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CMS Finalizes Repeal of Medicare "Breakthrough" Device Coverage Rule, Pledges to Invite Further Industry Input

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On November 15, 2021, the Centers for Medicare and Medicaid Services ("CMS") issued a final rule[1] implementing, without substantial modification, its September proposed rule[2] to repeal the prior administration's Medicare Coverage of Innovative Technology final rule (the "Repealed MCIT rule").[3] The repeal will be effective as of December 15, 2021, the same day the Repealed MCIT rule was supposed to have taken effect.

Effect of the Repeal: Maintaining the Status Quo

As we previously reported, the effect of the repeal is that the current framework for Medicare coverage of breakthrough medical devices will remain in effect. Breakthrough devices will not receive automatic coverage, but instead will continue to be subject to claim-by-claim adjudication or national or local coverage determinations, made *after* FDA clearance or approval, that the device is "reasonable and necessary" for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. In addition, although the "reasonable and necessary" standard currently embodied in the Medicare Program Integrity Manual will remain, it will not be codified in regulation.

Future Coverage Policy Rulemaking

CMS's rationale for repeal was that the evidentiary standard for FDA clearance or approval—safety and effectiveness—differs from the Medicare reasonable and necessary standard. Moreover, because CMS believes that Medicare beneficiaries are under-represented in clinical trials, it lacks confidence that a breakthrough device meeting FDA's safety and effectiveness standards would be reasonable and necessary for diagnosis or treatment in the Medicare population. CMS also expressed concern that the Repealed MCIT rule would have unduly limited the Medicare program's ability to deny coverage for breakthrough devices found to be harmful to Medicare beneficiaries, was deficient in not requiring continued evidence development for breakthrough devices, and could have disincentivized development of innovative technologies that do not meet FDA's breakthrough device criteria.

However, CMS reiterated that it remains committed to exploring other policy options for coverage of innovative devices that better suit the needs of Medicare beneficiaries and other stakeholders. In response to concerns that the repeal would result in lost momentum towards creating an alternative expedited coverage pathway, CMS "reassure[d] stakeholders that CME does not intend to maintain the status quo." Specifically, CMS reports the following plans:

- Coverage process improvements. CMS plans to explore coverage process improvements, including:
    - Engaging the Agency for Healthcare Research and Quality ("AHRQ") to look into updating the study criteria employed in CMS's existing Coverage with Evidence Development ("CED") program for medical devices, and
    - Investigating options for expediting the current national coverage determination ("NCD") process.

[1] 86 Fed. Reg. 62944 (Nov. 15, 2021).
[2] 86 Fed. Reg. 51326 (Sep. 15, 2021).
[3] 86 Fed. Reg. 2987 (Jan. 14, 2021).

- Stakeholder input. CMS plans to engage with stakeholders to achieve appropriate coverage through existing mechanisms, including by:
    - Providing for public participation in a Medicare Evidence Development and Coverage Advisory Committee ("MEDCAC") meeting, if the AHRQ determines the CED study criteria should be updated.
    - Holding at least two stakeholder public meetings in calendar year 2022 to inform future policymaking.
    - Seeking input through listening sessions, town hall meetings, and informal engagement with manufacturers and other stakeholders.

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Ropes & Gray will continue to monitor developments in this area. If you have any questions, please contact one of the authors or your usual Ropes & Gray advisor.