



September 9, 2024

[Submitted electronically via www.regulations.gov]

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services (HHS)
Attention: CMS-1809-P
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Proposed Rule (RIN 0938-AV35)

Dear Administrator Brooks-LaSure:

On behalf of the American Pharmacists Association (APhA)-Academy of Pharmacy Practice and Management (APPM) Nuclear Pharmacy Practice Special Interest Group (SIG), APhA is pleased to submit comments on CMS' proposed rule (CMS-1809-P) for Calendar Year 2025 Medicare payment rates for hospital outpatient and Ambulatory Surgical Center services in anticipation of expanding patient access to important diagnostic radiopharmaceuticals with the adoption of the proposed rule in November 2024.

APhA is the largest association of pharmacists in the United States advancing the entire pharmacy profession. APhA represents pharmacists in all practice settings, including community pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and government facilities. Our members strive to improve medication use, advance patient care, and enhance public health. The APhA Nuclear SIG represents over 2,600 nuclear pharmacists and is the association home for nuclear pharmacists. APhA's Nuclear SIG provides a strong voice and regulatory support for nuclear pharmacy practice. The mission of APhA's Nuclear SIG is to support its members through APhA educational programming, communication, and legislative activities in order to uphold and promote nuclear pharmacy practice, advance pharmaceutical care, and recognize practice excellence.

[c. Proposed Payment for Diagnostic Radiopharmaceuticals \(FR 59212\)](#)

CMS explains that "under the OPPS, the costs associated with diagnostic radiopharmaceuticals are packaged into the payment for the nuclear medicine tests they are used with...we recognize

that in some specific circumstances, the payment amount for the nuclear medicine tests may not adequately account for the cost of certain specialized diagnostic radiopharmaceuticals, even when those agents may be the most clinically appropriate. Consequently, we are proposing refinements to the existing packaging policy to improve the accuracy of the overall payment amounts by paying separately for any diagnostic radiopharmaceutical with a per day cost greater than \$630 and removing their costs from the payment amounts for the nuclear medicine tests. Any diagnostic radiopharmaceutical with a per-day cost equal to or below that threshold would continue to be policy-packaged, with costs incorporated into the payment rates for the nuclear medicine tests.”

CMS is proposing to pay separately for diagnostic radiopharmaceuticals with per day costs above a threshold of \$630, which is approximately two times the volume-weighted average cost amount currently associated with diagnostic radiopharmaceuticals. CMS also proposes to update the \$630 threshold in CY 2026 and subsequent years by the Producer Price Index (PPI) for Pharmaceutical Preparations. CMS proposes to pay for separately payable diagnostic radiopharmaceuticals based on their Mean Unit Cost (MUC) derived from OPPS claims and seek comment on the use of Average Sales Price (ASP) for payment in future years.

For CY 2025, CMS applies an add-on payment for radiopharmaceuticals that use Tc-99m produced without use of highly enriched uranium (HEU). CMS is proposing for CY 2026 to replace the add-on payment for radiopharmaceuticals produced without the use of Tc-99m derived from non-HEU sources with an add-on payment for radiopharmaceuticals that use Tc-99m derived from domestically produced Mo-99.

Diagnostic radiopharmaceuticals are a critical part of the patient disease management process with over 20 million nuclear medicine procedures each year. These radiopharmaceuticals aid in the diagnosis of disease by providing both anatomical and functional information regarding physiologic processes at a molecular level, which enables health care providers to assess a patient’s current disease state for therapeutic (including radiotherapeutic) intervention.

Radiopharmaceutical drug development has brought to market several imperative diagnostic agents in recent years. These diagnostic radiopharmaceuticals have clinical utility in the diagnosis or management of disease states including prostate cancer, dementia, and neuroendocrine tumors with more in the pipeline for other hard to diagnose and treat disease states. CMS pass-through status has enabled patients’ access to these and future diagnostic radiopharmaceuticals; however, many of these agents recently lost or will soon lose this status. The loss of separate reimbursement significantly jeopardizes patient access to essential radiopharmaceuticals as the cost is not adequately accounted for in the current hospital-packaged reimbursement model for diagnostic procedures.

Accordingly, APhA strongly supports the proposed rule and agrees with CMS that “[t]his update should address challenges for patients in accessing these prescribed nuclear medicine

tests with higher-cost radiopharmaceuticals.” APhA believes the proposed rule is a significant step forward in preserving patient access to diagnostic radiopharmaceuticals providing health care providers the ability to improve patient disease state management and overall patient care and urges CMS to finalize these proposals.

Conclusion

Thank you again for allowing APhA the opportunity to comment on CMS’ proposed rule for Calendar Year 2025 Medicare payment rates for hospital outpatient and Ambulatory Surgical Center services. If you have any questions or need any additional information, please contact APhA at mbaxter@aphanet.org.

Sincerely,

A handwritten signature in black ink that reads "Michael Baxter". The script is cursive and fluid, with the first letters of each word being capitalized and prominent.

Michael Baxter
Vice President, Government Affairs