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May 25, 2021

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

Attachment

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) congratulates you on being confirmed as the Administrator of the Centers for Medicare and Medicaid Services (CMS).

Our Member companies' technologies play an essential role in our nation's healthcare infrastructure and are integral to the care pathways of evaluating, staging, managing, and effectively treating patients with cancer, heart disease, neurological degeneration, and numerous other medical conditions. We would like to work with you on development and implementation of policies that will:

- Ensure Medicare beneficiaries have ongoing access to MITA Member company technologies
- Streamline reimbursement policy processes, enabling more expedient, transparent, and predictable market access, and
- Promote development and adoption of innovative technologies.

I have expanded on these points in the attachment.

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We look forward to working with you and the Administration more broadly on developing and implementing policies that will ensure ongoing Medicare beneficiary access to MITA Member company technologies. If you have any questions, please have your staff contact me or 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.

1. **CMS should implement policies that support the financial viability of the healthcare sector and ensure ongoing Medicare beneficiary access to MITA Member company technologies**

COVID-19 Relief

As the Federal Government takes steps to navigate the current Public Health Emergency (PHE) and eventually transition into a post-pandemic environment, MITA urges CMS to implement policies that enable beneficiaries to access the care they need both now and in the future. We believe CMS can promote the viability of our healthcare infrastructure by working with healthcare providers and medical technology innovators to facilitate ongoing provision of reasonable and necessary healthcare services. Good policy will help the healthcare sector manage the current crisis, mitigate future public health consequences of the crisis, and promote ongoing financial viability and innovation in the healthcare sector.

Medical imaging technologies and focused ultrasound therapeutic procedures are also part of the non-emergent medical procedures that patients have had to delay due to the pandemic. These include procedures that are essential for the screening, diagnosis, staging, managing and effectively treating patients with cancer, heart disease, neurological degeneration, and numerous other medical conditions.

It is unclear what the continued effects of the pandemic will be on patient access to medical imaging and what impact to public health will result from drastically lower rates of imaging and screening over the past year. Already, given the COVID-19 pandemic, beneficiary access to annual or non-urgent imaging exams has been severely impaired.

CMS should devote resources to communicating to beneficiaries and practitioners the importance of rescheduling non-emergent care so that all missed care is expeditiously made up and beneficiaries do not get significantly off interval with their routine screenings and exams. MITA also recommends that CMS offer incentive payments to caregivers to catch up on any care that was foregone since the beginning of the PHE.

It has become clear that the COVID-19 pandemic has resulted in significant changes to utilization patterns and costs for healthcare services, including medical imaging. CMS should take steps to ensure that its rate-setting methodologies reflect the new realities of care. In particular, CMS should study the impact of the resources required for implementing new standards of infection control procedures on the practice expense assumptions for a wide variety of services, including medical imaging exams, physician office visits, focused ultrasound procedures, surgical procedures, and similar services. CMS should also study the validity of year 2020 data for future rate setting.

The healthcare sector will not immediately recover from the PHE and its economic consequences. To not compound the access, economic, and innovation challenges facing beneficiaries, providers, and medical technology manufacturers during the pandemic and its recovery phase, CMS should not implement new policies that would result in additional payment

cuts or unnecessary administrative burdens. A strong recovery will promote public health, enable beneficiary access, and support adoption of innovative medical imaging technologies such as artificial intelligence platforms, novel radiotracers, and new scanners for the future. As CMS looks to the future of the Medicare Part B program, we would like to work with the Agency to ensure that the cost of providing care in these settings is accurately reflected in payment policy.

The ongoing financial viability of physician offices and radiology departments will depend on adequate reimbursement that reflects the cost of providing care in these different care settings. The operations and financial structures of hospitals and physician offices are very different, meaning that different payment methodologies are necessary in order to ensure appropriate payment. The COVID-19 PHE has resulted in dramatic reductions in imaging utilization, creating new strains on provider finances and new public health concerns for patients. Taking action to lower payment rates in either site of care would have dramatic negative consequences for Medicare beneficiary access. Healthcare disparities could also be exacerbated if urban or rural imaging facilities were forced to close or reduce services due to payment reductions.

Significant payment reductions to specialty care providers resulting from changes to Evaluation and Management (E&M) payments finalized in CY2021 rulemaking were partially and temporarily averted after Congressional action. Additional work is needed to ensure that these draconian payment cuts are not implemented in the future. We look forward to working with CMS and Congress on policies that will ensure specialty care providers are appropriately paid for the care they provide.

2. **CMS should streamline reimbursement policy processes so as to enable expedient, transparent, and predictable market access**

Appropriate Coding, Coverage, and Payment for Imaging Drugs

CMS should work with manufacturers on consistent and appropriate HCPCS coding nomenclature for imaging drugs including contrast agents and diagnostic radiopharmaceuticals. Inconsistencies in coding nomenclature with dosage and unit value description has led to problems with claims adjudication, which has been documented and shared with the Agency. MITA would welcome the opportunity to continue working with the Agency on appropriate nomenclature for imaging agents.

CMS should modernize the coverage determination process for PET agents. PET is the most extensively reviewed technology in CMS history, with 19 National Coverage Assessments (NCAs), including eight reconsiderations, over the past 20 years. Coverage of non-oncologic PET diagnostic radiopharmaceuticals is limited due to outdated Preamble language in the Manual. The Preamble language in Section 220.6 of the Manual creates non-coverage of all PET not otherwise covered by an NCD, despite the fact that this language was not established by an NCD. CMS should remove this barrier to coverage given that the use of non-oncologic PET is well established.

CMS should discontinue packaging of diagnostic imaging drugs and pay separately for such products immediately. In so doing, CMS should consider the following:

- CMS has acknowledged that packaging certain drugs can be a barrier to patient access
- Two APC panels have recommended separate payment of diagnostic radiopharmaceuticals
- MedPAC has recognized packaging of certain drugs may impact access
- Congress is preparing to reintroduce legislation from the 116th Congress

Advanced imaging diagnostic radiopharmaceuticals continue to be inappropriately packaged in the Medicare hospital outpatient setting. Under the current inequitable payment methodology, many hospitals are unable to cover the cost of newer, targeted diagnostic radiopharmaceuticals. They should be treated like other FDA approved drugs and paid separately under HOPPS.

After a three-year period of separate or "pass-through" reimbursement, CMS deems diagnostic radiopharmaceuticals as supplies and reimburses only as part of a packaged reimbursement rate (APC) far below actual costs. Packaging of diagnostic radiopharmaceuticals harms Medicare beneficiaries by imposing an artificial barrier in the hospital outpatient setting. The Agency's position that packaging would incentivize hospitals to use a cheaper alternative does not apply to newer diagnostic radiopharmaceuticals. These products are often the only available diagnostic and are not interchangeable with other products or services. Therefore, Medicare beneficiaries may not have access to diagnostics which provide important adjunctive clinical information which may impact their treatment and outcomes.

Further, the HOPPS packaging methodology of diagnostic radiopharmaceuticals does not adequately capture the cost of diagnostic radiopharmaceuticals. Our Member companies have provided to CMS evidence of hospitals discontinuing or never adopting these clinically advanced imaging procedures due to artificially low Medicare payment rates. As a result, less precise diagnostic information may lead to suboptimal clinical decisions and outcomes for Medicare beneficiaries.

On August 31, 2020, the Advisory Panel on Hospital Outpatient Payment recommended that CMS pay separately for all diagnostic radiopharmaceuticals. This is the second such Panel to support separate payment of diagnostic radiopharmaceuticals.

The most recent MedPAC report (June 2020) discussed separately payable drugs. In this report, MedPAC stated, "Some drugs should be paid separately because they are not ancillary. These drugs are the purpose for a visit…" Given the specific utility of diagnostic drugs, it is our belief that these products are the reason for the visit and therefore qualify for separate payment.

The MedPAC Report addresses for the first time (in Chapter 6) Medicare's packaged payment policies in the OPPS, including directly addressing the characteristics of "ancillary items" that MedPAC staff believe should not be packaged. First, after repeatedly noting that "not all ancillary items should be packaged," MedPAC explains that packaging costly or infrequently used "ancillary items" can pose an "excessive" financial risk to hospitals that will impact patient access.

We believe the MedPAC example is analogous to what occurs to diagnostic radiopharmaceuticals under packaging policies. These products are low volume and comparatively expensive to other drugs included in the assigned APC. The newer generation, non-generic diagnostics are the drugs most egregiously impacted by the methodology under which CMS averages and bundles the nuclear medicine APCs.

These policies harm Medicare beneficiaries by putting strong financial pressure on providers to avoid the use of certain diagnostic radiopharmaceuticals. As MedPAC notes on page 169 (PDF page 189) this puts "providers at excessive financial risk, which can lead them to avoid infrequently used or high-cost drugs and adversely affect access to treatments that may improve patient care, which, in turn, can adversely affect incentives for drug innovation."

Legislation introduced in the 116th Congress (HR 3772 - the Medicare Diagnostic Radiopharmaceutical Payment Equity Act) would have required CMS pay separately for diagnostic radiopharmaceuticals approved by the FDA on or after January 1, 2008 and have a per day cost that meets or exceeds $500. We expect similar legislation will be introduced shortly and encourage CMS to use its authority to adopt the provisions of the bill.

Establishing Appropriate Rate Setting Methodologies

Current cost-reporting practices do not accurately reflect a hospital's true cost of delivering imaging and focused ultrasound therapy services. Cost-reporting is currently administratively burdensome and overly complicated, meaning that some costs are not reported accurately by some providers. This is further compounded by payment policies such as packaging and comprehensive APCs which make capturing and reporting costs even more challenging for hospitals.

MITA urges CMS to work with affected parties prior to the release of the CY 2022 HOPPS proposed rule on detailed instructions to hospitals that address the appropriate reporting of nonstandard cost center codes. This would improve the accuracy of the cost center data used to calculate CT and MRI CCRs applicable to the payment rates calculated under HOPPS.

Since costs are not being accurately reported, funding is not being properly accounted for within the payment system, as evidenced by the downward payment trajectory of imaging APCs over the last several years. This presents potential challenges to hospital economics regarding the purchase of imaging equipment.

MITA is concerned about the impact these costing requirements have on the continued access to medical imaging and focused ultrasound therapy services for Medicare beneficiaries. Without complete diagnostic information, precision care pathways and optimal patient outcomes are at risk. CMS should implement sound payment methodologies that effectively capture hospital costs in furnishing imaging and focused ultrasound therapy services.

Improving the Coding Application Process

In October 2020, CMS issued a proposed rule that would, among other things, make changes to the application process for HCPCS codes. CMS should establish a transparent, collaborative,

well-resourced and efficient process for granting new code applications. MITA encourages CMS to finalize this rule with the changes we recommended in our comments, including:

- Continuing to have public meetings for drug applications
- Establishment of and adherence to concrete timelines for reaching decisions on coding applications
- Eliminating limits on re-submission of applications
- Coding for PET drugs should be based on "per study dose" versus "per milliliter/millicurie" because of half-life radioactive decay, and other unique properties which makes billing confusing and often incorrect

3. CMS should implement policies that promote development and adoption of innovative technologies

Encouraging Adoption of AI Solutions

Recently, there has been a significant amount of attention directed at the transformative potential of advanced computer-driven, algorithm-based, and AI solutions for imaging. These 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.

In particular, examples of how these products will meet the Quadruple Aim include:

- Improving population health
    - Achieving more accurate diagnoses via algorithms that improve detection, characterization, monitoring, and therapeutic treatment of disease
    - Realizing improved image quality via advanced reconstruction techniques
- Enhancing patient experiences
    - Lower patient radiation and contrast dose through optimization and management algorithms
    - Enhanced therapeutic procedures through optimized image guidance and treatment monitoring
    - Reduced time to diagnosis and initiation of an appropriate care pathway
    - Direction to appropriate sites of service which offer optimal care pathways, improving patient outcomes
- Avoiding unnecessary costs and driving cost efficiency
    - Reducing errors, redundant tests, and hospital acquired conditions
    - Facilitating appropriate imaging services via enhanced clinical decision support
    - Avoiding costs of continued health decline and associated outcomes and treatment via more accurate and expedient care
    - Enhancing patient safety
- Improving the experiences of clinicians and healthcare staff
    - Decreasing variability in diagnostic accuracy between readers and facilities
    - Automatically annotating and evaluating images with concerning findings, allowing for more focused physician interpretation and reporting
    - Automating tasks such as dose management and patient positioning

- Improving machine up-time via monitoring of device malfunction and servicing events

Current reimbursement systems present significant challenges to the adoption of high-value AI-based imaging technologies. As CMS states in CY2021 PFS Final Rule: "technologies that use algorithms, artificial intelligence, or other new forms of analysis to determine a course of treatment… the analysis portion of the service cannot adequately be reflected under the PFS payment methodology."[1] We would like to partner with CMS to align policy incentives that appropriately reward early adoption and ongoing innovation for advanced software-based solutions. Appropriate provider reimbursement will be a significant driver of adoption and patient access.

Although these products will bring great value to the healthcare system, investment in their adoption must not be constrained by premature or excessive bureaucracy and must be incentivized via:

- Transparent, predictable, and accountable coverage processes that have consistent, clearly stated criteria for AI-based technologies
- Nimble and accurate code development processes that quickly identify new technologies as they come to market and identify services performed by AI technologies
- Waiver of burdensome and non-patient-centric requirements such as prior authorization for services that use AI-based technologies
- Concrete payment mechanisms, including:
    - Inclusion of AI costs in the direct practice expense (PE)
    - Ongoing eligibility of AI-enabled devices for the New Technology Add-on Payment (NTAP)
    - Avoiding packaging for AI-enabled imaging technologies
    - Quality metrics built around use of AI,
    - Building the use of AI into value-based care calculations,
    - Making the value of AI explicit within bundled payments,
    - Voluntary incentive programs for innovators and providers that rapidly adopt approved AI-based technologies.

Policymakers, payers, providers, innovators, and other key parties should consider and begin public discussions on reimbursement mechanisms to promote adoption of AI-based imaging technologies that will aid in the achievement of the healthcare Quadruple Aim.

<u>Implement the MCIT Final Rule</u>

MITA supports periodic reexamination of the regulations that grant patients access to medical products and services. As medical technologies mature and proliferate, MITA believes that manufacturers and innovators should have access to expedient, transparent, and predictable pathways to bring their products to patients. Modern regulatory approaches make sense for modern medical device technologies.

[1] https://www.govinfo.gov/content/pkg/FR-2020-12-28/html/2020-26815.htm

In August of 2020, CMS issued the MCIT proposed rule to create a Medicare coverage pathway that would expedite beneficiary access to innovative medical devices with FDA "breakthrough" designation. The MCIT program would also update the definition of the "reasonable and necessary" criteria under which CMS determines whether or not to cover a product or service. This rule was finalized on January 12, 2021, but flagged by the Biden Administration for additional review.

We encourage the Biden Administration to release this rule and move quickly toward implementation of this program. We also encourage the Biden Administration to expand this program to other innovative technologies.

The MCIT program formulated in this rulemaking would approximate an ideal pathway for bringing innovative medical solutions through FDA marketing authorization and CMS coverage determination. As discussed in the proposed rule, only a handful of devices have received "breakthrough" marketing authorization by the FDA. This will still leave numerous innovative medical solutions in limbo. CMS should expand this program and develop more expansive criteria for inclusion in the program to ensure efficient market access for other advanced imaging solutions and software, novel radiopharmaceuticals and contrast agents, and high intensity focused ultrasound therapies. CMS should also consider extending the coverage period to five years or longer and developing similar efficiencies in the coding and payment processes.