September 9, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20001

Re: [CMS-1809-P] Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs; Including the Hospital Inpatient Quality Reporting Program; Health and Safety Standards for Obstetrical Services in Hospitals and Critical Access Hospitals; Prior Authorization; Requests for Information; Medicaid and CHIP Continuous Eligibility; Medicare Clinic Services Four Walls Exceptions; Individuals Currently or Formerly in Custody of Penal Authorities; Revision to Medicare Special Enrollment Period for Formerly Incarcerated Individuals; and All-Inclusive Rate Add-On Payment for High-Cost Drugs Provided by Indian Health Service and Tribal Facilities

Dear Administrator Brooks-LaSure:

On behalf of the American Society of Nuclear Cardiology (ASNC), I appreciate the opportunity to provide comment on the CY 2025 Hospital Outpatient Prospective Payment System (OPPS) proposed rule, published in the *Federal Register* on Monday, July 22, 2024 (89 Fed. Reg. 59186).

ASNC is a greater than 4,900-member professional medical society, which provides a variety of continuing medical education programs related to the role of nuclear cardiology in patient-centered cardiovascular imaging, develops standards and guidelines for training and practice, promotes accreditation and certification within the nuclear cardiology field, and is a major advocate for furthering research and excellence in nuclear cardiology.

ASNC offers comment on the following:

- **PROPOSED PAYMENT FOR DIAGNOSTIC RADIOPHARMACEUTICALS**
- **CARDIAC POSITRON EMISSION TOMOGRAPHY (PET)/ COMPUTED TOMOGRAPHY (CT) STUDIES**

- **ADD ON PAYMENT FOR RADIOPHARMACEUTICAL TECHNETIUM-99M (TC-99M)**

PROPOSED PAYMENT FOR DIAGNOSTIC RADIOPHARMACEUTICALS

The Hospital Outpatient Prospective Payment System (OPPS) currently packages several categories of non pass-through drugs, biologicals, and radiopharmaceuticals regardless of the cost of the products. CMS refers to these products as "policy- packaged" drugs, biologicals, and radiopharmaceuticals. Payment for the policy packaged products that function as supplies when used in a diagnostic test or procedures is packaged with the payment for the related procedure or service. CMS finalized a policy that packaged radiopharmaceuticals in the CY2008 OPPS final rule. The rationale underlying the packaging policy was that diagnostic radiopharmaceuticals are always intended to be used with nuclear medicine procedures and function as supplies when used in a procedure. CMS continues to underscore the concept of packaging costs into a single aggregate payment as a key feature of a prospective payment system that encourages hospital efficiencies and allows hospitals to manage their resources with optimal flexibility.

Since the inception of the policy, stakeholders have raised concerns about the inadequacy of payment as a result of the packaging radiopharmaceuticals and have argued that in some cases the nuclear medicine APC payment rate is lower than the payment rate for the diagnostic radiopharmaceutical itself creating barriers to nuclear medicine services for beneficiaries, particularly those who rely on safety net hospitals for their care. Similarly, interested parties have argued that certain disease states which depend on the use of radiopharmaceuticals are uniquely disadvantaged and have difficulty recruiting hospitals in clinical studies because of the packaging policy.

In response to these concerns, CMS sought comment on new approaches to payment of diagnostic radiopharmaceuticals in the CY2024 OPPS Proposed rule. In particular, CMS proposed four approaches that could enhance beneficiary access to certain radiopharmaceuticals while maintaining the principles of the OPPS. First, CMS solicited feedback on paying separately for diagnostic radiopharmaceuticals with per-day costs above the OPPS drug packaging threshold of $140 or another threshold that may be greater or less than the drug packaging threshold. CMS also sought feedback on restructuring the nuclear medicine APCs for services that use high-cost radiopharmaceuticals or recommendations regarding a policy that would adopt CPT codes that describe the disease state being diagnosed or diagnostic indication for a particular class of radiopharmaceuticals.

In response to the CY2024 comment solicitation, ASNC agreed the 2008 packaging policy creates barriers to access for high-cost, low-volume radiopharmaceuticals. However, ASNC raised significant concerns with the impact a policy of separate payment for radiopharmaceuticals would have on the nuclear medicine APCs. Specifically, ASNC objected to separate payment for the packaged radiopharmaceuticals because it would cause a decrease in nuclear medicine APC payment rates, particularly at the $140 per day cost threshold. ASNC

urged CMS to consider policy alternatives that would reduce the impact on the nuclear medicine APCs as it tried to simultaneously address concerns for high-cost, low-volume radiopharmaceuticals that are policy packaged.

PROPOSED PACKAGING THRESHOLD FOR DIAGNOSTIC RADIOPHARMACEUTICALS

For 2025, CMS proposes to pay separately for any diagnostic radiopharmaceutical with a per day cost greater than $630. Thus, any radiopharmaceutical with a per day cost below that threshold would continue to be policy packaged as it is under the current policy.

ASNC acknowledges CMS' proposing packing proposal is intended to address barriers to beneficiary access for high-cost, low-volume radiopharmaceuticals. We appreciate CMS proposes a payment methodology that seeks to focus separate payment policy on "only those diagnostic radiopharmaceuticals whose costs significantly exceed the approximate amount of payment already attributed to the product in the nuclear medicine APC."[1] Focusing separate payment on only the radiopharmaceuticals whose costs significantly exceed the approximate amount of payment already attributed to the product will help concentrate the effects of unbundling radiopharmaceuticals to only those products that are most likely to create access issues for beneficiaries and reduce the wider effects on the nuclear medicine APCs.

To be clear, a threshold of $630 does not mean that there are no deleterious effects on the nuclear medicine APCs. For example, 5593- Level 3 Nuclear Medicine and Related Services is projected to fall from the current payment rate of $1,352.98 to $1,305.81. Single Photon Emission Tomography (SPECT) codes in this APC will receive a payment cut with no corollary benefit from separate payment since the radiopharmaceutical used in conjunction with this service, Technetium-99m, is well under the $630 threshold. Similarly, Positron Emission Tomography (PET) codes in APC 5594-Level 4 Nuclear Medicine and Related Services are reduced from $1,490.60 to $1,458.10. Rubidium- 82 (Rb-82) and Ammonia (N-13) have mean unit costs of $200.49 and $208.65 respectively and would remain bundled into the procedure payment for both services.

AMOUNT OF SEPARATE PAYMENT FOR DIAGNOSTIC RADIOPHARMACEUTICALS EXCEEDING THE THRESHOLD

CMS explains it proposes to determine a per day cost of non-pass-through diagnostic radiopharmaceuticals that exceed the $630 payment and assign them to an APC, making the product a specified covered outpatient drug. Ordinarily, CMS would use the Average Sales Price (ASP) methodology to pay for these products. However, radiopharmaceuticals are not required to submit data on ASP, and CMS notes the data it does have is limited, does not reflect what it would expect based on the cost and mean unit cost data submitted by hospitals, and is not usable for payment purposes. Therefore, CMS believes manufacturers should have the opportunity to

[1] CENTERS FOR MEDICARE &MEDICAID SERVICES, CY2025 Hospital Outpatient Prospective Payment System Proposed Rule

submit, certify, or restate the ASPs of their products and is proposing to use mean unit cost as an alternative for 2025.

ASNC supports the use of mean unit cost as a reasonable alternative methodology for payment of radiopharmaceuticals that exceed the $630 threshold for CY2025. However, ASNC agrees that ASP should be considered in future years and is strongly supportive of CMS' continued dialogue with manufacturers to understand some of the unique challenges associated with meeting the reporting requirements for ASP.

In summary, the $630 threshold for separate payment is the minimum that would be acceptable in ASNC's view.A threshold of $630 protects nuclear cardiology services from steeper cuts than a lower threshold while improving beneficiary access to services that rely on high-cost radiopharmaceuticals. We appreciate CMS took a thoughtful approach to its proposed policy by using a methodology that sets the per day cost threshold at two times the average offset amount so the effects of its proposed policy would be limited and that only the radiopharmaceuticals with significant costs are pulled out for separate payment. ASNC urges CMS to continue to engage in a dialogue with stakeholders if this policy is finalized to monitor for any unintended impact on nuclear cardiology and other services.

CARDIAC POSITRON EMISSION TOMOGRAPHY (PET)/ COMPUTED TOMOGRAPHY (CT) STUDIES (APCS 1520 AND 1522)

For CY2025, CMS uses CY2023 claims data to determine proposals for APC placement for services described by CPT codes 7843, 78432, and 78433.

CMS' proposes to assign CPT code 78431 to APC1522 (New Technology- Level 22 ($2001-$2500)) with a payment rate of $2,250.50. CMS' proposal is based on over 26,000 single frequency claims that resulted in a geometric mean of $2,350. ASNC supports the proposed APC placement of 78431 for CY2025 and is pleased that reimbursement for this service will remain stable in the upcoming year. ASNC has been adamant in previous years' rulemaking that PET/CT services are a new technology that have variations in cost charges as hospitals account for the true costs of providing services. We are hopeful that geometric mean costs and hospital reporting is stabilizing and that data reported to CMS will support stable reimbursement rates in future years.

For CPT code 78432, CMS applied the universal low volume New Technology APC policy and chose the highest of geometric mean cost, arithmetic mean cost, or median costs based on 4 years of claims data. For this service the highest cost is the arithmetic mean cost of $1,923. That cost is over the cost band for APC 1520 (New Technology- Level 20 ($1801-$1900) and, therefore, CMS proposes reassigning the procedure to APC 1521 (New Technology -Level 21 ($1901-$2000)) with a payment rate of $1950.50. ASNC supports the APC placement of 78432 and the application of the low volume New Technology APC policy.

Finally, claims data analysis showed that there were over 1,400 single frequency claims for 78433 and the geometric mean for the service is $2,010. The geometric mean is over the cost

band for APC 1521(New Technology-Level 21($1901-$2000) which is the current APC assignment for 78433. Accordingly, CMS proposes to reassign 78433 to APC 1522 (New Technology- Level 22 ($2001-$2500)) with a payment rate of 2,250.50 for CY2025. ASNC recommends that CMS finalize the proposal to reassign 78433 in APC 1522.

ADD ON PAYMENT FOR RADIOPHARMACEUTICAL TECHNETIUM-99M (TC-99M)

In 2013, CMS finalized a policy to provide an additional payment of $10 for Tc-99m derived by non-HEU (highly enriched uranium) sources. This policy was part of an effort to eliminate domestic reliance on international reactors that used highly enriched uranium (HEU) to produce Tc-99m.

Effective Jan 2, 2022, the Secretary of Energy certified that there was sufficient global supply of Mo-99 without the use of HEU to meet the needs of patients in the United States. Thus, CMS began to reassess the need for the add on payment for non-HEU derived Tc99m but determined that the HCPCS code Q9969 should be extended through the end of CY2025 to ensure adequate payment for non-HEU sourced Tc-99m. ASNC applauded CMS' add on payment for non-HEU derived Tc-99m at the outset of the policy and continues to support the extension of the add on code until the end of CY2025.

In addition, CMS proposes using its equitable adjustment authority to implement a new $10 per dose add-on payment for radiopharmaceuticals that use Tc-99m derived from domestically produced Mo-99 starting on January 1, 2026. We applaud this effort and urge CMS to consult with stakeholders regarding the most efficient and effective method of establishing this new add on code.

CONCLUSION

ASNC appreciates the opportunity to comment on the OPPS CY2025 Proposed Rule. As always, ASNC welcomes discussion of questions or concerns regarding any of the above comments. Please contact Georgia Lawrence, Director, Regulatory Affairs at glawrence@asnc.org.

Sincerely,

Lawrence Phillips, MD

President,
American Society of Nuclear Cardiology


ASNC