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Lawmakers Press CMS To Enact MCIT Breakthrough Device Coverage Rule

by [Elizabeth Orr](#)

The Medicare rule, which was delayed by 60 days under a broader regulatory freeze, is seen as critical to the reimbursement of innovative devices.

The US Centers for Medicare and Medicaid Services should put a new rule that will allow reimbursement for devices on the Food and Drug Administration's breakthrough device pathway into effect on the original target date of 15 March, four members of Congress said in a [recent letter](#) to CMS acting administrator Liz Richter.

The Medicare Coverage for Innovative Technologies (MCIT) final rule, issued on 12 January, allows Medicare to reimburse for breakthrough devices for up to four years from the day a device is cleared by the FDA. It's intended to allow beneficiaries to access breakthrough technology more quickly and encourage manufacturers to prioritize developing evidence about a device's effectiveness in the Medicare population. The regulation has broad support from stakeholders (Also see "[Industry Praises CMS Final MCIT Reimbursement Rule; Urges Biden Team To Implement It](#)" - Medtech Insight, 13 Jan, 2021.)

But the swift enactment of the rule has been threatened by a freeze imposed by the Biden administration on so-called "midnight regulations" issued during the waning days of the Trump administration. The 20 January action told executive department heads to hit the pause button on all regulations that had not yet been put into effect and confer with the director of the Office of Management and Budget before renewing any regulatory activity. MCIT was affected because it had been issued only eight days before the announcement of the freeze. (Also see "[Biden Regulatory Freeze Could Slam Brakes On SUNSET Reg Review Rule From HHS](#)" - Medtech Insight, 21 Jan, 2021.)

The 24 February Congressional letter urges the CMS to stick to MCIT's original effectiveness date

of 15 March. To do otherwise, the representatives say, will keep critical technology from seniors who can benefit from swift access.

“Delaying the effective date of the final rule risks unintended consequences for ... patients.” – Suzan DelBene, Terri Sewell, Tony Cárdenas & Andy Kim

The letter was signed by Reps. Suzan DelBene, D-WA, Terri Sewell, D-AL, Tony Cárdenas, D-CA, and Andy Kim, D-NJ. All four previously co-sponsored legislation introduced by DelBene in 2018 and 2019 that would have allowed swifter reimbursement for breakthrough devices. (Also see [“CMS Could Streamline Coverage For Breakthrough Medtech Under House Proposal”](#) - Medtech Insight, 6 Jun, 2018.)

“MCIT allows for coverage of FDA-designated breakthrough devices, which treat patient populations with limited or no treatment alternatives,” the lawmakers wrote. “Delaying the effective date of the final rule risks unintended consequences for these patients, including denying MCIT coverage to technologies that would otherwise be eligible for the program under the current implementation date.”

Industry Groups Express Support

AdvaMed president Scott Whitaker took to Twitter on 1 March to express support for the letter’s goals.

Thank you, [@RepDelBene](#), [@RepTerriSewell](#), [@RepCardenas](#), & [@RepAndyKimNJ](#), for making the case for MCIT to [@CMS_gov](#). Your leadership is critical to ensuring seniors have timely access to innovative [#medtech](#). <https://t.co/5aPbti6lpj>

– Scott Whitaker (@ScottWMedTech) [March 1, 2021](#)

Similarly, Medical Device Manufacturers Association CEO Mark Leahey said the group had been

working on MCIT for six years and called its swift implementation a key priority in a recent interview with *Medtech Insight*. (Also see "[Exclusive: Top Medical Device Lobbyist On User-Fee Talks, Biden And New Congress, Implementing MCIT Rule](#)" - Medtech Insight, 1 Feb, 2021.)

“Obviously, we're thrilled with the final rule coming out, but now it is caught up in a broader administrative pause that is typical when new administrations come in,” Leahey said. “So I think it is critically important that we'll be working with the Biden administration to get MCIT implemented as quickly as possible.”