

CMS DELAYS BREAKTHROUGH COVERAGE PATHWAY ADOPTION UNTIL DECEMBER

The Biden administration recently announced it's delaying the Trump-era rule on Medicare instantly covering FDA-approved breakthrough devices until December 15 despite a push by medical device makers and lawmakers to implement the pathway as soon as possible. CMS said it shares concerns the new coverage pathway could lead to Medicare covering devices that lack adequate value and safety assessments, and the agency worried it might not be able to pull coverage if a device is later found unsafe for Medicare patients.

At issue is an 11th-hour rule by the Trump administration that sets up a new coverage pathway called Medicare Coverage of Innovative Technology (MCIT). The pathway allows coverage of breakthrough devices for four years as soon as FDA authorizes the technology, and coverage beyond that would hinge on additional

data collected by the manufacturer. The rule also codified the Medicare definition of reasonable and necessary, which applies beyond medical devices.

The Biden administration initially moved the MCIT rule's effective date from March 15 until May 15 so it could hold an additional comment period to go over concerns like how breakthrough devices could work in older populations and the possibility that more devices might be eligible for coverage under the rule than initially thought.

Medical device manufacturers voiced their support of MCIT in public comments and in a meeting this week at the White House, but payers worried the pathway doesn't adequately evaluate safety, efficacy or value for the Medicare population.