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CMS Proposes Repeal of MCIT

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Health Care

On September 15, 2021, CMS published a proposed rule to repeal the Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary" Final Rule ("MCIT/RN Rule"), which was published on January 14, 2021 and was set to take effect on December 15, 2021. The MCIT/RN Rule would have created a pathway to provide nationwide Medicare coverage for medical devices simultaneous to a device's receipt of market authorization under FDA's Breakthrough Devices Program. The Medicare coverage would last for a period of four years after which a breakthrough device would either be covered through a National Coverage Determination or at the local-level by Medicare Administrative Contractor discretion. The MCIT/RN Rule was intended to address concerns that delay or uncertainty around Medicare coverage hampered beneficiary access to innovative technologies. In addition to establishing the MCIT pathway, the MCIT/RN Rule would have codified CMS's longstanding definition of "reasonable and necessary" with an additional modification requiring future subregulatory guidance specifying how and when the agency would consider commercial insurer coverage policies. Pursuant to the Biden Administration's "Regulatory Freeze Pending Review," CMS published an interim final rule delaying the original MCIT/RN Rule effective date of March 17, 2021 to May 15, 2021, and later published another interim final rule delaying the date to December 15, 2021. As part of both interim final rules, CMS solicited public comments.

In deciding to repeal the MCIT/RN Rule, CMS identified that FDA and CMS are guided by different statutory standards: FDA must determine whether a device is safe and effective, and CMS must determine whether a device is reasonable and necessary for the diagnosis or treatment of illness or injury. CMS explained that accelerated coverage for breakthrough devices would result in inadequate evidence that the device is reasonable and necessary. In particular, CMS noted its concern that FDA regulations do not require clinical studies to include Medicare beneficiaries and as a result, MCIT might result in coverage of devices that do not have data demonstrating reasonableness and necessity for Medicare patients. CMS also described that coverage through the MCIT pathway could only be removed under limited circumstances, such as if FDA issued a safety communication, and thus impracticably limited CMS's authority. With respect to the definition of reasonable and necessary, CMS expressed concerns about the requirement to consider commercial insurer policies, but noted that it was seeking comment on whether only the commercial insurer portion of the rule should be repealed.

Comments on the proposed rule are due on October 15, 2021. In the proposed rule, CMS acknowledged that typically a 60-day comment period is required, but explained that, because CMS already sought public comment on the interim final rules delaying the effective date of the MCIT/RN Rule, and given the impending effective date, there is good cause to reduce the

comment period to 30 days to ensure that a final rule will be issued prior to December 15, 2021. Given this posture, CMS appears likely to finalize its proposal to repeal the MCIT. However, there still may be opportunity to expand coverage for breakthrough devices. In the proposed rule, CMS expressed a commitment to considering future policies and rulemaking to improve access to innovative technologies. And notably, draft legislation introduced over the summer as a follow-on to the 21st Century Cures Act, known as "Cures 2.0," includes a codification of the MCIT pathway.

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