107(d)(3)(E) are actions that affect the status of a geographical area and do not impose any additional regulatory requirements on sources beyond those imposed by state law. A redesignation to attainment does not in and of itself create any new requirements, but rather results in the applicability of requirements contained in the CAA for areas that have been redesignated to attainment. Moreover, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those already imposed by state law. For that reason, this action:

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this proposed action does not apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, this rulemaking does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because redesignation is an action that affects the status of a geographical area and does not impose any new regulatory requirements on tribes, impact any existing sources of air pollution on tribal lands, nor impair the maintenance of ozone national ambient air quality standards in tribal lands.

List of Subjects

40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

40 CFR Part 81

Environmental protection, Air pollution control, National parks, Wilderness areas.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: September 8, 2021.

Michelle L. Pirzadeh,

Acting Regional Administrator, Region 10.

[FR Doc. 2021–19801 Filed 9–14–21; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 405

[CMS–3372–P2]

RIN 0938–AT88

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

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would repeal the Medicare Coverage of Innovative Technology (MCIT) and Definition of ''Reasonable and Necessary'' final rule, which was published on January 14, 2021, and would be effective on December 15, 2021. We are providing a public comment period to allow interested parties to provide comments about the proposed repeal, our intent to conduct future rulemaking to explore an expedited coverage pathway that provides access to innovative beneficial technologies and the reasonable and necessary definition.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, by October 15, 2021.

ADDRESSES: In commenting, please refer to file code CMS–3372–P2. 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–P2, 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–P2, 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: Lori Ashby, (410)–786–6322 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

A. January 14, 2021 Final Rule

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 the ''MCIT/R&N final rule''). The MCIT/R&N final rule established a Medicare coverage pathway to provide Medicare beneficiaries nationwide with faster access to recently market authorized medical devices designated as breakthrough by the Food and Drug Administration (FDA). Under the final rule, 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 2021 Interim Final Rule (IFC) and May 2021 Final Rule To Delay Effective Date

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—

- The rulemaking process was procedurally adequate;
- We properly considered all relevant facts;
- We considered statutory or other legal obligations;
- We had reasonable judgment about the legally relevant policy considerations; and
- We 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 with comment period that went on display at the **Federal Register** and took effect on March 12, 2021 (hereinafter referred to as the ''March 2021 IFC''), and was published 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.

Many commenters on the March 2021 IFC supported further delaying the MCIT/R&N final rule. Based upon the public comments, we did not believe that it was in the best interest of Medicare beneficiaries for the MCIT/R&N final rule to become effective on May 15, 2021. Therefore, in a final rule that went on display at the **Federal Register** and took effect on May 14, 2021 (hereinafter referred to as the ''May 2021 final rule''), and was published in the May 18, 2021 **Federal Register** (86 FR 26849), we summarized the comments on the March 2021 IFC and further delayed the MCIT/R&N final rule effective date until December 15, 2021. We explained that the additional delay would provide us an opportunity to address all of the issues raised by stakeholders, especially those related to Medicare patient protections and evidence criteria. We announced that during the delay, we would determine appropriate next steps that are in the best interest of all Medicare stakeholders, and beneficiaries in particular.

II. Provisions of Proposed Regulations

We propose to repeal the MCIT/R&N final rule. Our rationale for our proposal as well as our requests for comments on this proposed rule are explained in the following section.

A. Proposed Repeal of Medicare Coverage of Innovative Technology Policy

CMS developed MCIT in part due to concerns that delays and uncertainty in Medicare coverage slowed innovation and impaired beneficiary access to important new technologies, specifically those designated as breakthrough devices by FDA. In response to these concerns, the rule provided 4 years of expedited coverage to FDA market authorized Breakthrough Devices on the first day of FDA market authorization or a select date up to 2 years after the market authorization date as requested by the device manufacturer. While the final rule did not require manufacturers to develop additional scientific evidence supporting the use of the Breakthrough Devices in the Medicare population, manufacturers were aware that, upon conclusion of MCIT coverage, the existing coverage pathways would be available (that is, reasonable and necessary determinations would be made via claim-by-claim adjudication, local coverage determinations (LCDs), and national coverage determinations (NCDs), which include the coverage with evidence development pathway). The NCD and LCD development processes include reviews of publicly available clinical evidence to determine whether or not the items or services are reasonable and necessary and would be covered by Medicare.

We believe that the finalized MCIT/R&N rule is not in the best interest of Medicare beneficiaries because the rule may provide coverage without adequate evidence that the Breakthrough Device would be a reasonable and necessary treatment for the Medicare patients that have the particular disease or condition that the device is intended to treat or diagnose. While the rule tried to address stakeholder concerns about accelerating coverage of new devices, significant concerns persist about the availability of clinical evidence on Breakthrough Devices when used in the Medicare population as well as the benefit or risks of these devices with respect to use in the Medicare population upon receipt of coverage. Based on the comments received throughout the development of the MCIT pathway, we do not believe that the final rule as currently drafted, is the best way to achieve the goals of MCIT as outlined in the MCIT/R&N final rule, in particular, to more precisely meet the needs Medicare beneficiaries and other stakeholders in a timely fashion. We believe that there are other ways to achieve our stated goals. This may include better utilizing existing pathways or conducting future rulemaking.

As noted in the May 2021 final rule, our prior policies permitted the Medicare program to deny coverage for particular devices if we learned that a particular device may be harmful to Medicare beneficiaries. Specifically, Medicare Administrative Contractors (MACs) could have denied claims under certain circumstances (86 FR 26851, May 18, 2021). Under the MCIT/R&N final rule, this case-specific flexibility would have been removed. While we could remove coverage through the NCD process, we would only be able to expeditiously remove a Breakthrough Device from the MCIT coverage pathway for limited reasons, such as if FDA issued a safety communication or warning letter regarding the

Breakthrough Device, or removed the marketing authorization for a device. We believe that this limitation on our authority is impracticable as it may lead to preventable harm to Medicare beneficiaries and it impedes Medicare's ability to make case-by-case determinations regarding whether a device is reasonable and necessary based on clinical evidence.

Further, while the finalized MCIT policy in the MCIT/R&N final rule would have provided expedited Medicare coverage following market authorization for breakthrough designated devices, there is currently no FDA requirement that Medicare beneficiaries must be included in clinical studies needed for market-authorization. Because the MCIT/R&N final rule did not require data concerning Medicare beneficiaries, there is the potential that Medicare would cover devices, even in the absence of data demonstrating that the device is reasonable and necessary for Medicare patients will benefit from the device. Additionally, several medical device manufacturers suggested that, for inclusion in MCIT, FDA pivotal studies should require inclusion of sufficient numbers of Medicare beneficiaries (86 FR 26851, May 18, 2021).

Certain proponents of accelerated Medicare coverage have argued that FDA's determination that a product meets applicable safety and effectiveness standards for marketing authorization should be sufficient to support Medicare coverage of Breakthrough Devices. However, after further consideration of all public comments, we no longer agree that the FDA safety and effectiveness standards alone are sufficient to support open-ended Medicare coverage. FDA and CMS act under different statutes that have different goals and the standard for coverage (that is, a determination that a device is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member) is not synonymous with standards for safety and efficacy standards for marketing authorization for the broader population. Among other things, FDA conducts premarket review of certain devices to evaluate their safety and effectiveness and determines if they meet the applicable standard to be marketed in the United States. In doing so, FDA relies on scientific and medical evidence that does not necessarily include patients from the Medicare population. In general, under the Medicare statute, CMS is charged with determining whether items and services are reasonable and necessary to diagnose or treat an illness or injury or to improve the functioning of a malformed body member. One consideration for CMS in making national coverage determinations under the reasonable and necessary statute is whether the item/service improves health outcomes for Medicare beneficiaries. It is important to determine whether Medicare beneficiaries' health outcomes are improved because these individuals are often older, with multiple comorbidities,[1] and are often underrepresented or not represented in many clinical studies.

1. Evidence Development and Patient Safety

The Medicare national coverage determination process includes a robust review of available clinical evidence and focuses on the Medicare population to make reasonable and necessary determinations. In contrast, the MCIT pathway would establish an expedited 4-year coverage pathway for all Breakthrough Devices that fall under a Medicare benefit category without a specific requirement that the device must demonstrate it is reasonable and necessary for 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 patients generally enrolled in early clinical trials. These considerations are often not addressed in the early device development process.

When we issued the MCIT/R&N final rule on January 14, 2021, we responded to commenters who suggested that CMS should take a different approach. Some commenters suggested that we should require manufacturers to provide data about Medicare outcomes before providing coverage as reasonable and necessary. Other commenters suggested that we provide incentives to manufacturers to include Medicare beneficiaries in clinical studies, similar to CMS's Coverage with Evidence Development (CED) paradigm, before coverage under section 1862(a)(1)(A) of the Act was allowed (86 FR 2990, January 14, 2021).[2] In response to the March 2021 IFC, additional commenters supported evidence development as part of the requirements to participate in the MCIT pathway. Some commenters noted that some clinical trials that were conducted to support market authorization through the Breakthrough Devices pathway lack data on patients older than 65, patients with disabilities, and patients with end stage renal disease (ESRD). They asserted that the absence of this clinical information poses some uncertainty about whether FDA's determination of safety and efficacy could be generalized to the Medicare population (86 FR 26850 and 26851, May 18, 2021). CMS acknowledges that after further consideration of public comments, we have changed our position on this issue. In response to commenters' concerns about expedited coverage without adequate evidentiary support, CMS agrees that guaranteeing coverage for all Breakthrough Devices receiving market authorization for any Medicare patient could be problematic if there is no evidence demonstrating a health benefit or addressing the additional risks for Medicare beneficiaries (86 FR 26850 and 26851, May 18, 2021). We noted that a Breakthrough Device may only be beneficial in a subset of the Medicare population or when used only by clinicians within a certain specialty to ensure benefit. Without additional clinical evidence on the device's clinical utility for the Medicare population or appropriate providers, it is challenging to determine appropriate Medicare coverage of newly market-authorized Breakthrough Devices (86 FR 26850 and 26851, May 18, 2021).

We recognize that the breakthrough designation may be granted by FDA before sufficient clinical evidence is available to prove there is a health benefit for Medicare patients. FDA has explained in guidance that because decisions on requests for breakthrough designation will be made prior to marketing authorization, 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'' for purposes of the designation. This reasonable expectation can be ''supported by literature or preliminary data (bench, animal, or clinical)''.[3] Without sufficient

[1] Davide L Vetrano, MD, Katie Palmer, Ph.D., Alessandra Marengoni, MD, Ph.D., Emanuele Marzetti, MD, Ph.D., Fabrizia Lattanzio, MD, Ph.D., Regina Roller-Wirnsberger, MD, MME, Luz Lopez Samaniego, Ph.D., Leocadio Rodríguez-Mañas, MD, Ph.D., Roberto Bernabei, MD, Graziano Onder, MD, Ph.D., Frailty and Multimorbidity: A Systematic Review and Meta-analysis, *The Journals of Gerontology: Series A,* Volume 74, Issue 5, May 2019, Pages 659–666, *https://doi.org/10.1093/gerona/gly110.*

[2] CMS, Guidance for the Public, Industry, and CMS Staff Coverage with Evidence Development, available at *https://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=27.*

[3] Food and Drug Administration, Breakthrough Devices Program Guidance for Industry and Food

evidence developed to show the device improves health outcomes for Medicare beneficiaries, it may be challenging for the Medicare program to determine the health benefit of these devices for Medicare beneficiaries. Public comments expressed concern about how the Medicare population is often excluded from clinical trials due to age and health status.

Previously, in the MCIT/R&N final rule, we noted that ''device coverage under the MCIT pathway is reasonable and necessary for a duration of time under section 1862(a)(1)(A) of the Act because the device has met the very unique criteria of the FDA Breakthrough Devices Program'' (86 FR 2988, January 14, 2021).[4] Through further consideration of the breakthrough designation process, we have changed our position on this issue and determined that Breakthrough Device designation is not, by itself, sufficient for expedited Medicare coverage purposes. Rather, as explained previously, we understand that FDA may grant a device breakthrough designation when the device has shown a ''reasonable expectation'' of providing more effective treatment or diagnosis of a life-threatening or irreversibly debilitating disease or condition relative to the current U.S. SOC and that it meets the other criterion for designation in section 515B(b)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C) Act (21 U.S.C. 360e–3(b)(2)). In turn, we now do not believe it is in the best interest of Medicare beneficiaries to base expedited, multiyear, broad national coverage through section 1862(a)(1)(A) of the Act on this designation alone.

Clinical studies that are conducted in order to gain market authorization for FDA Breakthrough Devices may not always include information on patients with similar demographics and characteristics of the Medicare population. Additionally, there may be devices designated as breakthrough that do not have adequate data on the effectiveness of the device for the Medicare population. Without requiring any evidence specific to the Medicare patients, there may not be any evidence to demonstrate whether the device is beneficial or not after the conclusion of MCIT coverage after 4 years. Without such evidence, it is possible that Medicare would be covering and paying for devices that may have little or no Medicare relevant clinical evidence to assist physicians and patients in making potentially life-saving treatment decisions. Evidence-based coverage policy is essential to our objective of improving health outcomes while delivering greater value. Supportive clinical evidence that ensures a device is both safe and effective and reasonable and necessary in the Medicare population is crucial in order to grant coverage for a device under section 1862(a)(1)(A) of the Act. Such evidence is used to determine whether a new technology meets the appropriateness criteria of the longstanding Medicare Program Integrity Manual Chapter 13 definition of reasonable and necessary.[5] We believe that it is important to require manufacturers participating in an innovative coverage pathway, such as MCIT, to produce evidence that demonstrates the health benefit of the device and the related services for patients with demographics similar to that of the Medicare population.

In response to the March 2021 IFC, some commenters cited evidence that FDA-mandated postmarket studies are not reliably completed (less than 20 percent of required studies are completed within 3 to 5 years after market authorization),[6] and asserted that evidence demonstrating a device's health benefit in Medicare beneficiaries is essential. Commenters also recommended that CMS outline in guidance documents the types of evidence that would be acceptable for applications for national or local coverage determinations once the MCIT pathway's 4 years had expired, such as real-world data or randomized, controlled trials (86 FR 26851, May 18, 2021). By voluntarily developing this evidence during the time a device is covered under the MCIT pathway, the manufacturer could have the evidence base needed for one of the other coverage pathways after the MCIT pathway ends. However, the MCIT/R&N final rule did not require manufacturers of Breakthrough Devices to develop evidence as part of their participation requirements under MCIT. In the May 2021 final rule, we noted that numerous commenters, including physicians with experience in clinical research and medical specialty societies, sought modifications to the MCIT/R&N final rule regarding evidence development, including the addition of real-world evidence requirements.

As was noted by commenters in response to the March 2021 IFC that delayed the MCIT/R&N final rule until December 15, 2021, early and unrestricted adoption of devices may have consequences that may not be easy to reverse. CMS expects physicians to consider the available evidence and assess the care needs of each patient when considering the best treatment options. However, by guaranteeing coverage of devices based solely on breakthrough status and FDA marketing authorization, rather than also taking into account whether the device provides an effective, reasonable and necessary treatment for Medicare patients, there may be an incentive for physicians to use a device that has coverage under the MCIT pathway rather than a device that is not covered under the MCIT pathway but is nonetheless covered under an existing coverage pathway and that may be more beneficial to patients. This early adoption by physicians could potentially lead to these devices being prematurely viewed as the standard of care, which could adversely impact beneficiaries if there is another item or service available to treat the patient that has an evidence-base to suggest that it may lead to better health outcomes. We believe that providers' clinical treatment decisions should take the individual needs of the patient into account; therefore, we seek to avoid the appearance of incentivizing the use of MCIT-covered devices when an alternative item or service may be more appropriate.

While the MCIT/R&N final rule may provide beneficiaries and manufacturers an assurance of national Medicare coverage, evidence development under MCIT as previously finalized is voluntary and there was no requirement that manufacturers conduct studies to generate evidence to demonstrate clinical benefit to Medicare patients. We acknowledge that we no longer believe that voluntary evidence development is in the best interests of Medicare beneficiaries as we believe such evidence is key to determining the best treatments for Medicare patients to ensure that the benefits of treatments outweigh the potential harms. For devices that lack evidence that is generalizable to the Medicare population, we believe it is important for evidence to be developed and some public commenters suggested that we establish the coverage criteria (for example, provider experience, site of service, availability of supporting services) to ensure delivery of high-quality, evidence-based care.

and Drug Administration Staff, 9, available at: *https://www.fda.gov/media/108135/download.*

[4] 86 FR 2988 (January 14, 2021) *available at https://www.govinfo.gov/content/pkg/FR-2021-01-14/pdf/2021-00707.pdf.*

[5] CMS, Medicare Program Integrity Manual, Chapter 13, 13.5.4, *available at https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/pim83c13.pdf.*

[6] Rathi et al.

While we are proposing to repeal the MCIT/R&N final rule, this action would not prohibit coverage of Breakthrough Devices. As we noted in the May 2021 final rule, 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. Many of the eligible Breakthrough Devices are coverable and payable through existing mechanisms. Some Breakthrough Devices may be addressed by an existing LCD or NCD. New items and services can also be adjudicated on a claim-by-claim basis and be covered and paid under the applicable Medicare payment system if the MAC determines them to be reasonable and necessary for specific patients upon a more individualized MAC assessment. The MACs take into account a beneficiary's particular clinical circumstances to determine whether a beneficiary may benefit from the device. CMS acknowledges, among other factors, that MCIT was developed in response to stakeholder concerns about time lags and coverage uncertainty for devices subject to claim-by-claim coverage determinations.

2. Limitations of the MCIT Pathway

The MCIT/R&N final rule limited MCIT only to Breakthrough Devices that are designated as part of FDA's Breakthrough Devices Program. In accordance with section 515B of the FD&C (21 U.S.C. 360e–3), FDA's Breakthrough Devices Program is for certain medical devices and device-led combination products, and can include lab tests.[7] To be granted a Breakthrough Device designation under the Breakthrough Devices Program, medical devices and device-led combination products must meet two criteria. The first criterion is that the device provides for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions. The second criterion is that the device must satisfy one of the following elements:

- It represents a breakthrough technology.
- No approved or cleared alternatives exist.
- It offers significant advantages over existing approved or cleared alternatives.
- Device availability is in the best interest of patients (for more information see 21 U.S.C. 360e–3(b)(2)).

[7] Breakthrough Devices Program Guidance for Industry and Food and Drug Administration Staff, available at *https://www.fda.gov/media/108135/download.*

We acknowledge that some stakeholders, and device manufacturers in particular, supported MCIT and the concept of faster coverage.

Some commenters to the September 2020 MCIT/R&N proposed rule expressed concern that the MCIT pathway could give specific technologies an unfair advantage that would be unavailable to subsequent market entrants, thereby decreasing innovation and market competition (86 FR 2998). Commenters submitted a variety of alternative approaches to covering second-to-market and non-breakthrough designated new technology to remedy this unintended consequence. Some commenters supported that CMS cover iterative refinements of the same Breakthrough Device for the duration of the original device's MCIT term. Other commenters suggested coverage under the MCIT pathway for subsequent similar breakthrough and non-breakthrough designated devices of the same type and indication for the balance of the first device's MCIT term. Yet other commenters proposed that new market entrants that are very similar to a Breakthrough Device should each receive the full 4 years of MCIT coverage, not tied to the timeline of the original product. Commenters also suggested policies related to coverage options for second-to-market or subsequent technologies of the same type, even for the same indication or subsequent-to-market non-breakthrough designated technologies that fall under the same class or category as the predicate breakthrough technology and approved for the same indication.

CMS acknowledges that we have changed our policy position on this issue after further consideration of public comments. We agree with commenters that there are many drawbacks to limiting coverage through the MCIT pathway only to those devices that are part of the Breakthrough Devices Program. As noted previously, the potential incentives created by offering immediate coverage of Breakthrough Devices may disincentivize development of innovative technologies that do not meet the criteria for the Breakthrough Devices Program, such as some non-breakthrough-designated second-to-market devices and subsequent technologies of the same type. Additionally, we now believe a more flexible coverage pathway that leverages existing statutory authorities may be better able to provide faster coverage of new technologies to Medicare beneficiaries while prioritizing patient health and outcomes. CMS invites public comment on our proposal to repeal the MCIT coverage pathway of the MCIT/R&N final rule for the reasons previously described.

3. Future Coverage Policy Rulemaking

While we are proposing to repeal the MCIT/R&N final rule as it is currently written, we are considering future policies and potential rulemaking to provide improved access to innovative and beneficial technologies. We are 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.

B. Definition of ''Reasonable and Necessary''

In general, section 1862(a)(1)(A) of the Act permits Medicare payment under Part A or Part B for items or services that are reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. The definition of ''reasonable and necessary'' in the MCIT/R&N final rule mirrored the longstanding CMS Program Integrity Manual's definition of ''reasonable and necessary'' with a modification to the appropriateness factor to specify when and how (upon publication of guidance) we would utilize commercial insurer coverage policies.

Expanding the reasonable and necessary definition to systematically consider commercial insurer coverage presents implementation and appeals process challenges that would likely persist. In the preamble to the MCIT/R&N final rule, we stated our intention to gather additional public input on the methodology by which commercial insurers' policies are determined to be relevant to the reasonable and necessary appropriateness criteria in response to commenters concerns that the commercial insurer appropriateness criteria was vague. We stated that not later than 12 months after the effective date of the MCIT/R&N final rule (that is, December 15, 2021), we would publish for public comment, a draft methodology for determining when commercial insurers' policies could be considered to meet the reasonable and necessary definition appropriateness criteria for coverage of an item or service. Comments received in response to the March 2021 IFC expressed concern about how the commercial insurer policy provision would be implemented. Commenters also expressed concerns that the R&N definition included in the MCIT/R&N

final rule, and more specifically the commercial insurance aspects of the definition, will remove existing flexibilities and potentially impact CMS' ability to ensure equitable health care access for all Medicare beneficiaries. Additionally, commenters suggested that the reasonable and necessary definition should be included in a separate rule as MCIT because R&N are independent and distinct provisions with different implications for Medicare policy. In light of our proposal to repeal the R&N definition, including the commercial insurance aspects of the MCIT/R&N final rule, we will not be issuing subregulatory guidance by March 15, 2022 on consideration of commercial insurer coverage polices when there is insufficient evidence to make a national or local coverage determination.

While we are proposing to fully repeal the MCIT/R&N final rule as it is currently written, we invite comments on the R&N aspect of our proposal. In lieu of fully repealing the R&N rule, should the final rule instead merely repeal the commercial insurance aspects of the rule? If CMS does consider future rulemaking to include defining reasonable and necessary, what criteria should CMS consider as part of the reasonable and necessary definition? For example, should CMS maintain the codification of the definition of ''Reasonable and Necessary'' as found in the Chapter 13 of the CMS Program Integrity Manual (PIM) or consider different criteria?

C. Effect of Proposed Repeal

If the MCIT/R&N final rule is repealed as proposed, the revisions to part 405 of Title 42 of the Code of Federal Regulations would not occur and the text would remain unchanged. Specifically, a definition of ''reasonable and necessary'' would not be included among the terms defined at 42 CFR 405.201(b) and the guidance that the rule would have required (subregulatory guidance on the topic of utilization of commercial insurer polies) would not be introduced. Additionally, Subpart F, which wholly consisted of Medicare Coverage of Innovative Technology, would not be added, and Subpart F would remain reserved for other purposes.

III. Regulatory Impact Statement

This proposed rule would repeal the MCIT pathway and codification of the definition of ''reasonable and necessary.'' Because the January 2021 final rule effective date was delayed until December 15, 2021, the MCIT coverage pathway and definition of ''reasonable and necessary'' have not been implemented, and no payments for items and services could have been made in relation to these provisions since they have not taken effect. In the January 2021 final rule, we included a robust regulatory impact analysis of these provisions. Because the final rule has not gone into effect, and this proposal would repeal the provisions, there has not been an impact from these provisions nor would there be an impact, relative to current coverage practice, upon repeal; however, effects would be non-negligible relative to the future trajectory without this proposed repeal.

In the MCIT/R&N final rule, we examined the impact of the final rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). The MCIT/R&N 2021 final rule reached the economic threshold and thus was considered a major rule. Because this proposed rule would completely repeal the provisions, this proposed rule also reaches the economic threshold and its finalization is anticipated to be a major rule.

A. MCIT Pathway

CMS considered alternatives to repealing the MCIT pathway and the definition of reasonable and necessary, such as maintaining the provisions of the MCIT/R&N final rule and further delaying the effective date. For the reasons described in detail in section II. of this proposed rule such as patient safety and need for further public engagement, we chose to propose to repeal the provisions. We note that further delay of the MCIT/R&N final rule would not alter the patient safety concerns inherent in the MCIT pathway.

As described in the MCIT/R&N final rule, the impacts of the MCIT pathway and defining ''reasonable and necessary'' were hard to quantify without knowing the specific Breakthrough Devices that would seek MCIT and other items and services that would be included in future NCDs and LCDs and the criteria that CMS will use for determining which commercial insurers will be considered.

B. ''Reasonable and Necessary'' Definition

In order to demonstrate the potential impact on Medicare spending for the definition of ''reasonable and necessary'' in the MCIT/R&N final rule we developed scenarios that illustrated the impact of implementing the two alternatives considered (no change/not codifying a definition and codifying a definition). One of the options was making no change, that is not codifying the definition of ''reasonable and necessary'' in regulations. The impact for no change was $0, thus, we reflect that value in Table 1 as repealing the MCIT/R&N final rule would have the same impact. The number of NCDs and LCDs finalized in a given year can vary and the cost of items and services within the coverage decisions varies. Further, while we reviewed coverage of items and services, we did not take into account unique Medicare rules regarding which type of providers/clinicians may furnish certain services, place of service requirements, or payment rules. Our analysis was based on whether Medicare covered or non-covered an item or service and whether we could find coverage for that item or service by any commercial insurer. Lastly, this impact analysis was based on the numbers of NCDs and LCDs finalized in 2020 (see Table 1).

In 2020, CMS and the MACs finalized 3 NCDs and 31 LCDs (This number represents new LCDs in 2020 and made publicly available via the Medicare Coverage Database. If more than one MAC jurisdiction issued an LCD on the same item or service with the same coverage decision, only 1 of the LCDs was included in the count.)

Of the NCDs finalized in 2020, all 3 resulted in expanded national Medicare coverage. Because none of those NCDs resulted in non-coverage, we did not evaluate whether commercial insurers would have covered the item or service. Therefore, based on 2020 data for NCDs only, the impact would be $0.

Of the 31 LCDs, 27 provided Medicare positive coverage and 4 resulted in non-coverage. For those items and services non-covered we identified 3 of those items and services were covered in at least 1 commercial insurer policy. For these non-covered items and services we established that the possible range of the cumulative cost of covering them could be from $0 to $3.4 billion for a single year (based on price and approximate Medicare beneficiary utilization). Because our analysis looked for any commercial insurer that covered the item or service, the cost may be less when utilizing commercial insurer polices that represent a majority of covered lives. In addition, even if a commercial insurer covers an item or service, the final rule did not require automatic Medicare coverage. Therefore, not all items and services that are non-covered by Medicare but covered by commercial insurance would be presumed covered under the MCIT/R&N final rule. Rather, commercial insurer coverage would have been a factor that CMS would have taken into account as part of the body of evidence in determining coverage through the NCD and LCDs processes. Because not all commercial insurer positive coverage will necessarily translate to Medicare coverage and because CMS was to define which types of commercial insurers (based on majority of covered lives) would be relevant, we believe that commercial insurer coverage impact is likely much smaller, closer to 15 to 25 percent of $3.4 billion, that is, $51 to $880 million.

TABLE 1—ILLUSTRATED IMPACT FOR THE MEDICARE PROGRAM BY DEFINITION OF REASONABLE AND NECESSARY

	Estimated change in Medicare costs for the alternatives considered for the MCIT/R&N final rule		Commercial insurer coverage as sole determinant
	No change (not codifying a definition)	Codified definition	
Coverage Determinations (NCDs and LCDs).	$0	$51–880 million	$3.4+ billion.

C. MCIT Pathway

In the MCIT/R&N final rule specifically for MCIT, we considered regulatory alternatives to combine Medicare coverage with clinical evidence development under section 1862(a)(1)(E) of the Act, to take no regulatory action, or to adjust the duration of the MCIT pathway. The impact of implementing the MCIT pathway was difficult to determine without knowing the specific Breakthrough Devices that would be covered. In addition, many of these devices would be eligible for coverage in the absence of the rule, such as through a local or national coverage determination, so the impact for certain items may be the acceleration of coverage by just a few months. Furthermore, some of these devices would be covered immediately if the MACs decide to pay for them, which would result in no impact on Medicare spending for devices approved under this pathway. However, it is possible that some of these Breakthrough Devices would not otherwise be eligible for coverage in the absence of the rule. Because it was not known how these new technologies would otherwise come to market and be reimbursed, it was not possible to develop a point estimate of the impact. In general, we believed the MCIT coverage pathway would range in impact from having no impact on Medicare spending, to a temporary cost for innovations that are adopted under an accelerated basis.

The decision to enter the MCIT pathway would have been voluntary for the manufacturer. Because manufacturers typically join the Medicare coverage pathway that is most financially beneficial to them, this could result in selection against the existing program coverage pathways (to what degree is unknown at this point). In addition, the past trend of new technology costing more than existing technology could lead to a higher cost for Medicare if this trend continued for technologies enrolling in the MCIT pathway. Nevertheless, new technology may also mitigate ongoing chronic health issues or improve efficiency of services thereby reducing some costs for Medicare.

To demonstrate the potential impact on Medicare spending, for the MCIT/R&N final rule the CMS Office of the Actuary (OACT) developed three hypothetical scenarios that illustrate the impact of implementing the MCIT pathway. Scenarios two and three assumed that the device would not have been eligible for coverage in the absence of the proposed rule (see Table 2). The illustration used the new devices that applied for a NTAP in FY 2020 as a proxy for the new devices that would utilize the MCIT pathway. The submitted cost and anticipated utilization for these devices was published in the **Federal Register**.[8] In addition, we assumed that two manufacturers would elect to utilize the MCIT pathway in the first year, three manufacturers in the second year, four manufacturers in the third year, and five manufacturers in the fourth year each year for all three scenarios. This assumption is based on the number of medical devices that received FY 2020 NTAP and were non-covered in at least one MAC jurisdiction by LCDs and related articles and our impression from the FDA that the number of devices granted breakthrough status is increasing. For the first scenario, the no-cost scenario, we assumed that all the devices would be eligible for coverage in the absence of MCIT. If the devices received coverage and payment nationally and at the same time then there would be no additional cost under this pathway. For the second scenario, the low-cost scenario, we assumed that the new technologies would have the average costs ($2,044) and utilization (2,322 patients) of similar technologies included in the FY 2020 NTAP application cycle. Therefore, to estimate the first year of MCIT, we multiplied the add-on payment for a new device by the anticipated utilization for a new device by the number of anticipated devices in the pathway ($2,044 × 2,322 × 2 = $ 9.5 million). For the third scenario, the high-cost scenario, we assumed the new technologies would receive the maximum add-on payment from the FY2020 NTAP application cycle ($22,425) and the highest utilization of a device (6,500 patients). Therefore, to estimate for the first year of MCIT, we estimated similarly ($22,425 × 6,500 patients × 2 = $ 291.5 million). For subsequent years, we increased the number of anticipated devices in the

[8] FY 2020 Hospital Inpatient Prospective Payment System (IPPS) Proposed Rule (84 FR 19640 and 19641) (May 3, 2019) *available at https://www.govinfo.gov/content/pkg/FR-2019-05-03/pdf/2019-08330.pdf* (accessed October 17, 2019).

pathway by three, four, and five in the last two scenarios until 2024.[9] In addition to not taking into account inflation, the illustration does not reflect any offsets for the costs of these technologies that would be utilized through existing authorities nor the cost of other treatments (except as noted). It is not possible to explicitly quantify these offsetting costs but they could substantially reduce or eliminate the net program cost. However, by assuming that only two to five manufacturers would elect MCIT coverage, we implicitly assumed that, while more manufacturers could potentially elect coverage under MCIT, the majority of devices would have been covered under a different coverage pathway. Therefore, a substantial portion of the offsetting costs are implicitly reflected.

Based on this analysis, there was a range of potential impacts of MCIT as shown in Table 2. The difference between the three estimates demonstrates how sensitive the impact is to the cost and utilization of these unknown devices.

Because MCIT has not yet been implemented, we lack evidence with which to update the earlier estimates, so Table 2, only differs from the analogous table accompanying the MCIT/R&N final rule in terms of the sign (that is, the direction) on the estimates and a shifting of the time horizon by one year so as to avoid stating this proposed rule would have effects in the nearly-ended FY 2021.

TABLE 2—ILLUSTRATED IMPACT ON THE MEDICARE PROGRAM BY MCIT COVERAGE PATHWAY

	Costs (in millions)			
	FY 2022	FY 2023	FY 2024	FY 2025
No-cost Scenario	$0	$0	$0	$0
Low-cost Scenario	−9.5	−23.7	−42.7	−66.4
High-cost Scenario	−291.5	−728.8	−1,311.9	−2,040.7

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Some hospitals and other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $7.5 million to $38.5 million in any 1 year. Individuals and States are not included in the definition of a small entity. For the MCIT/R&N final rule, we reviewed the Small Business Administration's Table of Small Business Size Standards Matched to North American Industry Classification System (NAICS) Codes to determine the NAICS U.S. industry titles and size standards in millions of dollars and/or number of employees that apply to small businesses that could be impacted by this rule. We determined that small businesses potentially impacted by that rule include surgical and medical instrument manufacturers (NAICS code 339112, dollars not provided/1,000 employees), Offices of Physicians (except Mental Health Specialists) (NAICS code 621111, $12 million/employees not provided), and Freestanding Ambulatory Surgical and Emergency Centers (NAICS code 621493, $16.5 million/employees not provided). Because the impact of this proposed rule would be no change in current coverage policy, we determined that small businesses identified would not be impacted by this proposed rule. Given the nature of the breakthrough devices market authorized thus far and the timely notification of the MCIT/R&N final rule's delay of effective date, we do not anticipate that small businesses would have made investment decisions or experienced a loss of anticipated positive reimbursement as a result of the MCIT/R&N final rule. Because MCIT has not gone into effect, and we are proposing to repeal the rule, payments have not occurred nor would they occur under MCIT; therefore, the impact of this proposed rule is neither an increase nor decrease in revenue for providers. We are not preparing a further analysis for the RFA because we have determined, and the Secretary of the Department of Health and Human Services (the Secretary) certifies, that the proposed rule and this subsequent final rule will not have a significant negative economic impact on a substantial number of small entities because small entities are not being asked to undertake additional effort or take on additional costs outside of the ordinary course of business.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that the proposed rule and the final rule would not have a significant impact on the operations of a substantial number of small rural hospitals because small rural hospitals are not being asked to undertake additional effort or take on additional costs outside of the ordinary course of business. Obtaining Breakthrough Devices for patients is at the discretion of providers. We are not requiring the purchase and use of Breakthrough Devices. Providers should continue to work with their patients to choose the best treatment. For small rural hospitals that provide Breakthrough Devices to their patients, this proposed rule would not change the way they are currently covered through the Medicare program.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2021, that threshold was

[9] An indirect cost of the proposed rule would be increased distortions in the labor markets taxed to support the Medicare Trust Fund. Such distortions are sometimes referred to as marginal excess tax burden (METB), and Circular A–94—OMB's guidance on cost-benefit analysis of federal programs, available at *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A94/a094.pdf*—suggests that METB may be valued at roughly 25 percent of the estimated transfer attributed to a policy change; the Circular goes on to direct the inclusion of estimated METB change in supplementary analyses. If secondary costs—such as increased marginal excess tax burden is, in the case of this final rule—are included in regulatory impact analyses, then secondary benefits must be as well, in order to avoid inappropriately skewing the net benefits results, and including METB only in supplementary analyses provides some acknowledgement of this potential imbalance.

approximately $158 million. This proposed rule would have no consequential effect on State, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Since this final rule does not impose any costs on State or local governments, the requirements of Executive Order 13132 are not applicable.

In accordance with the provisions of Executive Order 12866, this final rule was reviewed by the Office of Management and Budget.

IV. Waiver of the 60-Day Public Comment Period

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) (5 U.S.C. 553(b). Section 1871(a)(2) of the Act provides, in relevant part, that no rule, requirement, or other statement of policy that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under Medicare shall take effect unless it is promulgated through notice and comment rulemaking. Unless there is a statutory exception, section 1871(b)(1) of the Act generally requires the Secretary to provide a period of not less than 60 days for public comment. Similarly, under 5 U.S.C. 553(b), the agency is required to publish a notice of proposed rulemaking in the **Federal Register** before a substantive rule takes effect.

However, section 1871(b)(2) of the Act, permits exceptions to the 60-day time period, including in situations where there would be good cause under 5 U.S.C. 553(b). Section 553(b) of the APA permits no public comment period when the agency, for good cause, finds the notice and public procedure are impracticable, unnecessary, or contrary to the public interest. We find good cause to reduce the public comment period to 30 days with respect to the proposed repeal of the MCIT/R&N final rule that would otherwise become effective on December 15, 2021. If we were to provide the full 60-day public comment period on this proposed rule, there would not be adequate opportunity to meaningfully consider public comments before a final action was needed. In addition, we have already provided two opportunities for public comments relating to the subject matter of this rule earlier this year in connection with the delay of the effective date. Although repealing a final rule is different than delaying the effective date, the familiarity with the subject matter reduces the time the public needs to formulate comments on this proposed rule. Based on the prior comment periods, we are aware that some public commenters opposed to the MCIT/R&N final rule are likely to support repeal, while other commenters were in favor of implementing that rule. The 30-day public comment period will provide another opportunity to submit views on the proposed repeal, as well as suggestions for future rulemaking. Under these specific circumstances, we find that a 60-day comment period is unnecessary and a 30-day public comment period will provide a sufficient opportunity for the public to fully participate in this rulemaking and that there is good cause to reduce the time period to 30 days.

We also find good cause to provide for a 30-day public comment period in light of the potential for harm to Medicare beneficiaries should this proposed repeal rule not be finalized before the effective date of the MCIT/R&N final rule. If we did not finalize this rule by the effective date, there would be confusion and uncertainty among beneficiaries and their treating clinicians of coverage if the proposed repeal rule became effective and then rescinded at a later date. To avoid confusion and uncertainty this rule must be finalized no later than December 15, 2021. In order for the repeal rule to be finalized by the current MCIT effective date of December 15, 2021, CMS would require 30 days for public comment once the proposed rule is posted, an additional 30 days for CMS to review the comments, draft and post the repeal final rule, and an additional 30-day notice before the repeal final rule becomes effective.

As noted previously, the MCIT/R&N final rule did not have sufficient patient protections. While the MCIT/R&N rule attempted to address concerns about accelerating coverage of new devices, significant concerns persist about the availability of clinical evidence on the devices when used in the Medicare population, including the benefit or risks of these devices with respect to use in the Medicare population. For example, there is no requirement that the studies for FDA market-approval include Medicare patients. Medicare patients have different clinical profiles and considerations due to the complexity of their medical conditions and concomitant treatments compared to other age groups. Further, the MCIT/R&N final rule takes away tools that CMS has to deny coverage when it becomes apparent that a particular device can be harmful to the Medicare population. To remove a device from Medicare coverage under MCIT/R&N final rule, FDA must issue a safety communication, warning letter, or remove the device from the market. Therefore, if CMS observes a trend of higher risk or harm with a device in the Medicare population, CMS authority to expeditiously deny, limit to the appropriate patient population or withdraw coverage is limited.

For all the aforementioned reasons, we find good cause to waive the 60-day comment period and provide a 30-day comment period for this proposed rule.

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. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on September 10, 2021.

List of Subjects in 42 CFR Part 405

Administrative practice and procedure, Diseases, Health facilities, Health professions, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR part 405 as set forth below:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

■ 1. The authority for part 405 continues to read as follows:

Authority: 42 U.S.C. 263a, 405(a), 1302, 1320b–12, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr, and 1395ww(k).

§ 405.201 [Amended]

■ 2. Section 405.201(b) is amended by removing the definition for ''Reasonable and necessary''.

Subpart F—[Removed and Reserved]

■ 3. Remove and reserve subpart F, consisting of §§ 405.601 through 405.607.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2021–20016 Filed 9–13–21; 4:15 pm]

BILLING CODE 4120–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 1, 2, 27

[WT Docket No. 19–348; DA 21–1024; FRS 44893]

Wireless Telecommunications Bureau Seeks Comment on the Selection Process for and Operation of the Reimbursement Clearinghouse for the 3.45 GHz Band

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: In this document, the Wireless Telecommunications Bureau (the Bureau) seeks comment on the appropriate industry stakeholders to form a search committee to select a Reimbursement Clearinghouse (Clearinghouse) to oversee the reimbursement of relocation expenses for certain secondary non-federal radiolocation licensees in the 3.45–3.55 GHz band (3.45 GHz band). The Bureau also seeks comment on other issues related to the Clearinghouse search committee process.

DATES: Interested parties may file comments on or before September 30, 2021; and reply comments on or before October 12, 2021.

ADDRESSES: You may submit comments, identified by WT Docket No. 19–348, by any of the following methods:

- *Electronic Filers:* Comments may be filed electronically using the internet by accessing the ECFS: *http://apps.fcc.gov/ecfs/* in docket number WT Docket No. 19–348. *See Electronic Filing of Documents in Rulemaking Proceedings,* 63 FR 24121 (1998).
- *Paper Filers:* Parties who choose to file by paper must file an original and one copy of each filing.
- Filings in response to this Public Notice may be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail. All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.
- Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9050 Junction Drive, Annapolis Junction, MD 20701. U.S. Postal Service first-class, Express, and Priority mail must be addressed to 45 L Street NE, Washington, DC 20554.
- Until further notice, the Commission no longer accepts any hand or messenger delivered filings. This is a temporary measure taken to help protect the health and safety of individuals, and to mitigate the transmission of COVID–19. *See FCC Announces Closure of FCC Headquarters Open Window and Change in Hand-Delivery Policy,* Public Notice, DA 20–304 (March 19, 2020). *https://www.fcc.gov/document/fcc-closes-headquarters-open-window-and-changes-hand-delivery-policy*.

FOR FURTHER INFORMATION CONTACT: Joyce Jones, Wireless Telecommunications Bureau, Mobility Division, (202) 418–1327 or *joyce.jones@fcc.gov*. For information regarding the PRA information collection requirements, contact Cathy Williams, Office of Managing Director, at 202–418–2918 or *Cathy.Williams@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of a Public Notice in WT Docket No. 19–348, DA 21–1024, released August 20, 2021. The full text of the Public Notice is available for public inspection at the following internet address: *https://www.fcc.gov/document/345-ghz-clearinghouse-search-committee-public-notice.* Alternative formats are available for people with disabilities (Braille, large print, electronic files, audio format), by sending an email to *FCC504@fcc.gov* or calling the Consumer and Governmental Affairs Bureau at 202–418–0530 (voice) or 202–418–0432 (TTY). Pursuant to §§ 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415, 1.419, interested parties may file comments on or before the dates indicated on the first page of this document.

Ex Parte Rules

This proceeding shall continue to be treated as a ''permit-but-disclose'' proceeding in accordance with the Commission's *ex parte* rules (47 CFR 1.1200). Persons making *ex parte* presentations must file a copy of any written presentation or a memorandum summarizing any oral presentation within two business days after the presentation (unless a different deadline applicable to the Sunshine period applies). Persons making oral *ex parte* presentations are reminded that memoranda summarizing the presentation must (1) list all persons attending or otherwise participating in the meeting at which the *ex parte* presentation was made, and (2) summarize all data presented and arguments made during the presentation. If the presentation consisted in whole or in part of the presentation of data or arguments already reflected in the presenter's written comments, memoranda or other filings in the proceeding, the presenter may provide citations to such data or arguments in his or her prior comments, memoranda, or other filings (specifying the relevant page and/or paragraph numbers where such data or arguments can be found) in lieu of summarizing them in the memorandum. Documents shown or given to Commission staff during *ex parte* meetings are deemed to be written *ex parte* presentations and must be filed consistent with rule 1.1206(b). In proceedings governed by rule 1.49(f) or for which the Commission has made available a method of electronic filing, written *ex parte* presentations and memoranda summarizing oral *ex parte* presentations, and all attachments thereto, must be filed through the electronic comment filing system available for that proceeding, and must be filed in their native format (*e.g.,* .doc, .xml, .ppt, searchable .pdf). Participants in this proceeding should familiarize themselves with the Commission's *ex parte* rules.

Supplemental Initial Regulatory Flexibility Analysis

As required by the Regulatory Flexibility Act of 1980 (RFA), the Bureau has prepared a Supplemental Initial Regulatory Flexibility Analysis (IRFA) of the possible significant economic impact on small entities of the policies and requirements proposed in the Public Notice. It requests written public comment on the Supplemental IRFA contained in the Public Notice. Comments must be filed in accordance with the same deadlines as comments filed in response to the Public Notice as set forth on the first page of this document and have a separate and distinct heading designating them as responses to the Supplemental IRFA. The Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, will send a copy of the Public Notice, including the Supplemental IRFA, to the Chief Counsel for Advocacy of the Small Business Administration.

Paperwork Reduction Act Analysis

This document contains proposed information collection requirements.