



January 3, 2024

Jesse M. Ehrenfeld, MD, MPH American Medical Association Board of Trustees AMA Plaza 330 N. Wabash Ave., Suite 39300 Chicago, IL 60611-5885

Dear Dr. Ehrenfeld,

We write on behalf of the American Society of Nuclear Cardiology (ASNC) and the American College of Cardiology (ACC) regarding Resolution 229; *Facilitating Appropriate Reimbursement of Diagnostic Radiopharmaceuticals* which was considered by Reference Committee B at the November 2023 AMA House of Delegates (HOD) meeting. The House of Delegates referred the resolution to the AMA Board of Trustees for decision. **The societies request the Board** *not* **adopt Resolution 229**.

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.

The ACC is the global leader in transforming cardiovascular care and improving heart health for all. As the preeminent source of professional medical education for the entire cardiovascular care team since 1949, and now with more than 56,000 members from over 140 countries, the ACC credentials cardiovascular professionals who meet stringent qualifications and leads in the formation of health policy, standards and guidelines. Through its world-renowned family of JACC Journals, NCDR registries, ACC Accreditation Services, global network of Member Sections, CardioSmart patient resources and more, the College is committed to ensuring a world where science, knowledge and innovation optimize patient care and outcomes.

The societies voiced concerns regarding Resolution 229 during the November 2023 Reference committee meeting. We also believe it is important to re-state our concerns to the AMA Board of Trustees as it considers the resolution.

Our chief concern with Resolution 229 is that it does not adequately address the complexity of the radiopharmaceutical hospital outpatient department payment policy and the likely implications of unbundling separate payment for radiopharmaceuticals over the \$140 per day cost threshold. We acknowledge the current packaging policy for radiopharmaceuticals in the outpatient setting can create barriers to beneficiary access, especially with regard to high-cost, low-volume radiopharmaceuticals.

In the CY2024 Hospital Outpatient Prospective Payment System (OPPS) proposed rule, the Centers for Medicare and Medicaid Services (CMS) solicited feedback from stakeholders on its current packaging policy for radiopharmaceuticals. Specifically, CMS asked stakeholders to comment on whether separate payment for radiopharmaceuticals above a \$140 per-day cost threshold is advisable (or some other per day cost threshold). CMS also requested feedback on other policy options such as APC restructuring, developing disease specific codes, or creating new payment structures for radiopharmaceuticals used in clinical trials.

In the CY2024 Hospital OPPS final rule, CMS stated that "overall there was not a general consensus among commenters as to the most effective way for CMS to reform its OPPS diagnostic radiopharmaceutical payment policy." The Agency did note, however, that commenters predominately focused on separate payment as the most effective policy solution but did not agree on a per-day cost threshold.

Our comments to CMS and in response to Resolution 229 at the AMA HOD meeting focused on the need to understand the specific impact on the nuclear medicine APCs 5591-5594 that would result from a change in packaging policy. Pulling the cost of radiopharmaceuticals out of the hospital charge data will cause a decrease in the geometric mean cost of the overall APC, and, consequently, a cut to the reimbursement rate. In the case of high-cost radiopharmaceuticals, any decrease to the resulting nuclear medicine APCs would be more than accounted for with the separately paid radiopharmaceutical. However, it is less clear the same would be true for radiopharmaceuticals with costs only slightly above an OPPS drug packaging threshold of a per-day cost of \$140.

Current legislation, the *Facilitating Innovative Nuclear Diagnostics Act of 2023* (H.R. 1199/ S.1544), would set separate payment for radiopharmaceuticals above a \$500 per-day cost threshold. The Council on Radionuclides and Radiopharmaceuticals notes in its 2024 Hospital OPPS comment letter that it developed "several simulations (using CY 2022 claims data)" to estimate the potential impact to the nuclear medicine procedure payment amounts by unpackaging radiopharmaceuticals at either the cost-per-day threshold of \$140 or \$500.¹ The results suggested the impact to the nuclear medicine procedures, as well as the number of nonnuclear medicine procedures effected, is "minimized" when the \$500 threshold was used.

¹ Comment on the CY2024 Hospital Outpatient Prospective Payment System, Council on Radionuclides and Radiopharmacueticals, *available at* https://www.regulations.gov/comment/CMS-2023-0120-1879

We are concerned that a threshold of \$140 would lead to reductions in payment for important cardiovascular tests which analyze cardiac structure and function to diagnose disease. Some of these services are performed at very large volumes—more than 1 million—and even small changes become significant at that scale.

While a payment threshold of \$500 may lessen any negative impact of unpackaging radiopharmaceuticals and addresses more challenging cases of under-payment for high-cost radiopharmaceuticals, it is nonetheless imperative to fully understand effects on all nuclear medicine APCs with comprehensive data before supporting a particular per-day cost threshold above which radiopharmaceuticals would be separately paid.

Reform to CMS' packaging policy for radiopharmaceutical payment may be appropriate if specific impact of the policy change can be well understood. However, Resolution 229 would direct the AMA to advocate for both the \$140 threshold and separate payment for radiopharmaceuticals without a much-needed impact analysis. The societies are also concerned those positions are too narrow and specific for the AMA to adopt on this issue, potentially opening the door for external and industry stakeholders to utilize the House of Delegates process to drive niche payment policy discussions in the future.

We appreciate the AMA Board of Trustees' consideration of this issue and would be pleased to provide additional information or answer questions. Please contact Camille Bonta at <u>cbonta@summithealthconsulting.com</u> or at (202) 320-3658 for any requests.

Sincerely,

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Lawrence Phillips, MD, FASNC

President American Society of Nuclear Cardiology

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B. Hadley Wilson, MD, FACC

President American College of Cardiolog