SNM
Advancing Molecular Imaging and Therapy

Submitted Electronically:
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Dr. Donald Berwick, MD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1504-P
200 Independence Avenue, SW
Washington, DC 20201

August 31, 2010

ATTN: File Code CMS-1504-P

Re: Medicare Program: Changes to the Hospital Outpatient Prospective Payment System and CY 2011 Payment Rates; Proposed Rule

Dear Dr. Berwick:

We are writing in response to the 2011 Hospital Outpatient Prospective Payment System (HOPPS) Proposed Rule, Federal Register Vol. 75, No. 148, August 3, 2010. The Society of Nuclear Medicine (SNM), representing more than 17,000 physicians, scientists, pharmacists and nuclear medicine technologists, appreciates 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:

- ASP Reporting for Therapeutic Radiopharmaceuticals
- Separately Payable Drugs Without Pass-Through Status
- Packaging of Diagnostic Radiopharmaceuticals
- Reimbursement for Cardiac PET Radiopharmaceuticals
- Modifier –FB
- Modifier –FC

ASP Reporting for Therapeutic Radiopharmaceuticals

The SNM appreciates CMS's continuation of a policy for separately payable therapeutic radiopharmaceuticals in CY 2011, thereby setting the prospective payment rate utilizing voluntary manufacturer-submitted average sales price (ASP) information, if available, or if not available using CMS claims data. The SNM also agrees with CMS's proposal to establish a new methodology for the development of an ASP + X payment rate as the best proxy for therapeutic radiopharmaceuticals' average acquisition and handling costs. We believe that this methodology should be extended to some diagnostic radiopharmaceuticals as we will note below.

Separately Payable Drugs Without Pass-Through Status

CMS has proposed to redistribute a total of $200 million ($50 million, or 8%, from uncoded packaged drugs and $150 million, or 25%, from coded packaged drugs) of pharmacy overhead/handling

costs from packaged drugs to separately payable drugs resulting in a *proposed* payment of ASP +6% (the SNM recognizes that this number may change once CMS has finalized its calculations for the final rule for CY 2011) for separately payable drugs. In general, redistributing this money is appropriate as it will help to create parity between the hospital and the physician settings. However, the SNM believes that CMS could have gone one step further , as detailed in comments submitted by the Biotechnology Industry Organization (BIO) at the August 2010 APC Panel Meeting, to account for the difference between low-cost and high-cost drugs, and could also better calculate the "plus" in its ASP + calculation, as detailed in comments submitted by the Alliance of Dedicated Cancer Centers at the August 2010 APC Panel Meeting. By redistributing only 8% of the total uncoded packaged drug costs ($50 million), CMS is likely to be overpaying for procedure APCs and underpaying for separately payable drugs because the overhead/handling costs that should be associated with these drugs is being spread into non-drug APCs. **SNM recommends that CMS use the same redistribution percentages (25%) for both coded and uncoded packaged drugs as the basis for calculating payment for separately payable drugs prior to determining the "plus" in the ASP + calculation while finalizing payment rates for CY 2011.**

Packaging of Diagnostic Radiopharmaceuticals

The SNM once again disagrees with CMS's decision to continue packaging diagnostic radiopharmaceuticals in with the major procedure payment, regardless of their per-day costs. The SNM believes that all radiopharmaceuticals should be treated as drugs following drug payment policies. As SNM has mentioned many times in the past (most recently, in our August 21, 2009 letter on the Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2010 Payment Rates; Proposed Rule) for many individual (CPT) nuclear medicine procedures, the choice of radiopharmaceutical is solely dependent on the clinical reason for which the procedure was ordered. While we concur with some level of packaging based on cost, we disagree with CMS's approach to package all diagnostic radiopharmaceuticals. Radiopharmaceuticals are drugs, and should be reimbursed as such.

While the SNM does agree that pricing of radiopharmaceuticals has continued to be a challenge, we remain concerned that by packaging diagnostic radiopharmaceuticals the full costs are not being captured in the HOPPS under the conventional hospital charge data reduced to costs. **Therefore, we suggest that CMS change its policy and pay separately for high cost radiopharmaceuticals (those that cost more than $200 by claims data), while keeping the low cost radiopharmaceuticals packaged.** This request is consistent with a presentation given by the SNM at an APC Panel Meeting (September, 2007) in which we suggested that the current packaging system pays reasonably for low cost radiopharmaceuticals but "falls apart" for radiopharmaceuticals costing around $200-$300, or more, per dose (see Table 1 below).

SNM further suggests that if CMS chooses to set a higher threshold for diagnostic radiopharmaceuticals than they do for drugs, and if CMS chooses to treat these diagnostic radiopharmaceuticals akin to a pass-through product, that CMS implement the offset for these high cost radiopharmaceuticals in the same manner AdreView (HCPCS Level II A9582), a diagnostic radiopharmaceutical used for the detection of neuroendocrine tumors, is treated. CMS currently accepts ASP data for AdreView through its pass-through status provision. AdreView has proven that this policy can, and does work for diagnostic radiopharmaceuticals. We believe that this or the drug payment policy is reasonable, and should be extended to other high cost diagnostic radiopharmaceuticals in the tumor imaging or other categories as we discuss below. **Additionally, we suggest CMS post the offset files for HOPPS at the same time the proposed rules are issued.** Without these files, we are unable to predict or comment prior to final offsets being imposed. Adequate pricing of all radiopharmaceuticals is particularly important as new technologies are developed and utilized.

Table 1

CPT/ HCPCS Description	2007 (Proposed)		2008 (Proposed)		2009 (Proposed)		Percent Change in Volume
	Median Unit Cost	Total Units	Median Unit Cost	Total Units	Median Unit Cost	Total Units	
A9507: Indium In-111 capromab pendetide, diagnostic, per study dose, up to 10 millicuries	$822.30	2256	$800.95	2192	$807.84	1704	-32%
A9521: Technetium TC-99m exametazime, diagnostic, per study dose, up to 25 millicuries	$303.04	4268	$307.00	4204	$299.60	3713	-15%
A9542: Indium In-111 ibritumomab tiuxetan, diagnostic, per study dose, up to 5 millicuries	$1220.89	368	$1065.33	310	$1098.48	247	-49%
A9544: Iodine i-131 tositumomab, diagnostic, per study dose	$1421.05	168	$1215.88	139	$1221.00	113	-49%
A9547: Indium in-111 oxyquinoline, diagnostic, per 0.5 millicurie	$279.36	5505	$297.77	4549	$305.78	4102	-34%
A9548: Indium in-111 pentetate, diagnostic, per 0.5 millicurie	$221.61	5047	$229.86	5319	$242.92	5062	.3%
A9555: Rubidium rb-82, diagnostic, per study dose, up to 60 millicuries	$258.32	4862	$221.46	7179	$214.19	9670	49%
A9570: Indium in-111 labeled autologous white blood cells, diagnostic, per study dose			$376.17	1290	$404.35	1523	15%
A9572: Indium in-111 pentetreotide, diagnostic, per study dose, up to 6 millicuries			$312.78	9645	$378.00	8717	-11%

(Data taken from Claims Data provided in the Changes to the Hospital Outpatient Prospective Payment System Proposed Rules for 2009, 2010, and 2011.)

We have no doubt that CMS agrees that cost alone should not be the deciding component that drives the use of one or the other imaging agents. However, underpayment based on hospital charge data will dissuade the use of potentially improved and highly specific imaging and therapeutic agents. As the SNM has mentioned in previous letters on this subject (specifically in our January 27, 2008 letter on the Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2008 Payment Rates; Final Rule), this can be avoided by consideration and use of external cost data provided by manufacturers because we do not believe that hospital data accurately reflects the true acquisition cost for these drugs. At the same 2007 APC Panel meeting mentioned above, the SNM presented data from a survey that showed a wide disparity, consisted with "charge compression" of higher cost diagnostic and therapeutic radiopharmaceuticals when compared to the CMS claims data. If the cost of these current or new radiopharmaceuticals cannot be captured by hospitals, these potentially lifesaving treatment options may not be available to Medicare beneficiaries because hospitals will simply stop providing these services.

In addition, as we have mentioned in previous letters (most recently in our August 21, 2009 letter on the Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2010 Payment Rates; Proposed Rule), the SNM requests that CMS consider, at a minimum, un-packaging diagnostic radiopharmaceuticals for APC 0406 (Level I Tumor/Infection Imaging), 0414 (Level II Tumor/Infection Imaging) and 0408 (Level III Tumor/Infection Imaging) for radiopharmaceuticals with costs of $200.00 or more, as we believe the current packaging is encouraging hospitals to either discontinue the use of clinically appropriate studies, or shift the procedures to other less appropriate services because the payment rates for these procedures are not covering the cost of the radiopharmaceutical, let alone the cost of the procedure. The current payment policy encourages the use of less expensive radiopharmaceuticals even when they are ***not substitutable*** for those that are more expensive. Absent a solution, as hospitals continue to remain pressured to keep their costs down and not implement or maintain new procedures that are not reimbursed adequately, Medicare beneficiaries are likely to receive outdated technology, less effective, and often lower-priced radiopharmaceuticals which would greatly impact their standard of care. CMS analysis of data between CY 2007 and CY 2009 noticed that "very little change in the frequency of hospitals reporting one or more diagnostic radiopharmaceutical between CY 2007 and CY 2009." In CY 2008 CMS began to require the reporting of a radiolabeled product when billing a nuclear medicine procedure. CMS believes "that the modest increases in frequency of reporting diagnostic radiopharmaceuticals and the percentage of reporting hospitals generally reflects hospitals adhering to [their] reporting requirements." As you can see in Table 2 (below), with the exception of 78801 and 78802, the frequency of these procedures has, in fact, risen, some by as much as 17 percent. While at the same time, there has been a significant decrease in the use of expensive diagnostic radiopharmaceuticals (see Table 1, above), possibly suggesting that hospitals are selecting to substitute lower-cost diagnostic radiopharmaceuticals. Our expert review of these radiopharmaceuticals and the clinical use show they are **not substitutable**. Therefore, we believe volume is increasing slightly for the less expensive procedures, which is unrelated to the decreases in the products used for different indications. **In light of this discrepancy, CMS should analyze all radiopharmaceuticals, including the indications for use, to better understand if Medicare beneficiaries are suffering from decreases in specific non-substitutable procedures.** The SNM is concerned that because of the discrepancy in utilization rates, providers may be inappropriately shifting to older, higher radiation, less sensitive diagnostic radiopharmaceuticals, or worse, discontinuing to offer the procedure altogether, which would result in inappropriate patient care.

Table 2

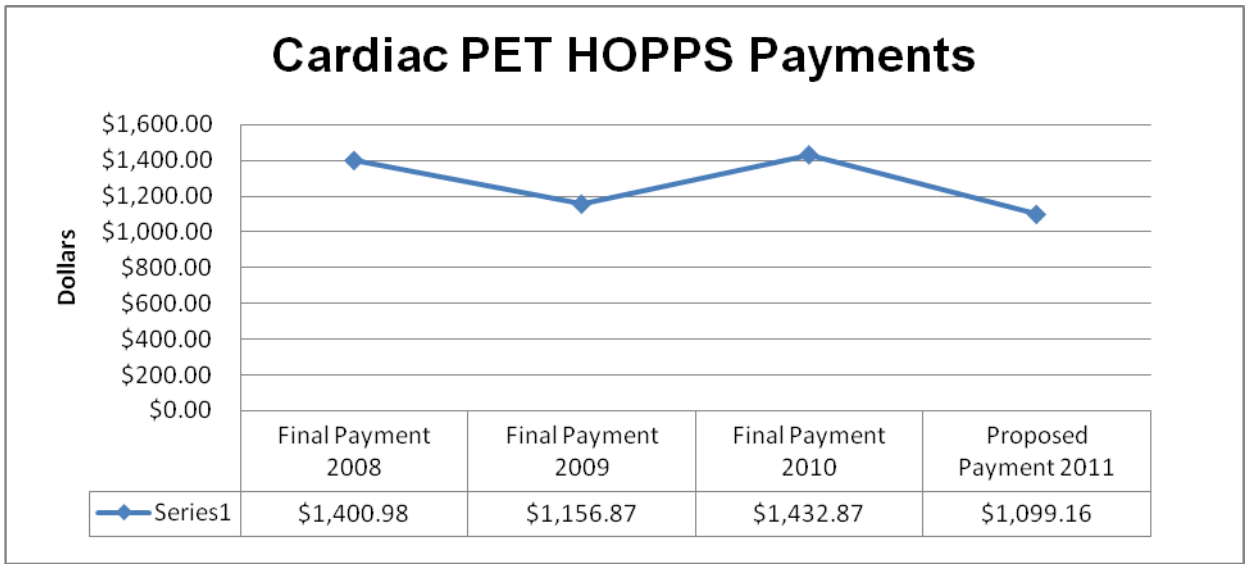
CPT/ HCPCS: Description	2009 (Proposed)		2010 (Proposed)		2011 (Proposed)		Percent Change in Frequency
	Median Cost	Total Frequency	Median Cost	Total Frequency	Median Cost	Total Frequency	
78800: Radiopharmaceutical localization of tumor or distribution of radiopharmaceutical agent(s); limited area	$267.54	1226	$254.58	1032	$278.73	1354	9%
78801: Radiopharmaceutical localization of tumor or distribution of radiopharmaceutical agent(s); multiple areas	$479.65	1624	$390.59	1610	$348.17	1702	4%

CPT/ HCPCS: Description	2009 (Proposed)		2010 (Proposed)		2011 (Proposed)		Percent Change in Frequency
	Median Cost	Total Frequency	Median Cost	Total Frequency	Median Cost	Total Frequency	
78802: Radiopharmaceutical localization of tumor or distribution of radiopharmaceutical agent(s); whole body, single day imaging	$480.42	4643	$538.83	3780	$488.67	3521	-32%
78803: Radiopharmaceutical localization of tumor or distribution of radiopharmaceutical agent(s); tomographic (SPECT)	$476.01	8263	$591.39	8899	$418.73	9905	17%
78804: Radiopharmaceutical localization of tumor or distribution of radiopharmaceutical agent(s); whole body, requiring 2 or more days imaging	$1006.48	2657	$1058.83	2840	$914.81	3162	16%

(Data taken from the Changes to the Hospital Outpatient Prospective Payment System Proposed Rules for the indicated years.)

Reimbursement for Cardiac PET Radiopharmaceuticals

As you can see from the following chart, the payment rates for Cardiac PET radiopharmaceuticals have fluctuated wildly over the past four years. With such irrational payments, hospitals cannot reasonably manage their departments. **The SNM suggests that any variations in payment rates of 10 percent or more be reviewed, and adjustments made, to try to fix such wide variations.** SNM is supportive of CMS investigating these discrepancies in order to analyze whether or not the payment fluctuations are having a negative impact on adoption of these procedures and radiopharmaceuticals.



Modifier –FB

The SNM is pleased with the clarification provided by CMS regarding use the "FB" modifier to report the use of free or full credit radiopharmaceuticals. While we believe that this is rare, there are some

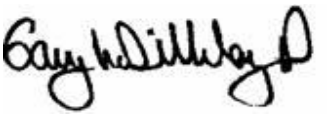
instances where it does occur and this is an appropriate way for hospitals to easily handle those situations. We agree that while the modifier is specific to devices, it does capture "the concept of the hospital receiving a key component of the service without cost." Use of this modifier will allow hospitals to accurately report, and be paid for, nuclear medicine procedures.

Modifier –FC

In the proposed rules, CMS discusses the possible use of the "FC" modifier to report the use of reduced cost radiopharmaceuticals to replace a previously provided diagnostic radiopharmaceutical. CMS has asked for public comment on when a diagnostic radiopharmaceutical is provided for a significantly reduced price and whether the "FC" modifier is appropriate. The SNM agrees with CMS's decision to not implement this as partial pricing is not typical in the nuclear medicine field, and hospitals already have a mechanism to set two different charges for the same radiopharmaceutical to account for any reduced costs.

The SNM appreciates the opportunity to comment on this HOPPS 2011 Proposed Rule to the CMS. As always, the SNM is ready to discuss any of its comments or meet with CMS on the above issues. Please contact Cindy Tomlinson, Associate Director, Health Policy and Regulatory Affairs at ctomlinson@snm.org or 703.326.1187.

Respectfully Submitted,



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