SOCIETY OF NUCLEAR MEDICINE AND MOLECULAR IMAGING

August 26, 2015

Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1633-P
P.O. Box 8013
Baltimore, MD 21244-8013

Re: Medicare Program: Changes to the Hospital Outpatient Prospective Payment System and CY 2016 Payment Rates; Proposed Rule CMS-1633-P

Dear Administrator Slavitt:

We are writing in response to the Calendar Year (CY) 2016 Hospital Outpatient Prospective Payment System (HOPPS) Proposed Rule, published July 8, 2015 in *Federal Register* Vol. 80 No. 130 p. 39200. 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:

- Proposed APC Restructuring for Nuclear Medicine Services
- Proposed OPPS Treatment of New CPT and Level II HCPCS Codes
  - CPT 782XA and 782XB
- Off-Campus Provider-Based Departments
- CMS Offset File
- Q9969 Code

Proposed APC Restructuring

While SNMMI appreciates CMS's recognition of the difficulty of nuclear medicine's organ based structure, we are disappointed that our proposal was not included in the CY 2016 proposed rule. On February 4, 2015, SNMMI met with CMS to discuss our proposed reconfiguration of the nuclear medicine APCs for the CY 2016 proposed rule. Our proposal (we have attached our comment letter) suggested that CMS reconfigure the diagnostic procedure APCs from 22 to eight for CY 2016, in combination with 10 new APC groups of diagnostic radiopharmaceuticals. The basis of this eight procedure structure at a high level includes, nuclear medicine versus nuclear cardiology, non-imaging, therapy, and PET and four levels of nuclear medicine with resources such as time to perform and analyze, supplies and regulatory requirements in groupings for services such as; planar limited and multiple imaging studies, whole body studies or two study procedures or SPECT or finally multiple day studies. In 2014, CMS packaged, stress testing and the stress agents with the nuclear cardiology services,

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these resources are very different and we therefore maintained those services separate, so as to maintain clinical and resource homogeneity. However, in the proposed rule, CMS reconfigured all these procedure codes into only four APC groups.

The SNMMI spent well over a year reviewing reconfigurations and options for alternative APC groups for CMS to consider. In the end, a fundamental issue remained in that all groups packaged the diagnostic radiopharmaceutical in with each group. This does not address some high cost, low volume diagnostic radiopharmaceuticals in the CMS packaging model. We shared several examples with CMS of diagnostic radiopharmaceuticals which were on pass-through status for two to three years, when pass-through was over and the procedures were placed into APC groups there were several instances where, the cost of the radiopharmaceutical was not covered and hospitals would be losing money for each procedure, on the cost of the radiopharmaceutical alone, not including the total cost of doing these procedures. These losses result in patient access issues, where some hospitals have stopped performing these high cost low volume procedures, and patients are required to travel long distances to larger hospitals, which are willing to absorb such losses.

The SNMMI, using the CMS packaging concept, modeled diagnostic radiopharmaceutical groups to be paid separately from the procedure, as a solution to these and future issues. The diagnostic radiopharmaceutical APC groups are configured based on either hospital claims data or ASP+6 data when available. Using ASP+6 or hospital claims data are both policies, which exist for drugs as well as for therapeutic radiopharmaceuticals, which demonstrates there is precedent in utilizing this approach. We are sensitive to CMS expansions of packaging and we are not suggesting that CMS pay separately and individually, as they do for drugs. We have compiled APC bands, developed using CMS volume, to create a weighted average among similar cost radiopharmaceuticals.

As this first step is critical to the success of a reconfiguration of the nuclear medicine APC group, **the SNMMI respectfully requests that CMS reconsider and propose for public comment period to implement APCs for groups of diagnostic radiopharmaceuticals that will be paid separately from the nuclear medicine APC procedure groups for CY 2017.**

We reviewed the CMS restructure of the nuclear medicine APCs, while there are some similarities to the SNMMI proposal, there are some major differences that we believe are critical for CMS to modify. Of note, we do not agree with combining PET services in with general nuclear medicine procedures. Specifically, CPTs 78459, 78491, 78492, 78811 through 78816 and 78608 are all PET services and those should remain in a diagnostic PET APC group separate from other non-PET services. The resources for PET services are very different from general nuclear medicine services and it would not make sense to combine them with services such as SPECT myocardial perfusion imaging, which is currently driving the payment rate for the CMS proposed APC 5593. **Therefore, the SNMMI recommends CMS maintain PET services in a separate APC grouping.**

On August 24, 2015 the SNMMI and other stakeholders presented testimony to the APC HOP Advisor Panel, subsequently the panel recommended CMS move CPT code 78811 into APC 5593 and then split APC 5593 into two APCs, one containing all the PET CPT codes and one containing the remaining non-PET studies. **This HOP Advisory Panel recommendation is consistent with the SNMMI recommendation to maintain all PET in one APC group. Therefore we strongly urge CMS to modify their proposal consistent with the SNMMI and the HOP Advisory Panel recommendation to maintain PET in a**

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separate APC group from other nuclear medicine APC groups. The SNMMI with the assistance of our data consultant, Braid Forbes Health Research, has simulated a split of APC 5593, and the results are listed in Table 1 below.

Table 1. HOPPS CY 2016 Simulation of Split of APC 5593

APC	APC Description	CMS Singles	CMS Geo Mean	WPA Singles	WPA Geo Mean	Simulation Singles	Simulation Geo Mean
5593	Level 3 NM	858,777	$1,238.90	860,244	$1,240.69	860,244	$1,240.69
5593A	NM & Related non PET Level 3 split (0331T, 0332T,78451, 78452, 78454, 78607, 78647, 78804)					599,138	$1,189.41
5593B	NM PET Imaging Level 3 split (78459, 78491, 78492, 78608, 78811, 78812, 78813, 78814, 78815, 78816)					261,210	$1,366.67

Similar to the PET issue described above, we are extremely concerned that CMS has placed nuclear medicine therapy services in with nuclear medicine diagnostic non-imaging services. Again we believe that non imaging equipment and supplies require different resources from therapeutic services and therefore we recommend CMS split the CPT codes with 79xxx from the 78xxx services. We believe that non-imaging and therapy should be in separate APCs based on the resources and the clinical differences in these services.

Some other specific points for CMS to consider:

1.) The SNMMI proposal separates nuclear cardiology from nuclear medicine, as we believe the expanded packaging that includes the stress agent and the stress test, makes those services significantly different from other nuclear medicine services. While we are open to review some of the nuclear cardiology services with nuclear medicine APCs, such as gated blood pool imaging, the SPECT, multiple studies that include the stress agent and the treadmill service would not be an appropriate grouping;

2.) CPT 78075 was placed by CMS in APC 5592. The mean data from CPT 78075 is $919.28 and is a better fit to be placed in the same APC group as CPT 78804, as these studies are both multiple day and require several sets of imaging. In the SNMMI proposal they are placed together in our NM Level 4 APC procedure group;

3.) All nuclear medicine CPT codes should be able to find a location in NM APC groups, the CMS proposal places four (4) nuclear medicine APCs in X-ray and related services APCs. CPT 78445, CPT 78457-78458 and 78456 all should be placed in NM APCs and we have specific recommendations in our detailed excel proposal attached;

4.) There is one non-nuclear medicine service, CPT 75563 *Cardiac magnetic resonance imaging for morphology and function without contrast material(s), followed by contrast material(s) and further sequences; with stress imaging* that currently in CY 2015 and proposed for CY 2016, are to remain in nuclear medicine APCs. We disagree that the resources for an MRI are similar to those resources for nuclear medicine services. We believe there is a more clinically relevant APC grouping outside of nuclear medicine APCs, where this can be placed. We are concerned that the consolidations proposed by CMS have placed services into APC groups with less and less clinical homogeneity. We caution CMS for two reasons, one to maintain a clinically cohesive grouping is a fundamental foundation of APC groupings, and secondly, the consolidation may have taken a few steps too far.

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In summary, the SNMMI APC Reconfiguration Task Force is a team of physicians, technologists, pharmacists, and coders who review in depth society guidelines and hospital practices in nuclear medicine to provide a thoughtful proposal taking into account CMS's packaging preferences. We believe our proposal 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 the APCs, we believe our proposal will provide hospitals the stability, and CMS the packaging, while serving our patients.

Therefore, the SNMMI respectfully requests that CMS reevaluate the current proposed nuclear medicine APC restructuring and, instead, adopt the SNMMI proposed reconfiguration in the final CY 2016 or CY 2017 HOPPS rule.

Off-Campus Provider-Based Departments

The CY 2015 HOPPS final rule stated that while many commenters agreed that there was a need to collect information on the frequency, type, and payment of services furnished in off-campus PBDs of hospitals, some expressed concern that the HCPCS modifier would create an additional administrative burden for providers. **SNMMI remains concerned that this policy will be mandatory after January 1, 2016, yet this was not mentioned in the proposed rule. We continue to request 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 is effective January 1, 2016. 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 prior to the mandatory implementation date.**

Proposed OPPS Placement of New CPT 782XA and 782XB

CMS posted new CY 2016 CPT codes in Addendum B to the proposed rule with short descriptors only. CMS lists them again in Addendum O to the proposed rule with long descriptors. CMS is also proposing to finalize the status indicator and APC assignments for these codes (with their final CPT code numbers) in the CY 2016 OPPS/ASC final rule with comment period. We appreciate CMS listing the proposed APC placements and proposed long descriptions in Addendum O for these new codes in the proposed rule. We believe this allows for transparency and opportunity for public comment prior to payment rates being implemented.

The SNMMI did review the proposed placements of two new services 782XA and 782XB and we disagree to place these two new services in the same APC group as the Gastric Emptying study CPT 78264 as there is significantly different work and radiopharmaceuticals used for the two new codes. We are attaching the SNMMI guideline for small bowel and colon transit studies. As stated in the protocols, there are more resources used for the small bowel such as more images, analysis, supplies, and radiopharmaceutical for those services, compared to a gastric emptying study performed alone without small bowel or colon transit follow up. Additionally, when performing for GES, small bowel and colon, the imaging occurs over multiple days and multiple analyses are performed, therefore we believe the782XA is more comparable to work of CPT 78206, 78709 and 78582 and 782XB is more comparable

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to CPT 78804 in resources. **We respectfully request CMS place the two new CPT codes in APCs 5592 and 5593 respectively or if CMS accepts the SNNMI proposal these codes would be placed in the same APC group as the codes listed above or in Table 2 below.**

Table 2. Proposed OPPS Placement of CPT 782XA and 782XB

CMS Listing of Proposed New Service	Long Description	Comment Indicator (CI)	CMS Proposed APC Placement	SNMMI Proposed APC Placement
782XA	Gastric emptying imaging study (eg, solid, liquid, or both); with small bowel transit, up to 24 hours	NP	5591	5592 or same APC as CPT 78206, 78709 and 78582
782XB	Gastric emptying imaging study (eg, solid, liquid, or both); with small bowel and colon transit, multiple days	NP	5591	5593 or same APC as CPT 78804

CMS Offset File

SNMMI remains concerned with the format and implementation of these off-set files as CMS lists all the unconditionally packaged products together, such as, diagnostic radiopharmaceuticals, stress agents, contrast agents and skin substitutes, while only reporting out one total offset payment amount by APC category. Without separate offset files for each category of unconditionally packaged group, CMS would remove supplemental resources when a pass-through product of a diagnostic radiopharmaceutical or a stress agent becomes available. For example, HCPCS code A9586 *Florbetapir F18, diagnostic, per study dose, up to 10 millicuries* is most commonly reported with CPT code 78811 *Positron emission tomography (PET) imaging; limited area (e.g., chest, head/neck)* or 78814 *Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; limited area (e.g., chest, head/neck)*, paid in CY 2015 in the PET grouping, APC 0308. This is an APC that packages PET services, cardiac procedures and oncology procedures, which would always package the radiopharmaceutical and the pharmaceutical stress agent. As a result, the offset amount for CY 2015 is $227.57. This reimbursement is accounting for both the packaged RPs and the packaged stress agent drugs. For a more accurate and appropriate payments, CMS should clarify which portion is attributable to the diagnostic radiopharmaceutical and which is attributable to the packaged stress agent. Without this clarification, removing the $227.57 payment from the procedure payment ($1,285.72) would also be removing the costs and payment for the stress agents and thus underpaying for the service on average. **This is an issue today for CY 2015, as detailed in our example, and will be of great concern in the near future. As such, this issue needs prompt attention. Therefore, SNMMI respectfully recommends that CMS create an offset file separating the diagnostic radiopharmaceuticals from the contrast and stress agents and any skin substitutes.** Additionally, CMS continues to only provide off-set files only with the final rule and, as a result, comments can only be provided after these files are released. **SNMMI respectfully requests that CMS release these files**

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during the open comment period following the proposed rule so the public will have complete information for commenting on proposals to CMS.

Q9969 Code

While SNMMI appreciates CMS continuing Q9969 in the CY 2016 proposed rule, 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 6,064 units of Q9969 in the CY 2014 data. For CY 2013 data, there were 1675 units of Q9969, while we agree the volume from 2013 to 2014 is increasing the volume compared to the total volume of nuclear medicine services pale in comparison. Specifically, of the 1,707,795 procedures (CPT 78012-78999) billed, Q9969 only made up 0.35% 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. **As a result, 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.**

Observation C-APC

CMS is proposing to create a C-APC for observation services to provide comprehensive payment for all services received when receiving comprehensive observation services, defined as a non-surgical encounter with a high level outpatient hospital visit and 8 or more hours of observation. Copayments under the OPPS for any service are capped at the inpatient deductible amount. SNMMI appreciates CMS's attempt to reduce waste and fraud, but believes this proposed recommendation is overly complicated and needs further examination and review, prior to implementation. For example, a percent of the time, observation patients will need a myocardial perfusion study. The society has concerns with packaging these tests in with the observation C-APC. **As such, SNMMI respectfully requests a delay in implementing the observation services C-APC, so the community can analyze the impact and any unintended consequences**.

SNMMI appreciates the opportunity to comment on this HOPPS CY 2016 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 or by phone at 703-326-1182.

Respectfully Submitted,

Gary L. Dillehay, MD, FACNM, FACR
Chair, SNMMI Coding & Reimbursement Committee

Attachment: **SNMMI Colon and Small Bowel Guideline**

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February 13, 2015

Chris Ritter, PhD
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Re: SNMMI Proposal for CY 2016 Reconfiguration of Nuclear Medicine APCs

Dear Dr. Ritter,

The Society of Nuclear Medicine and Molecular Imaging (SNMMI) would like to thank you and your staff for the time and attention at our February 4, 2015 meeting to discuss our proposed reconfiguration of the nuclear medicine APCs for Calendar Year (CY) 2016. SNMMI's 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.

As we discussed, SNMMI's leadership and membership are both concerned with diagnostic (Dx) radiopharmaceutical (Rp) costs and the current Hospital Outpatient Prospective Payment System (HOPPS) APC structure. We believe these costs hinder the use or adoption of nuclear medicine procedures and their Dx Rps. As we mentioned in our meeting, SNMMI is greatly concerned for our patients as some hospitals have stopped performing services and they are forced to go elsewhere for their testing. We are also concerned for innovation and sustained products as we have seen companies such as Bayer, Siemens, GE Healthcare (new oncology tracers) & GlaxoSmithKline (Bexxar) exit or reduce participation in the nuclear medicine market in recent years.

During our meeting, we outlined several specific examples where diagnostic radiopharmaceuticals were available for pass-through. However, as these products come off pass-through status, the APC placement for these packaged services are falling well below (at the time, a $1500 differential) the cost of just the radiopharmaceutical alone, not to mention the time, equipment and supplies for that service. The two examples we discussed were AdreView™ (HCPCS code A9582) and DaTscan™ (HCPCS code A9584). We also discussed issues related to sole sourced products. In some instances, the costs to the hospitals have increased close to the cost of the APC procedure payment. To that end, SNMMI has been reviewing the claims data and running simulations for alternate APC configurations. These configurations identify and evaluate alternative APC groupings which incorporate packaging as a principle to achieve appropriate payment in the HOPPS setting for all nuclear medicine services.

As we discussed, the current nuclear medicine APC structure is an organ/system based structure, loosely modeled after the AMA CPT subcategories. There are currently 22 APCs for diagnostic nuclear medicine services and all diagnostic radiopharmaceuticals are packaged into these procedure based groupings.

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The attached proposal only addresses the diagnostic nuclear medicine procedures and the diagnostic radiopharmaceuticals for CMS's consideration in the CY 2016 HOPPS rule. We do not propose changing the therapeutic APC structure at this time as we have not encountered issues with the therapeutic radiopharmaceutical procedure policy.

SNMMI reviewed many different options from the skin substitute High and Low model, Composite model and Comprehensive model, all of which had the fundamental issue of high cost or low volume services not being captured well in the current HOPPS system. While pass-through is helpful to new products, it is temporary and does not address issues we identified with existing diagnostic radiopharmaceuticals. Consistent with our goal to provide CMS with an option that incorporates packaging as a principle, we offer the following recommendation:

1.) **SNMMI respectfully requests CMS consider paying for diagnostic radiopharmaceuticals separate from the procedure payment, but packaged into new radiopharmaceutical APC groupings** based on bands identified by mean per unit day costs or, if available, by ASP +6 per day cost groupings and paid as a weighted average rate for each grouping. We respectfully request that CMS accept and use for rate setting, any voluntarily supplied average sale price data from the manufacturers for diagnostic radiopharmaceutical. We request that CMS treat these as significant for a status indicator so that two radiopharmaceuticals in a single grouping may each be paid. This would allow for nuclear medicine procedures that either use dual isotopes or where the service is a different separate procedure that requires different radiopharmaceuticals. We also suggest that each individual radiopharmaceutical payment be based on (1) unit since the calculation has been brought to the average per day use of each radiopharmaceutical. Attached is an excel spreadsheet using the 2013 units and mean information as well as the publically available ASP+6 information available. We have calculated an estimated payment rate performing a weighted average consistent with CMS methodology. SNMMI also supports a $95 threshold for the diagnostic radiopharmaceutical APCs consistent with the drug policy. Further details on the methodology for the Dx Rp grouping can be found on the attached spreadsheet. CMS may have more current or additional ASP data. If so, we suggest they use the most current data that is available and voluntarily supplied.

2.) In consideration that CMS might pay for the diagnostic radiopharmaceutical in a separate group from the procedure, we have looked at the current groupings. We believe that if CMS is able to implement our number one request, we have identified an alternate method to pay for the procedure. **SNMMI recommends that CMS consider the proposal that reconfigures the procedures from 22 to 8 for CY 2016 in combination with the packaged 10 APC groups of diagnostic radiopharmaceuticals. The basis of this 8 procedure structure at a high level is planar limited and multiple, separate from whole body or two study procedures and separate from SPECT or multiple day studies. However, SNMMI does not support a change to this new structure of nuclear medicine procedure APCs unless the radiopharmaceutical APCs are created and paid separate from the procedure APCs.** We have provided a detailed CPT code to revised grouping (attached) for CMS consideration as well as some simulations from our consultant with details of the analysis below.

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Braid Forbes Health Research
Detail of the analysis:

Table 1: Simulation of proposed mapping on 2014 and 2015 final rule file (2012 and 2013 data - see spreadsheet)

CMS's methodology for determining costs for rate-setting was applied to the proposed new reconfiguration of the nuclear medicine APCs. We used CMS's claims data for the CY 2015 final rule. This was compared to the analysis sent to CMS in the spring, which was based on the 2014 final rule file. In the proposed configuration, the APCs were collapsed to eight. These proposed APCs, the count of claims that could be used for rate setting, known as 'singles,' **(2014 - Column C, 2015 - Column E)** and the geometric mean cost (**2014 - Column D, 2015 - Column F**) are shown in Table 1 (attached). The APC code (**Column A)** is just for our reference. If accepted, CMS would assign APC numbers. We have also provided our proposed APC description **(Column B)**.

The ratio of the geometric mean cost to the payment rate in the 2015 final rule data was used to estimate a payment rate using the new geometric mean and the proposed APC reconfiguration (the ratio is 0.9636). The estimated payments were compared using the geometric mean cost adjusted to payments using this ratio and the payments under the actual 2015 payment rates.

Table 2: Procedure to APC mapping (see spreadsheet)

The accompanying spreadsheet has a table (2) that shows, for each APC, the procedure codes that map to that APC. The columns in the table are:

- **(Columns E/F/G)** Our simulation of geometric mean cost and number of claims used in rate-setting (singles)
- **(Column H/I)** CMS's calculation of singles and geometric mean cost
- **(Column J/K)** Current 2014 APCs and payment rates
- **(Column L)** The percentage difference between the geometric mean cost for the proposed APCs and current 2014 payment rate. This approximates the difference in payment that would occur if the proposed APC mapping were accepted
- **(Column M)** The total procedure volume in 2012
- **(Column N/O/P)** Test of budget neutrality of the reconfiguration: comparison of the sum of total procedure volume multiplied by the current 2014 payment rate and sum of the total procedure volume multiplied by the estimated payment using the adjusted proposed APC geometric mean cost.

Table 3: Diagnostic radiopharmaceutical groups (see spreadsheet)

- **(Column A)** Our Dx Rp group or status indicator if packaged N or G pass-through
- **(Column B)** HCPCS Level II code
- **(Column C)** Short description HCPCS code
- **(Column D** From CMS drug mean files - Volume in Days used for weighting

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- **(Column F)** Calculation utilizing the CMS drug mean files reporting the average units per day times the mean cost. Average Unit Per Day Cost = AUPD Costs

- **(Column G)** Projected payment rate for APC group

Miscellaneous items important to the discussion:

Previously mixed nuclear medicine and other procedure APCs

The following APCs have a mix of nuclear medicine codes and non-nuclear medicine codes according to the CMS definitions in 2015:

- 0263 Level I Miscellaneous Radiology Procedures
- 0317 Level II Miscellaneous Radiology Procedures
- 0393 Hematologic Processing & Studies

We are proposing to take the nuclear medicine codes out of these APCs and include them in the new proposed eight nuclear medicine APCs. We modeled how taking nuclear medicine codes out these APCs would affect the geometric mean cost. **Our models show that the geometric mean would change by less than 0.2% in each case. Therefore, there would be almost no change to the payment rate by removing the nuclear medicine codes.**

Currently, code 75563 (Cardiac MRI w/stress image & dye) is assigned to APC 0377 (Level II Cardiac Imaging). All other codes under this APC are nuclear medicine procedures and are included in the proposed reorganization. Possible placement for this "orphan" code is APC 0317 (Level II Miscellaneous Radiology Procedures) or APC 0435 (Level III Extended EEG, Sleep, and Cardiovascular Studies).

- If code 75563 were included in APC 0317, the geometric mean of APC 0317 would decrease by 1.6%.
- If code 75563 were included in APC 0435, there would be practically no change in the APC since this APC has over 350 thousand single claims and 75563 has only 1,100 with a geometric mean within 10% of the geometric mean.

CPT 75563 has a geometric mean cost of $801.05 and a payment rate of $1,140.10 in 2015. The payment rate is $812.89 for APC 0317 is and $853.96 for APC 0435. We believe that the American College of Radiology (ACR) and the Society for Cardiovascular Magnetic Resonance (SCMR), along with CMS early data review, should identify the most appropriate new APC placement for CPT 75563 rather than SNMMI suggesting a placement. However, we do not recommend this service remain in with the proposed nuclear medicine structure, as the costs for MRI studies are not homogeneous to nuclear medicine services.

In summary, we respectfully request that CMS create diagnostic radiopharmaceutical APC groups paid separately from the reconfigured nuclear medicine procedure APC groups. We believe that CMS has the authority to address particularly expensive or rarely used procedures that might result in insufficient payments to hospitals and which could adversely affect beneficiary access to medically necessary services. Additionally, we have attached MedPAC's 2005 Report to Congress, which states that radioactive materials require greater handling resources than drugs. We believe the report is supportive

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as a minimum for CMS to consider accepting voluntarily supplied ASP from manufacturers and use the ASP+6 rates in the packaged diagnostic radiopharmaceutical groupings. As we discussed at our meeting,

we have reached out to our data consultant to run further analysis to review the shifts we discussed. We will share that data with CMS when it becomes available.

SNMMI appreciates the opportunity to provide CMS with this option for CY 2016. 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 or by phone at 703-326-1182.

Respectfully submitted,

Gary L. Dillehay, MD, FACNM, FACR
Chair, Coding and Reimbursement Committee
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Virginia Papas, CAE
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Industry Forum
American College of Cardiology
American College of Nuclear Medicine
American College of Radiology
American Hospital Association
American Society of Nuclear Cardiology
National Association of Nuclear Pharmacies
Society for Cardiovascular Magnetic Resonance
World Molecular Imaging Society
SNMMI APC Remodeling Task Force
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