September 11, 2023

Ms. Chiquita Brooks-LaSure
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
ATTN: CMS-1784-P
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

Re: [CMS-1784-P] Medicare Program: CY 204 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; etc.

Dear Administrator Brooks-LaSure:

We at the Society of Nuclear Medicine and Molecular Imaging (SNMMI) and American College of Nuclear Medicine are writing in response to the calendar year (CY) 2024 Physician Fee Schedule (PFS) Proposed Rule. Our organizations set the standard for molecular imaging and nuclear medicine practice by creating guidelines, sharing information through journals and meetings, and leading advocacy on key issues that affect molecular imaging and therapy, research, and practice. We appreciate the opportunity to provide comments to assist the Centers for Medicare & Medicaid Services (CMS) in further refining the PFS payment policies. We focus our comments on several areas of interest and importance to our members.

I. CMS Should Work Quickly to Resume the Appropriate Use Criteria for Advanced Diagnostic Imaging Program

SNMMI and ACNM support the Appropriate Use Criteria (AUC) for Advanced Diagnostic Imaging program and the requirement that ordering professionals consult with specified applicable AUC through a qualified clinical decision support mechanism for applicable imaging services for purposes of payment under the physician fee, hospital outpatient, and ASC payment systems. In the proposed rule, CMS cites operational challenges related to implementation of the program, including an inability of the claims processing system to automate claim processing edits for the program. The agency states that this raises concerns over data integrity, accuracy and beneficiary access. As a result, CMS proposes to pause the program and rescind the existing regulation at 42 C.F.R. § 414.94.
We are disappointed by the proposed decision but understand that resolving such operational issues is necessary and appreciate the agency’s efforts to ensure the program is appropriately implemented. We believe, however, that CMS should promptly address such issues, so that the statutorily required program can quickly resume. Additionally, while we understand CMS’ reasoning for discontinuing the educational and operational testing phase of the program at this time, we urge CMS to set a timeline for its reevaluation and promulgation of new regulations for the program, so that those phases can continue.

II. CMS Should Retain Measure #147 Under the Medicare Quality Payment Program

The SNMMI and ACNM appreciate CMS’ continued attention to the Quality Payment Program (QPP) and its adoption of measures, including those relevant to nuclear medicine. We are dismayed, however, by CMS’ proposal to remove Quality Measure #147 ("Nuclear Medicine: Correlation with Existing Imaging Studies for All Patients Undergoing Bone Scintigraphy") beginning with CY 2024 performance period/2026 Merit-based Incentive Payment System (MIPS) payment year. CMS’ rationale for removal is that the measure has reached the end of the topped out lifecycle and that it has limited opportunity to improve clinical outcomes. We disagree with CMS’ assessment and urge the agency to retain the measure under the program.

As a steward of the measure, SNMMI and ACNM believe the removal of this measure poses the risk of setting a platform for decreased quality and less correlation of bone scan findings with other relevant diagnostic imaging modalities. Additionally, removal of this measure would significantly impact nuclear medicine practitioners given that this is the only MIPS measure applicable to them and would effectively exclude this group of practitioners from the QPP. Such an outcome could also frustrate the goals of the program if these practitioners disengage from value-based care.

SNMMI and ACNM recommend that CMS not finalize its proposal and retain this measure while we develop additional MIPS measures of value that can be used to improve patient care and ultimately drive better patient outcomes in a value-based care model. That would strike a reasonable balance given the continued relevance of bone scans. Indeed, the measure remains meaningful given that bone scans are commonly used clinical tools for the detection bone metastasis, evaluation of fractures/trauma, as well as bony infections. The literature describes opportunities where a bone scan can validate or change a patient’s treatment plan.

Additionally, bone scans remain a valuable tool, for example, for prostate cancer patients, even though prostate-specific membrane antigen (PSMA) PET has supplanted bone scans in many instances, including in the biochemical recurrent stage as well early high risk disease assessment.  

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1 88 Fed. Reg. 52839. Measure Description: “Percentage of final reports for all patients, regardless of age, undergoing bone scintigraphy that include physician documentation of correlation with existing relevant imaging studies (e.g., x-ray, Magnetic Resonance Imaging (MRI), Computed Tomography (CT), etc.) that were performed.

2 88 Fed. Reg. 53078. CMS cites topped out status based on current MIPS benchmarking data.

3 A case presented by Zhao, et al, illustrates recent findings that PSMA may also be overexpressed in tissues other than the prostate cancer, such as myeloma and renal cancer. Because the “Pitfalls” of $^{68}$Ga-PSMA-PET/CT in the diagnosis of bone metastasis of prostate cancer cannot be avoided, it is necessary to integrate the PET/CT, bone
That is particularly true in situations where PSMA is of limited use as a diagnostic imaging agent (e.g., prostate cancer patients do not produce PSMA)\(^4\) or where coverage for PSMA PET is limited or unavailable. Bone scans may also be used in complement to other modalities to stage other cancers such as for example breast cancer patients. Furthermore, given the restricted coverage for NaF PET under Medicare, bone scans are a cost-effective study for the diagnosis and management of bone metastases in a wide range of cancer types. Finally, we note that bone scans are valuable in assessing non-oncological indications as well. Altogether, we request that CMS not finalize its proposal and instead retain measure #147 for the CY 2024 MIPS.

### III. Evaluation and Management (E/M) Add-On Code

SNMMI and ACNM appreciate that CMS revised their understanding of how often the E/M add-on code (G2211) will be reported and reduced the utilization assumptions from the previous 90 percent to 38 percent in the current proposed rule. However, this utilization still accounts for nearly all of the 2024 budget neutrality reduction proposed for 2024 and we share the concerns raised by the AMA and others stakeholders about the impact the add-on code will have on physician payment. The lack of clarity surrounding the appropriate circumstances for reporting this code makes it difficult for physicians and other qualified healthcare professionals to know when they should and should not be reporting the code and raises questions about the accuracy of CMS budget neutrality adjustment. We are also concerned about the potential implications for patient cost-sharing. We join with the AMA and urge the agency to further refine the utilization assumptions to prevent unwarranted reductions in the Medicare conversion factor.

### IV. Restrictions on NaF PET

SNMMI and ACNM remain concerned that outdated national coverage determinations (NCDs) that are inappropriately limiting access to PET services. We appreciate that CMS has initiated the NCD process and proposed to eliminate restrictions on beta amyloid PET (NCD 220.6.20). We urge CMS to also retire NCD 220.6.19 Positron Emission Tomography NaF-18 (NaF-18 PET) to Identify Bone Metastasis of Cancer.

In rulemaking for 2022, CMS finalized a proposal to cover non-oncologic PET tracers at the discretion of the Medicare Administrative Contractors (MACs). We believe that coverage of NaF PET for the diagnosis of patients with non-oncologic conditions should also be at MAC discretion. To align with the broader PET coverage policy, we recommend that CMS retire NCD 220.6.19 in the final rule, effective January 1, 2023.

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4 Data from the VISION trial was presented at the 2021 American Society of Clinical Oncology meeting. In that pivotal trial, of the 1,003 patients screened with PET/CT, 49 (4.9%) had no PSMA-positive metastatic lesions. While PSMA PET/CT can be a standard for most prostate cancer patients, some will not express PSMA thus bone scans are needed for evaluation of bone metastases. https://doi.org/10.2967/jnumed.122.264128
V. Medicare Provider and Supplier Enrollment Proposals

SNMMI and ACNM appreciate CMS’ attempts to strengthen components of the Medicare enrollment process and combat potential fraud, waste, and abuse using its enrollment authorities. We share CMS’ commitment to ensuring the protection of beneficiaries and the Medicare trust fund and agree that only qualified practitioners should be enrolled and furnish services under the program. While we understand the agency’s general reasoning for its proposals and the vulnerabilities it seeks to address, we have significant concerns that the proposals are overbroad in places, may unfairly or unnecessarily subject providers and suppliers to enrollment revocation or denial procedures, and will be difficult to navigate without further clarification. SNMMI also questions whether some of CMS’ proposals are needed given that other suitable enforcement mechanisms already exist. We highlight some of our concerns below, which we urge the agency to carefully consider to ensure that patient care is not disrupted and suppliers and providers remain subject to predictable and fair enrollment rules.

We are particularly troubled by the breadth of CMS’ proposal that it may revoke or deny a provider’s or supplier’s enrollment for misdemeanor convictions within the previous 10 years (proposed 42 CFR §§ 424.535(a)(16)(ii)(C) and 424.530(a)(16), respectively). This would be sweeping given that under the proposal, an enrollment revocation or denial could be triggered by a misdemeanor conviction of the supplier/provider or any owner, managing employee or organization, officer, or director thereof. Although CMS provides qualifying language in the proposed regulations that such misdemeanors must place the Medicare program or its beneficiaries at immediate risk, the language lacks sufficient guardrails and clarity. As drafted, the proposed regulations leave open the possibility that suppliers/providers could face enrollment revocations or denials for misdemeanor convictions involving minor offenses that carry lighter penalties (e.g., a fine), reflecting the state’s view that these violations are less serious. We assume that is not CMS’ intent. We also find the proposed 10-year look back period excessive. We assume that CMS is aligning with the time frame for felony convictions, but the look back period should be more limited for misdemeanors, which typically are less severe in nature and have greater variability. Accordingly, if CMS finalizes changes to the enrollment procedures, we urge CMS to narrow the scope of the provision, provide greater clarity, and offer other examples of the types of misdemeanors relevant to Medicare that would rise to the level of an enrollment denial or revocation.

We also disagree with CMS’ proposal to reduce from 30 days to 15 days the time period for a provider or supplier to reverse a revocation based on the adverse activities of an individual by terminating the business relationship with that individual. As CMS is aware, it is administratively and financially difficult to immediately terminate business relationships and we believe 15 days is not sufficient to unwind the problematic relationship, hire and replace key personnel, etc. Moreover, CMS’ concerns that the provider or supplier would not act expeditiously to sever ties with the party are unfounded – it would not serve a supplier or provider seeking to reverse the revocation to continue the business relationship any longer than is necessary. We believe the existing 30-day period is appropriate and request that CMS not finalize its proposal.
Finally, we appreciate CMS’ willingness, in response to prior requests, to further clarify what constitutes a “pattern or practice” for purposes of enrollment revocations but we disagree with its proposal that as few as three instances of non-compliant claims or abusive prescriptions or orders could constitute a pattern that would justify revoking enrollment. Indeed, by CMS’ own admission in the proposed rule, the number is small. It also seems misguided since the agency believes this threshold would trigger a revocation in only the rarest of circumstances and for egregious non-compliance. Three instances would seem to describe non-compliance that is sporadic or isolated – not patterns or practices. The proposed threshold also increases the likelihood that innocent behavior is unnecessarily targeted (e.g., the submission of three non-compliant claims could simply represent mistakes or billing errors). Instead, we urge the agency to further refine the definition and threshold to capture behavior/actions that are more widespread or systemic – not a handful of occurrences.

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SNMMI and ACNM appreciate the opportunity to comment on the CY 2024 PFS Proposed Rule. If it would be helpful, we are ready to discuss any of its comments or meet with CMS on the above issues. In this regard, please contact Julia Bellinger, Director of Health Policy at jbellinger@snmmi.org or (703) 326-1182.

Respectfully Submitted,

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