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September 11, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue S.W.
Washington, DC 20201

Re: Comments on CMS–1786–P: CY 2023 Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; etc.

Dear Administrator Brooks-LaSure:

As the premier trade association representing the manufacturers of medical imaging equipment, radiopharmaceuticals, contrast media, and focused ultrasound devices, the Medical Imaging & Technology Alliance (MITA) is submitting the following comments on the referenced Centers for Medicare & Medicaid Services Proposed Rule on Medicare payment rates and policies for services paid under the Hospital Outpatient Prospective Payment System (HOPPS).

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1. MITA Response to Radiopharmaceuticals RFI

In the time that has transpired since CMS first implemented its packaging policy for radiopharmaceuticals in 2008, much has changed with regard to the development of new targeted radiopharmaceuticals. CMS has evolved and changed its payment policies in this time, and we appreciate the Agency's willingness to now reevaluate this outdated policy and replace it with one that more accurately reflects current medical practice that will keep pace with innovation.

MITA has long advocated for ending the policy packaging for diagnostic radiopharmaceuticals because CMS' current packaging policy has reduced patient access to such products. In the Proposed Rule, CMS specifically solicits comments on the following potential policy options:

- Paying separately for diagnostic radiopharmaceuticals with per-day costs above the HOPPS drug packaging threshold;
- Establishing a specific per-day cost threshold that may be greater or less than the HOPPS drug packaging threshold;
- Restructuring Ambulatory Payment Classifications (APCs), including by adding nuclear medicine APCs for services that utilize high-cost diagnostic radiopharmaceuticals;
- Creating specific payment policies for diagnostic radiopharmaceuticals used in clinical trials; and

- Adopting codes that incorporate the disease state being diagnosed or a diagnostic indication of a particular class of diagnostic radiopharmaceuticals.

As described below, **MITA strongly supports establishing separate payment based on Average Sales Price (ASP) methodology for diagnostic radiopharmaceuticals in the CY 2024 Final Rule. MITA urges CMS to make such a change in the final rule, as there is sufficient evidence (presented by MITA and others) to make this long-overdue change immediately.** There is significant published evidence that advanced diagnostic radiopharmaceuticals provide unique clinical information compared to other diagnostic modalities, so it is important that a revised payment policy, which doesn't limit patient access, be implemented in CY 2024.

MITA represents companies whose sales comprise more than 90 percent of the global market for medical imaging technology, and we are the collective voice of positron emission tomography (PET) and single-photon emission computed tomography (SPECT) radiopharmaceutical developers, manufacturers, and distributors. Advances in nuclear medicine allow clinicians to more effectively identify and target disease, thereby providing more and potentially earlier options for treatment resulting in better patient outcomes.

MITA's detailed responses to the topics set forth in the Proposed Rule are below.

I. Current Packaging Policy of Diagnostic Radiopharmaceuticals Limits Beneficiary Access

A. Published evidence demonstrates that advanced diagnostic radiopharmaceuticals provide unique clinical information compared to other diagnostic modalities.

Advanced diagnostic radiopharmaceuticals play a critical role in the management of Medicare beneficiaries with complex conditions such as cancer, cardiac disease, Alzheimer's disease and Parkinson's disease. Advanced procedures that use newer, Food & Drug Administration (FDA)-approved innovative diagnostic radiopharmaceuticals provide physicians with more precise diagnostic information than other diagnostic modalities. These innovative diagnostics can also lead to more appropriate treatment and reduce the utilization of unnecessary treatments that may be both expensive and debilitating for patients.

An extensive body of evidence has been accumulated across both CMS-approved and other clinical studies that **clearly support the clinical utility of diagnostic radiopharmaceuticals in the clinical management of patients**. For example, within the Imaging Dementia—Evidence For Amyloid Scanning (IDEAS) Study, a CMS-approved Coverage with Evidence Development (CED) protocol, the data shows that beta amyloid PET scans that rely on innovative diagnostic radiopharmaceuticals led physicians to change their management in more than 60%.[1] This underlines the important role of these radiopharmaceuticals in the diagnostic workup of patients with cognitive impairment, especially for ruling out an incorrect etiologic diagnosis. Beyond the IDEAS study, more than thirty published studies have confirmed that utilizing beta amyloid PET leads to changes in diagnosis and treatment management plans. This information, which can support a more accurate and earlier diagnosis, improves patients' health outcomes by providing physicians with better diagnostic information resulting in appropriate treatment.

A systematic literature review of 98 studies on the role of imaging techniques in patients with early recurrent prostate cancer was conducted and researchers found "the superiority of PSMA-targeted tracers

[1] Rabinovici GD, Gatsonis C, Apgar C, et al. Association of Amyloid Positron Emission Tomography With Subsequent Change in Clinical Management Among Medicare Beneficiaries With Mild Cognitive Impairment or Dementia. JAMA. 2019;321(13):1286–1294. doi:10.1001/jama.2019.2000.

over the older tracers in patients with early [biochemical recurrence]".[2] Researchers found that localization of the recurrence of prostate cancer, even when the PSA levels are still very low, when advanced diagnostic radiopharmaceuticals were used (e.g., 18F fluoro-deoxy-glucose,11C choline,18F (fluoro) (methyl)choline, 11C acetate, 18F FACBC (fluciclovine) and prostate-specific membrane antigen (PSMA)-based tracers). In contrast, they found that other imaging modalities that did not use advanced diagnostic radiopharmaceuticals had limited detection of disease (*i.e.*, localization) or that they were not sensitive enough to identify local recurrence at low PSA levels.

Researchers have also conducted a retrospective analysis of the Center for Prostate Disease Research database that supports the clinical utility of advanced diagnostic radiopharmaceuticals.[3] Their findings showed that "[p]atients with biochemical recurrence after radical prostatectomy have a low probability of […] a positive CT scan (14.0%) within 3 years of biochemical recurrence." The discussion noted that "it has been [the researchers'] impression that these radiologic tests are rarely helpful in disease management" but they revised this after their analysis and concluded that CT scans "have improved substantially, which may enhance its sensitivity for the detection of recurrent disease."

B. Advanced diagnostic radiopharmaceuticals are often not interchangeable.

In some instances, patients also have no comparable diagnostic option to these advanced diagnostic radiopharmaceuticals, which may result in physicians prescribing less effective alternatives and a resultant inaccurate diagnosis or treatment plan. For example, precision diagnosis is becoming increasingly vital to cancer care (*e.g.*, neuroendocrine tumors, recurrent prostate cancer) and diagnostic radiopharmaceuticals have a crucial role in tailoring therapy to individuals to ensure accurate patient selection and administration of targeted therapy. This is taking place in the field of "theranostics" which combines a diagnostic and a therapeutic and relies on diagnostic radiopharmaceuticals being similarly structured and sharing a molecular-specific target within the patient to be able to provide treatment. This field empowers clinicians to leverage molecular imaging techniques to detect, customize, and monitor therapy responses. Theranostics rely on diagnostic radiopharmaceuticals to identify tumor locations within the body and radioligand therapies to precisely deliver radiation to targeted cells, with the objective of minimizing harm to neighboring tissues.

CMS' position that packaging incentivizes hospitals to use a lower-cost alternative also simply does not apply to advanced diagnostic radiopharmaceuticals where there may be no alternative as in the examples above. Thus, the packaging policy results in Medicare beneficiaries not having access to diagnostics that provide important adjunctive clinical information that may impact their treatment and outcomes.

C. *CMS' packaging policy applicable to diagnostic radiopharmaceuticals has reduced patient access to advanced diagnostic radiopharmaceuticals.*

Diagnostic radiopharmaceuticals are statutorily classified as drugs and must be approved by the FDA. However, since 2008, in the hospital outpatient setting, CMS inappropriately classifies diagnostic radiopharmaceuticals as supplies rather than drugs. This leads to packaged reimbursement rates far below actual costs after a three-year period of "pass-through" reimbursement.

[2] De Visschere PJL, Standaert C, Fütterer JJ, Villeirs GM, Panebianco V, Walz J, Maurer T, Hadaschik BA, Lecouvet FE, Giannarini G, Fanti S. A Systematic Review on the Role of Imaging in Early Recurrent Prostate Cancer. Eur Urol Oncol. 2019 Feb;2(1):47-76. doi: 10.1016/j.euo.2018.09.010. Epub 2018 Oct 24. PMID: 30929846.

[3] Kane CJ, Amling CL, Johnstone PA, Pak N, Lance RS, Thrasher JB, Foley JP, Riffenburgh RH, Moul JW. Limited value of bone scintigraphy and computed tomography in assessing biochemical failure after radical prostatectomy. Urology. 2003 Mar;61(3):607-11. doi: 10.1016/s0090-4295(02)02411-1. PMID: 12639656.

Automatically packaging these higher cost precision diagnostic radiopharmaceuticals, which typically have lower volume, into procedure APCs fundamentally does not work. This is because the cost of these advanced diagnostic radiopharmaceuticals often significantly exceeds the cost of the packaged procedure reimbursement. MITA member companies have provided CMS with evidence of hospitals discontinuing or never adopting these clinically advanced imaging procedures due to inappropriately low Medicare payment rates. As a result, patients, frequently in underserved and rural communities, often lack access to advanced diagnostic radiopharmaceuticals. CMS has been provided data demonstrating access issues across multiple disease states as a result of CMS's packaged payment of diagnostic radiopharmaceuticals.

This packaging policy has resulted in a decrease in the number of hospital outpatient facilities that can provide access to advanced diagnostic radiopharmaceuticals. This was evidenced in a 2021 Government Accountability Office (GAO) report on Part B drug payment for certain high-cost drugs, that found, for 3 of the 4 drugs within the scope of the report (which included, predominantly, diagnostic radiopharmaceuticals in one disease state), there was higher use when the drugs were eligible for pass-through payments and lower use when their payments were packaged. The GAO also outlined that the use of larger payment bundles—which involves packaging and payment using APC groups—is intended to provide "*hospitals* with […] incentives to furnish services efficiently. This includes the incentive for hospitals to use the most cost-efficient item that meets the patient's needs."[4] However, this policy does not account for access from the patient's perspective, particularly in the case of diagnostic radiopharmaceutical where it is the only option appropriate for a unique clinical scenario. Patient access to diagnostic radiopharmaceuticals, thus, hinges on whether the hospital determines it is financially feasible to provide the service with a packaged advanced diagnostic radiopharmaceutical and CMS' packaging policy makes it more challenging for hospitals to do so. Consequentially, this will limit access to therapies that depend on amyloid confirmation.

To this point, many hospitals chose not to participate in New IDEAS and cited the Medicare outpatient packaged policy for diagnostic radiopharmaceuticals as a barrier. There were 164 hospital outpatient departments involved in the first IDEAS Study and only 25 in the New IDEAS Study as of August 15, 2023. The same GAO report found that hospitals that had originally participated in the original IDEAS Study declined to participate because "the packaged payment would cause them to incur a financial loss for each procedure performed".[5] This loss was attributed to the pass-through payments for three diagnostic radiopharmaceuticals expiring at the time the New IDEAS Study would start, so the payment for the diagnostic radiopharmaceutical would be packaged with the payment for the APC group for nuclear medicine and related services. In addition to the decline of hospital participation from the IDEAS Study to the New IDEAS Study, hospital outpatient departments have also been furnishing fewer scans in the second iteration of the study. As of August 15, 2023, only 17 outpatient departments that have participated in the New IDEAS Study administered a single beta amyloid PET scan. These 17 facilities accounted for 8.2% of the scans performed. Whereas, under the IDEAS Study, 140 outpatient departments had furnished such a scan under the study.

II. MITA Supports Separate Payment for Diagnostic Radiopharmaceuticals

MITA appreciates CMS proposing alternatives to end the packaging policy of diagnostic radiopharmaceuticals. **MITA urges CMS in the Final Rule to provide separate outpatient payment based on the ASP + 6% methodology for all diagnostic radiopharmaceuticals above a specified threshold.**

[4] GAO, Medicare Part B: Payments and Use for Selected New, High-Cost Drugs (GAO-21-252) at 8, Mar. 1, 2021. Available at https://www.gao.gov/assets/gao-21-252.pdf.
[5] *Id*. at 24.

To assist in the analysis of the alternatives presented by CMS in the Proposed Rule, MITA engaged The Moran Company to analyze HOPPS payment data[6] for advanced diagnostic radiopharmaceuticals to determine the effect of CMS' proposed alternatives. *In their analysis, they found that only separate payment of diagnostic radiopharmaceuticals would provide sufficient payment levels for radiopharmaceuticals to ensure hospital outpatient departments would not incur a financial loss for radiopharmaceutical procedures.*

Under CMS' current payment policy, advanced diagnostic radiopharmaceuticals are packaged as a part of the PET or SPECT imaging under either APC 5591, 5593, or 5594. Moran's analysis of claims data for these APC groups showed that when such products were packaged, the APCs for each procedure code had a geometric mean cost that would consume nearly all of, if not exceed, the APC payment rate. The range of costs across diagnostic radiopharmaceuticals is wide, which results in payment discrepancies that are also wide. In turn, with the current payment policy, low priced, high volume diagnostic radiopharmaceuticals are reimbursed significantly over their average cost per claim.

For example, the three most frequently billed procedure codes that include diagnostic radiopharmaceuticals (78815, 78816, and 78803) are bundled into APCs 5593 and 5594. When 78815 is bundled into APC 5594, the geometric mean cost for the procedure code is $1,523.61 and the payment rate for the APC is $1,507.82. This cost, even without considering the individual services involved and the specific advanced diagnostic radiopharmaceutical used as a part of the PET imaging, *exceeds* the payment rate for the APC. The same issue arises when 78816 is bundled into APC 5594, and the geometric mean cost is even higher at $1,600.69. When 78803 is bundled into 5593 for a SPECT scan, the geometric mean cost ($1,135.15) is slightly lower than the payment rate ($1,373.83), but that fails to account for the most commonly used radiopharmaceutical with this procedure code has an average cost per claim of $1,437.89 – which is higher than the payment rate. It is important to note that the entire cost is not reflected on the claims because CMS does not require diagnostic radiopharmaceuticals to be reported on the claim. CMS' cost estimation process is far from accurate. In sum, this shows how unsustainable the current packaging policy is for advanced diagnostic radiopharmaceuticals because, on average, a hospital outpatient department would incur a loss when furnishing the items and services associated with these APCs.

We also highlight that removing higher-cost radiopharmaceuticals from the packaging system would correct some of the current overpayment for the high-volume, lower-cost radiopharmaceuticals. For example, paying separately rather than packaging would end the overpayment of Fludeoxyglucose F18 and F-sodium fluoride. In looking at the claims for the three most frequent procedure codes for Fludeoxyglucose F18, which are 78815, 78816, and 78608, the diagnostic radiopharmaceutical has an average cost per claim that was $220.00, $222.00, and $177.17, respectively for each code. The claims for these codes are critical for CMS to review because Fludeoxyglucose F18 represents between 87.5% to 97.6% of the claims billed to the code that CMS uses to set the payment rates for their APC group. When Fludeoxyglucose F18 is billed under each of those codes, it is bundled into APC 5594, which has a payment rate of $1,507.82. This is over 8.5 times less than the average cost per claim for the diagnostic radiopharmaceutical in 78608. The average costs per claim for the other two procedure codes (78815 and 78816) are similarly a small portion of the APC payment rate.

For procedure codes 78813 and 78815 for F-sodium fluoride, the diagnostic radiopharmaceutical had an average cost per claim of $607.89 and $115.00, respectively. When it is billed under either code, as is the case for Fludeoxyglucose F18, it is bundled into APC 5594 with a payment rate of $1,507.82. While the APC includes other services like the PET scan, the amount that is paid for this APC is more than twice

[6] Data Source: 2024 HOPPS Proposed Rule (PR) Rate Setting Data, 2024 HOPPS PR Cost Statistics File, and 2024 PR Addendum B.

the average cost per claim for the diagnostic radiopharmaceutical in the case of 78813 or even more so in the case of 78815.

Taken together, the average cost per claim for Fludeoxyglucose F18 and F-sodium fluoride shows the resultant overpayment for advanced diagnostic radiopharmaceuticals under CMS' current packaging policy. MITA supports payment rates for these products being representative of their costs, just as is the case for the widespread underpayment described above.

As demonstrated by Moran's analysis, only separate payment of diagnostic radiopharmaceuticals would increase payment rates to the point that it would prevent hospital outpatient departments from incurring a financial loss for each procedure performed. **Thus, MITA urges CMS to end its packaging policy of diagnostic radiopharmaceuticals and pay separately for such products.** Establishing a separate payment policy for diagnostic radiopharmaceuticals would support the availability of these more specialized services, providing CMS the opportunity to do so in a nearly budget neutral manner. This would normalize the payment rates for both low priced, high volume and high priced, low volume diagnostic radiopharmaceuticals, providing CMS the opportunity to do so in a nearly budget neutral manner.

We also appreciate that CMS sought comment on a policy option to provide for separate payment for radiopharmaceuticals with per-day costs that exceed the packaging threshold of $140 and similarly stakeholders have commented in support of a higher threshold at $500. MITA agrees with CMS that the $140 drug packaging threshold is widely understood. MITA defers to CMS as to which threshold would be appropriate.

As CMS evaluates the implementation of a separate payment threshold, we would welcome the opportunity to more completely share our data and analysis to assist with this decision. We also identified violations of other CMS payment policies such as the 2 times rule.

III. Alternate Payment Options Would Not Resolve Beneficiary Access Issues

The alternative payment option that provides for a high-cost nuclear medicine APC for services that utilize high-cost diagnostic radiopharmaceuticals will not sufficiently address underpayment to hospitals because it would replicate the current payment challenges of the APCs. This approach would continue the current payment policy for certain high-cost diagnostic radiopharmaceuticals as supplies through a packaged payment system because it would set payment based on an average the cost of these diagnostic radiopharmaceuticals amongst other radiopharmaceuticals that range in costs. As MITA member companies have experienced, the result is that CMS will overpay for some products and underpay other products. Further, another challenge in administering a high-cost nuclear medicine APC approach is that CMS historically has not required HCPCS codes for radiopharmaceuticals to be included on claims for diagnostic radiopharmaceuticals. This is particularly problematic if CMS takes a similar approach to determine the APC groups for nuclear medicines as the agency had done when stratifying skin substitutes into a high and low APC group. Here, CMS made categorizations based on the Medicare claims data, rather than ASP or invoice data. But, because CMS has not required HCPCS codes for radiopharmaceuticals to be included on submitted claims, the claims data that could be used under this approach may not be fully representative of the historical utilization of diagnostic radiopharmaceuticals.

Similarly, a policy that would establish an exception solely for diagnostic radiopharmaceuticals used in clinical trials is too limited and would not mitigate the widespread underpayment challenge that has limited beneficiary access to targeted diagnostic radiopharmaceuticals that provide important clinical information. Clinical trials represent a small percentage of Medicare beneficiaries who receive diagnostic radiopharmaceuticals. For most patients who are not enrolled in clinical trials, hospitals would be left

with the status quo of underpayment. Manufacturers are less likely to develop new advanced diagnostic products if the opportunity for appropriate payment of diagnostic radiopharmaceuticals is limited to a clinical trial.

Indication-specific codes also do not address diagnostic radiopharmaceuticals approved for multiple indications and would make this such an alternative challenging to administer. The negative impact of policy packaging is widespread across numerous disease areas and indications for use. This complexity arises from many advanced diagnostic radiopharmaceuticals receiving FDA-approval for multiple indications, but the request for information does not address how radiopharmaceuticals with multiple indications would be coded. Among others, the following diagnostic radiopharmaceuticals have received FDA-approval for multiple indications addressing several disease states.

Diagnostic Radiopharmaceutical	Impacted Disease States
Fluorine-18 fludeoxyglucose	Various cancers; coronary artery disease; neurological conditions.
Iodine I-123 ioflupane	Parkinsonian syndromes; dementia with Lewy bodies.
Technetium-99m exametazime	Altered regional cerebral perfusion in stroke; intra-abdominal infection and inflammatory bowel disease.
Technetium-99m tetrofosmin	Coronary artery disease; heart disease.
Thallium-201 chloride	Ischemic heart disease; myocardial infarction.

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For the foregoing reasons, we urge CMS in the CY 2024 Final Rule to establish separate outpatient payment for diagnostic radiopharmaceuticals. We summarize our recommendations with respect to the alternatives specified by CMS as follows:

- Establishing separate payment for diagnostic radiopharmaceuticals, including a per-day cost threshold based on an ASP methodology;
- Restructuring APCs will not address the historical underpayment of diagnostic radiopharmaceuticals;
- Contemporary experience proves that creating specific payment policies for diagnostic radiopharmaceuticals used in clinical trials will not address widespread beneficiary access and underpayment issues; and
- Not adopting codes that incorporate the disease state being diagnosed or a diagnostic indication of a particular class of diagnostic radiopharmaceuticals, because it will increase administrative complexities.

Thank you for your consideration of our comments. We welcome the opportunity to have a broader discussion of the data and analysis that supports **our recommendation of separate payment** to address the resolution of any unintended policy consequences.

2. Proposed Adoption of the Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Hospital Level—Outpatient) Measure

We support efforts to improve patient care, but we do not believe this measure will improve patient outcomes. Therefore, we ask CMS to remove the subsection from the proposed rule. The requirements outlined in the subsection use metrics that have not been vetted by consensus standards organizations

(e.g., International Electrotechnical Commission (IEC)), raise both technical implementation and device generalizability concerns, and do not represent the current scientific consensus.

The CT Global Noise metric is not included in any IEC consensus standard, to which CT manufacturers adhere and regulators recognize. It has not been vetted by all stakeholders for accuracy and appropriateness. Should a criterion not be met, it is also unclear if that would reflect a true image quality issue or result from misassumptions in the metric design for the system and protocol.

If implemented, the lack of a precise definition of CT Global Noise would mean that a manufacturer could not determine whether systems in the field or in development would meet the criteria for given reference protocols, which would leave manufacturers unable to address customer questions or assist in protocol adjustments.

While Size Specific Dose Estimate (SSDE) and Dose Length Product (DLP) are included in IEC, a combined SSDE-DLP is not. As such, manufacturers do not provide SSDE-DLP values for user reference. A single limit does not adequately accommodate for variations in individual patient height and weight and poses significant challenges. Therefore, the value of these new metrics and their ability to reflect on appropriate scanner usage is unclear.

The details of the development of these metrics and the data used to generate them remain unclear. Without a comprehensive understanding of the metrics' foundations, it is impossible to determine their validity and relevance to patient outcomes when applied to CT scanners of different make, model, age, and technical specifications. High sampling rates, non-linear reconstruction algorithms, and other critical attributes will also impact image quality. Further, there is no mechanism for updating the metrics/limits as technology advances. Therefore, it is unclear whether the metrics proposed serve the best interest of all patients, particularly those who rely upon systems that may not have been used to develop the criterion.

The implementation of these metrics may contradict the systems' instructions for use. This increases the potential risks of poor image quality, such as misdiagnosis or delayed treatment decisions. It is crucial to weigh the potential benefits against the potential harms and ensure that patient care remains the top priority.

By disregarding scientific considerations and processes, the proposed metrics overlook essential factors that contribute to diagnostic accuracy and the delivery of high-quality care. Neglecting such elements may hinder the production of good quality images, leading to potential consequences such as re-imaging and missing crucial clinical information.

Finally, it is concerning that a private third-party has been designated as both a software-as-a-service (SaaS) provider and data custodian for the metrics proposed in this section. This decision would centralize authority to a single private entity, limiting competition and hindering transparency and fairness.

3. MITA Response to Non-Opioid Treatments RFI

Section 4135(a) and (b) of The Consolidated Appropriations Act (CAA), 2023 (Pub. L. 117–328), titled Access to Non-Opioid Treatments for Pain Relief provides for temporary additional payments for non-opioid treatments for pain relief furnished on or after January 1, 2025, and before January 1, 2028. MITA appreciates that in preparation for this January 1, 2025, implementation, the Agency is soliciting input regarding the potential qualifying drugs, biologicals and devices for this three-year separate payment program.

MITA urges the Agency to implement a definition that would also allow for separate payment of devices, specifically ultrasound equipment, when it is used to guide the injection of non-opioid treatments for pain relief. Performing an ultrasound guidance procedure when injecting a non-opioid drug increases the effectiveness of that drug for post-surgical pain control. The ultrasound guidance procedure allows for increased accuracy of the placement of the drug at the surgical site.

We believe the Agency needs to adopt a definition for this new program that allows for the combination of the use of devices and drugs, versus just the individual components, for the purposes of separate payment for a non-opioid treatment for pain relief. This assumes that the combination would also meet the definitional requirement of having demonstrated via peer-reviewed literature, the ability to replace, reduce, or avoid intraoperative or postoperative opioid use or the quantity of opioids prescribed. A growing body of medical research supports the use of ultrasound guidance for regional anesthesia. For example, with ultrasound guidance compared to peripheral nerve stimulation, there was shown to be a significant decrease in the risk of vascular puncture (risk ratio of .16); an increase in the nerve block duration by 25%; and a 29% faster onset time.[7]

A study published in the June 2013 Academic Emergency Medicine (AEM) Journal reported that, for older adults in the ED suffering from hip fracture-related pain (over the course of 4 hours), ultrasound-guided three-in-one femoral nerve blocks significantly reduced both pain intensity and the amount of rescue analgesia needed when used as an adjunct to standard treatment with parenteral opioids. The same study also found that standard parenteral opioid-only pain management offered ineffective pain control in the study cohort of patients with severe pain from hip fractures.[8]

These are just two examples of the many peer-reviewed articles that could be provided to the Agency if it established an on-line email address or portal prior to an Agency announced deadline for nominations of non-opioid treatments for pain relief prior to the publication of the CY 2025 Proposed Hospital Outpatient Prospective Payment System Rule. Stakeholders should be provided with the opportunity to nominate any medical device, drug, or biological or combination thereof that they believe meets the definition of 'non-opioid treatment for pain relief" per the CAA, 2023 statute and submit copies directly to the Agency of peer-review journal articles demonstrating opioid reduction, in addition to this proposed rule.

Regarding appropriate HCPCS coding for the processing of claims for the combination of an ultrasound guidance procedure and a non-opioid pain relief drug, the ultrasound guidance procedure is represented by CPT code 76942 – Ultrasonic guidance for needle placement (e.g., biopsy, aspiration, injection, localization device), imaging supervision and interpretation – and an example of a non-opioid pain relief drug that is currently injected with ultrasound guidance is C9290 – Injection, bupivacaine liposome, 1 mg. The Agency could change the status indictor on CPT code 76942 from "N" to "Q1," allowing Medicare Administrative Contractors (MACs) to process claims with a combination of CPT code 76942 and HCPCS codes for non-opioid pain relief drugs, such as C9290.

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[7] Abrahams MS, Aziz MF, et al. Ultrasound guidance compared with electrical neurostimulation for peripheral nerve block: a systematic review and meta-analysis of randomized controlled trials. Br J Anaesth. 2009;102(3):408-17.

[8] Beaudoin FL, Haran JP, et al. A comparison of ultrasound-guided three-in-one femoral nerve block versus parenteral opioids alone for analgesia in emergency department patients. Acad Emerg Med. 2013 Jun ;20(6):584-91. doi: 10.1111/acem.12154.

4. CMS should continue the $10 add-on payment for non-HEU radiopharmaceuticals

Most of the Molybdenum-99 used for producing Technetium (Tc-99m) radioisotopes for diagnostic imaging services has historically been produced in legacy reactors outside of the United States using highly enriched uranium (HEU) targets. Alternative methods for producing Tc-99m without HEU were demonstrated to be technologically and economically viable. The United States Government has supported the conversion of all medical radioisotope production to non-HEU sources as an important step in international nonproliferation and nuclear security efforts and has provided funding for the establishment of domestic non-HEU production. The transition to using non-HEU sources, including Low Enriched Uranium targets (LEU), in the production of Mo-99 is now virtually complete.

It was expected that a change in the supply source for the radioisotope used for modern medical imaging would introduce new costs into the payment system that were not accounted for in the historical claims data. To that end, beginning in CY 2013, CMS finalized a policy to provide an additional payment of $10 per dose for the marginal cost for radioisotopes produced by non-HEU sources (77 FR 68323).

However, as mentioned in the Proposed Rule, the Secretary of Energy issued a new certification regarding the supply of non-HEU-sourced Mo-99 effective January 2, 2022 (86 FR 73270). This certification stated that there is a sufficient global supply of Mo-99 produced without the use of HEU available to meet the needs of patients in the United States.

As the Agency explained in the CY 2023 HOPPS, the claims data that would be used to set payment rates for CY 2024 contain claims for diagnostic radiopharmaceuticals that reflect both HEU-sourced Tc-99m and non-HEU-sourced Tc-99m, rather than radiopharmaceuticals sourced solely from non-HEU Tc-99m. Therefore, providers who use radiopharmaceuticals in CY 2024 that contain only non-HEU-sourced Tc-99m might not receive a payment that is reflective of the radiopharmaceutical's current cost without the add-on payment. CMS believed that extending the additional $10 add-on payment described by HCPCS code Q9969 for non-HEU-sourced Tc-99m through the end of CY 2024 would ensure adequate payment for non-HEU-sourced Tc-99m.

This policy was based on the Secretary of Energy's certification that the last HEU reactor that produces Mo-99 for medical providers in the United States would finish its conversion to a non-HEU reactor by December 31, 2022, and that all Tc-99m used for radiopharmaceuticals in 2023 would be produced from non-HEU sources. However, conversion of the last HEU reactor that produces Tc-99m to a non-HEU reactor did not occur until March 2023, so it is possible that some claims for diagnostic radiopharmaceuticals in CY 2023 would report the cost of HEU-sourced Tc-99m.

CMS is proposing to continue the additional $10 payment through December 31, 2025, as beginning in CY 2026, the Medicare claims data used to set payment rates will reflect the full cost of non-HEU-sourced Tc-99m.

MITA supports extending the additional $10 add-on payment described by HCPCS code Q9969. We also believe that the $10 payment should be adjusted upward as there has been no inflation adjustment since it was introduced in 2013, and the beneficiary co-pay should also be eliminated. We further encourage CMS not to end the $10 add-on payment, but rather to make it permanent, either by continuing the Q9969 indefinitely or by integrating it into each of the relevant nuclear medicine APCs. MITA supports the continuation of this policy and urges CMS to do more to simplify administration by end-users. MITA requests that CMS explicitly include this policy in the final rule.

5. HOPPS Payment for Algorithm-Based Healthcare Services, Including Software as a Service

Algorithm-based healthcare services (ABHS), which include Software as a Service (SaaS) procedures, are rapidly developing and becoming increasingly important to deliver optimal patient care. ABHS are clinical analytical services delivered by FDA-cleared devices to a healthcare practitioner that use artificial intelligence, machine learning, or other similarly designed software to produce clinical outputs for the diagnosis or treatment of a patient's condition. ABHS provide quantitative and qualitative analyses, including new, additional clinical outputs that detect, analyze, or interpret data to improve screening, detection, diagnosis, and treatment of disease.

However, provider adoption and beneficiary access to ABHS are conditioned on whether there are appropriate Medicare payment pathways as developers need stability and certainty when investing the significant resources needed to develop ABHS. In the CY 2023 HOPPS final rule, CMS established a policy for the separate payment of SaaS add-on codes, excluding SaaS from the packaged payment policy at 42 CFR 419.2(b)(18). As we commented in response to the CY 2023 HOPPS proposed rule, MITA was greatly encouraged with CMS's steps to address the uniqueness of ABHS, recognizing the need for separate payment and consideration of these services. As CMS recognized in the CY 2023 HOPPS final rule, the number of such services going through the FDA review process has and will continue to rapidly increase. As such, we recommend CMS establish a dedicated section of the HOPPS rule to ABHS, as opposed to limiting discussion and consideration of these services within the New Technology APC section of the preamble text. Further, we encourage CMS to provide much needed stability and certainty regarding SaaS by formalizing the exception to the packaged payment policy in regulatory text. We offer the following recommended revision at 42 CFR 419.2:

419.2 Basis of payment.
* * *

(b) ***Determination of outpatient prospective payment rates: Packaged costs.***

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(18) Certain services described by add-on codes except as provided in § 419.2(d).

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(d) ***Determination of hospital outpatient prospective payment rates: Separately paid costs.*** Software as a Service procedures assigned to CPT add-on codes will be paid separately at an amount equal to the amount of the payment for the add-on procedure when the service is furnished without the standalone CPT code. These codes will be assigned to identical ambulatory payment classifications and status indicator assignments as their standalone codes. Separate payment will be made available for these services if the following criteria are met:

(1) The service has been approved by the FDA and has received a CPT code; and

(2) The service is billed concurrent with the associated service code.

Beyond the current SaaS pathway, MITA believes that additional changes are needed to ensure appropriate payment systems are in place for ABHS. We therefore offer the following three recommendations.

First, we ask the agency to establish a new application process within the New Technology APC pathway for ABHS, through which ABHS services that have CPT codes, as well as those that lack CPT codes, could be eligible for payment. This process would be tailored to the unique characteristics of ABHS, while staying true to the policy priorities CMS established as part of the current New Technology APC application requirements (including the creation of procedural C-codes as needed). Creating a dedicated pathway would allow ABHS developers to apply for a New Technology APC based on specific questions and criteria that reflect the impact of ABHS on care pathways and how these services assist practitioners in the delivery of care. MITA is developing the contours and key features of a New Technology APC for

ABHS application and welcome the opportunity to meet with CMS to discuss this recommendation further.

Second, we encourage CMS to modify the current New Technology APC policies as they relate to ABHS both currently assigned to a New Technology APC and for future ABHS (including via a potential New Technology APC for ABHS application pathway). Specifically, we recommend CMS: (1) provide stability for ABHS developers by assigning ABHS to a New Technology APC for at least five years; and (2) waive the Universal Low Volume APC policy for ABHS assigned to a New Technology APC. Both of these recommendations are intended to ensure stability during the New Technology APC period. As it relates to the five-year price stability period, we note that this aligns with the lifespan of a Category III code and is necessary to ensure appropriate data collection and analysis can occur while hospitals adopt ABHS. Further, the five-year stability is intended to ensure there are not variations in New Technology APC assignment based on misreported or omitted cost information. In recent years, we have seen how annual fluctuations cause confusion among adopters and creates a chilling effect on innovation.

This rationale also applies to the recommended waiver of the Universal Low Volume APC policy for ABHS. In this proposed rule, CMS proposes to apply the Universal Low Volume APC policy to one ABHS (Liver Multiscan Service, APC 1505), but proposes not to apply this policy to another ABHS (QMRCP, APC 1511). While we agree with CMS's rationale that one claim for QMRCP appears to be an outlier and therefore should not impact its New Technology APC assignment, we highlight the dichotomy in treatment of these two ABHS, especially considering there were only 39 claims for Liver Multiscan Service. It is well-known and understood that innovative technologies like ABHS require stability and certainty to ensure continued development and beneficiary access. We believe it is in the best interest of Medicare beneficiaries and their providers to have stable access to and consistent payment for innovative technology like ABHS.

Third, we urge CMS to be proactive in considering clinical APC assignments for ABHS. While some ABHS can be appropriately assigned to an existing clinical APC, CMS should begin to consider policy options for future ABHS that may not meet the criteria for assignment to current clinical APCs. In recognition of the continual evolution of ABHS, we urge CMS to continue to work with developers to ensure ABHS can be appropriately transitioned out of New Technology APC payments after five years and be assigned to an appropriate clinical APC.

6. CMS should finalize its proposal to assign Fractional Flow Reserve derived from Computed Tomography (FFRct) to APC 5724

For patients with suspected cardiac disease, use of FFRct has been proven to reduce reliance on invasive testing to arrive at a diagnosis. Clinical studies have demonstrated that use of FFRct in patients with planned invasive procedures allowed physicians to cancel 61% of invasive coronary angiograms, delivering significant cost-savings ($3,109 per-patient) using 2015 CMS reimbursement rates.

For CY 2023, CMS assigned FFRct to APC 5724 (Level 4 Diagnostic Tests and Related Services) because "[FFRct] is a diagnostic service, and the HOPPS has a clinical APC series for diagnostic tests and related services" and because this APC was appropriate from a resource perspective. For CY 2024, the CPT Editorial Panel approved the replacement of Category III codes 0501T–0504T with a single new Category I code (7X005) to report FFRct and CMS proposes to assign 7X005 to the same APC. For the same reasons as in CY 2023, CMS should finalize its proposal to assign FFRct to APC 5724.

7. CMS should revise the payment indicator for breast localization codes

MITA requests a payment indicator revision for breast localization codes 19281, 19283, 19285, and 19287. There is no payment made for these services (CPT codes 19281, 19283, 19285, and 19287) when furnished in the ASC setting due to it's N1 payment indicator. In 2023, these procedures were designated as device intensive. Given the significant geometric mean costs for these procedures, the failure to make any payment to ASCs for these procedures creates a significant barrier to access in the ASC place of service. We request that CMS revise the payment indicator for the breast localization placement procedures to one that allows for payment in the ASC setting of device intensives procedures, such as "J8".

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If you have any questions, please contact Peter Weems at 703-841-3238 or by email at pweems@medicalimaging.org.

Sincerely,

Patrick Hope
Executive Director, MITA

MITA is the collective voice of medical imaging equipment and radiopharmaceutical manufacturers, innovators and product developers. It represents companies whose sales comprise more than 90 percent of the global market for medical imaging technology. These technologies include: magnetic resonance imaging (MRI), medical X-Ray equipment, computed tomography (CT) scanners, ultrasound, nuclear imaging, radiopharmaceuticals, and imaging information systems. Advancements in medical imaging are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. The industry is extremely important to American healthcare and noted for its continual drive for innovation, fast-as-possible product introduction cycles, complex technologies, and multifaceted supply chains. Individually and collectively, these attributes result in unique concerns as the industry strives toward the goal of providing patients with the safest, most advanced medical imaging currently available.