DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 405

[CMS–3372–F2]

RIN 0938–AT88

Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of ''Reasonable and Necessary''; Delay of Effective Date

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

ACTION: Final rule.

SUMMARY: This final rule 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 January 14, 2021 **Federal Register**.

DATES: As of May 14, 2021, the effective date of the final rule amending 42 CFR part 405, published at 86 FR 2987, January 14, 2021, and delayed at 86 FR 14542, March 17, 2021, is further delayed until December 15, 2021.

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SUPPLEMENTARY INFORMATION:

I. Background

A. Introduction

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) (hereinafter referred to as MCIT/R&N final rule). 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). Under the final rule as currently written, MCIT would 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. The MCIT/R&N final rule would also implement 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.

B. March 17, 2021 Interim Final Rule (IFC)

In response to the January 20, 2021 memorandum from the Assistant to the President and Chief of Staff titled ''Regulatory Freeze Pending Review'' (''Regulatory Freeze Memorandum'') (86 FR 7424, January 28, 2021) and guidance on implementation of the memorandum issued by the Office of Management and Budget (OMB) in Memorandum M–21–14 dated January 20, 2021, we determined that a 60-day delay of the effective date of the MCIT/R&N final rule was 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, in an interim final rule that took effect on March 12, 2021, and appeared in the March 17, 2021 **Federal Register** (86 FR 14542), we (1) delayed the MCIT/R&N final rule effective date until May 15, 2021 (that is, 60 days after the original effective date of March 15, 2021); and (2) opened a 30-day public comment period on the facts, law, and policy underlying the MCIT/R&N final rule.

C. Review of Public Comments on the Delay of the MCIT/R&N Final Rule

We received approximately 215 timely pieces of correspondence in response to the interim final rule delaying the effective date of the MCIT/R&N final rule.

In this section of this final rule, we summarize our response to comments on the delay of the MCIT/R&N final rule. To the extent applicable, we intend to also consider these comments for future rulemaking.

Comment: Some manufacturers, in particular those with FDA designated breakthrough devices that have been market authorized, as well as the industry groups representing them commented that the MCIT/R&N final rule should be implemented without further delay. Although they acknowledged certain operational issues remain, specifically coding and payment for applicable devices and/or the services in which they are used, these commenters suggested those issues could be overcome by adapting existing processes such as inpatient new technology add on payment (NTAP) and outpatient hospital transitional pass-through payment to determine coding and payment, at least when these devices are used in the hospital setting. These commenters also expressed that they believe patient safety provisions in the final rule are sufficient to protect beneficiaries.

Other manufacturers that have FDA breakthrough designated devices but generally have yet to receive market authorization were supportive of a MCIT policy that would be more comprehensive and that includes specified guidance and expedited processes for benefit category determination, coding, and payment. These manufacturers support a delay of the MCIT/R&N final rule to the extent that such a delay would lead to a more comprehensive policy than the one that would be effective in May 2021.

Response: The current MCIT/R&N final rule solely relates to coverage of certain devices under Medicare; it does not establish a benefit category determination (BCD), medical coding, nor payment rates for any devices. While we recognize that some commenters support a different policy that would address benefit category determinations, coding, and payment, in addition to coverage, the MCIT/R&N final rule was not designed to address factors beyond Medicare coverage. Further, while the rule eliminates coverage uncertainty early after FDA market authorization for those devices with a clear benefit category, the rule did not directly address the operational issues, such as how the agency would establish coding and payment.

Comment: Several individual physicians and members of the public submitted comments supporting implementation of the MCIT/R&N final rule given the promise of breakthrough devices for their specialties or disease states of concern: Chronic obstructive pulmonary disease (COPD), prostate care, heart failure, stroke, opioid use disorder, oncology, and sleep disorders. On the other hand, some commenters suggested that the final MCIT/R&N rule provided automatic coverage for breakthrough devices without adequate evidentiary support.

Response: We are aware that breakthrough devices span numerous clinical specialties. We note that MCIT would be one of several coverage pathways (that is, claim-by-claim adjudication, local coverage, National Coverage Determination (NCD)) for breakthrough devices. Even without the MCIT/R&N final rule in effect, a review of claims data showed that breakthrough devices have received and are receiving Medicare coverage when medically

necessary. CMS reviewed fee-for-service claims data for several recent market-authorized breakthrough devices. The majority of the FDA market authorized breakthrough devices that would have been eligible for the MCIT pathway were already paid through an existing mechanism or were predominantly directed to a pediatric population. Of those that would be separately payable by Medicare on a claim-by-claim basis, the reviewed devices, were covered and paid under the applicable Medicare payment system.

Regarding commenters' concerns about automatic coverage without evidentiary support, we share commenters' concerns that guaranteeing coverage for all breakthrough devices receiving market-authorization for any Medicare patient with possibly minimal or no evidence on the Medicare population and no requirement to develop evidence on the Medicare population could be problematic in ensuring these devices are demonstrating value and do not have additional risks for Medicare beneficiaries. For example, a breakthrough device may only be beneficial in a subset of the Medicare population or when used only by specialized clinicians to ensure benefit. Without additional clinical evidence on the device's clinical utility for the Medicare population, it is challenging to determine appropriate coverage of these newly market-authorized devices.

Comment: Multiple stakeholders (manufacturers, physicians, associations) commented that CMS should modify the MCIT policy in some way. A substantial number of comments from a variety of stakeholders expressed evidentiary concerns with MCIT as currently designed, including that the current MCIT/R&N final rule's pathway establishes an open-ended coverage commitment for all breakthrough devices without demonstrating a health benefit in the Medicare population. Additionally, commenters were concerned that the current MCIT/R&N final rule does not specify, nor can it require, coverage criteria beyond the FDA indication(s) for use, and that evidence development under MCIT is voluntary, and narrowing coverage after MCIT expires will be challenging for devices that do not have a documented, proven benefit for Medicare patients. Many of these stakeholders recommend that CMS leverage or broaden the existing coverage with evidence development (CED) pathway to provide more timely and appropriate access to new technologies. These commenters encouraged CMS to require post market studies and data collection as part of MCIT to ensure that beneficiaries are gaining access to new technologies that improve health outcomes. Several breakthrough device manufacturers suggested that, for inclusion in MCIT, a portion of FDA pivotal studies should include a portion of Medicare beneficiaries. One breakthrough device manufacturer suggested that 25 percent of patients in the pivotal study should be Medicare beneficiaries for MCIT; otherwise, CED would be more appropriate.

Response: We agree that for breakthrough devices for which studies did not include Medicare populations or populations with characteristics similar to the Medicare population CED or a similar evidence development process would strengthen the evidence base relevant to Medicare patients. In past NCDs, we have leveraged FDA required post-market studies in CED decisions.

In contrast to the NCD process which involves a robust review of available clinical evidence, especially for the Medicare population, to determine whether the item or service is reasonable and necessary for Medicare beneficiaries, the current MCIT pathway in the MCIT/R&N final rule establishes a 4-year coverage commitment for all breakthrough devices that have a benefit category without a specific requirement that the device must demonstrate a health benefit or that the benefits outweigh harms in the Medicare population. In general, Medicare patients have more comorbidities and often require additional and higher acuity clinical treatments which may impact the outcomes differently than the usual patients enrolled in early studies. Medicare has also focused on real world data or implementation studies to understand how items and services perform when more broadly used in general practice in the Medicare population. These considerations are often not addressed in the early device development process.

We also note that FDA grants breakthrough designation early in a device's product lifecycle. In part, the FDA considers ''whether there is a reasonable expectation that a device could provide for more effective treatment or diagnosis relative to the current standard of care (SOC) in the U.S. A complete set of clinical data is not required for designation.'' [1] At the time a device is granted breakthrough status by the FDA, little may be known about the benefits and harms of the device. We recognize the importance of breakthrough technologies that provide for more effective treatment of life-threatening and irreversibly debilitating diseases and conditions when no effective treatment exists.

In cases where there is greater uncertainty surrounding the benefit-risk profile of a breakthrough device, some commenters have suggested that more relevant evidence is needed for Medicare patients to determine health benefit, to mitigate harms that may not be apparent in initial studies with small sample sizes, and to understand the balance of benefits and harms when breakthrough devices are used more broadly in Medicare patients. The additional delay announced in this rule will provide an opportunity to ensure that the objections to the rule are adequately considered. We will consider ways to diminish uncertainty with respect to Medicare coverage by building upon the evidence foundation established during the market authorization process or combining that evidence with other approaches like CED to expedite coverage in appropriate instances.

For CMS, the evidence base underlying the FDA's decision to approve or clear a device for particular indications for use has been crucial for determining Medicare coverage through the NCD process. CMS looks to the evidence supporting FDA market authorization and the device indications for use for evidence generalizable to the Medicare population, data on improvement in health outcomes, and durability of those outcomes. If there are no data on those elements, it is difficult for CMS to make an evidence-based decision whether the device is reasonable and necessary for the Medicare population.

The current MCIT/R&N final rule does not specify any coverage criteria beyond the FDA indication(s) for use for which FDA has approved or cleared the device. The current final rule would provide coverage when a device is used according to approved or cleared indication(s) for use. A device's approved or cleared indications for use may not include information that is important or particularly relevant for Medicare patients and clinicians when making treatment decisions. With breakthrough devices, as mentioned by some commenters, the patients included in device studies generally are not Medicare beneficiaries who often have multiple comorbidities and higher acuity of illness.

The data used to determine whether a device meets applicable FDA safety

[1] U.S. Department of Health and Human Services, Food and Drug Administration Breakthrough Devices Program: Guidance for Industry and Food and Drug Administration Staff 9 (December 18, 2018), *available at https://www.fda.gov/media/108135/download.*

and effectiveness requirements for its approved or cleared indication(s) for use may not be able to answer questions such as the following:

- Does the benefit differ for older and/or frailer patients with specific comorbidities?
- Are clinician experience or facility requirements needed to ensure good health outcomes or to prevent certain harms in those patients?

These guidelines and recommendations have often been part of NCDs, but were not included in the MCIT policy. When making NCDs, CMS sometimes develops clinician and institutional requirements after careful review of expert physicians' specialty society guidelines and clinical study results. Additional rulemaking may provide a further opportunity for the public to opine on whether these types of restrictions are needed when covering breakthrough devices.

Comment: Manufacturers acknowledged the need to develop evidence to achieve long-term coverage, and many indicated their intent to develop real world evidence (RWE). Some stated that MCIT would incentivize manufacturers to develop RWE following market authorization and sought guidance from CMS on desired elements.

Response: Whether evidence development is voluntary or required for coverage, we value manufacturer, CMS, and FDA coordination on RWE development for coverage and/or post-market studies. Establishing the RWE guidance sought by manufacturers and some physicians would be beneficial and that further stakeholder engagement would best inform the guidance. CMS has multiple pathways to facilitate engagement such as the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) and the public input process through the **Federal Register**. We are also receptive to informal engagement with stakeholders, including with manufacturers who pursue this evidence development approach. We are aware that best practices for RWE generation are in development by some stakeholders. However, when a device receives breakthrough designation by the FDA, there is currently no clinical study requirement for market-authorization that Medicare patients must be included. Without relevant Medicare data, including RWE, under the MCIT/R&N final rule, CMS may be covering devices with no data demonstrating that Medicare patients will not be harmed or will benefit from the device. Currently, when CMS sees a trend indicative of a potentially harmful device, we are sometimes able to deny coverage through Medicare Administrative Contractors. Under the MCIT/R&N final rule, this authority has been removed as we may only remove a breakthrough device from the MCIT coverage pathway for limited reasons, including if FDA issues a safety communication, warning letter, or removes the device from the market. Further, under the current final rule, if CMS is seeing a trend of higher risk specifically in the Medicare population, CMS' authority with respect to coverage for Medicare determinations is limited without an FDA action, which would not just take the Medicare population experience into account. That is, the FDA's review of devices is for the entirety of the intended patient population rather than within the narrower Medicare population.

Comment: Some stakeholders continued to express concern that reliance on breakthrough designation ceded decision-making authority on what is reasonable and necessary for Medicare patients to an FDA decision very early in the product lifecycle. A number of physician commenters with experience in clinical evidence noted a number of compelling evidentiary concerns, including their assertion that the MCIT policy is flawed because of a lack of evidence that breakthroughs benefit Medicare beneficiaries. One manufacturer suggested that pivotal studies should have to demonstrate patient benefit in the Medicare population in order to obtain MCIT coverage.

Response: The FDA criteria to determine whether a device is designated as a breakthrough is different from the criteria and evidence CMS reviews to determine appropriateness for the Medicare population. The FDA does not routinely require data on Medicare patients. The relevant data is key for Medicare national coverage decision-making to ensure that Medicare is paying for devices that are beneficial to Medicare patients. While the goal of the MCIT/R&N final rule was to expedite coverage to speed access to innovative treatments, the immediacy of coverage must be balanced with ensuring that the Medicare program is covering appropriate devices for the Medicare population. Without any data or minimal clinical data to make this determination, it is challenging to ensure that breakthrough devices are beneficial to the Medicare population. We will further consider public comments seeking modifications to MCIT that might allow for expedited coverage while seeking to ensure devices are safe for Medicare patients even when those breakthrough devices do not have an evidence base that is generalizable to Medicare beneficiaries.

Comment: Medical specialty societies also sought modifications to the MCIT/R&N final rule regarding evidence development, specifically the addition of RWE requirements and a clarification of CMS' CED authorities. Commenters specifically recommended post market studies, data collection, and recommended CED as a potential pathway to address uncertainty in health outcomes. In lieu of MCIT, commenters recommended using the Parallel Review program for devices with a broad evidence base and a CED for devices with a developing evidence base.

Response: We appreciate these comments and refer to our earlier responses addressing similar issues regarding evidence development and RWE-related comments. CED has been utilized for many years to allow beneficiary access while simultaneously fostering evidence development. The public comments suggest there is an interest in additional guidance on CED. Knowing where there are gaps in clinical evidence for a device or type of devices is a preliminary question asked and researched by CMS and FDA. This gap analysis with respect to the Medicare reasonable and necessary criteria is a precursor to CED parameters for a given item or service. We are aware that manufacturers are interested in more input from CMS on what evidence needs to be developed for coverage, including a discussion of the gap analysis. Based on the comments from manufacturers that indicated they were already developing or would develop evidence following market authorization, we believe there is also interest in coordination with CMS to create an evidence development plan that is fit-for-purpose in line with manufacturer coverage goals to ensure that Medicare patients are protected.

Comment: Several health plans participating in Medicare Advantage (MA) and their advocacy associations submitted comments that raised concerns with the MCIT/R&N final rule. Associations specifically indicated that the final rule should be rescinded and not implemented. In general, they recommend post market data collection and use of existing coverage pathways. One health plan noted several concerns for the MA plans if the MCIT/R&N final rule is implemented specific to bids and plan payment rates and related downstream effects for beneficiaries such as increased out of pocket costs, fewer benefits, and perhaps even fewer plan offerings.

Response: There is not a substantive discussion on how the MCIT pathway would affect MA plans in the MCIT/R&N final rule. Under current law, MA plans are required to offer coverage of reasonable and necessary items and services covered under part A and part B on terms at least as favorable as those adopted by fee for service Medicare. CMS did not fully consider the MA effects in the MCIT/R&N final rule. Specifically, the cost implications for MA plans of blanket national coverage and all of the associated costs to the breakthrough device was not fully explored. For example, if a breakthrough device was implanted, Medicare would pay not just for the device, but also for the reasonable and necessary procedures and related care and services such as the surgery, and related visits to prepare for surgery and follow up. These non-device costs were not considered in the regulatory impact analysis (RIA).

Comment: Some commenters noted that the MCIT/R&N final rule could potentially lead to increased fraud, waste and abuse. A commenter noted that, under the final rule, the current MCIT construct offering guaranteed Medicare payment for 3 to 4 years with broad-based coverage criteria and minimal limitations for a massive patient population is a strong scenario for fraud.

Response: We believe the commenters are suggesting that the expanded coverage may encourage greater use of these devices than they believe is warranted. Because these determinations would depend on specific facts, CMS would follow its normal process in the event there was a concern of fraud or abuse.

Comment: Another stakeholder raised concerns that the MCIT/R&N final rule as currently constructed only considers industry's perspective and does not take into account physician and patient perspectives. They further noted that for MCIT there is no established mechanism in place for those stakeholders to provide comments regarding their concerns about using these technologies on the Medicare population. To that end, they claim that the current MCIT/R&N final rule lacks the transparency and accountability found in the existing NCD and LCD processes.

Response: We appreciate these comments. We acknowledge that the MCIT/R&N final rule as currently designed does not provide the same level of opportunities for public participation as stakeholders have become accustomed to with the established NCD and LCD processes where, for each item or service considered for coverage, stakeholders have an opportunity to comment.

Comment: Regarding operational issues for MCIT, manufacturers commented that the existing processes in place for BCD, coding, and payment should work for MCIT, and that early coordination with CMS shortly after breakthrough designation should allow for time for these processes to play out. Commenters, including several manufacturers, recommended that CMS establish provisional codes and payment for breakthrough devices as part of the MCIT pathway to ensure availability of codes and payment at the time of FDA approval. They also recommended that CMS formalize an operational framework with a predictable timeline to conduct evidence reviews, develop benefit category determinations, codes, and payment.

Response: We will take these suggestions under consideration for future rulemaking.

Comment: Commenters indicated that the newly public information about the volume increase in the Breakthrough Device volume [2] was not a concern and that it should not impede implementation of the MCIT/R&N final rule. Others stated that the RIA was sufficient because not all devices designated as breakthrough would ultimately achieve market authorization after the 4-year period. Still others believed the RIA was insufficient because they believe there would be more breakthrough devices market authorized than included in the estimate. In light of the increase in volume, a commenter suggested considering mechanisms, such as establishing user fees, to increase resources through dedicated appropriation or other mechanisms.

Response: We must take into consideration the number of possible devices that will be approved through the MCIT pathway. Further, under the MCIT/R&N final rule any breakthrough device that receives FDA market-authorization is potentially covered for any Medicare patient without evidence of its benefit generated in the Medicare population. Beyond limits in the indications for use for which FDA approves or clears a device, CMS does not have the authority under the finalized MCIT policy to further define clinical parameters to narrow or expand national coverage. In addition, all related care and services associated with the device are covered which could include additional visits and maintenance of the device. CMS did not factor these costs in the RIA. This analysis has an impact on ensuring there are sufficient resources for the program to run efficiently. As with any program, sufficient resources are key to efficient and timely operations.

Comment: Most manufacturers commented that the patient protections in place in the final rule, specifically the reliance on FDA safety and efficacy requirements to grant coverage to breakthrough devices under MCIT, were sufficient to prevent beneficiary harm.

Response: As finalized in the MCIT/R&N final rule, devices could be used on Medicare patients without any evidence of the devices' clinical utility in the Medicare population. To remove a device from Medicare coverage under MCIT, FDA must issue a safety communication, warning letter, or remove the device from the market. Under the MCIT/R&N final rule, if CMS observes a trend of higher risk, specifically in the Medicare population, CMS authority to deny coverage is limited. For example, if a CMS contractor (for example, a Medicare Administrative Contractor (MAC)) identifies a pattern or trend of significant patient harm or death related to an MCIT device, there is no procedure to quickly remove coverage for the device until and unless the FDA acts. We believe that the public should have an additional opportunity to comment on this policy.

Comment: A commenter recommends that MCIT coverage could be offered to the class of the breakthrough device including device iterations and follow-on competitive devices. The commenter suggested that CMS direct an evidence review at the end of the 4 years of MCIT coverage for a particular device determine which coverage pathway would be most appropriate to ensure the most benefit to Medicare patients.

Response: Clinical evidence development that includes Medicare beneficiaries is central to ensuring that Medicare patients are receiving optimal clinical care and minimizing risk when possible. While examining data on a group of similar breakthrough devices and identifying gaps in the evidence base may be a greater effort initially than the evidence review for one device, it could result in efficiencies across several components within CMS and inform coverage in a more comprehensive manner than MCIT, which is one device at a time. We will

[2] U.S. Department of Health and Human Services, Food and Drug Administration, Reflections on a Record Year for Novel Device Innovation Despite COVID–19 Challenges (Feb. 16, 2021), *available at https://www.fda.gov/news-events/fda-voices/reflections-record-year-novel-device-innovation-despite-covid-19-challenges.*

seek additional public comments on this topic when considering any proposed changes.

Comment: Some stakeholders supported defining ''reasonable and necessary'' in regulation while others do not believe a codified definition is necessary. Commenters expressed concerns about transparency of commercial coverage polices and believed the rule could unnecessarily restrict coverage by relying on commercial insurer policies designed for a different population with different incentives. Furthermore, the majority of public comments from patient advocates, policy ''think tanks,'' health insurance advocates and manufacturers did not support including commercial insurer criteria in the definition. Most public comments noted that CMS can (and has) reviewed commercial policies in recent years as part of a national coverage analysis. Other commenters suggested separating and reissuing separate rules for the definition of ''reasonable and necessary'' and MCIT because they were viewed as too distinct.

Response: We will consider this comment for future rulemaking.

C. Impracticability of Implementation by May 15, 2021

As noted previously, many commenters on the March 2021 IFC supported delaying the MCIT/R&N final rule. Based upon the public comments expressing significant evidentiary concerns, we do not believe that it is in the best interest of Medicare beneficiaries for the MCIT/R&N final rule to become effective May 15, 2021. Under the current rule, there no requirement for evidence that MCIT devices will specifically benefit the Medicare target population. Additionally, the final rule takes away tools the CMS has to deny coverage when it becomes apparent that a particular device can be harmful to the Medicare population. If the rule goes into effect, and a device is later found to be harmful to Medicare recipients is approved under the MCIT pathway, CMS would be limited in the actions it can take to withdraw or modify coverage to protect beneficiaries.

As was noted by some commenters, early and unrestricted adoption of devices may have consequences that may not be easy to reverse. Commenters referenced publications that highlight the relationship between manufacturers and physicians and claimed that the potential for manufacturers to influence physician behavior will persist if coverage is guaranteed under MCIT. Guaranteed coverage under MCIT may further stimulate providers to adopt these technologies and could potentially lead to these technologies being prematurely viewed as standard of care which could adversely impact beneficiaries if a product does not ultimately receive Medicare coverage. Additionally, providers may make capital and capacity investments that could pose challenges to withdrawing coverage.

A common theme among some commenters is that, under the MCIT/R&N final rule as currently written, the evidence used to support FDA clearance or approval of a breakthrough device is not generalizable to the Medicare population since the Medicare population is often not adequately represented in clinical trials. Commenters noted that existing Medicare coverage paradigms rely on careful consideration of the tradeoffs between benefits and risks for the Medicare population and adequate evidence that demonstrates improved health outcomes. Commenters expressed concerns that devices covered under MCIT would not achieve that standard. Additionally, commenters cited several published studies that noted that approval of many breakthrough devices relied upon intermediate endpoints which do not always translate into real world improved health outcomes. Multiple commenters also pointed out that a major limitation of the MCIT pathway under the MCIT/R&N final rule is that manufacturers are not required or incentivized to conduct clinical trials to generate additional evidence, and contended that it is unlikely that manufacturers will voluntarily choose to do so. Further, the shift of the burden of evidence development entirely to manufacturers undermines CMS' ability to support evidence development or establish the coverage criteria (for example, provider experience, location of service, availability of supporting services) that are central to delivery of high-quality, evidence-based care for devices with insufficient evidence of a health benefit for Medicare patients. An additional delay in the effective date would allow time for CMS to address the evidentiary concerns raised by stakeholders and consider how to better balance the needs of all stakeholders and beneficiaries in particular.

Additionally, there is significant uncertainty surrounding coding and payment for new MCIT devices since these issues were not addressed in the MCIT/R&N final rule. If the MCIT/R&N final rule goes into effect, we believe there could be confusion and disruption stemming from devices receiving MCIT approval without a clear path for appropriate coding and payment. The delay will allow CMS time to ensure the public has a clear understanding of the pathways to coverage, coding, and payment.

Further, the delay gives CMS time to evaluate stakeholders' recommendation of whether the reasonable and necessary definition should be a separate rule. There were a number of stakeholder comments supporting delaying defining ''reasonable and necessary'' in regulation. Commenters did not believe a codified definition was necessary or thought the rule could unnecessarily restrict coverage by relying on commercial insurer policies. Furthermore, the majority of public comments from patient advocates, policy think tanks, health insurance advocates and manufactures did not support including commercial insurer criteria in the definition. Most public comments noted that CMS can (and has) reviewed commercial policies in recent years as part of a national coverage analysis.

Future rulemaking will provide an opportunity for us to fully consider the significant objections to the rule, and will provide another opportunity for the public to present contrary facts and arguments.

II. Provisions of the Final Rule

This final rule would further delay the effective date of the MCIT/R&N final rule until December 15, 2021, to provide CMS an opportunity to address all of the issues raised by stakeholders, especially Medicare patient protections, evidence criteria and lack of coordination between coverage, coding and payment as noted previously. During the delay, we will determine appropriate next steps that are in the best interest of all Medicare stakeholders, and beneficiaries in particular.

This final rule delays the effective date of the January 2021 MCIT/R&N final rule as specified in the **DATES** section of this final rule.

III. Waiver of the 30-Day Delay in Effective Date

The Administrative Procedure Act, 5 U.S.C. 553(d), 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. The purpose of the 30-day delay is to allow the public to prepare to implement the new final rule. We find good cause to waive the 30-day delay in the effective date because the further extension will maintain the status quo, so the public does not need notice to adjust their

behavior as a result of the additional delay. Moreover, allowing the prior rule to go into effect would defeat the purpose of the delay rule and result in the same difficulties that were identified regarding reversing course once the rule was in place and would be contrary to the public interest.

Dated: May 13, 2021.

Xavier Becerra,

Secretary, Department of Health and Human Services.

I, Elizabeth Richter, Acting Administrator of the Centers for Medicare & Medicaid Services,

Approved This Document on May 12, 2021

[FR Doc. 2021–10466 Filed 5–14–21; 4:15 pm]

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