT code where the modifier would clearly apply showing examples to assist since implementation. We continue to believe that reporting a HCPCS modifier for off-campus provider-based departments would be an administrative burden and would welcome less burdensome options. We look forward to seeing modifications and clarifications in future CMS official publications.

Proposal to Make the Transitional Pass-Through Payment Period 3 Years for All Pass-Through Drugs, Biologicals, and Radiopharmaceuticals and Expire Pass-Through Status on a Quarterly Rather than Annual Basis

SNMMI fully supports CMS's recommended policy change to amend the pass-through period for radiopharmaceuticals to a period of at least 2 years, but no more than 3 years, after the payment was first made for the product as a hospital outpatient service under Medicare Part B. SNMMI also supports the change to expire pass-through status for a quarterly period and begin on an annual basis.

Q9969 Code

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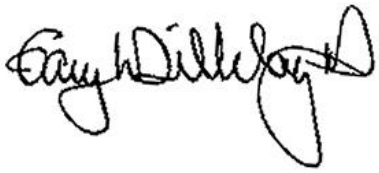
SNMMI appreciates CMS continuing Q9969 in the CY 2017 final rule. SNMMI reiterates that it is important that it continue into CY 2017 and beyond. We do not believe there is rationale to discontinue the code as the utilization is currently very low. According to the "Line Item Files," there were 14,948 units of Q9969 in the 2015 data, 6,064 units in the CY 2014 data and 1,675 units for 2013. While we agree the volume from 2013 to 2015 is increasing, the volume compared to the total volume of nuclear medicine services pale in comparison. Specifically, of the 1,711, 551 procedures (CPT 78012-78999) billed, Q9969 only made up 0.87% of the total. Less than 1 percent is far from a utilization that would be acceptable to consider discontinuation of the Q9969 code and payment. SNMMI respectfully asks CMS to continue Q9969 and the payment policy for the CY 2017 rule and work with stakeholders regarding a phase out plan based on utilization and adoption of non-HEU Technetium by the nuclear medicine community.

SNMMI appreciates the opportunity to comment on the HOPPS CY 2017 Proposed 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, Director, Health Policy and Regulatory Affairs, by email at sbunning@snmmi.org or by phone at 703-326-1182.

Respectfully Submitted,

Sally Schwarz, MS, RPh, BSNP
President



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