September 12, 2025

The Honorable Mehmet Oz
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-1834-P] Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Program; Overall Hospital Quality Star Rating; and Hospital Price Transparency

Dear Administrator Oz:

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 Thursday, July 17, 2025 (90 Fed. Reg. 33476).

ASNC is a greater than 5,700-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.

Nuclear cardiology procedures play a vital role in diagnosing and managing life-threatening cardiovascular diseases for Medicare beneficiaries. We are concerned that certain payment proposals, if finalized, would jeopardize patient access to timely and accurate diagnosis.

ASNC offers comment on the following:

- **PROPOSED PAYMENT FOR DIAGNOSTIC RADIOPHARMACEUTICALS**
- **PROPOSED REIMBURSEMENT FOR 78803 (RADIOPHARMACEUTICAL LOCALIZATION OF TUMOR, INFLAMMATORY PROCESS OR DISTRIBUTION OF RADIOPHARMACEUTICAL AGENT(S) (INCLUDES VASCULAR FLOW AND BLOOD POOL IMAGING, WHEN**

PERFORMED); TOMOGRAPHIC (SPECT), SINGLE AREA (EG, HEAD, NECK, CHEST PELVIS), SINGLE DAY IMAGING

- **93017- CARDIOVASCULAR STRESS TESTING USING MAXIMAL OR SUBMAXIMAL TREADMILL OR BICYCLE EXERCISE, CONTINUOUS ELECTROCARDIOGRAPHIC MONITORING, AND/ OR PHARMACOLOGICAL STRESS; TRACING ONLY, WITHOUT INTERPRETATION AND REPORT**

- **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) packaged several categories of non pass-through drugs, biologicals, and radiopharmaceuticals regardless of the cost of the product in 2008. 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. 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.

In 2025, in response to stakeholders' concerns about the inadequacy of payment as a result of packaging radiopharmaceuticals, CMS finalized its proposal to separately pay for radiopharmaceuticals with a per day cost above a $630 dollar payment threshold. In addition, CMS finalized a policy to pay for qualifying non pass through diagnostic radiopharmaceuticals with claims data based on mean unit cost data derived from hospital claims because average sales prices (ASP) data was not usable for purposes of payment.

For 2026, CMS proposes to use the most recent data from the average PPI level for Pharmaceuticals for Human Use, Prescription to the nearest $5 increment and proposes a threshold amount of $655 per day. CMS notes that it will update this figure in the final rule if an additional quarterly update is available at that time. ASNC supports CMS' proposal to update the $630 per day threshold to $655 per day in accordance with PPI data. **ASNC encourages CMS to continue working with stakeholders to establish the most appropriate means of developing separate payment amounts for radiopharmaceuticals and appreciates that CMS is open to feedback regarding challenges associated with reporting ASP for radiopharmaceuticals.**

PROPOSED REIMBURSEMENT FOR 78803 (RADIOPHARMACEUTICAL LOCALIZATION OF TUMOR, INFLAMMATORY PROCESS OR DISTRIBUTION OF RADIOPHARMACEUTICAL AGENT(S) (INCLUDES VASCULAR FLOW AND BLOOD POOL IMAGING, WHEN PERFORMED); TOMOGRAPHIC (SPECT), SINGLE AREA (EG, HEAD, NECK, CHEST, PELVIS), SINGLE DAY IMAGING

CMS proposes the reassignment of 78803(*Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); tomographic (SPECT) single area (eg, head, neck, chest, pelvis), single day imaging* from nuclear medicine APC 5593 to APC5592. This reassignment results in a negative 57% adjustment to payment rates for 78803.

CPT	Description	APC 2025	APC 2026 PROPOSED	2025 PAYMENT	2026 PROPOSED	% CHANGE
78803	Radiopharmaceutical localization of tumor, inflammatory process, or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); tomographic (SPECT), single area (eg, head, neck, chest, pelvis), or acquisition, single day imaging.	5593	5592	$1305.48	$558.70	-57%

ASNC has significant concerns with the extreme cut to payment for CPT code 78803 that results from the proposed APC reassignment. Physicians rely on stability in reimbursement rates to enable them to plan for practice expenses, supplies, and any required capital investment in the coming year. A cut of this magnitude seriously impairs the ability of nuclear cardiologists to provide this service and diagnose high mortality conditions.

This code is most often used in the diagnosis and treatment of Transthyretin Cardiac Amyloidosis as it detects amyloid using Single Photon Emission Tomography (SPECT) with 99m TC- pyrophosphate. [1] Cardiac Amyloidosis is a form of cardiomyopathy that comes from accumulation of misfolded protein deposits in the heart and, if left untreated, results in a median survival of less than 6 months. [2] Cardiac Amyloidosis can be detected using other tests but they

[1] Dorbala, et al, *ASNC Cardiac Amyloidosis Practice Points Update: 99m Technetium- Pyrophosphate Imaging for Tranthyretin Cardiac Amyloidosis*, Feb. 2106, *available at* ASNC Cardiac Amyloidosis Practice Points Update – ASNC

[2] Dorbala, et. al., *ASNC/AHA/ASE/EANM/HFSA/ISA/SCMR/SNMMI expert consensus recommendations for multimodality imaging in cardiac amyloidosis: Part 1 of 2—evidence based and standardized methods of imaging*, Journal of Nuclear Cardiology, Volume 26, Issue 6, 2065-2123

are not as specific and are more invasive for the patient. For example, the alternative to a PYP scan is an Endomyocardial Biopsy., an invasive and more costly test. 93595 is the CPT code associated with endomyocardial biopsy and its current APC is 5183- Level 3 Vascular Procedures with a payment rate of $3,254.23.

The geometric mean data associated with 78803 decreased sharply in the from the 2024 to 2025 final rule. In 2024, the geometric mean cost of 78803 was $1,136.62 and it fell to $588.32 in the 2025 final rule. A number of services in nuclear medicine APC 5593 had cost data using high cost low volume radiopharmaceuticals. That cost data was pulled out of APC 5593 when CMS made the decision to separately pay for radiopharmaceuticals over the $630 payment threshold. Physicians and hospitals need time to properly account for resources and inputs associated with 78803 for services that do not use high cost radiopharmaceuticals. **Thus, ASNC urges CMS to collect several years of geometric mean data before reassigning 78803 to APC 5592.** PYP has experienced several shortages over the past few years and hospitals must switch to alternatives such as HDP or HMDP when those shortages happen. It may take a longer time to understand the changes in data that have resulted than the short comment period associated with the CY2026 proposed rule.

	Geometric Mean- 2024 Final	Geometric Mean – 2025 Final	Geometric Mean-2026 Proposed	Total Frequency-2025	Total Frequency-2026
78803	$1,136.62	$588.04	$593.32	27,799	28,384

ASNC also asks that CMS provide more transparency regarding the upper and lower cut off points for reassignment of CPT codes from one APC to another and provide written rationale in the text of the rule if a service is reassigned to a new APC. Additional information on exact thresholds and ranges that determined a service should be moved to an APC would also be helpful for providers to understand CMS' methodology more clearly.

93017- CARDIOVASCULAR STRESS TESTING USING MAXIMAL OR SUBMAXIMAL TREADMILL OR BICYCLE EXERCISE, CONTINUOUS ELECTROCARDIOGRAPHIC MONITORING, AND/ OR PHARMACOLOGICAL STRESS; TRACING ONLY, WITHOUT INTERPRETATION AND REPORT

CMS proposed a downward adjustment of approximately 29% to code 93017- *Cardiovascular stress test using maximal or submaximal treadmill or bicycle exercise, continuous electrocardiographic monitoring, and/or pharmacological stress; tracing only, without interpretation and report.* Stress testing with a treadmill or bicycle is an important part of the diagnosis of coronary artery disease and is used to stress the heart to take images of cardiac perfusion, or blood flow, through the heart to look for blockages or areas of reduced blood flow.

CPT	Description	2025 Final Rate	2026 Proposed Rate	% Change
93017	Cardiovascular stress test using maximal or submaximal treadmill or bicycle exercise, continuous electrocardiographic monitoring, and/or pharmacological stress; tracing only, without interpretation and report	$311.40	$221.14	-28.99

CMS proposes the significant cut to payment for 93017 despite an uptick in geometric mean data from CY2025 to CY2026. In 2025, the geometric mean for 93107 was $273.34 and it went up to $276.82 in 2026 proposed data files. ASNC examined the data from the file release associated with the proposed rule and is aware of a number of new services added in to APC 5722 in concert with some services being reassigned. If CMS could provide more rationale about the influx of new services into the 5722 APC that would be appreciated. Given the substantial cut to payment despite steady geometric mean cost data, ASNC urges CMS to refrain from finalizing the CY2026 payment rate until more data about other changes in the APC can be released and analyzed.

	Geometric Mean-2025 Final	Geometric Mean-2026 Proposed
93017	$273.34	$276.82

CARDIAC POSITRON EMISSION TOMOGRAPHY (PET)/ COMPUTED TOMOGRAPHY (CT) STUDIES

For CY2026, CMS uses CY2024 claims data to determine proposals for APC placement for services described by CPT codes 78431, 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 for CY2026. CMS' proposal is based on over 30,000 single frequency claims that resulted in a geometric mean of $2,200. ASNC supports the proposed APC placement of 78431 for CY2026 and is encouraged that reimbursement for this service will remain stable in the upcoming year.

For CPT code 78432, CMS used 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 $1,737. The arithmetic mean indicates that the appropriate cost band for 78432 is 1519 (New Technology-Level 19($1701-1800)) with a payment rate of $1750.50. ASNC is disappointed with the falling geometric mean of costs associated with 78432 and realizes the complexity of accurate data

reporting for such a low volume services. ASNC appreciates CMS' application of the low volume new technology APC policy.

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. We ask that CMS consider analyzing additional years of data before reassigning 78432.

For 78433, claims data analysis showed over 1,400 single frequency claims for 78433 with a geometric mean of $2,037. 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 CY2026. ASNC supports the proposed reassignment of 78433 and urges CMS to finalize the proposal to reassign 78433 in APC 1522.

ADD ON PAYMENT FOR RADIOPHARMACEUTICAL TECHNETIUM-99M (TC-99M) DERIVED FROM DOMESTICALLY PRODUCED MOLYBDENUM-99 (MO-99)

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. In 2023, CMS explained that it believed that the 2023 data set used in rate setting for 2025 would include claims that only used non-HEU sourced Tc-99m and thus finalized a policy to end the $10 add on payment for Tc-99m derived by non-HEU (highly enriched uranium) sources in the 2024 OPPS rule. Payment for non-HEU sourced Tc-99m continued through December 2025.

The Department of Energy (DOE) and other stakeholders alerted CMS to an additional issue which CMS discussed in the 2025 OPPS final rule. DOE and others informed CMS of the degree to which foreign governments have historically subsidized the production of Mo-99 resulting in prices that are artificially low when compared with the real costs of production. CMS finalized a proposal to establish a new add on payment of $10 per dose for domestically produced Tc-99m starting on January 1, 2026. CMS charged the DOE and the National Nuclear Security Administration (NNSA) with establishing criterion to determine what constitutes a dose with sufficient domestically produced Tc-99m. NNSA and DOE recommend, and CMS proposes, to define domestically Tc-99m as a dose of Tc-99m generated from domestically produced Mo-99. Domestically produced Mo-99 is Mo-99 that is both irradiated and processed in the United States. CMS proposes to establish HCPCS C-code C917X which will provide $10 add on payment for hospitals that are able to certify that at least 50% of the Mo-99 in the Tc-99m generator to produce the Tc-99m was domestically produced Mo-99.

ASNC appreciates and supports the $10 per dose add on payment for domestically produced Tc-99m. ASNC also supports the proposed definitions recommended by the DOE and

NNSA and agrees that any dose that hospitals are able to certify has at least 50% of the Mo-99 in the Tc-99m generator to produce TC-99m should qualify as domestically produced and should, therefore, qualify for the $10 add on payment.

CONCLUSION

ASNC appreciates the opportunity to comment on the OPPS CY2026 Proposed Rule. We urge CMS to reconsider payment proposals that would significantly reduce reimbursement for nuclear cardiology services and to work collaboratively with the physician community to ensure Medicare beneficiaries maintain access to timely, safe, and evidence-based cardiovascular imaging. 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,

Panithaya Chareonthaitawee, MD

President,

American Society of Nuclear Cardiology