MITA
MEDICAL IMAGING
& TECHNOLOGY ALLIANCE
A DIVISION OF NEMA

1300 North 17th Street ▪ Suite 900
Arlington, Virginia 22209
Tel: 703.841.3200
Fax: 703.841.3392
www.medicalimaging.org

September 13, 2022

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-1772-P— CY 2023 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Proposed Rule

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).

Our comments address the following:

1. The proposed decrease to the HOPPS conversation factor based on increased reimbursement rates for drugs acquired through the 340B program will negatively impact providers
2. MITA encourages CMS to develop policies that accurately capture the cost of adopting and providing AI-enabled services
3. MITA recommends extension of pass-through status for products affected by the COVID-19 pandemic
4. CMS should modify the HOPPS payment methodology in CY 2023 to establish separate payment for certain diagnostic radiopharmaceuticals based on ASP + 6%
5. MITA supports reassignment of CPT 55880 to APC 5376
6. CMS should finalize its proposal to assign Fractional Flow Reserve derived from Computed Tomography (FFRct) to APC 5724
7. MITA supports assignment of certain breast imaging localization CPT codes to APC 5072
8. MITA supports reassignment of CPT 0398T to APC 5464
9. CMS's proposal to remove the $10 add-on payment for non-HEU radiopharmaceuticals will negatively impact beneficiary access to advanced imaging

* * * *

1. **The proposed decrease to the HOPPS conversation factor based on increased reimbursement rates for drugs acquired through the 340B program will negatively impact providers**

In light of the Supreme Court's decision in *American Hospital Association v. Becerra*, CMS proposes to revert to its prior policy of setting payment to providers for drugs acquired through the 340B program at ASP + 6% and budget neutralize this increase for CY 2023 with a corresponding decrease to the HOPPS conversion factor. CMS estimates that it would need to apply an offset of approximately $1.96 billion, via a decrease to the HOPPS conversion factor. This would reduce most/all APCs payment by approximately 3 – 4 percent at a time when healthcare inflation is increasing rapidly due to post-COVID 19 supply chain issues and increased cost of nurse and other allied healthcare professionals' salaries

Given the magnitude of CMS' proposal to decrease the HOPPS conversion factor—combined with the compounding, cumulative effect of other proposed payment reductions, we encourage CMS not to finalize this offset for CY 2023 and to instead engage with stakeholders prior to the CY 2024 proposed rule to identify other multi-year remedies, not unlike the situation CMS faced several years ago with the coding intensity adjustment "re-payment" in the Inpatient Prospective Payment System. The current CMS proposal to decrease the HOPPS conversation factor for CY 2023 would have a significant impact on providers at a time when most hospitals are operating at a year-to-date margin of negative 1%. Therefore, MITA recommends that in the Final HOPPS Rule for CY 2023, CMS the set the calculation of payment rates in addendums A and B without considering the American Hospital Association decision and urges CMS to convene a townhall forum and dialog prior to publishing an alternative approach in the proposed rule for CY 2024 and subsequent calendar years based on comments received in response to this Proposed Rule.

2. **MITA encourages CMS to develop policies that accurately capture the cost of adopting and providing AI-enabled services**

In this proposed rule, CMS seeks public comment on a payment approach for what it is calling "Software as a Service" or SaaS.

MITA is encouraged by CMS' payment proposal for one type of use case for Software as a Service (SaaS) in the CY 2023 proposed HOPPS rule. Innovative artificial intelligence (AI) software products—in alignment with the Quadruple Aim—promise to bring about (1) greater efficiency and effectiveness in the delivery of healthcare by improving population health, (2) enhancing patient experiences, (3) avoiding unnecessary costs and driving cost efficiency, and (4) improving the experiences of clinicians and healthcare staff.

However, realizing the maximum potential of AI software technologies that use images as an input for the procedure or that are used in the acquisition and interpretation of images during a procedure, requires an alignment of Medicare payment policies to appropriately recognize the costs to hospitals of adoption and ongoing use of SaaS. In addition to finalizing this initial proposal for one type of use of SaaS for CY 2023, CMS should also announce in the CY 2023 Final HOPPS Rule a formal process for collecting and responding to input from interested parties and a collaborative process that ensures development and implementation of appropriate payment policies for all use cases of SaaS. We would encourage CMS to seek stakeholder input on AI valuation across all other settings of care. These opportunities for input should be iterative and collaborative, and in addition to annual rulemaking, allowing for quicker development and exchange of policy ideas. MITA has given considerable thought to AI valuation and payment in the hospital and physician office settings and would be glad to work with CMS on a continual basis with monthly meetings to define all needed elements for a comprehensive, long-term payment

policy for procedures that use AI-enabled software or medical devices with AI-enabled software in the care of Medicare beneficiaries for further rulemaking. A process both with external stakeholders and across various departments (e.g., FDA, HHS, CMS) will be critical to ensuring definitions and clinical and reimbursement pathways are consistent and stable.

An important first step for developing appropriate payment policy for all types and uses of SaaS technologies will be the adoption by CMS of terminology that supports and describes the discrete categories of software. In this proposed rule, CMS is seeking comment on what it is calling "Software as a Service." CMS appears to be creating a new definition versus using the definitions already in use by the FDA or the definitions in use by the CPT Editorial Panel in the descriptors for procedures described by the recently created CPT codes. Although there is extensive discussion in this proposed rule about what is meant by this term, it is unclear how this term aligns with already well established and described terms regarding AI software and medical devices. The Food & Drug Administration (FDA) has adopted the term "Software as a Medical Device" and authorized the marketing of numerous technologies in this regulatory category.[1] The American Medical Association (AMA) has adopted "CPT Appendix S: AI taxonomy for medical services & procedures" to provide guidance for classifying various software applications based on level of functionality and clinician involvement.[2]

Alignment around a commonly accepted set of terms for AI software products and the functions they perform will be critical for ensuring innovators can chart a clear path from FDA premarket review through Medicare and the reimbursement processes of coding, coverage, and payment, ensuring patient access to these innovative technologies and services.

While MITA supports CMS's policy proposal to separately pay for SaaS, we are also providing additional comments on the following for CMS' consideration: (1) a definition of AI-enhanced medical devices; (2) a reimbursement pathway for AI-enhanced medical devices; (3) ensuring consistency across payment systems; and (4) addressing and mitigating bias in AI and SaaS.

a. Definition of AI-enhanced medical devices

In the CY 2023 HOPPS proposed rule, CMS recognizes that AI, machine learning, and CDS software have been available for many years and that the number of FDA-approved software devices continues to increase rapidly. CMS proposes payment for SaaS, which CMS states are algorithm-driven services that that "assist" practitioners in making clinical assessments (e.g., clinical decision support software, clinical risk modeling, computer aided detection (CAD)), on a subscription or per-use basis. When describing CAD, CMS notes that this type of SaaS "aid[s] or augment[s]" clinical decision making. Thus, within the singular discussion of SaaS, CMS utilizes two of the three categories of AI applications included in the AMA's AI taxonomy – "assistive" and "augmentative".

We strongly believe CMS should adopt more clear and consistent definitions for AI-enhanced medical devices that incorporate the terms defined in the AMA AI Taxonomy, codifying these terms and their definitions across both coding and payment. This would accomplish the goal of ensuring consistent definitions across agencies and as developed by other stakeholders. Carefully crafting such a definition at the outset of coverage and reimbursement decisions will be critical in providing stability for industry as they continue to develop and innovate AI for health care. A weakness of CMS' current SaaS proposals is that it does not acknowledge software that is built into a diagnostic imaging device, which leads to the question of whether only stand-alone SaaS would be separately payable, or whether SaaS built into a medical device (i.e., AI-enhanced medical device) would also receive separate payment. If approved for

[1] https://www.fda.gov/medical-devices/digital-health-center-excellence/software-medical-device-samd
[2] https://www.ama-assn.org/practice-management/cpt/cpt-appendix-s-ai-taxonomy-medical-services-procedures

the same use and clinical indication, there is no meaningful difference between SaaS that is a standalone software device and software that is built right into the medical device. They could perform the same functions in a manner consistent with CMS's proposed reimbursement approach for such technology. Therefore, we recommend that CMS explicitly state separate reimbursement for SaaS is available for both stand-alone software devices and those that are integrated into a piece of imaging equipment.

To address these issues and concerns, we hope CMS will coordinate with all stakeholders, including industry, to establish transparent and clear definitions. We offer the following definition that is consistent with the AMA AI Taxonomy for consideration when AI or other software is specifically built into the machine or when such software is utilized to add new, additional functionality for use in the acquisition of images:

An AI-enhanced medical device is an FDA-approved or cleared software, algorithm, or enhanced device that: (1) assists the clinician user's ability to provide care; (2) augments the clinical information obtained, including by providing information that informs a treatment plan; or (3) autonomously performs a medically necessary function.

CMS also seeks feedback on how to identify services that should be separately recognized as an analysis distinct from both the underlying imaging test or the professional service paid under the PFS. We believe there are several instances when AI/software should be separately recognized and reimbursed including, but not limited to, the following functions:

1. Provides new fundamentally different data or output than that of the underlying imaging test
2. Provides new data that could not be resolved or manually or visually derived from imaging no matter how much time the physician reviews or using previously available equipment (e.g., FFRct data cannot be obtained from visual examination of CT data)
3. SaaS that is equivalent to or replaces MD work but performs it more efficiently should be paid at the same professional rate as the MD work
4. SaaS that is performed in a different location by a different provider, that could be performed days or weeks following the underlying imaging procedure
5. SaaS that improves health equity should be separately payable

b. <u>Reimbursement pathway for AI-enhanced medical devices</u>

We appreciate CMS's work on SaaS and recognition that AI functions need to be reimbursed separately as the costs of these software "in many instances…exceed the costs of the imaging service." Doing so enables providers and hospitals to confidently acquire and use innovative technology to offer patients the best possible care. In this proposed rule, there is acknowledgement or intentionality from CMS to pay separately for certain AI, with which we strongly support. However, we reiterate our definitional concerns. As described in the proposed rule, SaaS encompasses an enhanced version of what the AMA has categorized as assistive AI. In other words, it appears CMS is proposing to reimburse for certain assistive AI, should they meet certain criteria as described in the proposed rule. By extension, all augmentative and autonomous AI (as defined by the AMA) should also be separately payable when covered under the HOPPS.

With respect to CMS's proposed framework for reimbursing such software, we do not believe creating new C-codes for each type of AI is a reasonable permanent solution and should be discussed in the final HOPPS rule as temporary. MITA acknowledges the many challenges with incorporating AI into the existing HOPPS reimbursement framework, but cautions against relying on C-codes as a long-term solution. Instead, we suggest creating separate APCs for imaging services enhanced by AI, not unlike

what is the case today with imaging services with contrast. Under this potential framework, those AI devices recognized with CPT codes that meet the assistive criteria or are augmentative or autonomous would be included in these "imaging with AI" APCs. We believe this will allow for HOPPS payments via a framework that providers already understand and are familiar with. We believe this categorization will incentivize the adoption and use of AI enabled medical devices.

In addition, we support CMS's proposal to not recognize the CPT add-on codes as established by the AMA and to instead create new temporary C-codes to determine the volume of "billed together" data for these new add-on codes and the imaging codes that they are billed with. We believe this is consistent with CMS's definitional approach, that separately paying for AI is the appropriate path forward and will help to ensure consistency across payment systems.

As CMS continues to consider the path forward for reimbursing AI and AI-enhanced medical devices, we reiterate our prior comments urging a separate process to facilitate continued interaction and engagement with appropriate stakeholders.

c. Ensuring consistency across payment systems

In the proposed rule, CMS describes the historical treatment of Fractional Flow Reserve derived from Computed Tomography (CPT code 0503T) and its assignment to New Technology APC 1516. We believe the process used in determining the appropriate pricing and reimbursement for this technology is appropriate. Specifically, establishing pricing based on information provided by the developer is an appropriate method to gather costs for all other AI technology under the HOPPS. We recommend that CMS adopt the same cost model process that is uses for the New Technology APC application and assignment process for initial payment assignment of a SaaS and/or AI enabled medical device. MITA also believes a minimum of three years and maximum of five years will be necessary for CMS to accumulate relevant data to make an appropriate clinical APC assignment for these services.

Furthermore, MITA supports the model whereby the geometric mean cost for FFRct was utilized to identify a code to which FFRct could be crosswalked for payment under the Physician Fee Schedule (PFS). We generally agree with CMS's conclusions in the CY 2022 PFS final rule regarding this crosswalk approach for SaaS and/or AI enabled medical devices that are first valued under HOPPS. We note with caution, however, that such a process should not be applied retrospectively for all prior software, devices, or services. Instead, we urge that the process be utilized for those instances where CMS must establish new costs and clinical APC assignments for future AI and software innovations.

Thus, we recommend CMS formalize a process that establishes initial costs for AI under the HOPPS based on developer supplied pricing information, like the New Technology APC cost model requirement. This amount would be used for at least three but no more than five years, while CMS collects hospital cost information to identify the appropriate clinical APC assignment. During this time period, CMS should crosswalk the identified costs under the HOPPS to an appropriate code under the PFS. We believe this approach will minimize burdens on physicians and hospitals acquiring such technology while also providing stability and certainty for increased adoption.

Upon crosswalking to the PFS, however, we believe there should be an opportunity for review of the crosswalked cost amount (e.g., via the submission of more recent invoices). Because hospitals and physician practices have different cost structures, there should be a similar acknowledgement and flexibility should physicians incur greater costs than hospitals in acquiring such technology. MITA would support relying on existing CMS processes to update the cost inputs and ultimately the code to which the HOPPS-reimbursed AI service is crosswalked. We believe this framework is consistent with ensuring access to care across health care settings and payment systems, while also minimizing the need for

updates or administrative burdens as prices will initially be established via industry-supplied information and hospital cost reports. We note, however, that there may be AI or software developed that is utilized initially and/or more frequently in a non-hospital setting. The payment systems must recognize and be adaptable to these inevitable situations, including allowing for an accurate determination of cost inputs under the PFS. While we seek to streamline the reimbursement pathways, we again urge for flexibility as developers continue to innovate in this space for use in different care settings.

d. Addressing and mitigating bias in AI and SaaS

MITA member companies go to great lengths to mitigate bias inherent in clinical algorithms and provide transparency into how these technologies are developed. While elimination of bias in clinical algorithms is not a tenable goal, identification and mitigation of bias is always an ongoing objective. Further, clinical algorithm developers seek to be transparent about identified biases in clinical algorithms and educate caregivers about the existence of these biases so as to minimize impact to patient care.

Medical imaging algorithm developers have extensive experience balancing the risks and benefits provided by a product to provide a safe, effective device. Risk management processes, quality management systems, and intensive training programs all reflect a commitment to products which improve patient care. Regulatory oversight by FDA offers further confirmation that the products are safe and effective.

Medical device manufacturers adhere to long-established and widely adopted industry standards: ISO 14971, "Medical devices — Application of risk management to medical devices" and ISO 13485, "Medical devices — Quality management systems — Requirements for regulatory purposes". These standards, which are updated regularly and represent several decades of collective and codified experience, set the foundation for medical device development and embody our commitment to patient safety. This experience translates readily to new technologies—including AI and ML.

Existing premarket and postmarket regulatory oversight reinforces this commitment. Our technologies are subject to extensive premarket review by the FDA to determine their safety and effectiveness, as well as ongoing postmarket surveillance to identify and mitigate any emergent concerns once introduced to market. FDA authorized medical devices can only be marketed according to the product's FDA regulated label that provides clear instructions for use and identifies the indications and populations for which the device may be used. Data curation practices, dataset balancing, and algorithm testing are performed based upon FDA requirements related to our device claims. FDA verifies these requirements are met during the regulatory review process. For example, medical imaging device developers address age concerns and considerations through careful database stratification and labelling development which is approved through FDA processes.

3. MITA recommends extension of pass-through status for products affected by the COVID-19 pandemic

As a result of the ongoing COVID-19 pandemic, patient access to new technologies, including those granted pass-through status since 2020, has been severely hampered. During the pandemic, patients have not always been able to receive the care they need, when they need it, resulting in delayed care and

diagnosis of certain diseases at a later state.[3456789101112131 4] The goal of granting a product pass-through status is to facilitate access to innovative devices, drugs, and biologics while CMS collects data to determine accurate payment rates.

However, the effects of the COVID-19 pandemic have confounded Medicare data and severely impeded patient access. This is of particular importance for PET imaging using diagnostic radiopharmaceuticals where at the end of their pass-through status, the cost of the diagnostic radiopharmaceutical is packaged into the APC payment for the Positron Emissions Tomography (PET) or PET/CT imaging procedure.

We continue to be deeply concerned about the accuracy of recent claims data for rate-setting for pass-through designated products. We expect that CMS will see similar impacts during some or all of CY 2022, including patterns of reduced utilization, just as has been the case in CY 2020 and 2021 for PET imaging procedures using diagnostic radiopharmaceutical tracers with pass-through status. Consequently, claims data will not reflect normal utilization for these pass-through products.

Furthermore, recently approved products have been impacted by Medicare claims processing challenges, which have also negatively impacted their utilization rates and cost patterns in the claims data which Medicare uses in its rate-setting.

Specifically, beneficiary access to the following products has been substantially impacted:

- Detectnet™ (copper Cu 64 dotatate) (A9592) – Error in the 2021 FISS file caused claims to not be accepted for processing by the Medicare Administrative Contractors (MACs), resulting in significant under representation in the claims data. CMS until CY 2022 did not correct FISS file.
- Cerianna™ (fluroestradiol F 18) (A9591) – Inaccurate payment rate of $0.752/mCi listed, resulting in severe impairment of product access and claims reporting

MITA believes these claims processing issues had a direct impact on an entire year, CY 2021, of the data collection for rate setting purposes for these two diagnostic radiopharmaceuticals with pass-through status and the nuclear medicine APCs, specifically APC 5594, Level 4 Nuclear Medicine, since these diagnostic radiopharmaceuticals principally use one CPT code, 78815. Beyond a delay in claims processing and data collection, we believe this error impacted utilization and distorted the Medicare claims dataset for these two tracers, thereby frustrating the purposes of transitional pass-through status.

[3] The Impact of COVID-19 on Patients With Cancer, Am J Clin Oncol 2021;44:580–587
[4] Editorial: Impact of the Covid-19 Pandemic on Breast Cancer Treatment and Patient Experience, Ann Surg Oncol (2022) 29:1502–1503
[5] Two-month stop in mammographic screening significantly impacts on breast cancer stage at diagnosis and upfront treatment in the COVID era, https://doi.org/10.1016/j.esmoop.2021.100055
[6] Racial and socioeconomic inequities in breast cancer screening before and during the COVID-19 pandemic: analysis of two cohorts of women 50 years +, Breast Cancer (2022) 29:740–746, https://doi.org/10.1007/s12282-022-01352-2
[7] The Impact of the COVID-19 Pandemic on Cancer Care and Health-Related Quality of Life of Non-Hispanic Black/African American, Hispanic/Latina and Non-Hispanic White Women Diagnosed with Breast Cancer in the U.S.: A Mixed-Methods Study Protocol, Int. J. Environ. Res. Public Health 2021, 18, 13084. https:// doi.org/10.3390/ijerph182413084
[8] Impact of the COVID-19 Pandemic on Breast Cancer Mortality in the US: Estimates From Collaborative Simulation Modeling, JNCI J Natl Cancer Inst (2021) 113(11): djab097
[9] Breast cancer diagnosis and treatment during the COVID-19 pandemic in a nationwide, insured population, Breast Cancer Research and Treatment (2022) 194:475–482, https://doi.org/10.1007/s10549-022-06634-z
[10] Cancer case trends following the onset of the COVID-19 pandemic: A community-based observational study with extended follow-up, Cancer 2022;128:1475-1482
[11] Assessing the impact of the COVID-19 pandemic on breast cancer screening and diagnosis rates: A rapid review and meta-analysis, J Med Screen 1–10
[12] Impact of the COVID-19 Pandemic on Breast Cancer Screening and Operative Treatment, The American Surgeon 2022, Vol. 88(6) 1051–1053
[13] Implications for health system resilience: Quantifying the impact of the COVID-19-related stay at home orders on cancer screenings and diagnoses in southeastern North Carolina, USA, Preventive Medicine 158 (2022) 107010
[14] The impact of the Covid-19 pandemic on breast cancer early detection and screening, Preventive Medicine 151 (2021) 106585

For these reasons, MITA asks that CMS exercise its equitable adjustment authority and extend those diagnostic radiopharmaceuticals with pass-through status by one year, even if such pass-through status does not expire during CY 2023 to ensure that their claims data reflects real utilization rates and patients have access to these innovative technologies. This will allow for adequate payment of these innovative technologies in the nuclear medicine APCs once their pass-through status is over, maintaining consistency with the calendar year cycle of the HOPPS/ASC PPS.

4. CMS should modify the HOPPS payment methodology in CY 2023 to establish separate payment for certain diagnostic radiopharmaceuticals based on ASP + 6%

Advanced imaging diagnostic radiopharmaceuticals continue to be inappropriately packaged in the Medicare hospital outpatient setting. Under the current inequitable payment methodology, hospital payment for the diagnostic radiopharmaceuticals is packaged with the scan even though the radiopharmaceuticals are separately approved by the FDA as drugs or biologicals. This policy results in reduced payments to hospitals, and limits beneficiary access to new, targeted diagnostic radiopharmaceuticals that provide important clinical information. 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. This can result in a lack of diagnosis, or use of less precise diagnostic information may lead to suboptimal clinical decisions and outcomes for Medicare beneficiaries.

The Agency's position that packaging incentivizes hospitals to use a lower cost alternative does not apply to newer diagnostic radiopharmaceuticals where there may be no alternative. In the final rule, MITA strongly recommends that CMS align diagnostic radiopharmaceutical payment with the methodology for separately covered outpatient drugs that are approved by the FDA. At present, the CMS packaging policy applies to drugs that exceed a cost threshold of $135. For the same reasons, CMS should modify the HOPPS payment methodology for diagnostic radiopharmaceuticals to establish separate payment based on ASP + 6% that exceed a cost threshold of $500. Such an approach would also be consistent with legislation currently under consideration by Congress (S. 2609/H.R. 4479) to require CMS to pay separately for diagnostic radiopharmaceuticals that are approved by the FDA on or after January 1, 2008 and exceed a cost of $500. We support this bipartisan legislation and request CMS use their authority to adopt the provisions of the bill.

5. MITA supports reassignment of CPT 55880 to APC 5376

CMS is proposing to reassign CPT 55880: *Ablation of malignant prostate tissue, transrectal, with high intensity-focused ultrasound (HIFU), including ultrasound guidance* from APC 5375 to APC 5376. MITA supports this proposal given that the higher APC is more reflective of the costs of providing this service and will ensure appropriate payment.

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. Despite

these proven clinical and economic benefits, CMS payment rates have fluctuated widely since assignment of the service to a new technology APC in 2018. For CY 2020, CMS proposed a payment reduction to $750 and finalized a payment rate of $950. For the last three years, payment has been stable despite a proposed reduction to $850 in CY 2021.

To provide a stable payment rate that covers the cost of the service, CMS should finalize its proposal to assign FFRct to APC 5724 (Level 4 Diagnostic Tests and Related Services). As CMS noted, "[FFRct] is a diagnostic service, and the HOPPS has a clinical APC series for diagnostic tests and related services." MITA agrees that this is the correct APC series for the FFRct service and that Level 4, with a payment rate of around $961, is the most appropriate from a resource perspective. In the proposed rule, CMS acknowledges that the part of the FFRct service described by CPT code 0503T costs $1,100. In recognition of access issues that fluctuating payment relying on the geometric mean cost is causing for beneficiaries, CMS should finalize its proposal to assign FFRct to APC 5724.

7. MITA supports assignment of certain breast imaging localization CPT codes to APC 5072

CMS should finalize reassignment of CPT 19281 to APC 5072. CMS is proposing to reassign CPT 19281: *Placement of breast localization device(s) (eg, clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; first lesion, including mammographic guidance* from APC 5071 to APC 5072. MITA supports this proposal given the resources involved and considering the other procedures assigned to APC 5072, such as the percutaneous breast biopsy procedures.

CMS should assign CPT 19283, 19285, and 19287 to APC 5072. CPT codes 19283, 19285 and 19287 are part of a series of codes representing placement of breast localization devices. Along with CPT 19281, these codes represent the "first lesion" and only differ by the type of imaging guidance used (mammographic, stereotactic, ultrasound, MRI). From a clinical coherence perspective, all the first lesion percutaneous placement of breast localization devices should be assigned to the same APC, as they are very similar procedures. Notably, the geometric means of CPT codes 19283 ($1,035.46) and 19285 ($1,032.06) are close to the geometric mean of CPT code 19281, which is already proposed to move to APC 5072, and all are much above the geometric mean for APC 5071, further warranting reassignment. It is important to have access to these procedures with each of the different guidance modalities due to their clinical coherence, and to avoid discrepancy in imaging guidance choice driven by payment level. Therefore, CMS should assign CPT codes 19283, 19285 and 19287 to APC 5072.

8. MITA supports reassignment of CPT 0398T to APC 5464

Magnetic Resonance guided Focused Ultrasound (MRgFUS) is a non-invasive, real-time monitored and controlled surgical procedure that uses continuous diagnostic-quality magnetic resonance imaging with high-power, focused ultrasound energy (non-ionizing radiation) to provide an efficient, outpatient treatment. Currently, the Food and Drug Administration (FDA) has approved the following neurosurgical applications of MRgFUS using the Insightec Exablate equipment: Essential Tremor, Tremor Dominant Parkinson's Disease, and most recently Parkinson's Disease. The neurosurgical use of MRgFUS is reported using CPT code 0398T (Magnetic resonance image guided high intensity focused ultrasound (MRgFUS), stereotactic ablation lesion, intracranial for movement disorder including stereotactic navigation and frame placement when performed). This treatment fills a gap between medical therapy (which may not provide relief from patients) and the highly invasive deep brain stimulation procedure. Accordingly, MITA believes it is important that this service remain available for Medicare beneficiaries.

For CY 2023, CPT code 0398T is proposed to be placed in APC 5463, which has a proposed payment of $12,866. The proposed placement in APC 5463 fails to compensate hospitals for the resources expended to furnish the procedure, thus impeding Medicare beneficiary access to this treatment option. We understand that over the past few years of claims data, there is a distinct trend showing both an increase in volume (claims) and geometric means for this procedure such that reassignment to APC 5464 should now be considered.

MITA therefore recommends CMS reassign CPT code 0398T to APC 5464 (Level 4 Neurostimulator and Related Procedures) for CY 2023, to ensure this treatment option remains available to Medicare beneficiaries who would benefit from the treatment.

9. CMS's proposal to remove the $10 add-on payment for non-HEU radiopharmaceuticals will negatively impact beneficiary access to advanced imaging

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.

CMS is proposing to end the additional $10 add-on payment described by HCPCS code Q9969 for non-HEU sourced Tc-99m beginning with CY 2025.

We are concerned that his proposal will negatively impact beneficiary access to advanced imaging because it places financial pressure on providers to avoid or less frequently use non-HEU radiopharmaceuticals.

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.

* * * *

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.