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September 6, 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: CMS-1770-P— CY 2023 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies

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).

Our comments address the following policy proposals:

1. CMS should mitigate significant payment cuts resulting from multiple significant policy changes
2. CMS should recognize the value of certain high value, underutilized imaging services
3. MITA supports the exclusion of radiopharmaceuticals and imaging agents from the discarded drug refund under the PFS based on statutory language
4. MITA is concerned with the proposal to package skin substitutes under the PFS and requests that the final rule confirm that CMS does not have the legal authority to package radiopharmaceuticals
5. CMS should expand its coverage of colorectal cancer screening to include computed tomography colonography
6. CMS should not implement changes to the Medicare Economic Index
7. CMS should correct technical errors related to Malpractice RVUs
8. MITA supports the proposal to continue national payment established in CY 2022 for certain services that utilize innovative technologies and artificial intelligence
9. CMS should continue to work with stakeholders in the development of appropriate payment policies for AI technologies
10. CMS should correct rank order issues related to neuromuscular ultrasound codes
11. MITA continues to support implementation of appropriate use criteria policies

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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 4.4% reduction in the Conversion Factor (CF), dropping from $34.6062 to $33.0775. This reduction is due to the elimination of a 3% increase provided by Congress and a budget neutrality adjustment (-1.55%), resulting largely from E/M code change implementation in non-office/outpatient settings.

CMS is also proposing to implement the second year of the clinical labor pricing update. We remain concerned about the effects of this policy, specifically the disproportionate impact it has on physician services that include high-cost supplies and equipment such as diagnostic imaging devices.

These combined policy changes 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.

2) CMS should recognize the value of certain high value, underutilized imaging services

In this proposed rule, CMS seeks comments on ways to identify specific services and to recognize possible barriers to improved access to these kinds of high value, potentially underutilized services by Medicare beneficiaries. CMS is also seeking comment regarding how it might best mitigate some of these obstacles.

Screening saves lives, but is currently underutilized, including those screenings where a referral is part of the "Welcome to Medicare" Physical Exam. This low uptake of appropriate screening is resulting in unnecessary suffering, death, and healthcare costs. As part of the Healthy People 2030 initiative, the Centers for Disease Control and Prevention, has established screening targets and objectives for the US population. We are still falling short of meeting these targets, and we must do more must to promote access and adherence to screening exams:

	Baseline	Target
Females who get screened for breast cancer[1]	76.4% (2019)	80.5%
Adults who get screened for colorectal cancer[2]	65.2% (2018)	74.4%
Adults who get screened for lung cancer[3]	4.5% (2015)	7.5%
Reduce the proportion of adults with osteoporosis[4]	7.3% (2013-2014)	5.5%

There is also evidence that screening for abdominal aortic aneurysm (AAA) is underutilized.[5] The United States Preventive Services Task Force (USPSTF) recommends a one-time screening for AAA with

[1] https://health.gov/healthypeople/objectives-and-data/browse-objectives/cancer/increase-proportion-females-who-get-screened-breast-cancer-c-05
[2] https://health.gov/healthypeople/objectives-and-data/browse-objectives/cancer/increase-proportion-adults-who-get-screened-colorectal-cancer-c-07
[3] https://health.gov/healthypeople/objectives-and-data/browse-objectives/cancer/increase-proportion-adults-who-get-screened-lung-cancer-c-03
[4] https://health.gov/healthypeople/objectives-and-data/browse-objectives/osteoporosis/reduce-proportion-adults-osteoporosis-o-01
[5] https://www.sciencedirect.com/science/article/abs/pii/S0890509621009432#:~:text=Conclusions-,Screening%20for%20AAA%20per%20USPSTF%20guidelines%20is%20underutilized%20with%20evidence,provider%20screening%20rates%20are%20low.

ultrasonography in men aged 65-75 who have ever smoked. Unfortunately, overall screening uptake for AAA has been found to be less than 7%. Black patients are 27% less likely to be screened than white patients.[6]

Appropriate utilization of imaging-based screening exams can help meet these targets. Mammography, (including digital breast tomosynthesis), CT colonography, low-dose CT lung cancer screening, and dual energy X-ray absorptiometry (DEXA) can detect disease at an early stage, reducing disease burden, mortality, and healthcare costs.

Under-utilization of critical screening services was further compounded during the COVID-19 pandemic. As has been reported[7][8][9][10], screening fell dramatically over the last few years, potentially increasing the burden of cancer and other disease on the American public. It is vitally important that CMS take whatever action it can to ensure that screening exams that were missed during the public health emergency are made up and that overall screening rates are increased.

We further recommend that CMS ensure patients have access to appropriate chest imaging in line with recently updated clinical guidelines. The 2021 AHA/ACC/ASE/CHEST/SAEM/SCCT/SCMR Guideline for the Evaluation and Diagnosis of Chest Pain: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines[11] highlight the value of multiple imaging modalities for diagnosing patients with chest pain.

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

CMS is proposing to implement 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. CMS is proposing regulatory text in Code of Federal Regulations (CFR) to implement the statutory language for CY 2023. In particular, the new section 414.902 proposes to define the term "refundable single-dose container or single-use package drug" as excluding a drug that is "a diagnostic radiopharmaceutical, or an imaging agent as identified in the drug's FDA approved labeling." MITA supports CMS' proposal with the below clarifications regarding contrast agents.

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

[6] ibid
[7] Changes in Cancer Screening in the US During the COVID-19 Pandemic, JAMA, https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2792956
[8] Association of Cancer Screening Deficit in the United States With the COVID-19 Pandemic, JAMA Oncology https://pubmed.ncbi.nlm.nih.gov/33914015/
[9] A national quality improvement study identifying and addressing cancer screening deficits due to the COVID-19 pandemic, Cancer, https://pubmed.ncbi.nlm.nih.gov/35307815/
[10] The Impact of COVID-19 on Cancer Screening: Challenges and Opportunities, JMIR Cancer, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7599065/
[11] https://www.jacc.org/doi/10.1016/j.jacc.2021.07.053

guidance, the FDA clarifies that contrast agents are included in the more-general category of imaging agents. In the Final Rule, CMS should explicitly confirm that imaging agents includes contrast agents.

4) MITA is concerned with the proposal to package skin substitutes under the PFS and requests that the final rule confirm that CMS does not have the legal authority to package radiopharmaceuticals

CMS is proposing to treat skin substitutes (including synthetic skin substitutes) as incident to supplies as described under section 1861(s)(2)(A) of the Act when furnished in non-facility settings and to include the costs of these products as resource inputs in establishing practice expense RVUs for associated physician's services effective January 1, 2024.[12] CMS has proposed to reclassify skin substitutes as wound care products, in conflict with the agency's longtime practice of treating them as biologicals. Given our concerns with the proposal with respect to skin substitutes, we request in the final rule that CMS confirm that the agency does not have the legal authority to package radiopharmaceuticals and treat them as incident to supplies. Radiopharmaceuticals administered in physician offices are specifically paid separately based in the MMA authorizing a "continuation of [the existing] payment methodology for radiopharmaceuticals." Section 303(h) of the MMA states, "***Nothing in the amendments made by this section shall be construed as changing the payment methodology under part B of title XVII of the Social Security Act for radiopharmaceuticals, including the use by carriers of invoice pricing methodology***." CMS also provided guidance to contractors on implementing the MMA (and section 303(h)) through its Manual System. CMS acknowledges that section 303(h) creates an exception to the general requirement that reimbursements for drugs will be paid based on 106 percent of the ASP. Specifically, the current transmittal interprets section 303(h) as follows: "***The payment allowance limits for radiopharmaceuticals are not subject to the ASP payment methodology. Contractors should determine payment limits for radiopharmaceuticals based on the methodology in place as of November 2003 in the case of radiopharmaceuticals furnished in other than the hospital outpatient department.***"

Based on the statutory language and long-standing CMS policy, it is clear that Congress has required CMS to allow separate payment for radiopharmaceuticals.

5) CMS should expand its coverage of colorectal cancer screening to include computed tomography colonography

Medicare coverage for colorectal cancer (CRC) screening tests under Part B are described in statutes (sections 1861(s)(2)(R), 1861(pp), 1862(a)(1)(H) and 1834(d) of the Act), regulation (42 CFR 410.37), and National Coverage Determination (NCD) (Section 210.3 of the Medicare National Coverage Determinations Manual). The statute and regulations expressly authorize the Secretary to add other tests and procedures (and modifications to tests and procedures) for CRC screening with such frequency and payment limits as the Secretary finds appropriate based on consultation with appropriate organizations.

CMS is proposing to expand Medicare coverage of certain CRC screening tests by reducing the minimum age payment limitation to 45 years in regulations at § 410.37 and in NCD 210.3. CMS is also proposing to modify the payment limitation for other CRC screening tests identified in § 410.37 and in NCD 210.3 to permit coverage for individuals to begin at age 45.

CMS claims in the proposed rule that this would align coverage with a recently revised recommendation by the United States Preventive Services Task Force (USPSTF) for certain CRC tests. CMS also claims that these proposals directly support President Biden's Cancer Moonshot Goal to cut the age adjusted death rate from cancer by at least 50 percent and address his recent Proclamation of March as National

[12] 87 Fed. Red. 46029.

Colorectal Cancer Awareness Month. The proclamation stated that "early stages of colorectal cancer often emerge without symptoms, and it is important to begin regular screenings starting at the age of 45."

We applaud the Agency's efforts to increase access to CRC screening, particularly given the ability of certain screening exams to catch this cancer at very early, highly treatable stages. We are discouraged, however, that CMS continues to deny coverage to computed tomography colonography (CTC).

In its most recent recommendation statement, the USPSTF expanded the population for which it would recommend screening by assigning a "B" grade to screening for adults ages 45 to 49 years. An "A" grade is assigned to screening for populations in ages 50 to 75 years. The Task Force also discusses the value of a variety of screening exams, including CTC. This enhanced recommendation follows on from the American Cancer Society which lowered its recommended age for screening from age 50 to age 45 in 2018.

CRC is somewhat unique in that certain tests—including CTC—can detect it in a pre-cancerous stage. For this reason, the USPSTF cited in its 2016 final recommendation statement for CRC, "the best screening test is the one that gets done, and the USPSTF concludes that maximizing the total proportion of the eligible population that receives screening will result in the greatest reduction in colorectal cancer deaths."

MITA strongly supports the principle that "the best test is the one that gets done." This is why we are deeply disappointed that CMS continues to deny coverage to CTC, a less invasive exam that generally does not require anesthesia.

In order to best align with the most recent USPSTF CRC screening recommendation statement and President Biden's Cancer Moonshot initiative, CMS should take swift action to cover CTC for Medicare beneficiaries and ensure appropriate payment.

6) CMS should not implement changes to the Medicare Economic Index

CMS is proposing to rebase and revise the Medicare Economic Index (MEI) in this proposed rule, with an implementation date of 2024. Current MEI weights are based primarily on results from the American Medical Association's (AMA) PPI survey, based on 2006 data. CMS is proposing to use data from the Census Bureau's Service Annual Survey (SAS) as the primary source for the new weights. CMS proposes to supplement the SAS data with other sources when SAS does not provide the necessary detail. While the proposal does not affect overall spending, the proposed changes lead to substantial changes in the weights for many of the key components of physician practice expense, creating redistributive effects across specialties. The Agency is seeking comment on implementation time frame, including a possible multiyear transition period given the significance of the proposal.

We are concerned about the effects of these changes, particularly in light of the other significant policy and payment changes in this proposed rule. Until more data and stakeholder input has been accrued and analyzed, CMS should not finalize this proposal. We request that CMS not finalize this proposal for CY 2023 and instead continue to work with stakeholders on development of appropriate policy.

7) CMS should correct technical errors related to Malpractice RVUs

CMS is proposing methodological improvements to the development of the professional liability insurance (PLI) premium data using in the calculation of malpractice RVUs. CMS is proposing to change from using risk factor scores, created via a processing of benchmarking each specialty to the physician specialty with the lowest premiums, to a risk index score which benchmarks each specialty's premiums to

the volume-weighted average of all specialties. MITA believes that while CMS noted in the proposed rule that it was their understanding that this change to the method of create the risk index had no impact on the actual malpractice RVUs, it actually does have a negative impact on imaging procedures.

We understand this change may have in fact contributed to a technical error negatively impacting all CPT/HCPCS codes, of which imaging procedures are the vast majority, with the Professional Component (PC)/ Technical Component (TC) split. When services have separately billable PC and TC components, the payment for the global service malpractice RVU equals the sum of the payment for the TC component (reported separately using the -TC modifier) and PC (reported separately using -26 modifier).

MITA urges CMS to correct this technical error before finalizing MP RVUs for 1/1/2023. If CMS is unable to resolve the error, we recommend that CMS delay implementation and apply the previous methodology for the calculation of the malpractice RVUs for PC/TC codes until the technical error is corrected.

8) MITA supports the proposal to continue national payment established in CY 2022 for certain services that utilize innovative technologies and artificial intelligence

MITA supports the Agency's proposal to continue the national payment established in CY 2022 for innovative services such as Remote Retinal Imaging (CPT code 92229) and Fractional Flow Reserve derived from Computed Tomography, or FFRct (CPT code 0503T). As CMS has indicated in the preamble of the rule for the past few years, Remote Retinal Imaging and FFRct are "similar to other technologies that use algorithms, artificial intelligence, or other innovative forms of analysis to determine a course of treatment, where the analysis portion of the service cannot adequately be reflected under the PE methodology." As such, MITA applauds CMS' creative thinking to employ alternative methodologies to appropriately reimburse providers for these services and supports continuation of these payments rates for CY 2023.

As we will describe in our comment letter to the CY 2023 HOPPS proposed rule, MITA supports the Agency's continued approach of establishing the costs of innovative technologies that use algorithms, artificial intelligence, or other software under the HOPPS, and then crosswalking those amounts to the appropriate CPT code under the PFS. We believe that setting these 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.

In addition, we urge CMS to work with the American Medical Association (AMA), the Food and Drug Administration (FDA), and other stakeholders to establish consistent definitions that align with the AMA's AI taxonomy and those being developed by the FDA for use in premarket review. Consistency at each stage – development, marketing authorization, coding, coverage, and payment – are essential for all health care stakeholders that seek to leverage new innovations to improve health care for beneficiaries. Furthermore, a defined reimbursement pathway that spans both the HOPPS and PFS will reduce burdens for CMS, manufacturers, and providers, while enabling access to AI-enhanced medical devices regardless of where the service is provided.

9) CMS should continue to work with stakeholders in the development of appropriate payment policies for AI technologies

As part of the CY 2022 rulemaking process, CMS solicited feedback to help better understand the resource costs for services involving the use of innovative technologies, including but not limited to software algorithms, artificial intelligence (AI) and machine learning (ML). MITA submitted extensive

comments in response to this solicitation. CMS is also seeking stakeholder feedback as part of the CY 2023 HOPPS rulemaking process on what it is calling "Software as a Service" (SaaS). MITA will be providing comments in response to this solicitation as well.

AI products—in alignment with the Quintuple[13] Aim—promise to achieve greater efficiency and effectiveness in the delivery of healthcare by (1) improving population health, (2) enhancing patient experiences, (3) avoiding unnecessary costs and driving cost efficiency, (4) improving the experiences of clinicians and healthcare staff, and (5) advancing health equity.

Realizing the maximum potential of AI technologies will, however, require an alignment of policy incentives that appropriately reward early adoption and ongoing innovation. The policy development process needs to involve ample opportunity for input from interested and affected stakeholders. Gathering information from all stakeholders will support the development and implementation of appropriate policy to promote patient access. As it works on the development of an AI/ML reimbursement policy, CMS should implement a more flexible process to gather stakeholder input, including outside the annual rulemaking process. These opportunities for input should be iterative and collaborative, allowing for more timely development and exchange of policy ideas. MITA has given considerable thought to AI valuation and payment in hospital and physician office settings and looks forward to working with CMS in anticipation of the CY 2024 rulemaking cycle.

CMS should also be clear regarding how it plans to respond to stakeholder input, including that received as from the RFI questions contained in the CY 2022 PFS proposed rule.

Finally, we urge CMS to consider policies that provide the greatest flexibility and adaptability, in particular as they relate to the fast-paced innovation in AI, software, and algorithms. As CMS has identified in prior rulemaking, there are many health care-specific AI that are and will be available in the near future. As these technologies evolve, the health care landscape will similarly shift. A rigid payment system that can only be updated on an annual basis does not support the continued innovation and adoption of AI. As part of this, we believe existing mechanisms should be protected to ensure the appropriate valuation of AI. For example, while developer-supplied price information and hospital cost reports will initially reflect the cost of new technologies, there are likely instances where those costs will not reflect the costs incurred by physician practices or should pricing evolve based on new, clinically meaningful capabilities. We believe CMS should maintain flexibility to account for these differences by health care setting (i.e., via the submission and consideration of invoices under the PFS) to ensure beneficiaries have access to these innovations wherever they choose to access health care services.

10) CMS should correct rank order issues related to neuromuscular ultrasound codes

MITA is concerned that CMS is intentionally creating a rank order anomaly by not approving the RUC recommendations for CPT codes 76881, 76882 and 76XX0. Having a complete imaging code, 76882, be paid less by Medicare where the procedure has to include ultrasound imaging of all the extremity components, muscles, tendons, joints, and any other questionable tissue or masses versus a limited procedure, CPT code 76882, where imaging of only one element is needed to bill the code, is not a precedent within the PFS that MITA can support.

The PFS is based on relativity with more extensive, more intense procedures being reimbursed more than less intensive procedures. Therefore, MITA would ask that CMS revise its proposal and agree to the RUC recommended work RVUs of 0.90, 0.69, and 1.21 as interim for CY 2023 and refer these codes back to

[13] https://jamanetwork.com/journals/jama/article-abstract/2788483

the RUC for a new, re-survey process that addresses the concerns of CMS that are causing it to propose a rank order anomaly. In the history of the PFS, rank order issues within code families have a been a reason for codes to be referred back to the RUC to be addressed in a new survey. This needs to happen in the instance of these three codes/ultrasound imaging procedures

11) MITA continues to support implementation of appropriate use criteria policies

In accordance with Section 218(b) of PAMA, CMS will require that ordering professionals consult specified applicable appropriate use criteria (AUC) through qualified clinical decision support mechanisms (CDSMs) for applicable imaging services furnished in an applicable setting, paid for under an applicable payment system. MITA has long supported development and implementation of an appropriate use criteria (AUC) policy that would help to ensure that patients get the right scan at the right time.

In previous rulemaking, CMS delayed the penalty phase for the AUC program until January 1, 2023 or the first day of the year after expiration of the COVID-19 public health emergency (PHE). CMS instated this delay in light of the significant hardships faced by healthcare providers during the COVID-19 PHE as well as the investment that many practices have already made in AUC systems. CMS does not discuss AUC policy in this proposed rule despite the upcoming implementation date and the July 15, 2022 renewal of the PHE. We are concerned that this will result in confusion regarding what will be required on January 1, 2023. CMS should clarify these requirements in the final rule and undertake other educational efforts in the meantime (e.g., Open Door Forums) to mitigate confusion among healthcare providers and patients.

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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.