



**MITA**<sup>®</sup>  
MEDICAL IMAGING  
& TECHNOLOGY ALLIANCE  
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October 15, 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

**Re: CMS-3372-P2— Medicare Program: Medicare Coverage of Innovative Technology and Definition of Reasonable and Necessary**

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 proposed rule repealing the Medicare Coverage of Innovative Technology (MCIT) and Definition of “Reasonable and Necessary” final rule, which was published on January 14, 2021, and would be effective on December 15, 2021.

In the previously finalized rule, CMS created a Medicare coverage pathway that would expedite beneficiary access to innovative medical devices with Food and Drug Administration (FDA) “Breakthrough” designation. This rule also updated the definition of the “reasonable and necessary” criteria under which CMS determines whether to cover a product or service.

MITA expressed support for the MCIT program as well as the codification of “reasonable and necessary” in comments submitted to the docket on the proposed rule.<sup>1</sup> In our comments, we discussed the need for medical technology developers to have access to expedient, transparent, and predictable pathways to bring innovative products to Medicare beneficiaries. We also urged that the MCIT program be expanded beyond just “Breakthrough” technologies given that not all innovative products earn this designation.

We stand by these comments and are disappointed in the proposed repeal of the MCIT program. The MCIT program in the finalized rule would have approximated an ideal pathway for bringing innovative medical solutions through FDA marketing authorization and CMS coverage determination. It would have also more generally clarified the Medicare coverage determination process by codifying a definition of the “reasonable and necessary” coverage criteria.

MITA Member companies continue to develop innovative technologies—including advanced digital health technologies powered by artificial intelligence (AI) and machine learning (ML). The pathway from

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<sup>1</sup> <https://www.regulations.gov/comment/CMS-2020-0098-0182>

regulatory authorization to Medicare beneficiary access must keep pace with innovation, which is expected to accelerate. Otherwise, novel technologies will languish in bureaucratic review, create unnecessary barriers to Medicare beneficiary access and stifle innovation.

We urge CMS to continue to work with medical technology innovators, healthcare providers, patients, and others to improve and expedite the path from FDA marketing authorization to CMS coverage.

In its proposal to repeal the MCIT program, CMS cites certain operational challenges that it believes cannot be resolved prior to implementation and indicates that it has reconsidered certain aspects of the rule, such as how to determine what devices should qualify for the pathway and whether to require mandatory collection of clinical evidence and other data during the initial coverage period. We believe that these challenges are solvable and since there has been extensive public engagement on these topics, now is the time to solve them.

CMS should swiftly issue a new proposed rule to seek solutions to these challenges and move forward with improvements to the Medicare coverage process.

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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](mailto:pweems@medicalimaging.org).

Sincerely,

A handwritten signature in black ink, appearing to read "Patrick Hope". The signature is fluid and cursive, with a large initial "P" and a long horizontal stroke at the end.

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.*