

# PUBLICATION

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## CMS Finalizes Repeal Of Regulatory Definition Of "Reasonable And Necessary"

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The Centers for Medicare & Medicaid Services (CMS) issued a Final Rule on November 15, 2021, (November 2021 Final Rule) repealing its regulatory definition of "reasonable and necessary," which had previously been finalized in a January 14, 2021 Final Rule (January 2021 Final Rule) issued by the Trump Administration. The January 2021 Final Rule was delayed in March 2021 for review under the Biden Administration's Regulatory Freeze Pending Review Memorandum, and CMS published a Proposed Rule for its repeal in September 2021.

### Reasonable and Necessary Definition

The prior January 2021 Final Rule codified a regulatory definition of "reasonable and necessary" which implemented standards for making determinations under Section 1862(a)(1)(A) of the Social Security Act (SSA) for items and services furnished under Medicare Parts A and B. The regulation incorporated the existing definition of the term set forth in CMS's Program Integrity Manual, but added appropriateness criteria that provided for consideration of coverage determinations by commercial insurers. Commenters had previously expressed concern over how the commercial insurance aspect of the definition would be implemented and its impact on agency flexibility to determine coverage policies. In repealing the definition, CMS stated that it believed additional stakeholder feedback was necessary before promulgating a regulatory definition.

### MCIT Pathway

In addition to the "reasonable and necessary" definition, the January 2021 Final Rule contained provisions establishing a pathway to provide Medicare beneficiaries with faster access to recently market authorized medical devices designated as breakthrough by the FDA through Medicare Coverage of Innovative Technology (MCIT) requirements. These MCIT provisions were also repealed in the November 2021 Final Rule, based on CMS concerns that the process did not contain sufficient beneficiary protections.

### Key Takeaways

The concept of "reasonable and necessary" is the legal foundation for Medicare coverage determinations under Section 1862(a)(1)(A) of the SSA, yet has long remained a subjective determination. Based on CMS's commentary in repealing the January 2021 Final Rule, it seems unlikely that a new attempt at regulatory clarification will come any time soon. However, the longstanding definition in Medicare Program Integrity Manual (MPIM), CMS Pub. 100-08, ch. 13, Section 13.5.4 remains a source of guidance on how the concept will be assessed.

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