

# PUBLICATION

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## CMS Delays Regulatory Definition of Reasonable and Necessary

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**Although Centers for Medicare & Medicaid Services (CMS) finalized its regulatory definition of reasonable and necessary through its recently published Final Rule, the Final Rule has now become subject to review under the Biden Administration's January 20, 2021 Regulatory Freeze Pending Review Memorandum.**

On March 17, 2021, CMS published an [Interim Final Rule](#) (86 Fed. Reg 14542) delaying the effective date and establishing a public comment period for the Final Rule for Medicare Coverage of Innovative Technology and Definition of "Reasonable and Necessary." The Interim Final Rule delays the initial March 15, 2021 effective date for 60 days until May 15, 2021. The Interim Final Rule also provides a 30-day public comment period to allow interested parties to provide comments about issues of fact, law, and policy raised by the rule. CMS states that it would determine whether further actions are appropriate, which could include revising or rescinding the Final Rule. Comments are due by **April 16, 2021**.

### Regulatory Freeze Pending Review Memorandum

In [guidance issued by the Office of Management and Budget \(OMB\)](#) to implement the Administration's January 20, 2021 Regulatory Freeze Pending Review Memorandum, the OMB directed agencies to consider delaying the effective date of rules published in the Federal Register that have not yet become effective for purposes of reviewing any questions of fact, law, and policy the rules may raise. In particular, the agencies are meant to consider the following factors in determining whether to delay:

- The rulemaking process was procedurally adequate;
- The rule reflected proper consideration of all relevant facts;
- The rule reflected due consideration of the agency's statutory or other legal obligations;
- The rule is based on a reasonable judgment about the legally relevant policy considerations;
- The rulemaking process was open and transparent;
- Objections to the rule were adequately considered, including whether interested parties had fair opportunities to present contrary facts and arguments;
- Interested parties had the benefit of access to the facts, data, or other analyses on which the agency relied; and
- The final rule found adequate support in the rulemaking period.

In this case, CMS explained that it determined a 60-day delay was appropriate to ensure that the rulemaking process was procedurally adequate; the agency properly considered all facts; the agency considered statutory or other legal obligations; the agency had reasonable judgment about the legally relevant policy

considerations; and the agency adequately considered public comments objecting to certain elements of the rule, including whether interested parties had fair opportunities to present contrary facts and arguments.

### **Regulatory Definition of Reasonable and Necessary**

The **Final Rule** promulgated a regulatory definition for "reasonable and necessary" and also addressed Medicare Coverage of Innovative Technology (MCIT) requirements. And, while the Interim Final Rule raises potential concerns and invitation for public comment regarding aspects of the MCIT pathway for coverage, CMS also discussed particular issues related to the "reasonable and necessary" regulatory definition. Specifically, CMS noted that public commenters to the **Proposed Rule** raised a potential lack of clarity because CMS did not include sufficient detail in the Proposed Rule about the impact of commercial insurance coverage, thus, the commenters felt they could not adequately or meaningfully comment. CMS explained that some commenters suggested that the agency should publish another Proposed Rule with significantly more detail.

CMS now seeks public comment on whether the public had adequate opportunity to comment on the Proposed Rule and whether CMS adequately responded to objections to the Proposed Rule, including whether interested parties had fair opportunities to present contrary facts and arguments that may help improve the Final Rule. Finally, CMS is inviting additional public comments on whether the rule should be amended, rescinded, delayed pending further review, or allowed to go into effect. After it reviews any comments it receives, CMS may determine there is a need to postpone the effective date further to allow additional time to consider issues of fact, law, and policy or to reconsider the rule.

### **Key Takeaways**

The regulatory definition would have perhaps provided some additional insight to the subjective terms "reasonable and necessary." Whether an item or service is medically reasonable and necessary forms the overarching legal basis for Medicare coverage determinations pursuant to **Section 1862(a)(1)(A) of the Social Security Act**; most clarifications to this statutory definition are welcomed. However, at least one prong of the new regulatory definition was different than the longstanding Medicare Program Integrity Manual (MPIM), CMS Pub. 100-08, ch. 13, Section 13.5.4 definition. This was proposed 42 C.F.R. Section 405.201(b)(iii)(F) which stated, as an element of the definition for reasonable and necessary:

F. Not later than March 15, 2022, CMS will issue draft subregulatory guidance on the methodology of which commercial insurers are relevant based on the measurement of majority of covered lives. For national and local coverage determinations, which have insufficient evidence to meet paragraphs (b)(3)(i) through (v) of this section, CMS will consider coverage to the extent the items or service are covered by a majority of commercial insurers. As part of CMS' consideration, CMS will include in the national or local coverage determination its reasoning for its decision if coverage is different than the majority of commercial insurers.

86 Fed. Reg. 2987, 3009 (Final Rule, January 14, 2021). It seems fair to conclude that there may not have been sufficient detail about the impact of commercial insurance coverage to understand exactly what this factor means, especially as subsection (b)(iii)(F) was finalized. Therefore, while any additional guidance is usually helpful for the interpretation of "reasonable and necessary," it is ideal to have a clear, concise and easily understood regulatory definition. Either way, CMS should soon decide if it will amend, rescind, or further delay the Final Rule, including the regulatory definition of "reasonable and necessary."

For more information, please contact any member of the **[Baker Donelson Reimbursement Team](#)**.