

August 31, 2026

Mehmet Oz, MD, MBA
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

RE: CMS-1850-P – Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; and Quality Reporting Programs; etc.

Dear Administrator Oz:

The American Society of Nuclear Cardiology (ASNC) appreciates the opportunity to comment on the CY 2027 Hospital Outpatient Prospective Payment System (OPPS) proposed rule, published in the *Federal Register* on July 7, 2026.

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. ASNC offers comment on the following:

- Procedures Assigned to New Technology Ambulatory Payment Classification (APC) Groups for CY 2027
 - Nuclear Medicine and Related Services APC Series (APC 5591 through 5594)
- Proposed Payment for Diagnostic Radiopharmaceuticals
- Payment for Imaging Without Contrast Services at Provider-based Departments
- OPPS Payments for Software as a Medical Service (SaMS) Diagnostic Services

PROCEDURES ASSIGNED TO NEW TECHNOLOGY APC GROUPS FOR CY 2027

Nuclear Medicine and Related Services APC Series (APC 5591 through 5594)

The current Nuclear Medicine and Related Services APC series (APC 5591 through 5594) was created as a part of the APC restructuring and consolidation in the CY2016 OPPS/ASC final rule. Previous versions of the Nuclear Medicine APC groupings went from eight APCs to four APC categories and the four-level APC structure has been maintained since 2016.

In the 2025 OPPS/ASC final rule, CMS finalized a policy to separately pay for diagnostic radiopharmaceuticals with per-day costs higher than a specified threshold amount (\$630 in 2025

and proposed to be \$665 in 2027). As a result of this policy, costs that were previously packaged with their associated services are now separately paid. This has led to the differences between the four levels of APC geometric mean costs becoming less distinct. For example, if CMS were to maintain the four level APC structure found in the CY2026 OPPS/ASC final rule for Nuclear Medicine and related services using the NPRM claims data it would result in a geometric mean costs for level 3 (5593) of \$1,367.99 while the geometric mean costs for Level 4 APC would be \$1,497.06. CMS states that given the “relative proximity of the APC geometric mean costs and the clinical and cost similarities between the APCs in the Nuclear Medicine and Related Services Series, we believe that it is appropriate to reorganize the Nuclear Medicine and Related Services APC series for the CY2027 OPPS.”

In addition, CMS concludes that CPT codes 78431 [*Myocardial imaging, positron emission tomography (pet), 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*], 78432 [*Myocardial imaging, positron emission tomography (pet), combined perfusion with metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), dual radiotracer (eg, myocardial viability);*], and 78433 [*Myocardial imaging, positron emission tomography (pet), combined perfusion with metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), dual radiotracer (eg, myocardial viability);* have sufficient CY2025 claims data available to be assigned to clinical APCs for CY2027 OPPS ratesetting. CMS proposes assigning these codes to APC 5594 (Level 4 Nuclear Medicine and Related Services).

ASNC strongly supports CMS’s proposed reorganization of the Nuclear Medicine and Related Services APC Series.

We agree the geometric mean cost ranges between 5593 and 5594 were in relatively close proximity. CMS’s proposal would reassign certain services into 5593 that were previously assigned to 5594 with relatively close geometric mean costs.

For example, CPT code 78452 [*Myocardial perfusion imaging, tomographic (SPECT) (including attenuation correction, qualitative or quantitative wall motion, ejection fraction by first pass or gated technique, additional quantification, when performed); multiple studies, at rest and/ or stress (exercise or pharmacologic) and/ or redistribution and / or rest reinjection* has a geometric mean cost of \$1,404.19 and would maintain its assignment in 5593 and 78492-*Myocardial imaging, positron emission tomography (PET), perfusion study (including ventricular wall motion [s] and/ or ejection fraction [s], when performed); multiple studies at rest and stress (exercise or pharmacologic)]* with a geometric mean cost of \$1,247.09 is reassigned to 5593 as it was previously assigned to 5594. These two codes have a spread in geometric mean cost of \$157.10 and had previously been assigned to separate APCs.

Cardiac Positron Emission Tomography (PET)/ Computed Tomography (CT) Studies (APC 5594)

ASNC strongly supports CMS's proposal to reassign the PET/CT CPT codes (78431, 78432, and 78433) to the Nuclear Medicine and Related Services APC 5594. As CMS notes, these services were assigned to the New Technology APCs beginning January 1, 2020 because they were new services that did not have sufficient claims history to establish accurate payment rates. CMS explained that over the past six years, CPT code 78431 and 78433 have had increasing volumes and relatively stable geometric mean costs. However, 78432, which is clinically related to 78431 and 78433, has had low claims volume and variable geometric mean costs reported in the claims data. This led CMS to keep the PET/CT CPT codes assigned to the New Technology APCs in the CY2026 HOPD final rule.

ASNC agrees that 78432 has low claims data and variability in geometric mean costs. 78432 has only 41 total frequency claims with a geometric mean costs of \$1,791.82 in the data used for ratesetting in CY2027. This is compared with 9 single frequency claims with a geometric mean cost of \$1,276.30 in the data used in ratesetting for the CY2024 HOPD final rule. The claims data associated with 78432 should not vary so significantly from other PET/CT Services. 78432 requires similar services to 78431 but rather than using two injections of the same radiotracer, two different tracers are injected for image acquisition; one for the perfusion study and one for the metabolic study. In addition, the tracer used for the metabolic study, fluorodeoxyglucose (FDG), needs additional prep time than those used in the perfusion study. This service should require additional staff and clinical time than services in 78431. Given that the volume of the service for 78432 is so low, it could be that hospitals struggle to accurately account for services required to provide the service.

In addition, CMS says that they believe that services provided by CPT codes 78431 through 78433 are clinically similar to services in the Nuclear Medicine and Related Services APC series but have dramatically different resource inputs than other services in the APC series. ASNC agrees that PET/CT services are clinically similar to other services in the Nuclear Medicine series but it is true that the resources required to provide PET/CT services are significantly higher than other services in the Nuclear Medicine APC series. For example, costs associated with a PET/CT camera are substantially higher than SPECT or non-hybrid imaging cameras. **Therefore, ASNC agrees that is appropriate to place PET/CT services in APC 5594.**

ASNC is concerned that 78830-*Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); tomographic (SPECT) with concurrently acquired computed tomography (CT) transmission scan for anatomical review, localization and determination/detection of pathology, single area (eg, head, neck, chest, pelvis) or acquisition, single day imaging* will be reassigned from 5593 to 5592. This code is clinically important and is used in the diagnosis and treatment of Transthyretin Cardiac Amyloidosis as it detects amyloid using Single Photon Emission Tomography (SPECT) and Computed Tomography with 99m TC- pyrophosphate.¹ Cardiac Amyloidosis is a form of cardiomyopathy that comes from

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

accumulation of misfolded protein deposits in the heart and, if left untreated, has a high mortality rate. [2] Cardiac Amyloidosis can be detected using other tests but they are not as specific, are more invasive for the patient, and are more costly to Medicare.² For example, the alternative to a PYP scan is an Endomyocardial Biopsy. 93505 is the CPT code associated with endomyocardial biopsy where the provider takes a tissue sample from the innermost layer of the heart muscle. Its current APC is 5183- Level 3 Vascular Procedures with a payment rate of \$3,254.23. We are concerned that a decline of reimbursement of this magnitude could lead to patient access issues for this critical testing.

ASNC is aware that costs associated with 78830 are the impetus for the APC reassignment to 5592 but we remain concerned about a move to more expensive, more invasive tests for the diagnosis of transthyretin cardiac amyloidosis. ASNC would request a phased in approach before the code is reassigned. This would allow a few years of claims data to be accumulated after a number of radiopharmaceuticals associated with this code were pulled out to be separately paid when CMS finalized its policy to separately pay for diagnostic radiopharmaceuticals over a \$655 per day threshold.

PROPOSED PAYMENT FOR DIAGNOSTIC RADIOPHARMACEUTICALS

ASNC encourages CMS to continue working with stakeholders to establish the most appropriate means for developing separate payment amounts for radiopharmaceuticals. We are encouraged that CMS remains open to feedback from manufacturers regarding challenges associated with reporting ASP for radiopharmaceuticals and is looking to improve payment accuracy for separately payable radiopharmaceuticals. We are pleased that CMS is using input from stakeholders and is focused on arriving at consistent, validated, and universal reporting to determine if ASP is a viable payment methodology in future years. We look forward to the ASP reporting Framework for Diagnostic Radiopharmaceuticals being posted on the Hospital Outpatient Prospective Payment Department's website.

Further, we support CMS's continued use of its current methodology to calculate the per-day cost of diagnostic radiopharmaceuticals that establishes the packaging threshold – the fourth-quarter moving Produce Price Index (PPI) levels for Pharmaceutical for Human Use, Prescription. Based on this methodology, CMS states the \$630 threshold would trend forward to \$665 per day for CY 2027. Further, we support updating of this number in the final rule if more recent data becomes available in the intervening time.

PAYMENT FOR IMAGING WITHOUT CONTRAST SERVICES AT PROVIDER-BASED DEPARTMENTS

Neutralizing Medicare payment rates across settings of care are based on a presumption that physician fee schedule rates are adequate. There has been significant practice consolidation and acquisition in cardiology following physician fee schedule reductions, including highly disruptive payment policy changes in 2010 that resulted in steep cuts to cardiovascular imaging services. The lack of an annual inflationary adjustment, CMS' new efficiency adjustment, and

² Dorbala, et. al., *ASNC/AHA/ASE/EANM/HFSA/ISA/SCMR/SNMCI 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

costly administrative burdens continue to drive physicians to sell their practices or become employed directly out of medical school. We urge CMS to consider that current fee schedule reimbursement rates are driving practice consolidation and acquisition. Therefore, as these rates are financially unsustainable, they should not be adopted for services billed under the hospital outpatient prospective payment system.

While we have concerns generally about the application of site-neutral payment policies, CMS is correct in *not* applying its proposed policy to imaging *with* contrast or other agents, like radiopharmaceuticals.

While nuclear cardiac imaging, including SPECT and PET, do not rely on traditional radiopaque or magnetic contrast agents, these tests use radiopharmaceuticals -- a combination of a radioactive isotope and pharmacologic agent. Patient complexity can also vary significantly based on site of service. Patients with unstable cardiovascular disease, higher BMI, and those at risk of complications during stress testing are often referred to hospital outpatient departments for testing and require more staff, greater monitoring and emergency capabilities. These are added costs not fully captured in fee-for-service rates. Further, because of the significant investments required to deliver nuclear cardiology services, including radiation safety compliance and emergency response capabilities during stress testing, Medicare payment should encourage, not inadvertently discourage investments in technologies, like PET, that provide greater diagnostic accuracy.

OPPS PAYMENTS FOR SOFTWARE AS A MEDICAL SERVICE (SAMS) DIAGNOSTIC SERVICES

We appreciate CMS' desire to dispel ambiguity and clarify the distinction between Software as a Service (SaaS), which describes general cloud-based computing service models, and software-based technologies that support clinical decision making through algorithmic analysis, including those that provide clinical or diagnostic functionality. As such CMS proposes to change its terminology from SaaS to Software as a Medical Service (SaMS). ASNC agrees that SaMS can be used as a broad business/industry description but it is important that SaMS not be confused with Software as a Medical Device, which has regulatory significance.

While the currently identified services do not include nuclear cardiology technologies, the policies finalized through this rulemaking may have significant implications for future nuclear cardiology applications.

As CMS considers standardizing its approach to payment for SaMS, ASNC supports a temporary, neutral transition that recognizes SaMS as a distinct category and preserves current payment levels; however, CMS should not treat its proposed interim New Technology APC approach as the final way of valuing these technologies.

We support that this interim period will allow CMS to gather claims and other information while considering how SaMS should ultimately be valued and appropriately reflect the resources required to furnish a SaMS service, which may include things like software infrastructure, maintenance and updates, and clinical validation.

CONCLUSION

ASNC appreciates the opportunity to comment on the OPPS CY2027 Proposed Rule and is available to answer questions regarding any of the above comments. Please contact Georgia Lawrence, Director, Regulatory Affairs at glawrence@asnc.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Jamieson Bourque, MD". The signature is fluid and cursive, with a long horizontal stroke extending from the middle of the name.

Jamieson Bourque, MD
President,
American Society of Nuclear Cardiology