September 9, 2024

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
US Department of Health & Human Services
200 Independence Avenue SW
Washington, DC 20543

Re: Medicare and Medicaid Programs; CY 2025 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Prescription Drug Inflation Rebate Program; and Medicare Overpayments

Dear Administrator Brooks-LaSure,

The American Society of Nuclear Cardiology (ASNC) appreciates the opportunity to provide comments on the CY 2025 Medicare Physician Fee Schedule (PFS) proposed rule (CMS-1807-P) as published in the *Federal Register* on July 30, 2024.

ASNC is a 4,900 member professional medical society, which provides a variety of continuing medical education programs related to nuclear cardiology and cardiovascular computed tomography, develops standards and guidelines for training and practice, promotes accreditation and certification with the nuclear cardiology field, and is a major advocate for furthering research and excellence in nuclear cardiology and cardiovascular computed tomography.

Specifically, ASNC offers comment on the following:

- Medicare CY 2025 Conversion Factor
- Payment for Medicare Telehealth Services
- Atherosclerotic cardiovascular disease (ASCVD) Risk Assessment and Management Services
- Payment of Radiopharmaceuticals in the Physician Office

MEDICARE CY 2025 CONVERSION FACTOR

The CY 2025 Medicare conversion factor is proposed to decrease for the fifth straight year by approximately 2.80 percent from $33.2875 to $32.3562. We understand this cut is largely the result of the expiration of a 2.93 percent temporary update to the conversion factor at the end of 2024 and a zero percent baseline update for 2025 under the Medicare Access and CHIP Reauthorization Act (MACRA). Unfortunately, these cuts coincide with ongoing growth

in the cost to practice medicine as CMS projects the increase in the Medicare Economic Index (MEI) for 2025 will be 3.6 percent.

ASNC is on record in support of providing physicians an annual payment update, beginning in 2025, that is tied to the MEI. This reform is fundamental to ensuring physician payment adequacy. There is also an urgency to reforming budget neutrality requirements to avoid cuts to the conversion factor and significant fee schedule redistribution in the future, including more frequent updates to prices and rates for direct cost inputs for practice expense relative value units which includes clinical wage rates, prices of medical supplies, and prices of equipment.

CY 2025 will be the fourth and final year of transition of the clinical staff wage increases. This inflationary update is budget neutral within the practice expense relative values, impacting those services with higher cost supplies and equipment the most severely. Even though CMS finalized a multi-year transition to mitigate the affect of payment changes due to the clinical labor pricing update, the impact fell hard on nuclear cardiology services at the same time reductions to the conversion factor were occurring, compounding the effect. When CMS finalized the clinical labor pricing update, the rate per minute for a nuclear medicine technologist went up from 0.62 to 0.88, a 43 percent increase. Because nuclear cardiology has a lower share of direct costs associated with clinical labor and has high-cost supplies, the result was a significant *decrease* in payment for nuclear cardiology services, including a 12 percent cut to myocardial perfusion imaging. These cuts, arising from budget neutrality requirements, were fundamentally unfair. While wages paid to technologists rose, as well as the costs of machines and equipment, CMS finalized a cut to these services to preserve budget neutrality.

In this proposed rule, CMS requests feedback on an "Advanced Primary Care Hybrid Payment" model. ***Any new approach to increase payment for primary care services under a hybrid model should be outside of the budget neutrality parameters in Medicare or not until such time that reforms to budget neutrality requirements are made***, including increasing the budget neutrality threshold from $20 million to $53 million, with regular indexing to MEI, as well as capping the year-to-year variance in the conversion factor at 2.5 percent and instituting a two-year look-back period for CMS to correct utilization misestimates prospectively.

As noted by Medicare's Trustees, the updates set by MACRA "do not vary based on underlying economic conditions, nor are they expected to keep pace with the average rate of physician cost increases."[1] Absent a change in the delivery system or level of update by subsequent legislation, the Trustees expect access to Medicare-participating physicians to become a significant issue in the long term. Given this prediction, we ask that CMS work collaboratively with Congress toward urgently needed reforms to the Medicare physician payment system.

PAYMENT FOR MEDICARE TELEHEALTH SERVICES

[1] 2023 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds https://www.cms.gov/oact/tr/2023

Section 4113 of the Consolidated Appropriations Act (CAA), 2023, extended the availability of telehealth services that can be furnished using audio-only technology and provided for the extension of other public health emergency (PHE)-related flexibilities including removal of the geographic and location limitations under section 1834(m) of the Act through Dec. 31, 2024. There is a growing body of evidence that points to the value of patient access to telehealth services. ASNC is encouraging Congress to extend, through at least 2025, the flexibilities that allow patients to receive telehealth services all over the country, not just in rural areas, and to receive these services in their home without having to go to a medical facility. The extensions by Congress of the PHE-related flexibilities have allowed for the collection of evidence of telehealth's effectiveness in more treatment areas to inform future policy decisions. For example, a study published last month shows that virtual care for congestive heart failure (CHF) isn't tied to a higher likelihood of emergency room visits or hospitalizations versus in-person care.[2] The study, conducted by Epic Research, examined the records of 62,129 patients diagnosed with CHF between Jan.1, 2017 and Dec. 31, 2022, who had five in-person outpatient and/or telehealth visits in the year following their CHF diagnosis. The study found that CHF patients with a higher proportion of telehealth visits were no more likely to have an emergency department visit or hospital admission for CHF than patients who had only in-person visits, suggesting that telehealth may be considered a substitute for in-person office visits for patients with CHF.

Audio-only Coverage

ASNC appreciates that CMS has come to believe it would be appropriate to allow interactive audio-only telecommunications technology when any telehealth service is furnished to a beneficiary in their home (when the patient's home is a permissible originating site) and when the distant site physician or practitioner is technically capable of using an interactive telecommunications system, but the patient is not capable of, or does not consent to, the use of video technology. As CMS recognizes in the rule, there is variable broadband access in patients' homes, and, even when technologically feasible, patients may not always wish to engage with their practitioner in their home using interactive audio *and* video. ***ASNC agrees and encourages CMS to finalize its proposal to expand the use of audio-only telehealth services.***

Distant Site Practitioner

CMS previously finalized through CY 2024 that it would continue to permit a distant site practitioner to use their currently enrolled practice location instead of their home address

[2] Kazaglis L, Barkley E, Bartelt K, Sandberg N. CHF Patients Who Received Care Through Telehealth Are No More Likely to Be Hospitalized Than Patients Who Received In-Person Care. Epic Research. https://epicresearch.org/articles/chf-patients-who-received-care-through-telehealth-are-no-more-likely-to-be-hospitalized-than-patients-who-received-in-person-care. Accessed on September 9, 2024.

when providing telehealth services from their home. ***We support CMS' proposal to extend its distant site policy through CY 2025 to protect safety and privacy of health care professionals.***

ASCVD RISK ASSESSMENT AND MANAGEMENT SERVICES

ASNC member physicians assess and manage ASCVD risk and appreciate CMS' proposal to build on the CMS Innovation Center's Million Hearts® model test, which coupled payments for cardiovascular risk assessment with cardiovascular care management. ***ASNC supports CMS' proposal to add new ASCVD risk assessment and management services starting in 2025 (new codes GCDRA and GCDRM, respectively), but we offer the following comments, as well as questions that we ask CMS to address in a final rule.***

The addition of services that include risk assessment and management should only follow evidence generated through model testing. We support payment for GCDRA and GCDRM on the basis the Million Hearts® model found that quantitative assessment of patients' ASCVD risk and providing high-risk beneficiaries with cardiovascular-focused care management services improved quality of care, including reducing the risk of death from a cardiovascular event by 11 percent.

ANSC supports that CMS is not proposing a specific tool that would have to be used for the ASCVD risk assessment, but we support that the assessment tool must be standardized and evidence-based. In addition to the proposed elements of the risk assessment, CMS proposes that billing practitioners may choose to assess for additional domains beyond those listed (e.g., demographic and modifiable risk factors) "if the tool used requires additional domains." The Multi-Ethnic Study of Atherosclerosis (MESA) Risk Score and Coronary Age Calculator, for example, estimates at 10-year coronary heart disease risk using traditional risk factors and a coronary artery calcium (CAC) score.[3] ***As it pertains to CAC, we ask CMS to clarify the following:***

1) A CAC score is an important predictor of future cardiovascular disease risk. If a patient obtains a CAC score, we believe a clinician should be able to account for that CAC score if it is available but not included as a domain in a risk assessment tool. ***Will clinicians be able to use a patient's CAC score if it is not included as a domain in the risk assessment tool?***

2) Oftentimes, coronary artery disease (CAD) is added to an electronic medical record problem list based on CAC score alone. If this happens, the codes for CAD could get added to notes and could preclude billing for a risk assessment. ***We ask CMS to clarify in the final rule whether a patient with a high CAC score would be considered as already having a cardiovascular disease diagnosis for the purpose of billing for risk assessment or the risk management services.***

[3] Multi-Ethnic Study of Atherosclerosis (MESA) Risk Score Calculator. https://internal.mesa-nhlbi.org/about/procedures/tools/mesa-score-risk-calculator

CMS proposes that if patient is without a current diagnosis of ASCVD, but is determined to be at medium or high risk for CVD (>15 percent in the next 10 years) as previously determined by the ASCVD risk assessment, then the practitioner would be eligible to bill for risk management services. We ask CMS to clarify in the final rule whether a practitioner could bill for risk management services if a patient was assessed previously (i.e., prior to this rule being finalized), has a risk of greater than 15 percent in the next 10 years, and for whom risk management services are already being provided.

CMS proposes to pay for the risk management code for beneficiaries with a medium-to-high risk score (greater than 15 precent in 10 years). The American Heart Association classifies intermediate 10-year risk for CAD at 7.5-19.9 percent.[4] ***How will CMS treat patients with an "intermediate" risk score of under 15 percent but greater than 7.5 percent if, based on a clinician's judgement and risk factors, it is determined the patient would benefit from risk management services?*** Would a patient with a risk score of 14 percent not benefit from risk management services? We believe a cut-off score of greater than 15 percent will exclude patients from risk management services who would otherwise benefit, and, therefore, the coverage of risk management services for patients with a risk score of less than 15 percent should account for some level of clinician judgement that is well-documented in the patient's medical record.

Lastly, ***the ASCVD risk assessment should not be required to be done on the same date as an evaluation and management (E/M) visit*** because, as CMS notes, the collection of data, including laboratory results, may not be available until after the E/M visit. Restricting the risk assessment to the E/M visit date may prevent optimal utilization of this service. CMS should consider allowing ASCVD risk assessment with other preventive services, such as the Welcome to Medicare and Annual Wellness visits.

PAYMENT OF RADIOPHARMACEUTICALS IN THE PHYSICIAN OFFICE

CMS proposes codifying regulations in §414.904(e)(6) that state that for radiopharmaceuticals furnished in settings other than the hospital outpatient department, Medicare Administrative Contractors (MACs) shall determine payment limits based on *any* methodology used to determine payment limits for radiopharmaceuticals in place prior to November 2003. CMS seeks to clarify that the passage of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108-173), which established a new average sales price (ASP) drug payment methodology for separately payable drugs, does not require MACs to change payment methodology for radiopharmaceuticals.

ASNC appreciates and encourages CMS to finalize the clarification that a MAC shall determine payment limits for radiopharmaceuticals based on any methodology in place prior to November 2003, including but not limited to invoice based pricing.

CONCLUSION

[4] PREVENTTM Online Calculator, American Heart Association. https://professional.heart.org/en/guidelines-and-statements/prevent-calculator

Thank you for the opportunity to comment on the CY2025 PFS proposed rule and issues of importance to nuclear cardiologists.

Any questions or requests for additional information should be directed to Georgia Lawrence, ASNC's Director of Regulatory Affairs at glawrence@asnc.org.

Sincerely,

Lawrence Phillips, MD
President,
American Society of Nuclear Cardiology