

AdvaMed Statement on Administration’s Opposition to Expanding Medicare Patient Access to Breakthrough Medicare Technologies

Government Affairs & Legislative / Payment & Reimbursement / September 13, 2021

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WASHINGTON, D.C. – AdvaMed, the leading global trade association for medical technology manufacturers, released the following statement from President and CEO Scott Whitaker on the Administration’s proposal to fully repeal the Medicare Coverage of Innovative Technologies (MCIT) rule that would have allowed immediate access to FDA-designated and -approved “breakthrough” technologies for Medicare patients suffering from debilitating illnesses and conditions that existing treatments and technologies are unable to address:

“It’s unfortunate for patients across the country that the Administration has decided to reject a rule to allow Medicare patients immediate access to breakthrough medical innovations. Any Medicare patient and their doctor who has exhausted all existing medical options should have immediate access to FDA-approved breakthrough medical technologies. That’s what this is all about. Doctors and patients should be trusted to make the right medical decision to treat a life-threatening condition. The federal government should incentivize access to these new breakthrough technologies. Repealing MCIT is the wrong decision for countless Medicare patients, and it’s the wrong decision for American medical innovation. Our goal in this country should be to spur and not inhibit innovation that will change patients’ lives. We will continue to make this important case with the Administration and Congress, and we are hopeful they will make the right decision.”

Under the rule **CMS has proposed to repeal**, Medicare would have provided immediate national coverage for four years for any new device or diagnostic designated as a “breakthrough” technology and deemed safe and effective by FDA. During that four-year coverage period, manufacturers could continue to provide the additional data needed to maintain coverage after the four-year coverage period expired. Under this rule, if the FDA approved a breakthrough technology, Medicare would have quickly covered it, ensuring immediate national coverage of devices for seniors in need of lifesaving treatments. MCIT ensures the safety and efficacy of breakthrough technologies: After receiving an FDA breakthrough designation, these technologies would still undergo the rigorous FDA review process – the global gold standard for medical safety and effectiveness – to achieve approval.

An op-ed by Whitaker on behalf of the MCIT rule can be found [here](#), and an op-ed by Dr. Anand Shah, an oncologist and former deputy commissioner at the FDA and former chief medical officer at the Center for Medicare & Medicaid Innovation on behalf of the rule can be found [here](#).

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AdvaMed member companies produce the medical devices, diagnostic products and digital health technologies that are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. AdvaMed members range from the largest to the smallest medical technology innovators and companies. For more information, visit www.advamed.org.

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Top MedTech Venture Investor Justin Klein Discusses the Importance of MCIT Rule & Delivering Innovative Technologies to Patients

September 13, 2021

Justin Klein recently joined AdvaMed CEO Scott Whitaker for an episode of MedTech POV to talk about his expansive career in medtech and some of today’s most pressing issues across the industry.

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AdvaMed Applauds President’s Focus on Testing, Vaccination

September 9, 2021

AdvaMed, the world’s leading trade association for medical technology companies—which includes the diagnostics companies that make Covid-19 tests—released the following statement from president and CEO Scott Whitaker:

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New Data Finds MedTech Industry Thrives in The Sunshine State

August 26, 2021

New data released by AdvaMed found that the medical technology industry is a critically important employer in Florida and contributes billions of dollars to state revenues and payroll.

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The Economic Impact of the Medical Technology Industry

August 16, 2021

This report provides a 2021 statistical update on the contributions of the medical technology industry to national and state economic conditions.

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New data released by the Advanced Medical Technology Association (AdvaMed) found that the medical technology (medtech) industry is a critically important employer in Massachusetts and contributes millions of dollars to state revenues and payroll taxes.

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August 12, 2021

Well-crafted tax policy on NOLs spurs innovation in new life-saving treatments and cures; and as we continue to emerge from the pandemic, there is no time more important for the Congress to foster further medical innovation.

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Breakthrough Device Designation: Understanding Regulatory and Reimbursement Implications Webinar

August 4, 2021

12:00 PM

ADVAMED EVENT — This timely webinar focused on the FDA breakthrough devices program and the implications for payment and coverage.



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