



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 405

[CMS-3372-IFC]

RIN 0938-AT88

Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary"; Delay of Effective Date; Public Comment Period

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Interim final rule; delayed effective date; request for comments.

SUMMARY: Consistent with the memorandum of January 20, 2021, from the Assistant to the President and Chief of Staff, titled "Regulatory Freeze Pending Review," this document delays the effective date of the final rule titled, "Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of 'Reasonable and Necessary'" published in the **Federal Register** on January 14, 2021, for 60 days. We are providing a 30-day public comment period to allow interested parties to provide comments about issues of fact, law, and policy raised by the rule and this information could be considered by the agency in determining whether further actions are appropriate, which could include whether to revise or rescind.

DATES: Effective date: As of [INSERT DATE OF FILING FOR PUBLIC INSPECTION AT THE **FEDERAL REGISTER**], the effective date of the final rule amending 42 CFR part 405 published at 86 FR 2987 on January 14, 2021, is delayed by this interim final rule until May 15, 2021.

Comment period: To be assured consideration, comments on the January 14, 2021 final rule and "Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of 'Reasonable and Necessary'" and this interim action must be received at one of the addresses

provided below, by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE **FEDERAL REGISTER**].

ADDRESSES: In commenting, please refer to file code CMS-3372-IFC.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to **<http://www.regulations.gov>**. Follow the "Submit a comment" instructions.
2. By regular mail. You may mail written comments to the following address ONLY:
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-3372-IFC,
P.O. Box 8013,
Baltimore, MD 21244-8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-3372-IFC,
Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Linda Gousis at (410) 786-2281 or

MCIT@cms.hhs.gov.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that website to view public comments. CMS will not post on Regulations.gov public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm the individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

I. Background

In the January 14, 2021 **Federal Register**, we published a final rule titled “Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of “Reasonable and Necessary”” (86 FR 2987). The January 2021 final rule established a Medicare coverage pathway to provide Medicare beneficiaries nationwide with faster access to new, innovative medical devices designated as breakthrough by the Food and Drug Administration (FDA). The MCIT pathway will result in 4 years of national Medicare coverage starting on the date of FDA market authorization or a manufacturer chosen date within 2 years thereafter. This January 2021 final rule also implemented regulatory standards to be used in making reasonable and necessary determinations under section 1862(a)(1)(A) of the Social Security Act (the Act) for items and services that are furnished under Medicare Parts A and B.

II. Provisions of the Interim Final Rule with Comment Period (IFC)

A. Purpose of this Action

On January 20, 2021, the Assistant to the President and Chief of Staff issued a

memorandum titled “Regulatory Freeze Pending Review” (“Regulatory Freeze Memorandum”) which, along with the guidance on implementation of the memorandum issued by the Office of Management and Budget (OMB) in Memorandum M-21-14 dated January 20, 2021, directs agencies to consider delaying the effective date of rules published in the **Federal Register** that have not yet become effective, consistent with applicable law, for the purpose of reviewing any questions of fact, law, and policy the rules may raise.

The OMB memorandum directed that the decision to delay should include consideration of whether--

- 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 record.

After considering this guidance, we determined that a 60-day delay is appropriate to ensure that: (1) the rulemaking process was procedurally adequate; (2) the agency properly considered all relevant facts; (3) the agency considered statutory or other legal obligations; (4) the agency had reasonable judgment about the legally relevant policy considerations; and (5) 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. Therefore, we are delaying the effective date of the January 2021 MCIT final rule and inviting 30 days of public comments subsequent to promulgation of this document consistent with the Regulatory Freeze Memorandum and OMB Memorandum M-21-14. Further, we appreciate the strong public interest in our rulemaking, and we are especially interested in public comments on each of the five decision criteria noted previously with respect to the January 2021 MCIT final rule.

Accordingly, this document delays the effective date of the January 2021 MCIT final rule as specified in the **DATES** section and opens a 30-day comment period on the facts, law, and policy underlying the rule.

B. Potential Concerns and Invitation for Public Comment

1. Operational Issues

The MCIT pathway would address uncertainty in Medicare coverage for newly FDA market-authorized breakthrough devices. While the rule would eliminate coverage uncertainty early after FDA market authorization and automates coverage “so that innovative products are brought to market faster,” the rule did not directly address operational issues, such as how the agency would establish coding and payment levels for particular devices, which are both central to prompt market access. CMS cannot be certain of the precise timing of FDA market authorizations and the exact indication for use of the devices until they become market authorized. However, in order to fully operationalize Medicare coverage for a particular breakthrough device, CMS must make other decisions before it can properly pay claims. Among those are whether the device falls within a Medicare benefit category under Part A (Hospital Insurance Benefits) or Part B (Supplementary Medical Insurance Program). These determinations are often called benefit category determinations or BCDs. In addition, we often must take into account the setting where the device is furnished, whether there is an existing payment methodology that applies to the particular breakthrough device (including, for example, whether a device would be paid under a bundled payment system or is separately payable). We

must also determine whether there is an appropriate billing code for the device in order to support electronic claims filing and efficient claims processing.

We recognize that some public comments on the September 1, 2020 MCIT proposed rule, especially from manufacturers, supported our initiating MCIT only after coverage, coding, and payment had been established. We underestimated the operational challenges highlighted by these comments. We seek comment on how CMS should resolve the operational issues, such as benefit category determinations, coding, and payment levels.

2. Overlapping Rules

CMS separately proposed a Benefit Category and Payment Determination process in the November 4, 2020 proposed rule titled “Benefit Category and Payment Determinations for DME, Prosthetic Devices, Orthotics and Prosthetics, Therapeutic Shoes and Inserts, Surgical Dressings, or Splints, Casts, and Other Devices Used for Reductions of Fractures and Dislocations” (DMEPOS) (85 FR 70358). (The comment period for the November 2020 proposed rule closed on January 4, 2021.) This proposed rule outlined a process to establish a BCD for Durable Medical Equipment (DME). The proposed rule has not been finalized. Because of the publication sequences of the MCIT public comment period ending on November 2, 2020 and the DMEPOS proposed rule being published 2 days after the MCIT comment period closed, it may not have allowed stakeholders to adequately comment on the integration of the two policies. While we recognize the proposed rule was specifically considering DMEPOS, and not all breakthrough devices fall within these categories, that rule may serve as a model for resolving similar operational issues that could expedite and facilitate Medicare payment. While CMS has not completed its public comment review of the DMEPOS payment rule, there are comments requesting that CMS align its processes. We seek comment on whether commenters

would have raised additional concerns if there had been an opportunity to comment on the DMEPOS payment and MCIT rules at the same time.

3. New Information: Breakthrough Device Volume

The regulatory impact analysis (RIA) published as part of the MCIT final rule was based on the expectation that the FDA breakthrough device program would initially apply to a relatively small number of devices based on the low number of breakthrough devices that had become market authorized. Using this information, we assumed this number would remain in a relatively steady state for the first few years and included this assumption in the RIA. The MCIT proposed rule stated that 2 to 5 devices would likely fall within the MCIT coverage pathway initially and would remain fairly consistent in the short term, and increase gradually thereafter. At that time, the publicly available FDA count of breakthrough device designations was from the end of fiscal year 2018, when there were 97 FDA-designated breakthrough devices. New data, publicly reported by the FDA on February 16, 2021 (<https://www.fda.gov/news-events/fda-voices/reflections-record-year-novel-device-innovation-despite-covid-19-challenges>), indicated that more than 400 devices have been designated as breakthrough. We recognize that not all of those devices will be market-authorized, and we cannot know the precise timing of those market authorizations. Recent public data suggests a larger number of market-authorized breakthrough devices may be eligible for MCIT. The public may not have had an opportunity to consider this aspect of potential growth. We seek comment on whether the assumption about the potential volume of FDA breakthrough devices was flawed such that the public did not have a meaningful opportunity to comment on the proposed rule.

4. Medicare Patient Benefit/Protection and Other Issues

Further, after the close of the MCIT public comment period, some experts raised questions in published articles about how breakthrough technology may work -in older patients and the evidence basis for Medicare coverage of these technologies (Bach. New York Times, December 1, 2020; <https://www.nytimes.com/2020/12/01/opinion/trump-medicare->

medicaid.html; Eroding Progress on Evidence and Outcomes: CMS's New Proposed Pathway for Medical Device Coverage. Neumann and Chambers. Health Affairs, December 2, 2020 and Medicare's New Device-Coverage Pathway - Breakthrough or Breakdown. Rathi, Johnston, Ross and Dhruva. New England Journal of Medicine, March 10, 2021). CMS is aware that Medicare patients often have different clinical profiles and considerations due to the complexity of their medical conditions and multiple treatments compared to other age groups. Because Medicare patients usually have more than one co-morbidity and are likely being treated for more than one condition, CMS has historically reviewed clinical evidence showing that the devices have been studied in the Medicare population or that outcomes are generalizable to the Medicare population. The various treatments may interact with each other, potentially affecting overall patient benefits.

Some public commenters challenged CMS' premise that the MCIT coverage could result in improved care for Medicare beneficiaries absent specific evidence that the MCIT eligible devices benefit the Medicare population. In response to the public comments, the MCIT final rule gives CMS authority to remove a breakthrough device from the MCIT pathway where a medical device safety communication or warning letter is issued by the FDA, or if the FDA revokes market authorization for a device. We seek comment on whether the revisions in the MCIT final rule adequately addressed the public's concern of clinical benefit to the Medicare population.

5. Public Request for a More Detailed Proposal

Public commenters on the proposed rule requested that we not finalize the rule because of a potential lack of clarity on the "reasonable and necessary" definition, which is the statutory standard for covering MCIT breakthrough devices after the coverage pathway ends and most items and services that fall under the Medicare fee-for-service program. These commenters stated that CMS did not include sufficient detail in the proposed rule about the impact of commercial insurance coverage and, therefore, suggested that they could not adequately or

meaningfully comment. Further, some commenters suggested that the agency should publish another proposed rule with significantly more detail. We seek comment on whether the public had adequate opportunity to comment on the proposed rule. We are also soliciting comment on 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 to improve the final rule.

6. Adequacy of Rulemaking Process

Lastly, OMB Memorandum M-21-14 requires agencies to consider, among other things, whether the rulemaking process was procedurally adequate and whether interested parties had a fair opportunity to present contrary facts and arguments. We are soliciting comment on the following:

- Whether there are any other procedural issues pertaining to the January 2021 MCIT rulemaking process.
- If there are other procedural issues, what are those issues and what should CMS do to remedy those issues?
- Should the January 2021 MCIT final rule be amended, rescinded, or further delayed pending review by the CMS or allowed to go into effect?

III. Waiver of Proposed Rulemaking and the 60-day Public Comment Periods

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment prior to a rule taking effect in accordance with section 1871 of the Act and section 553(b) of the Administrative Procedure Act (APA). Unless there is a statutory exception, section 1871(b)(1) of the Act generally requires the Secretary of the Department of Health and Human Services (the Secretary) to provide for notice of a proposed rule in the **Federal Register** and provide a period of not less than 60 days for public comment before establishing or changing a substantive legal standard regarding the matters enumerated by the statute. Similarly, under 5 U.S.C. 553(b) of the APA, the agency is required to publish a notice

of proposed rulemaking in the **Federal Register** before a substantive rule takes effect. Section 553(d) of the APA and section 1871(e)(1)(B)(i) of the Act usually require a 30-day delay in effective date after issuance or publication of a rule, subject to exceptions. Sections 553(b)(B) and 553(d)(3) of the APA provide for exceptions from the advance notice and comment requirement and the delay in effective date requirements. Sections 1871(b)(2)(C) and 1871(e)(1)(B)(ii) of the Act also provide exceptions from the notice and 60-day comment period and the 30-day delay in effective date. Section 553(b)(B) of the APA and section 1871(b)(2)(C) of the Act expressly authorize an agency to dispense with notice and comment rulemaking for good cause if the agency makes a finding that notice and comment procedures are impracticable, unnecessary, or contrary to the public interest.

We find that notice and comment rulemaking is impracticable, unnecessary, and contrary to the public interest with respect to the relatively short delay in the effective date of the final MCIT rule announced by this action. The final rule was published in the **Federal Register** on January 14, 2021. Even if the MCIT final rule were to go into effect on March 15, 2021, CMS would be unable to operationalize the program by that date. Because the agency is required to make other decisions, such as benefit category determinations, whether there is an existing payment methodology and whether there is an existing code or establishing code for the MCIT eligible breakthrough device, it would be impracticable to operationalize the MCIT rule on the March 15, 2021 effective date. These operational practicalities leave CMS incapable of implementing the MCIT program on March 15, 2021. Additionally, the higher than anticipated volume of devices receiving FDA breakthrough device designation exponentially complicates the operational concerns that we have identified. Further, public comments highlighted the importance of the agency having the ability to not only cover an FDA-designated breakthrough device expeditiously, but also to be able to have coding and payment levels established at the same time.

It would be impracticable to provide the normal 60-day comment period for such a brief

delay in the effective date because the rule would be effective before the public comments could be meaningfully considered. Given the March 15, 2021 effective date for the MCIT final rule, there is not sufficient time to adequately consider advance public comment on this delay and it would interfere with the public's interest in the orderly promulgation and implementation of regulations. We find good cause for dispensing with advance public comment because it is impracticable to provide a meaningful opportunity to comment before extending the effective date of the MCIT rule.

The White House memorandum also recommends that, for rules postponed for further review, agencies consider opening a 30-day comment period to allow interested parties to provide comments about issues of fact, law, and policy raised by those rules, and consider any requests for reconsideration involving such rules. Consistent with this guidance, we are requesting public comments on these topics, as well as the specific questions posed previously. After reviewing comments received in response to this notice, we 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 January 2021 MCIT final rule.

IV. Summary

This rule delays the effective date of January 2021 MCIT final rule to May 15, 2021 for further review of the of fact, law, and policy raised by the rule. This rule also invites 30 days of public comment and requests interested parties to provide comments about issues of fact, law, and policy raised by the January 14, 2021 final rule so that CMS can consider any requests for reconsideration involving the rule. We also invite additional public comments on whether the rule should be amended, rescinded, delayed pending further review, or allowed to go into effect.

For the reasons stated previously, we find that there is good cause under 5 U.S.C. 553(b)(B) and (d)(3) to publish this action without prior notice and comment, and for this action to become effective immediately upon publication in the **Federal Register**.

V. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually.

Norris Cochran,

Acting Secretary,

Department of Health and Human Services.

[FR Doc. 2021-05490 Filed: 3/12/2021 4:15 pm; Publication Date: 3/17/2021]