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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: CMS–1784–P—Medicare and Medicaid Programs: CY 2024 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment, 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 (CMS) Proposed Rule on Medicare payment rates and policies for services paid under the Physician Fee Schedule (PFS).

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1) **CMS should mitigate significant payment cuts resulting from multiple significant policy changes**

For CY 2023, CMS is proposing an approximately 3.36% reduction in the Conversion Factor (CF), dropping from $33.8872 to $32.7476. This will result in a 3% payment cut to radiology, a 3% cut to nuclear medicine, and a 4% cut to interventional radiology.

The ongoing payment cuts resulting from a confluence of policies exerting downward pressure on physician payment will cumulatively result in significant challenges for beneficiary access and the ongoing viability of physician practices, particularly in light of the ongoing economic effects of the COVID-19 pandemic. We urge CMS to take whatever steps it has within its authority to mitigate these payment cuts—including reducing the impact or delaying implementation—and to work with Congress on policies that will ensure the ongoing stability of the PFS. For example, CMS should either not implement HCPCS code G2211 or phase-in the impact of implementing HCPCS code G2211, if finalized, over four years. The budget neutrality offset associated with HCPCS code G2211 is a major contributor—90% by CMS' own estimates, of the -3.36% reduction to the proposed CY 2024 PFS conversion factor.

2) MITA supports the exclusion of radiopharmaceuticals and imaging agents from the discarded drug refund under the PFS based on statutory language

In previous rulemaking, CMS implemented Section 90004 of the Infrastructure Investment and Jobs Act (Pub. L. 117-9) that requires manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug payable under Medicare Part B. The Act excludes from these provisions a drug or biological that is either a radiopharmaceutical or an imaging agent.

As Congress correctly determined radiopharmaceuticals and imaging agents should be excluded from the discarded drug refund because they are typically prepared in a patient ready dose. In particular, due to the radioactive half-life of radiopharmaceuticals there is no discarded amount following administration. In the Proposed Rule, CMS notes that the proposal specifically includes contrast agents by reference to the FDA labeling guidance by stating, "[w]e propose to identify […] imaging agents (including contrast agents) […] by language describing them as such in FDA approved labeling." Under such FDA labeling guidance, the FDA clarifies that contrast agents are included in the more-general category of imaging agents. In the Final Rule, CMS should continue to explicitly confirm that imaging agents includes contrast agents. Additionally, given that imaging contrast agents and radiopharmaceuticals are excluded by law from the discarded drug refund policy, providers that bill separately for these agents should not have to report discarded amounts, if any, using the JW or JZ modifiers.

3) MITA Continues to Support Crosswalking Algorithm-Based Healthcare Services from HOPPS to PFS and Supports CMS's Decision to Crosswalk Fractional Flow Reserve with CT (CPT Code 7X005)

As described in our comment on the CY 2023 HOPPS proposed rule, MITA supports CMS's continued approach of establishing the costs of algorithm-based healthcare services (ABHS) under the HOPPS, and then crosswalking those amounts to the appropriate CPT code under the PFS. 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.

We believe that setting ABHS costs first based on developer-supplied information and then via hospital cost reports and submitted claims will reduce the burden on physician practices, ensure the cost inputs are derived from verifiable sources, and provide stability and certainty to increase adoption of these innovative technologies. Furthermore, a defined reimbursement pathway that spans both the HOPPS and PFS will reduce burdens for CMS, manufacturers, and providers, while enabling access to ABHS regardless of where the service is provided.

We would also like to remind CMS that use of HOPPS cost data to establish PFS payment rates is well within its authority. In response to concerns raised in the CY 2022 rule cycle, CMS stated that, "section 1848(c)(2)(N) of the Act authorizes our use of alternative approaches to establishing PE relative values using cost, charge, or other data from suppliers or providers of services in order to ensure accurate valuation of services under the PFS."[1]

[1] 86 Fed. Reg. at 65040. November 19 2021.

With this in mind, we support CMS's proposal for CY 2024 to maintain the previous valuation crosswalk to the technical component of CPT code 93457 for the new FFRct code 7X005 as this "will allow the geometric mean costs under the OPPS to continue to serve as a proxy for valuation." MITA applauds CMS's creative thinking to employ alternative methodologies to appropriately reimburse providers for these services and supports these proposals for CY 2024.

4) MITA Response to Request for Information (RFI) on Digital Therapies

In the proposed rule, CMS seeks public comment on a variety of topics related to digital therapies, including how such technology is imbedded in practice models, how practitioners and auxiliary staff are involved in furnishing remote physiologic monitoring (RPM) and remote therapeutic monitoring (RTM) services, what aspects of digital cognitive based therapy services should be considered when determining potential Medicare payment, and the scientific and clinical evidence of effectiveness that the agency should consider when determining whether digital therapeutics for behavioral health are reasonable and necessary. CMS notes that it is issuing this RFI because "[t]he widespread adoption and use of software technologies, including, but not limited to digital therapeutics, is creating new ways to treat patients."

MITA appreciates that CMS continues to seek information from stakeholders regarding software technologies for consideration in the future to address the growing adoption and use of such services. We recognize the challenges associated with adopting and implementing payment policies for these technologies, but strongly urge CMS to be clear in its use of terminology to ensure technologies that serve differing functions are not inadvertently grouped or inappropriately combined. MITA believes that ABHS, as we define earlier in this comment letter, are distinct from digital therapies as described in the RFI (e.g., RPM and RTM, which monitor physiologic and non-physiologic data).

Because both ABHS and digital therapies are at their core software technologies, MITA encourages the agency to carefully establish definitions and policies as it continues to consider payment for these services. By doing so, developers of ABHS and digital therapies alike will have clear guidance and specific definitions as these technologies are developed. As it relates specifically to ABHS, we reiterate our support for CMS' current policy of establishing ABHS costs first in the HOPPS via hospital cost reports and crosswalk those costs to the PFS since it is currently the least burdensome and most accurate methodology to value ABHS in the PFS.

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If you have any questions, please contact Peter Weems, Senior Director of Policy & Strategy, 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.