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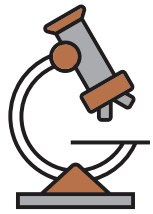


# *Repeal of Final Medicare Coverage Rule Regarding "Innovative Technology" and Implications for "Breakthrough" Medical Devices*

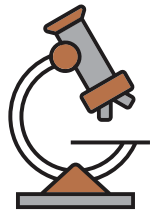
On November 12, 2021, the Centers for Medicare and Medicaid Services ("CMS") under the Biden administration repealed their final rule entitled "Medicare Coverage of Innovative Technology and Definition of 'Reasonable and Necessary'" ("MCIT/R&N"). The rule was published in the *Federal Register* on January 14, 2021 (86 FR 2987, Jan. 14, 2021), under the Trump administration. Following issuance of a "Regulatory Freeze Memorandum" from the Biden administration and an additional public comment period, CMS delayed the rule's effective date until December 15, 2021 (86 FR 26849, May 18, 2021), in order to "determine appropriate next steps that are in the best interest of all Medicare stakeholders, and beneficiaries in particular." (86 FR 51326, Sept. 15, 2021)

## BACKGROUND OF CMS RULE REGARDING "MEDICARE COVERAGE OF INNOVATIVE TECHNOLOGY"

The MCIT/R&N established a pathway to provide four years of national Medicare coverage for recent market-authorized medical devices designated by the U.S. Food & Drug Administration (FDA) as "Breakthrough Devices." The Breakthrough Devices Program was created to replace the Expedited Access Pathway and Priority Review and allows for certain medical devices to reach the market sooner, while maintaining statutory standards for approval. A manufacturer may voluntarily apply for "Breakthrough" designation if its device satisfies two criteria. The first is that the device "provide[s] for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions." (21 U.S.C. 360e-3(b)(1)). Second, the device must also satisfy at least one of the following: (1) it represents a breakthrough technology, (2) no approved or cleared alternative exists, (3) it offers significant advantages over existing approved or cleared alternatives, or (4) device availability is in the best interest of patients. (21 U.S.C. 360e-3(b)(2)). Under the MCIT/R&N, a manufacturer would receive four years of national Medicare coverage for its device starting either from the date of FDA market authorization, or a date chosen by the manufacturer within two years of the date of market authorization.

## WHY CMS REPEALED THE RULE

CMS is repealing the MCIT/R&N final rule because it believes it "is not in the best interest of Medicare beneficiaries." (86 FR 62945, Nov. 15, 2021) Specifically, there is no FDA requirement for Medicare beneficiaries to be included in clinical studies for market authorization, and the MCIT/R&N did not require such data to "fill th[e] gap." (86 FR 62945, Nov. 15, 2021) Typically, Medicare beneficiaries are older (at least 65 years of age) and often suffer from multiple comorbidities. Therefore, CMS has concerns the MCIT/R&N could result in Medicare covering devices that are not reasonable and necessary, or which could be potentially harmful to beneficiaries. Additionally, based on the language of the final rule, CMS would not be able to implement any safeguards to protect beneficiaries from the possibility of harm until expiration of the four-year coverage period. CMS also has the added concern that guaranteeing device coverage solely on receipt of breakthrough status may result in providers being incentivized to use MCIT/R&N-covered devices instead of alternative devices that are



"nonetheless covered under an existing coverage pathway and that may be more beneficial to patients." (86 FR 62948-49, Nov. 15, 2021) For these reasons, CMS has repealed the final rule.

## WILL CMS STILL ALLOW COVERAGE FOR "BREAKTHROUGH DEVICES"?

While the repeal of MCIT/R&N becomes effective December 15, CMS stresses that this action "does not prohibit coverage of Breakthrough Devices." (86 FR 62948, Nov. 15, 2021) With the increasing number of Breakthrough Devices achieving market authorization, CMS has observed through claims data that many such devices are "coverable and payable through existing mechanisms, such as bundled payments." (*Id.*) New device and service claims may also be adjudicated on a claim-by-claim basis and covered under existing Medicare payment systems. CMS acknowledged, however, that such payment paths may not meet stakeholders' expectations of "faster and more predicable coverage." (*Id.*)

Because the final rule's effective date was scheduled for December 15, the MCIT coverage pathway and definition of "Reasonable and Necessary" were never implemented and, therefore, no payments have been made under the rule. Moving forward, CMS stated that it is "committed to exploring other policy options and statutory authorities for coverage that better suit the needs of Medicare beneficiaries and other stakeholders when the items or services are supported by adequate evidence," (*id.*) and committed to hold at least two stakeholder public meetings on the subject in 2022.

### Additional Assistance

*For further assistance, please contact Dr. Kyle Mack, a member of our Life Sciences & Health Effects Practice Team or the Phillips Lytle attorney with whom you have a relationship.* ■

Phillips Lytle LLP

Albany Omni Plaza 30 South Pearl Street Albany, NY 12207-1537 (518) 472-1224
Buffalo One Canalside 125 Main Street Buffalo, NY 14203-2887 (716) 847-8400
Chautauqua 201 West Third Street Suite 205 Jamestown, NY 14701-4907 (716) 664-3906
Garden City 1205 Franklin Avenue Plaza Suite 390 Garden City, NY 11530-1629 (516) 742-5201
New York City 620 Eighth Ave 38th Floor New York, NY 10018-1442 (212) 759-4888
Rochester 28 East Main Street Suite 1400 Rochester, NY 14614-1935 (585) 238-2000
Washington, DC 1101 Pennsylvania Avenue NW Suite 300 Washington, DC 20004-2514 (202) 617-2700
Canada The Communitech Hub 151 Charles Street West Suite 100 The Tannery Kitchener, Ontario N2G 1H6 Canada (519) 570-4800