September 11, 2023

Ms. Chiquita Brooks-LaSure  
Centers for Medicare & Medicaid Services,  
Department of Health and Human Services,  
ATTN: CMS-1786-P  
Mail Stop C4-26-05  
7500 Security Blvd.  
Baltimore, MD 21244-1850

Re: [CMS-1786-P] Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment System; etc.

Dear Administrator Brooks-LaSure:

We at the Society of Nuclear Medicine and Molecular Imaging (SNMMI) and American College of Nuclear Medicine (ACNM) are writing in response to the 2024 Hospital Outpatient Prospective Payment System (OPPS) Proposed Rule. We appreciate the opportunity to provide comments to assist the Centers for Medicare & Medicaid Services (CMS) in further refining the OPPS.

Our comments focus primarily on the comment solicitation on the OPPS packaging policy for diagnostic radiopharmaceuticals. SNMMI and ACNM applaud CMS for making this solicitation and for acknowledging the significant concerns that stakeholders have about the impact that policy packaging has had on beneficiary access to necessary nuclear medicine procedures. We strongly urge CMS to treat diagnostic radiopharmaceuticals in the same manner as other drugs and to finalize separate payment for diagnostic radiopharmaceuticals that exceed the drug packaging threshold. We also address the ambulatory payment classification (APC) assignment for cardiac Positron Emission Tomography (PET)/Computed Tomography (CT) studies and the comment solicitation on patient and workforce safety quality measures. We discuss these comments in greater detail below.

I. OPPS Packaging Policy for Diagnostic Radiopharmaceuticals

SNMMI and ACNM greatly appreciate the opportunity to again engage with CMS on the OPPS policy that packages payment for all diagnostic radiopharmaceuticals without pass-through status into the payment for the nuclear medicine procedure.
SNMMI and ACNM have opposed this policy since it was first implemented in 2008. The diagnostic radiopharmaceutical is the critical element of the nuclear medicine procedure and selection of the radiopharmaceutical(s) affects the amount and specificity of the information obtained through the scan and plays a major role in the determination of patient management. The packaging policy treats all diagnostic radiopharmaceuticals as if they are interchangeable. Some diagnostic radiopharmaceuticals are used to diagnose and monitor many different types of diseases. For example, fluorodeoxyglucose (FDG) can be used to detect malignant lesions in numerous types of cancer including lung, colorectal, lymphoma, melanoma, breast, ovarian and brain. Other diagnostic radiopharmaceuticals are much more targeted to certain diseases such as specific cancers or neurological conditions and provide more specific clinical information. The resources needed to develop these targeted diagnostic radiopharmaceuticals are significant and therefore the cost of these radiotracers can be a few hundred times greater.

Under the packaging policy, Medicare pays for nuclear medicine procedures at the same rate, regardless of the cost of the diagnostic radiopharmaceutical that is best suited to the patient’s clinical condition. Because targeted diagnostic radiopharmaceuticals are used in a relatively small number of the nuclear medicine studies performed, the average cost for the radiopharmaceutical that is packaged into the Medicare payment amount largely reflects the cost of the more generally used products. As a result, the policy-packaged amount for diagnostic radiopharmaceuticals packaged into the APC payment is often well below the actual cost of furnishing the service plus these new diagnostic radiopharmaceuticals. This means that each time these services are performed the hospital loses money and has to charge the patients who cannot usually pay their invoice. The policy hampers patient access to 21st century health care, innovative products and reduces opportunities for further innovation. The negative consequences for beneficiaries include delayed diagnosis, increased radiation exposure, ineffective treatment plans, and delayed or inappropriate therapy selection.

We appreciate CMS’ willingness to reexamine this packaging policy and its comment solicitation on alternative approaches for diagnostic radiopharmaceuticals. We understand that CMS considers packaging to be a fundamental principle of the OPPS. However, as with all payment policies, CMS should ensure that its packaging policies are appropriate and consistent and refine them as needed to address emerging technology. We note that CMS has done this in other areas – for example, CMS generally packages add-on codes but has recently begun providing separate payment for certain add-on codes that reflect use of Software-as-a-Service.

Similar to the examples above, CMS should also refine the packaging policy for diagnostic radiopharmaceuticals. In addition to the introduction of targeted diagnostic radiopharmaceuticals, there also have been substantial gains in therapies and interventions, the uses of which are informed by the results of the nuclear medicine procedure. Most significantly, the Food and Drug Administration (FDA) has recently approved lecanemab to treat patients with mild cognitive impairment or mild Alzheimer’s disease who have documented evidence of beta-amyloid plaque in the brain. The gold-standard for identifying beta-amyloid plaque is a PET scan using one of the
following diagnostic radiopharmaceuticals: Amyvid™ (florbetapir F18), Neuraceq™ (florbetaben F18) and Vizamyl™ (flutemetamol F18). The proposed packaged payment rate for the PET procedure is comparable to or less than the cost of just the necessary diagnostic radiopharmaceutical alone. Unless CMS revises its packaging policy, many beneficiaries will not receive the testing needed to determine whether they are candidates for the only FDA approved product available to treat a disease that primarily affects patients of Medicare age. To ensure that Medicare payment policy does not inappropriately limit access to essential diagnostic procedures, we ask CMS to refine its packaging policy to provide separate payment for diagnostic radiopharmaceuticals.

A. SNMMI and ACNM recommend that CMS pay separately for diagnostic radiopharmaceuticals that exceed the per day cost threshold for drugs.

Given the wide variation in the cost of diagnostic radiopharmaceuticals, we believe the best way to appropriately pay for diagnostic radiopharmaceuticals is to pay separately for all radiotracers that exceed the per day cost threshold that CMS applies to all other types of drugs (proposed to be $140 for 2024). This approach will ensure that diagnostic radiopharmaceuticals are treated consistently with other types of drugs, particularly therapeutic radiopharmaceuticals. Some radiopharmaceuticals can be used for both diagnostic and therapeutic indications and are currently paid differently depending on the intended use. Applying the drug packaging threshold will provide consistent payment for such products and align with CMS’ existing OPPS drug packaging policy and proposed threshold.

Most importantly, separate payment will allow hospitals to provide the most clinically appropriate products to their patients without consistently being underpaid for the service. Diagnostics radiopharmaceuticals that exceed the drug cost threshold should be paid separately under the average sales price (ASP) methodology when ASP is available or based on the cost calculated from the Medicare claims data when ASP is not available, similar to the therapeutic radiopharmaceutical policy.

We appreciate CMS’ willingness to consider, depending on the comments, adopting as final one or more alternative payment mechanisms for radiopharmaceuticals for CY 2024.\(^1\) We urge CMS to adopt this policy in the final rule to be effective January 1, 2024, as a logical outgrowth of the comment solicitation on diagnostic radiopharmaceuticals and its proposed drug packaging policy to pay separately for other drugs that have a per day cost in excess of the drug packaging threshold. Administratively, this approach should be easy for CMS to implement since it is identical to the policy that CMS already applies to other drugs. It is also the more natural and expected approach given that CMS would simply be expanding the existing policy to include diagnostic radiopharmaceuticals. **Accordingly, SNMMI and ACNM strongly urge CMS to finalize separate payment for diagnostic radiopharmaceuticals that exceed the per day cost threshold applied to all other drugs.**

\(^1\) 88 Fed. Reg. 49579.
B. Alternatively, CMS could apply a higher cost threshold to more specifically target certain high-cost diagnostic radiopharmaceuticals.

As noted above, newer diagnostic radiopharmaceuticals typically have much higher costs than the most commonly used and older or well established radiotracers. Although we believe the existing OPPS packaging policy and proposed $140 threshold should be adopted for diagnostic radiopharmaceuticals for CY 2024, if CMS wanted to more specifically focus a refined payment policy on these products, it could adopt a higher cost threshold. For example, CMS could unpackage diagnostic radiopharmaceuticals, with a cost per day that exceeds $500 – a threshold that has been identified previously. As CMS acknowledges in the proposed rule, SNMMI, ACNM and other interested parties have suggested a $500 threshold in comments on previous rules. This same threshold is also included in the Facilitating Innovative Nuclear Diagnostics Act of 2023 (referred to as the FIND Act), which has been introduced in both houses of Congress with bipartisan support.

CMS also asked for information regarding how to choose an alternate threshold. In our prior comments, we stated that SNMMI, ACNM and other stakeholders reviewed the per day costs from HOPPS claims data, as CMS often does and looked for natural breaks in the per day costs so as to not advantage or disadvantage any similar radiotracers.

We reiterate that we believe the most appropriate threshold is the per day packaging threshold CMS already applies to all other drugs. However, if CMS determines it is appropriate to apply a different cost threshold for diagnostic radiopharmaceuticals, we urge CMS to adopt the $500 or any other threshold that defines a natural break, effective January 1, 2024.

C. CMS Should Not Adopt Other Possible Approaches Discussed in the Proposed Rule.

CMS also solicited comments about three additional approaches: whether it should revise the APC structure, including whether additional nuclear medicine APCs are needed; whether it should create specific payment policies for diagnostic radiopharmaceuticals used in clinical trials; and whether it should adopt codes that incorporate the disease state being diagnosed or a diagnostic indication of a particular class diagnostic radiopharmaceuticals. SNMMI and ACNM recommend that CMS not adopt any of these approaches at this time.

**APC Structure or Additional Nuclear Medicine APCs:** Any possible restructuring should be thoroughly exposed to stakeholder scrutiny before CMS pursues such an approach. To afford more meaningful comment and input, we recommend that CMS robustly describe potential approaches in future notice and comment rulemaking.

**Clinical Trials:** We believe that the negative impact of the packaging policy includes, but is not limited to, clinical trial radiotracers. SNMMI and ACNM do believe that the packaging policy has negatively affected the implementation of clinical trials involving nuclear medicine procedures, including studies of beta amyloid PET that were of particular interest to Medicare. However, we

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do not believe that CMS should implement changes that would only affect diagnostic radiopharmaceuticals furnished to patients in a clinical trial. We believe this would be a Band-Aid approach and not address the full issues facing the nuclear medicine community. We are also concerned that establishing new payment policies for products furnished in clinical trials could exacerbate the current challenges and create even more hurdles for trial participation. Instead, as noted above, we recommend that CMS address these issues by applying the same packaging policies that apply to other drugs to diagnostic radiopharmaceuticals.

**Indication-Specific Coding:** We are concerned that this approach could be administratively burdensome to both hospitals and CMS, but we require additional information beyond the brief discussion CMS has included in the proposed rule and that would afford greater stakeholder scrutiny of any potential approaches CMS may be considering. Accordingly, before pursuing this approach, we recommend that CMS provide detail about both the criteria for establishing codes and the process it would use to develop new coding in future rulemaking.

II. **Cardiac Positron Emission Tomography (PET)/Computed Tomography (CT) Studies (APCs 1522 and 1523)**

For CY 2024, CMS proposed to use CY 2022 claims data to determine OPPS payment rates, including the rates for cardiac PET-CT services (CPT 78431, 78432, and 78433). CPT code 78431 *Myocardial imaging, positron emission tomography, perfusion study (including ventricular wall motion(s), and/or ejection fraction(s), when performed); multiple studies at rest and stress (exercise or pharmacologic), with concurrently acquired computed tomography transmission scan.* Based on this data, CMS proposes to move 78431 from APC 1523 (New Technology—Level 23 ($2501–$3000)), where the procedure is currently assigned, to APC 1522 (New Technology—Level 22 ($2001–$2500)). This change would result in a reduction in payment of 22 percent, from the 2023 payment rate $2,750.50 to the proposed 2024 payment rate of $2,250.50. CMS also proposes to reassign 78432 *Myocardial imaging, positron emission tomography, combined perfusion with metabolic evaluation study (including ventricular wall motion(s), and/or ejection fraction(s), when performed), dual radiotracer (eg, myocardial viability)* from APC 1520 (New Technology—Level 20 ($1801–$1900)) to APC 1518 (New Technology—Level 18 ($1601–$1700)). CMS proposes to retain 78433 in its current APC assignment (APC 1521 (New Technology—Level 21 ($1901–$2000)).

SNMMI and ACNM disagree with the proposed assignments. The codes for cardiac PET-CT (CPT 78431, 78432 and 78433) were new in 2020, which coincided with the COVID-19 public health emergency (PHE). As with any new services, it takes time for hospitals to gain experience with the codes and for CMS to develop reliable data on the cost of performing services described by the code. SNMMI and ACNM are working to educate our members about these new codes and appropriately reporting the services they describe. During the initial adoption period, hospitals need a stable and predictable payment rate. CMS uses the new technology APC groups to facilitate payment during this implementation and adoption period. Absent predictability, hospitals will not invest in new technology and this can limit access by Medicare beneficiaries to innovations that
would improve patient care. We have become aware that there are only 110 hospitals that are currently reporting CPT 78431 and therefore we believe that this service is still considered new and in the adoption period.

CMS’ proposed APC assignments for 2024 are not consistent with the resources needed to perform these services. CPT code 78341 describes the performance of multiple PET procedures that require separate injections of the same tracer. CMS should maintain this service in APC 1523 and not reduce the rate by 22%. Further, CPT codes 78432 and 78433 describe two separate PET procedures that require separate injections of two different types of tracers. The cost of performing these services should be at least equal to, if not greater than, the cost of 78431. We believe that the low volume of claims for these procedures, particularly for 78342 for which there are 6 single frequency claims in the 2022 data, is distorting the appropriate relativity within this group of services. To avoid the resulting rank order anomaly, we recommend that CMS not finalize the proposed assignments and instead assign all three codes to APC 1523. All three of these codes were assigned to this APC in either 2022 or 2023 and we believe it more accurately captures the cost to the hospital of furnishing these services.

We do not believe that it benefits hospitals to keep moving APC groups year to year, which causes instability in payments and angst for hospitals. We believe there are lingering effects of COVID in terms of hospitals ordering and implementing new technology. We urge CMS to retain 78431 in APC 1523 and to move 78432 and 78433 into this APC. We urge CMS to maintain a stable environment for three to five years to allow appropriate adoption and implementation of these important services.

III. Comment Solicitation on Patient and Workforce Safety Quality Measures

CMS asked for input on several topics related to safety for hospital patients and workforce, including individual harms related to use of technology. Specifically, CMS asks about the potential for technology such as artificial intelligence (AI) to cause harm to patients and asks the following questions:

- Which technologies are of the most concern in terms of potential for harm?
- What measurable safety-related outcomes should CMS consider for the Hospital OQR program?
- What technologies could be leveraged to improve safety or facilitate its measurement?

SNMMI and ACNM appreciate CMS’ interest in capturing quality measures related to patient harm but does not recommend that CMS develop or adopt measures specific to AI. AI is being incorporated into many different types of procedures, including some nuclear medicine procedures, but each application is unique. It would be impossible to create a single measure that appropriately captures outcomes or risks associated with all of these different applications.
We also believe that guidelines developed by physician specialty societies are the best way to identify and encourage appropriate utilization of procedures, including procedures using AI. For example, SNMMI has developed appropriate use criteria to guide physician ordering of nuclear medicine scans, to avoid performing unnecessary studies that would expose patients to radiation without a clinical benefit. Such guidelines often take into consideration limitations of the evidence supporting clinical use of certain items, including patient populations that may be underrepresented in the available data. If CMS does pursue development of quality measures, such measures should capture alignment with guidelines.

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SNMMI and ACNM appreciate the opportunity to comment on the OPPS CY 2024 Proposed Rule to the CMS. As always, we are ready to discuss any of its comments or meet with CMS on the above issues. In this regard, please contact Julia Bellinger, Director of Health Policy at jbellinger@snmmi.org or (703) 326-1182.

Respectfully Submitted,

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