To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.*

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–10638 Add-On Payments for New Medical Services and Technologies Paid Under the Inpatient Prospective Payment System (IPPS)

Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires Federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Add-On Payments for New Medical Services and Technologies Paid Under the Inpatient Prospective Payment System (IPPS); *Use:* Sections 1886(d)(5)(K) and (L) of the Act establish a process of identifying and ensuring adequate payment for new medical services and technologies (sometimes collectively referred to in this section as ''new technologies'') under the Inpatient Prospective Payment System (IPPS). Section 1886(d)(5)(K)(vi) of the Act specifies that a medical service or technology will be considered new if it meets criteria established by the Secretary after notice and opportunity for public comment. Section 1886(d)(5)(K)(ii)(I) of the Act specifies that a new medical service or technology may be considered for NTAP if, ''based on the estimated costs incurred with respect to discharges involving such service or technology, the DRG prospective payment rate otherwise applicable to such discharges under this subsection is inadequate.''

In order to qualify for NTAP under the traditional pathway, a specific technology must be ''new'' and demonstrate that they are not substantially similar to existing technologies under the requirements of § 412.87(b)(2) of our regulations. The statutory provision contemplated the special payment treatment for new technologies until such time as data are available to reflect the cost of the technology in the DRG weights through recalibration (no less than 2 years and no more than 3 years). Alternative pathway technologies must also be ''new'' but are considered not substantially similar to existing technologies. Responses to the questions in the application help CMS determine if and how the applicant meets the established. *Form Number:* CMS–10638 (OMB control number: 0938–1347); *Frequency:* Yearly; *Affected Public:* Private Sector, Business or other for-profits and Not-for-profits institutions; *Number of Respondents:* 62; *Number of Responses:* 62; *Total Annual Hours:* 1,655. (For policy questions regarding this collection contact Sophia Chan at 410–786–8348.)

Dated: June 22, 2023.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2023–13659 Filed 6–26–23; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3421–NC]

Medicare Program; Transitional Coverage for Emerging Technologies

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

ACTION: Notice with comment period.

SUMMARY: This notice with comment period provides information to the public on the process we will use to provide transitional coverage for emerging technologies (TCET) through the national coverage determination (NCD) process under the Social Security Act (the Act). It also solicits public comment on the proposed TCET pathway.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, by 5 p.m. on August 28, 2023.

ADDRESSES: In commenting, refer to file code CMS–3421–NC.

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 regulatory document to *https://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–3421–NC, 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–3421–NC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

FOR FURTHER INFORMATION CONTACT: Lori Ashby, (410) 786–6322.

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: *https://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

This notice describes the process we will use to provide transitional coverage for emerging technologies (TCET) through the national coverage determination (NCD) process. The TCET pathway is designed to deliver transparent, predictable, and expedited national coverage for certain eligible Breakthrough Devices that are Food and Drug Administration (FDA) market authorized. It builds upon the Centers for Medicare & Medicaid Services' (CMS') experience with the Parallel Review program and the Coverage with Evidence Development (CED) pathway. Additionally, the TCET pathway reflects the feedback received from multiple stakeholder groups, including beneficiaries, patient groups, medical professionals and societies, medical device manufacturers, other Federal partners, and others involved in developing innovative medical devices. This feedback was obtained from informal and formal meetings, the comments we received as we conducted rulemaking for the Medicare Coverage of Innovative Technologies (MCIT) pathway (referenced later in this section) as well as during the listening sessions that were held following the repeal of the MCIT/Reasonable and Necessary (R&N) final rule (86 FR 62944, November 15, 2021). The TCET pathway described in this notice is intended to balance multiple considerations when making coverage determinations: (1) facilitating early, predictable and safe beneficiary access to new technologies; (2) reducing uncertainty about coverage by evaluating early the potential benefits and harms of technologies with innovators; and (3) encouraging evidence development if notable evidence gaps exist for coverage purposes. Further, the TCET pathway aims to coordinate benefit category determination, coding, and payment reviews and to allow any evidence gaps to be addressed through fit-for-purpose studies.

The Medicare program serves over 62 million beneficiaries and is the largest single health care purchaser in the U.S. Currently, approximately 60 percent of the total Medicare beneficiary population, or 36 million Medicare beneficiaries, receive coverage through Medicare fee-for-service (FFS). More than 1.1 billion Medicare FFS claims were processed in fiscal year (FY) 2021, comprised of approximately 221 million Part A claims (such as inpatient care in hospitals, skilled nursing facility care, hospice care, and home health care) and 956 million Part B claims (such as doctor and other health care services and outpatient care, durable medical equipment, and some preventive services), providing approximately $424 billion in Medicare FFS benefits.[1]

Medicare covers a wide range of items and services. In general, in order for an item or service to be covered under Medicare, it must meet the standard described in section 1862(a)(1)(A) of the Social Security Act (the Act)—that is, it must be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. CMS makes reasonable and necessary coverage decisions through various pathways in order to facilitate expeditious beneficiary access to items and services that meet the statutory standard for coverage. We recognize that new approaches are needed to make decisions on certain new items and services, such as medical devices, more quickly to provide expedited access to new and innovative medical technologies. On November 15, 2021 (86 FR 62944), CMS published a final rule that repealed an earlier rule that never became legally effective and thus was not implemented.[2] As promised in the repeal, CMS has conducted additional opportunities to engage with the public and stakeholders. We have incorporated that input, along with input gathered in MCIT rulemaking, into our plans to improve the Medicare coverage process when making decisions on certain emerging technologies at the national level.

One of the issues identified in the prior rulemaking was that the agency did not adequately address how certain steps, which are necessary to implement national coverage determinations for a new item or service, would be accomplished in a timely manner. Specifically, under the Medicare program an item or service must fall within the parameters of a benefit category that is within the scope of Part A or Part B. Commenters have requested that CMS explain how benefit category determinations (BCDs) will be made in connection with emerging technology. CMS was also encouraged to align coding and payment processes to facilitate coverage and payment for new or emerging technologies.

Over the last several years, stakeholders have expressed support for coverage process improvements and a new pathway that is more flexible, transparent, predictable, and collaborative. Additionally, stakeholders expressed that that they would like for CMS to develop a more agile, iterative evidence review process that considers real world evidence and fit-for-purpose evidence study designs. Further, we have heard concerns from stakeholders that device coverage lags further behind that of drugs and biologics and, devices are more in need of a program like TCET. In light of the unique FDA criteria for Breakthrough designation status (described later in this document), we are limiting the TCET pathway to certain eligible FDA-designated Breakthrough Devices, since we believe that this is the area with the most immediate need.

We are committed to establishing an alternative coverage pathway that better balances the needs of beneficiaries, patient groups, medical professionals and societies, medical device manufacturers, and others involved in developing innovative medical devices.

A. Current Medicare Coverage Mechanisms

Items and services, including medical devices, are currently covered in Medicare in one of three ways, presented here for context. The TCET pathway described in this notice will leverage the existing NCD pathway, and CED in particular, to provide a streamlined coverage pathway for emerging technologies. We note that the TCET pathway will not alter the existing standards for these coverage mechanisms.

1. Claim-by-Claim Adjudication

In the absence of an NCD or a local coverage determination (LCD), Medicare Administrative Contractors (MACs) make coverage decisions under section 1862(a)(1)(A) of the Act and may cover items and services on a claim-by-claim basis if the MAC determines them to be reasonable and necessary for individual patients. Though claims may be denied if they are not determined to be reasonable and necessary, the claim-by-claim adjudication pathway remains the fastest path to potential coverage. The majority of all Medicare Parts A and B claims have coverage determined through the claim-by-claim adjudication process.

2. Local Coverage Determinations (LCDs)

MACs develop LCDs under section 1862(a)(1)(A) that apply only within their geographic jurisdictions (see sections 1862(l)(6)(B) and 1869(f)(2)(B) of the Act). LCDs govern only the issuing MAC's claims adjudication and

[1] *https://www.cms.gov/Medicare/Medicare-Contracting/Medicare-Administrative-Contractors/What-is-a-MAC.*

[2] *https://www.govinfo.gov/content/pkg/FR-2021-11-15/pdf/2021-24916.pdf.*

are not controlling authorities for qualified independent contractors or administrative law judges in the claims adjudication process.

The MACs follow specific guidance for developing LCDs for Medicare coverage as outlined in the CMS Program Integrity Manual (PIM), Chapter 13. LCDs generally take 9 to 12 months to develop. MACs usually finalize proposed LCDs within 365 days from opening, per Chapter 13.5.1—Local Coverage of the PIM.[3] That chapter will continue to be used in making determinations under section 1862(a)(1)(A) of the Act for items and services at the local level.

3. National Coverage Determinations (NCDs)

The term ''national coverage determination'' is defined in section 1862(l)(6)(A) of the Act and means a determination by the Secretary of the Department of Health and Human Services (the Secretary) with respect to whether or not a particular item or service is covered nationally under Title XVIII of the Act. In general, NCDs are national policy statements published to identify the circumstances under which a particular item or service will be considered covered (or not covered) by Medicare. NCDs serve as generally applicable rules to ensure that similar claims for items or services are covered in the same manner. Often an NCD is written in terms of defined clinical characteristics that identify a population that may or may not receive Medicare coverage for a particular item or service. Traditionally, CMS relies heavily on health outcomes data to make NCDs.

Most NCDs have involved determinations under section 1862(a)(1)(A) of the Act, but NCDs can be made based on other provisions of the Act, such as section 1862(a)(1)(E) of the Act. Under section 1862(a)(1)(E) of the Act, Medicare has provided coverage for certain promising technologies with a limited evidence base on the condition that they are furnished in the context of approved clinical studies or with the collection of additional clinical data. CMS has used section 1862(a)(1)(E) of the Act to support the ''Coverage with Evidence Development'' or ''CED'' policy since July 12, 2006, and the most recent CED policy is described in our November 20, 2014 guidance document.[4] In general, CED enables providers and suppliers to perform high quality studies that we expect will produce evidence that may lead to positive national coverage determinations under section 1862(a)(1)(A) of the Act.

The Agency for Healthcare Research and Quality (AHRQ) reviews all CED NCDs established under section 1862(a)(1)(E) of the Act. Consistent with section 1142 of the Act, AHRQ collaborates with CMS to define standards for the clinical research studies to address the CED questions and meet the general standards for CED studies (*https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development*).

NCDs also include a determination on whether the item or service under consideration has a Medicare benefit category under Part A or Part B,[5] such as inpatient hospital services, physicians' services, durable medical equipment, or others. All items and services coverable by Medicare must fall within the scope of a statutory benefit category and many of these specific terms are defined under section 1861 of the Act and in implementing regulations. BCDs are made outside the Coverage and Analysis Group. While they may often be completed within 3 months, in some cases BCDs may take considerably longer. While CMS is working to better align the coverage and BCD review processes, manufacturers should be aware that in some cases benefit category reviews may not be completed within the accelerated timeframes needed for the TCET pathway. Moreover, in order to be covered, the item or service must not be excluded from coverage by statute or our regulations at 42 CFR part 411, subpart A. The NCD pathway, which has statutorily prescribed timeframes, generally takes 9 to 12 months to complete.[6]

In addition to these coverage pathways, CMS has established a Clinical Trial Policy (CTP) NCD 310.1. The CTP policy is applied when Medicare covers routine care items and services (but generally not the technology under investigation) in a clinical study that is supported by certain Federal agencies. The CTP coverage policy was developed in 2000.[7] We note that coverage under CED and the CTP may not occur at the same time. Additionally, this coverage policy has not generally been utilized by device manufacturers because they usually seek coverage of the device under investigation, which is not always available under the CTP.

Lastly, CMS has established the Parallel Review program. In the September 17, 2010 **Federal Register** (75 FR 57045), FDA and CMS announced their intention to initiate a Parallel Review pilot program in an effort to increase quality of patient health care by facilitating earlier access to innovative medical technologies for Medicare beneficiaries. In the October 24, 2016 **Federal Register** (81 FR 73113), FDA and CMS published a joint notice that announced and described the processes for the fully implemented Program for Parallel Review of Medical Devices.

Parallel Review is a mechanism for FDA and CMS to simultaneously review the clinical data submitted by a manufacturer about a medical device in order to help decrease the time between FDA's approval of an original or supplemental premarket approval (PMA) application or granting of a de novo classification request (De Novo request) and the subsequent CMS proposed NCD. Parallel Review has two stages: (1) FDA and CMS meet with the manufacturer to provide feedback on the proposed pivotal clinical trial; and (2) FDA and CMS concurrently review (''in parallel'') the clinical trial results submitted in the PMA application, or De Novo request. FDA and CMS independently review the data to determine whether it meets their respective Agency's standards and communicate with the manufacturer during their respective reviews. This program relies upon a technology having a quality evidence base to support the clinical analysis for the NCD.

B. Differences Between FDA and CMS Review

While FDA and CMS have a well-established history of collaboration in review of evidence for emerging medical technologies, FDA and CMS must consider different legal authorities and apply different statutory standards when making marketing authorization and coverage decisions, respectively, for medical devices. Generally, FDA makes marketing authorization decisions based on whether the relevant statutory standard for safety and effectiveness is met, while CMS generally makes NCDs based on whether an item or service is reasonable and necessary for the diagnosis or treatment of an illness or

[3] CMS Program Integrity Manual, Chapter 13 Local Coverage Determinations, available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/pim83c13.pdf.*

[4] The 2014 guidance document is available at *https://www.cms.gov/medicare-coverage-database/view/medicare-coverage-document.aspx?MCDId=27.*

[5] Note: Medicare does not develop NCDs for Part D.

[6] Section 1869(f)(4) of the Act.

[7] CMS, National Coverage Determination for Routine Costs in Clinical Trials available at *https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=1&fromdb=true.*

injury for individuals in the Medicare population.

These two reviews are separate and are conducted independently by the two agencies. At CMS, we respect the findings of our FDA colleagues and appreciate the expertise they bring to the premarket review process under the Federal Food, Drug, and Cosmetic Act (FD&C Act). The FDA review of devices does not focus specifically on the Medicare population.

Among other objectives, FDA conducts premarket review of certain devices to evaluate their safety and effectiveness and determine if they meet the applicable standard to be marketed in the United States. An FDA-regulated product must receive marketing authorization [8] (unless exempt from FDA premarket review) for at least one indication to be eligible for consideration of Medicare coverage (except in specific circumstances). However, FDA approval or clearance alone does not entitle that technology to Medicare coverage, given Medicare statutory coverage requirements. While FDA reviews devices to ensure they meet applicable safety and effectiveness standards, there is often limited evidence regarding whether the device is clinically beneficial for Medicare patients specifically because of the lack of evidence concerning individuals in the Medicare population. This is an important consideration for manufacturers and other interested parties who are seeking the most appropriate coverage pathway under Medicare. Where there is limited evidence on the health outcomes for individuals in the Medicare population, there may be insufficient evidence to support a fully favorable Medicare national coverage determination under section 1862(a)(1)(A) of the Act. In these instances, it is difficult to make a prospective national reasonable and necessary determination as to whether Medicare should cover the device with evidence development or should limit the NCD to coverage for only individuals with certain conditions or procedures performed by certain practitioners or health care facilities with expertise necessary to safely treat the individual with the new technology.

In general, as discussed, under the Medicare statute (section 1862(a)(1)(A) of the Act), Congress required CMS to determine 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 for an individual with Medicare. For CMS, the evidence base underlying FDA's decision to approve or clear a device for particular indications for use has often been crucial for determining Medicare coverage through the NCD process. CMS looks to the evidence supporting FDA market authorization and the device's approved or cleared 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 in the Medicare population, it is difficult for CMS to make an evidence-based decision whether the device is reasonable and necessary for the Medicare population.

Because Medicare beneficiaries are often older, with multiple comorbidities, and are often underrepresented or not represented in many clinical studies, CMS considers whether the evidence shows that the item or service will improve the health of Medicare patients.[9] According to a recent study,[10] [11] approximately 50 percent of Medicare patients have two or more diseases. Clinical studies that are conducted in order to gain FDA market authorization are not necessarily required to include participants with similar demographics and characteristics of the Medicare population. A potential reason there may not be a strong evidence base specific to the Medicare population could include the desire by device manufacturers to demonstrate the safety and effectiveness of a device as clearly as possible. To achieve this aim, many studies impose stringent exclusion criteria that disqualify individuals with certain characteristics, such as comorbidities and concomitant treatment, that might make the effect of the investigational device more difficult to determine. Consequently, the potential benefits and harms of a device for older patients with more comorbidities may not be well understood at the time of FDA market authorization.

C. FDA Breakthrough Devices Program

Under the TCET coverage pathway, CMS will coordinate with FDA and manufacturers of Breakthrough Devices as those devices move through the FDA premarket review processes to ensure timely Medicare coverage decisions following any FDA market authorization, as described in detail later in this section. The Breakthrough Devices Program is an evolution of the Expedited Access Pathway Program and the Priority Review Program. See section 515B of the FD&C Act, 21 U.S.C. 360e–3; see also final guidance for industry entitled, ''Breakthrough Devices Program.'' [12]

FDA's Breakthrough Devices Program is not for all new medical devices; rather, it is only for those that FDA determines meet the standards for Breakthrough Device designation. In accordance with section 515B of the FD&C Act (21 U.S.C. 360e–3), the Breakthrough Devices Program is for medical devices and device-led combination products [13] that 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, including the potential, compared to existing approved alternatives, to reduce or eliminate the need for hospitalization, improve patient quality of life, facilitate patients' ability to manage their own care (such as through self-directed personal assistance), or establish long-term clinical efficiencies; or device availability is in the best interest of patients (for more information see 21 U.S.C. 360e–3(b)(2)). These criteria make Breakthrough designated devices unique. Devices meeting these criteria

[8] Additional information on FDA marketing authorization, specifically device approvals, denials and clearances can be accessed here: *https://www.fda.gov/medical-devices/products-and-medical-procedures/device-approvals-denials-and-clearances.*

[9] 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.*

[10] Tan, Y.Y., Papez, V., Chang, W.H., Mueller, S.H., Denaxas, S., & Lai, A.G. (2022). Comparing clinical trial population representativeness to real-world populations: an external validity analysis encompassing 43 895 trials and 5 685 738 individuals across 989 unique drugs and 286 conditions in England. The Lancet Healthy Longevity, 3(10), e674–e689.

[11] Varma T, Mello M, Ross JS, et al Metrics, baseline scores, and a tool to improve sponsor performance on clinical trial diversity: retrospective cross sectional study BMJ Medicine 2023;2:e000395. doi: 10.1136/bmjmed–2022–000395.

[12] *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/breakthrough-devices-program.*

[13] Information on device-led combination products can be accessed here: *https://www.fda.gov/media/119958/download.*

are also likely to be highly relevant to the needs of the Medicare population, if the item or service falls within a Medicare benefit category.

II. Provisions of the Notice With Comment Period

This notice proposes to create the TCET pathway. Since the TCET pathway relies on our existing authorities, we believe that establishing TCET through a procedural notice rather than rulemaking has the advantages that it is faster to implement and can be more easily modified as we gain experience with the approach. We also describe the procedures for how stakeholders and the public at large may engage with CMS to facilitate the TCET pathway. The topics addressed in the notice include the following: (1) TCET general principles; (2) appropriate candidates for the TCET pathway; (3) procedures for the TCET pathway; and (4) general roles.

We continue to pursue our efforts to work with various sectors of the scientific and medical community to develop and publish guidance documents on our website that describe our approach when analyzing scientific and clinical evidence to develop an NCD. In response to stakeholder feedback, our proposed CED and Evidence Review guidance documents propose to incorporate robust fit-for-purpose evidence development where manufacturers may use fit-for-purpose studies to close any evidence gaps. Fit-for-purpose studies are those where the study design, analysis plan, and study data can credibly answer the research question. Additionally, CMS intends to publish a series of guidance documents that review health outcomes and their clinically meaningful differences within priority therapeutic areas. The public will have an opportunity to provide comments on these guidance documents which will be available on the CMS coverage website which can be accessed at *https://www.cms.gov/Medicare/Coverage/CoverageGenInfo/index.html.*

A. TCET Pathway—An Opportunity To Accelerate Patient Access to Beneficial Medical Products While Generating Evidence

Since CMS started covering technology in the context of clinical studies almost two decades ago, the timing of evidence development and the stages of the technology development lifecycle have evolved. Over the past few years, innovative technologies have come on the market earlier in the technology development lifecycle and reached the market with limited or developing evidence for coverage purposes. CMS has received inquiries for coverage of new technologies that are early in the product lifecycle, which means the clinical evidence is just starting to accumulate. For new technologies, it is rare that there is sufficient clinical evidence to support broad national coverage at this point.

In general, CMS relies heavily on health outcomes data, including but not limited to health outcomes data as it relates to the Medicare population, before proposing an NCD. Early in the product lifecycle, there is usually evidence about whether the product is safe and may produce the intended result: for example, a laboratory measurement, radiographic image, physical sign or other measure that is believed to predict clinical benefit, but is not itself a measure of clinical benefit. However, there is often little evidence in the early stages of the product lifestyle regarding health outcomes (for example, mortality, disease progression, quality of life). When premarket, pivotal clinical study data is collected to support an application to FDA for market authorization, it provides clinical evidence for a defined population enrolled in the study.

If there is health outcome evidence for a new technology, it may not be generalizable to the Medicare population if Medicare beneficiaries are insufficiently represented in pivotal clinical studies. Medicare beneficiaries have been historically underrepresented in pivotal studies due to age, access, multiple comorbidities, and concurrent treatments. When there is little or limited evidence, CMS may not have enough information to make a favorable NCD due to gaps in research about health outcomes, including potential safety risks to the Medicare population.

While CMS has attempted to streamline the NCD process with the Parallel Review program, we recognize that most emerging technologies are likely to have limited or developing bodies of clinical evidence that may not have included the Medicare population (that is, individuals over age 65, people with disabilities, and those with end stage renal disease). Many Medicare beneficiaries have comorbid medical conditions, and those factors may have limited their participation in certain clinical trials. Additionally, we recognize the importance that applicable clinical trials reflect the demographic and clinical diversity among the Medicare beneficiaries who are the intended users of the intervention. At a minimum, this includes attention to the intended users' racial and ethnic backgrounds, sex and gender, age, disabilities, important comorbidities, and depends on data being available on these characteristics and relevant social determinants of health. We believe that the TCET pathway can support manufacturers that are interested in working with CMS to generate additional evidence that is appropriate for Medicare beneficiaries and that may demonstrate improved health outcomes in the Medicare population to support more expeditious national Medicare coverage. While we believe that leveraging the statutorily established NCD process will allow us to responsibly cover new, innovative technologies with limited or developing evidence, it is important that we provide an evidence generation framework that, when appropriate, not only develops reliable evidence for patients and their physicians but also provides safeguards to ensure that Medicare beneficiaries are protected and continue to receive high quality care.

Specifically, CED has been used to support evidence development for certain innovative technologies that are likely to show benefit for the Medicare population when the available evidence is not sufficient to demonstrate that the technologies are reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member under section 1862(a)(1)(A) of the Act. In instances where there is limited evidence, CED may be an option for Medicare beneficiaries seeking earlier access to promising technologies. CED has been a pathway whereby, after a CMS and AHRQ review, Medicare covers items and services on the condition that they are furnished in the context of approved clinical studies or with the collection of additional clinical data. Participation in a CED trial is voluntary, but beneficiaries are protected by separate regulations including those at 45 CFR part 46 related to the protection of human research subjects.

CMS has issued a total of 26 NCDs requiring CEDs over the last two decades to provide Medicare beneficiary access to promising items and services that could not otherwise be covered under section 1862(a)(1)(A) of the Act. CMS has approved 109 CED studies and five national registries to facilitate evidence development for these CED NCDs. Forty-two of these studies have generated evidence across 14 topics covered under CED. Three CED NCD topics have had the CED requirement removed following an NCD reconsideration and have received national coverage.

With respect to evidence generation, the TCET pathway would build upon

CMS and AHRQ's ongoing collaboration on the CED NCD process. We anticipate that many of the NCDs conducted under the TCET pathway will result in CED decisions, and AHRQ will continue to review all CED NCDs consistent with current practice. Additionally, AHRQ will collaborate with CMS as resources allow on evidence development activities conducted to support Medicare coverage under the TCET pathway and will have opportunities to offer feedback throughout the process that will be shared with manufacturers. Approvals related to evidence development will be a joint CMS–AHRQ decision. CMS and AHRQ have made iterative refinements to the CED coverage pathway over time, and while we believe CED has reduced barriers to innovation and expanded beneficiary access to new technologies and therapies, our experience over the last several years indicates that further improvements can be made to the CED process. We believe that certain coverage decisions—in particular, those involving innovative devices—would benefit from a more systematic framework for CED that establishes a more predictable and transparent approach for the public when facilitating evidence development.

Working in conjunction with AHRQ, our goal is to improve CED so that it fulfills its potential as a mechanism that simultaneously reduces barriers for innovation and enables CMS to make better informed decisions on coverage for medical devices that improve health outcomes for Medicare beneficiaries. CMS believes that public input should inform this effort, and we will continue to provide numerous opportunities for stakeholders to engage with us as we convene future Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) meetings and update specific aspects of the CED paradigm.

For example, CMS has been actively collaborating with AHRQ on potential revisions to the general criteria for CED studies, originally described in 2014, to ensure the criteria are up to date and continue to maintain rigorous evidentiary standards. In November 2022, in order to better inform the CED process, AHRQ released a final report on ''The Analysis of Requirements for Coverage with Evidence Development (CED).'' [14] The AHRQ report was first released in draft form in September 2022 and the public had an opportunity to provide comment on the draft report. The AHRQ report served as the basis for discussion at the February 13–14, 2023 MEDCAC meeting. CMS convened the MEDCAC to examine the general requirements for clinical studies submitted for CMS coverage under CED. The MEDCAC panel consisted of a variety of experts on the topic and included an industry representative and patient advocate. MEDCAC guest panel members included representatives from FDA, AHRQ, and National Institutes of Health (NIH). Specifically, the MEDCAC evaluated the CED criteria to assure that studies informing CED are assessed using consistent, feasible, transparent and methodologically rigorous criteria. The MEDCAC advised CMS on whether the criteria are appropriate to ensure that studies approved to inform CED decisions will produce informative evidence that CMS can rely on when making future reasonable and necessary determinations.[15] AHRQ and CMS collaboratively evaluated the information discussed at the MEDCAC meeting as well as the MEDCAC panel scores and are considering corresponding refinements to the proposed new criteria. CMS is proposing updated criteria in a proposed CED guidance document and the public will have an opportunity to provide comment on that document. With respect to beneficiary safeguards, the NCD process allows for coverage with appropriate safeguards for Medicare beneficiaries including coverage criteria based on evidence regarding eligibility, frequency, provider experience, site of service or availability of supporting services. Specifically, CMS develops clinician and institutional requirements after careful review of expert physicians' specialty society guidelines and clinical study results. These guidelines and recommendations are often part of NCDs. Unless these coverage criteria are established within coverage determinations, devices could be provided by unqualified individuals, offered at inappropriate facilities, and utilized by patients who may be unlikely to benefit.

More specifically, coverage under a CED NCD can expedite earlier beneficiary access for individuals who volunteer to participate in the clinical studies of innovative technology while ensuring that systematic patient safeguards, including assurance that the technology is provided to clinically appropriate patients, are in place to reduce the potential risks of new technologies, or to new applications of older technologies. CMS' current CED guidance document contains specific criteria that details patient protections under CED. As we note earlier, we are proposing updated criteria that reflects the feedback received on the November 2022 AHRQ report and February 2023 MEDCAC in a proposed CED guidance document. Because the TCET pathway described in this document would utilize the existing CED NCD process, all of these safeguards would apply if finalized.

Stakeholder input is important to CMS and we are particularly interested in engagement with patient advocacy organizations and medical specialty societies as they have valuable expertise and first-hand experience in the field that will help CMS develop Medicare coverage policies. Because the TCET pathway would utilize the current NCD process, these opportunities for stakeholder engagement would also be available in TCET.

B. TCET General Principles

CMS is committed to ensuring Medicare beneficiaries have access to emerging technologies. CMS' goal is to finalize an NCD for technologies accepted into and continuing in the TCET pathway, within 6 months after FDA market authorization. The TCET pathway builds off of prior initiatives, including CED. The TCET pathway will meet the following principles:

- Medicare coverage under the TCET pathway is limited to certain Breakthrough Devices that receive market authorization for one or more indications for use covered by the Breakthrough Device designation when used according to those indications for use. Manufacturers of FDA-designated Breakthrough Devices that fall within a Medicare benefit category may self-nominate to participate in the TCET pathway on a voluntary basis. We note that many Breakthrough Devices are currently coverable without the TCET pathway because they are not separately payable (that is, the device may be furnished under a bundled payment, such as payment for a hospital stay) or they are addressed by an existing NCD. Others are not indicated for use in a population that includes Medicare beneficiaries (for example, those devices that are targeted toward a pediatric population).
- CMS may conduct an early evidence review (Evidence Preview, more details in section II.D.1.g. of this notice with comment period) before FDA decides on marketing authorization for the device and discuss with the manufacturer the best available coverage

[14] *https://effectivehealthcare.ahrq.gov/products/coverage-evidence-development/research-report.*

[15] Additional information on the MEDCAC can be found at *https://www.cms.gov/medicare-coverage-database/view/medcac-meeting.aspx?medcacid=79&year=all&sortBy=meetingdate&bc=15.*

pathways depending on the strength of the evidence.

- Prior to FDA marketing authorization, CMS may initiate discussions with manufacturers to discuss any evidence gaps for coverage purposes and the types of studies that may need to be completed to address the gaps, which could include the manufacturer developing an evidence development plan and confirming that there are appropriate safeguards for Medicare beneficiaries.
- If CMS determines that further evidence development (that is, CED) is the best coverage pathway, CMS will work with the manufacturers to reduce the burden on manufacturers, clinicians and patients while maintaining rigorous evidence requirements. CMS will work to ensure we are not requiring duplicative or conflicting evidence development with any FDA post-market requirements for the device.
- CMS does not believe that an NCD that requires CED as a condition of coverage should last indefinitely, including under the TCET pathway. If the evidence supports a favorable coverage decision under CED, coverage will be time-limited to facilitate the timely generation of sufficient evidence to inform patient and clinician decision making and to support a Medicare coverage determination under section 1862(a)(1)(A) of the Act.
- Manufacturers and CMS have the option to withdraw from the pathway up until CMS opens the NCD by posting a tracking sheet. CMS will not publicly disclose participation of a manufacturer in the TCET pathway prior to CMS' posting of an NCD tracking sheet, unless the manufacturer consents or has already made this information public or disclosure is required by law. If a manufacturer does not wish the information that would be revealed by the posting of the NCD tracking sheet to become public, it should withdraw from the TCET pathway prior to this point. CMS requests that a manufacturer who wishes to withdraw from the TCET pathway notify CMS by email at *TCET@cms.hhs.gov.*

C. Appropriate Candidates

Appropriate candidates for the TCET pathway would include those devices that are—

- FDA-designated Breakthrough Devices;
- Determined to be within a Medicare benefit category; [16]
- Not already the subject of an existing Medicare NCD; and
- Not otherwise excluded from coverage through law or regulation.[17]

In section 201(h)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)(1), the definition of device includes diagnostic laboratory tests. Diagnostic lab tests are a highly specific area of coverage policy development, and CMS has historically delegated review of many of these tests to specialized MACs. We believe that the majority of coverage determinations for diagnostic tests granted Breakthrough Designation should continue to be determined by the MAC through existing pathways.

D. Procedures for the TCET Pathway

The TCET pathway has three stages: (1) premarket; (2) coverage under the TCET pathway; and (3) transition to post-TCET coverage.

1. Premarket

a. Nominations for the TCET Pathway

The appropriate timeframe for manufacturers to submit TCET pathway nominations to CMS is approximately 12 months prior to anticipated FDA decision on a submission as determined by the manufacturer. Manufacturers are generally aware of when they intend to submit their application, and the FDA has agreed to review time goals as part of its device user fee program.[18] CMS encourages manufacturers not to delay submitting nominations to facilitate alignment among CMS benefit category determination, and coverage, coding and payment considerations.

The manufacturer may submit a nomination for the TCET pathway by sending an email to *TCET@cms.hhs.gov,* which indicates their interest in the pathway. CMS will acknowledge receipt of nominations by email. The following information will assist CMS in processing and responding to nominations:

- Name of the manufacturer and relevant contact information.
- Name of the product.
- Succinct description of the technology and disease or condition the device is intended to diagnose or treat.
- State of development of the technology (that is, in pre-clinical testing, in clinical trials, currently undergoing premarket review by FDA). The submission of a copy of FDA's letter granting Breakthrough Designation and the PMA application, De Novo request or premarket notification (510(k)) submission, if available, is preferred.
- A comprehensive list of peer-reviewed, English-language publications that support the nominated Breakthrough Device as applicable/available.
- A statement that the medical device is not excluded by statute from Part A or Part B Medicare coverage or both, and a list of Part A or Part B or both Medicare benefit categories, as applicable, into which the manufacturer believes the medical device falls. Additionally, manufacturers are encouraged to provide additional specific information to help to facilitate benefit category and coding determinations.

Two good sources of information to facilitate the development of nomination submissions are the CMS Coverage website at *https://www.cms.gov/Center/Special-Topic/Medicare-Coverage-Center* and the CMS Innovators' Guide to Navigating Medicare at *https://www.cms.gov/medicare/coverage/councilontechinnov/downloads/innovators-guide-master-7-23-15.pdf,* which provides information that may facilitate durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) BCDs, along with coverage, coding and payment processes, and considerations. We note that an updated version of the Innovators' Guide is forthcoming. The updated guide will reflect a new name, the CMS Guide for Medical Technology Companies and Other Interested Parties, which can be found at the URL we have requested for this upon release: *https://www.cms.gov/cms-guide-medical-tech-companies-other-parties.*

- A statement describing how the medical device addresses the health needs of the Medicare population.
- A brief statement explaining why the device is an appropriate candidate for the TCET pathway as described under the section II.C. of this document (''B. Appropriate Candidates'').

CMS will contact the manufacturer by email to confirm that a submitted nomination appears to be complete and is under review by CMS. This email will include the date that CMS initiated the review of the complete nomination. If

[16] For more information on benefit category determinations see the CMS Innovator's Guide to Navigating Medicare (*https://www.cms.gov/medicare/coverage/councilontechinnov/downloads/innovators-guide-master-7-23-15.pdf*). Please note that an updated version of the Innovators' Guide is forthcoming. The updated guide will reflect a new name, the CMS Guide for Medical Technology Companies and Other Interested Parties, which can be found here upon release (the URL we have requested for this is: *https://www.cms.gov/cms-guide-medical-tech-companies-other-parties*).

[17] Information on coverage exclusions can be accessed here: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c16.pdf.*

[18] For more information on the specific review time goals that apply to different types of device premarket submissions, see MDUFA Performance Goals and Procedures, Fiscal Years 2023 Through 2027 (*https://www.fda.gov/media/158308/download*).

the nomination is not complete, CMS will contact the manufacturer for more information.

b. CMS Consideration

CMS may contact the manufacturer to request supplemental information to ensure a timely review of the nomination. CMS commits to making at least a preliminary decision to provisionally accept or decline a nomination within 30 business days following the date noted in CMS' email to manufacturer as described previously and will communicate this information to the manufacturer by email. The process for determining whether or not the technology falls within a benefit category may take longer and, in those instances, CMS will send a subsequent email to the manufacturer communicating a final decision on the nomination when the benefit category review is completed.

c. Intake Meeting

Following the submission of a complete TCET nomination, CMS will offer an initial meeting with the manufacturer to review the nomination within 20 business days of receipt of a complete nomination. In this initial meeting, the manufacturer is expected to describe the device, its intended application, place of service, a high-level summary of the evidence supporting its use, and the anticipated timeframe for FDA review. CMS will answer any questions about the TCET process. CMS intends for these meetings to be held remotely to reduce travel burden on manufacturers and expeditiously meet these timeframes. These meetings will have a duration of 30 minutes. If a manufacturer declines to meet or if there is difficulty finding a mutually convenient time for the meeting, then CMS action on the nomination may be delayed.

d. Coordination With FDA

After CMS initiates review of a complete, formal nomination, representatives from CMS will meet with their counterparts at FDA to learn more information about the technology in the nomination to the extent the Agencies have not already done so. These discussions may help CMS gain a better understanding of the device and potential FDA review timing.

As noted in the Memorandum of Understanding [19] between FDA and CMS, FDA and CMS recognize that the following types of information transmitted between them in any medium and from any source must be protected from unauthorized disclosure: (1) trade secret and other confidential commercial information that would be protected from public disclosure pursuant to Exemption 4 of the Freedom of Information Act (FOIA); (2) personal privacy information, such as the information that would be protected from public disclosure pursuant to Exemption 6 or 7(c) of the FOIA; or (3) information that is otherwise protected from public disclosure by Federal statutes and their implementing regulations (for example, the Trade Secrets Act (18 U.S.C. 1905), the Privacy Act (5 U.S.C. 552a), the Freedom of Information Act (5 U.S.C. 552), the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*), and the Health Insurance Portability and Accountability Act (HIPAA), Public Law 104–191).

e. Benefit Category Review

Following discussions with FDA, CMS may initiate a benefit category review if all other pathway criteria have been met. Emerging devices may fit within a Medicare benefit category but that does not mean that all medical devices will fall within a benefit category. If CMS believes that the device, prior to a decision on its approval or clearance by FDA, is likely to be coverable through one or more benefit categories, the device may be accepted into the TCET pathway. This is an interim step that is subject to change upon FDA's decision regarding approval or clearance of the device by FDA. Acceptance into TCET should not be viewed as a final determination that a device fits within a benefit category. However, if it appears that a device, prior to a decision on its approval or clearance by FDA, will not fall under an existing benefit category, the TCET nomination will be denied and this rationale will be discussed in the denial letter. CMS will likely not assess every submitted application for a benefit category review, as the TCET pathway is limited in its size per the discussion that follows in section II.G. of this document.

f. Manufacturer Notification

As noted previously, upon completion of CMS' review of the nomination, including the initial meeting with the manufacturer, discussions with FDA, and benefit category determination, CMS will notify the manufacturer by email whether the product is an appropriate candidate for the TCET pathway at this time. In instances where CMS does not accept a nomination, CMS will offer a virtual meeting with the manufacturer to answer any questions and discuss other potential coverage pathways.

g. Evidence Preview

Following CMS' determination that the product is an appropriate candidate, CMS will initiate an Evidence Preview, which is a systematic literature review that would provide early feedback on the strengths and weaknesses of the publicly available evidence for a specific item or service. The Evidence Preview will be a focused, but not necessarily exhaustive, review that will help CMS to identify any material evidence shortfalls. We believe the review conducted for the Evidence Preview will offer greater efficiency, predictability and transparency to manufacturers and CMS on the state of the evidence and any notable evidence gaps for coverage purposes. It is intended to inform judgments by CMS and manufacturers about the best available existing coverage options for an item or service. CMS intends for the Evidence Preview to be conducted by a contractor using standardized evidence grading, risk of bias assessment, and applicability assessment according to a protocol initially developed in collaboration with AHRQ in 2020. In order to initiate an Evidence, Preview, CMS will request written permission from the manufacturer to share any confidential commercial information (CCI) included in the nomination submission with the contractor. CMS anticipates that the Evidence Preview will take approximately 12 weeks to complete once the review is initiated, following acknowledgement of an accepted nomination in the TCET pathway. More time may be needed to complete the review in the event the product is novel, has conflicting evidence or other unanticipated issues arise.

h. Evidence Preview Meeting

CMS will share the Evidence Preview with the manufacturer via email and will offer a meeting to discuss it. The Evidence Preview will have been previously shared with AHRQ and may also be shared with FDA to obtain their feedback, as relevant. Representatives from those Agencies may participate in the Evidence Preview meeting. Manufacturers will have an opportunity to propose corrections to any errors and raise any important concerns with the Evidence Preview.

CMS will review the manufacturer feedback on the Evidence Preview and work with our contractor to revise the draft, as appropriate, prior to finalization. Upon finalizing the

[19] *https://www.fda.gov/about-fda/domestic-mous/mou-225-10-0010.*

Evidence Preview, manufacturers may request a meeting to discuss the strengths and weaknesses of the evidence and discuss the available coverage pathways (examples include an NCD, which could include CED, or seeking coverage decisions made by a MAC). These meetings to discuss the Evidence Preview may be conducted virtually or in person and will be scheduled for 60 minutes.

For those manufacturers who withdraw from the TCET pathway following the completion of an Evidence Preview, there will be no publicly posted tracking sheet and no public notification that an Evidence Preview was completed. However, we believe it is in the best interests of patients and the Medicare program to share the Evidence Preview with the MACs to aid them in their decision making since the development of an Evidence Preview represents a substantial investment of public resources in a thorough evidence review for pre-market devices. We solicit public comment on this approach.

i. Manufacturer's Decision to Continue or Discontinue With the TCET Pathway

Upon finalization of the Evidence Preview, the manufacturer may decide to pursue national coverage under the TCET pathway or to discontinue with the pathway. If the manufacturer decides to continue, the next step would include a manufacturer's submission of a formal NCD letter expressing the manufacturer's desire for CMS to open a TCET NCD analysis. Most, if not all, of the information needed to begin the TCET NCD would be included in the initial TCET pathway nomination, however, CMS invites the manufacturer to submit any additional materials the manufacturer believes would support the TCET NCD request.

j. Evidence Development Plan (EDP)

If evidence gaps are identified by CMS and/or AHRQ during the Evidence Preview, the manufacturer should also submit an evidence development plan (EDP) to CMS that sufficiently addresses the evidence gaps identified in the Evidence Preview. The EDP should be submitted to CMS at the same time as the formal NCD request cover letter. The EDP may include traditional clinical study designs or fit-for-purpose study designs or both, including those that rely on secondary use of real-world data, provided that those study designs follow all applicable CMS guidance documents. Additional information can be found here: *https://www.cms.gov/Medicare/Coverage/DeterminationProcess/Medicare-Coverage-Guidance-Documents-*.

Over the last several years, and most recently during the two stakeholder listening sessions we held on February 17, and March 31, 2022, we heard from stakeholders that they would like for CMS to utilize a more agile, iterative evidence review process that considers fit-for-purpose (FFP) study designs, including those that make secondary use of real-world data. An FFP study is one where the study design, analysis plan, and study data are appropriate for the question the study aims to answer. FFP study designs scale sample size, duration, and study type, etc., based off of the utilization and risk profile of the item or service. We are partnering with AHRQ to consider how to incorporate greater flexibility into the CED paradigm by allowing FFP evidence study designs that meet rigorous CMS evidence requirements. Any updates will be communicated in guidance documents and potential rulemaking as applicable and will include an opportunity for public comment. We believe that FFP study designs will be less burdensome for manufacturers. We also believe that by incorporating FFP study designs, we will address one of the public's concerns that CED should be time-limited to facilitate the timely generation of evidence that can inform patient and clinician decision making and lead to predictable Medicare coverage.

Postmarket FFP study proposals, particularly those that rely on real world data, have the potential to generate evidence that complements tightly controlled premarket traditional clinical trials by demonstrating external validity. Nonetheless, manufacturers should be aware that these studies require considerable planning in data validation, linkage, and transformation; specification of the study protocol; data analysis; and reporting. The study design, patient inclusion criteria, primary and secondary endpoints, treatment setting, analytic approaches, timing of outcome assessment, and data sources should be fully pre-specified in the submitted protocol. When writing EDPs, manufacturers should propose clinically meaningful benchmarks for each study outcome and provide supporting evidence.

Manufacturers should conceive a continued access study that maintains market access between the period when the primary EDP is complete, the evidence review is refreshed, and a decision regarding post-TCET coverage is finalized. The continued access study may rely on a claims analysis, with a focus on device utilization, geographic variations in care, and access disparities for traditionally underserved populations.

k. EDP Submission Timing

Because of the tight timeframes that are needed to effectuate CMS' goal of finalizing a TCET NCD within 6 months after FDA market authorization, manufacturers are strongly encouraged to begin developing a rigorous proposed EDP as soon as possible after receiving the finalized Evidence Preview. To meet the goal of having a finalized EDP approximately 90 business days after FDA market authorization, the manufacturer is encouraged to submit an EDP to CMS as soon as possible after FDA market authorization.

l. EDP Meeting and Finalization of the EDP

Once CMS receives the EDP from the manufacturer, it will share the document with AHRQ. CMS will have 30 business days to review the proposed EDP and provide written feedback to the manufacturer. During this time, CMS will collaborate with AHRQ to evaluate the EDP to ensure that it meets established standards of scientific integrity and relevance to the Medicare population. CMS will incorporate AHRQ's feedback on the EDP and will share the consolidated feedback with the manufacturer by email. Soon after providing written feedback, CMS will schedule a meeting with the manufacturer, which may also include AHRQ, to discuss any recommended refinements and address any questions.

In the EDP meetings, the manufacturer should be prepared to demonstrate: (1) a compelling rationale for its evidence development plan; (2) the study design, analysis plan, and data are all fit for purpose; and (3) the study sufficiently addresses threats to internal validity. The EDP should include clear enrollment, follow-up, study completion dates, and the timing and content of scheduled updates to CMS on study progress. Manufacturers should present and justify their study outcomes and performance benchmarks.

Following the EDP meeting, the manufacturer and CMS will have another 60 business days from the date of the EDP meeting to make any adjustments to the EDP. We recognize that, in some instances, manufacturers may require additional time to develop and refine their EDP. In these instances, CMS may provide additional time to manufacturers but we note that delays in submitting and revising an EDP may substantially impact the overall timeline for providing coverage under the TCET pathway. Elements of the CMS and

AHRQ approved EDPs, specifically the non-proprietary information, will be made publicly available on the CMS website upon posting of the proposed TCET NCD. In instances where the manufacturer's EDP is insufficient to meet CMS' and AHRQ's established standards and is therefore not able to be approved, CMS may exercise its option to withdraw participation from the TCET pathway as noted in II.B. of this document. We anticipate this will be a rare occurrence as CMS will make every effort to provide flexibility and information to manufacturers to facilitate the development of EDPs.

2. Coverage Under the TCET Pathway

CMS follows the statutory requirements, which includes an open and transparent process, when developing coverage policy at the national level. Though some elements of coverage review can be accelerated, gathering and reviewing meaningful public comment takes time. When CMS undertakes an NCD, we draw upon our analysis of the available evidence to identify the specific beneficiaries and conditions of coverage that are appropriate for the item or service. CMS also strongly considers information from patient advocacy organizations, specialty society guidance, expert consensus and recommendations for beneficiary selection, provider training and certification requirements, and facility requirements.

a. CMS NCD Review and Timing

If a device that is accepted into the TCET pathway receives FDA marketing authorization, CMS will initiate the NCD process by posting a tracking sheet following FDA market authorization (that is, the date the device receives PMA approval; 510(k) clearance; or the granting of a De Novo request) pending a CMS and AHRQ-approved Evidence Development Plan (in cases where there are evidence gaps as identified in the Evidence Preview). The manufacturer may also request that their device be withdrawn from the TCET pathway at this stage in the process, in which case CMS would not proceed with the NCD review described in this section. As previously noted, the goal is to have a finalized EDP no later than 90 business days after FDA market authorization.

The process for Medicare coverage under the TCET pathway would follow the NCD statutory timeframes in section 1862(l) of the Act. CMS would start the process by posting a tracking sheet and elements of the finalized Evidence Preview, specifically the non-proprietary information, which would initiate the start of a 30-day public comment period. Following further CMS review and analysis of public comments, CMS would issue a proposed TCET NCD and EDP within 6 months of opening the NCD. There would be a 30-day public comment period on the proposed TCET NCD and EDP and a final TCET NCD would be due within 90 days of the release of the proposed TCET NCD. Our goal is to release the proposed and final NCD in advance of the statutory deadline that applies to all NCDs. More information on the NCD process is set forth in the August 7, 2013 **Federal Register** notice (78 FR 48164).

b. Request for Specific Stakeholder Input on the Evidence Base and Conditions of Coverage

Since the evidence base for these emerging technologies will likely be incomplete and practice standards not yet established, we believe that feedback from the relevant specialty societies and patient advocacy organizations, in particular their expert input and recommended conditions of coverage (with special attention to appropriate beneficiary safeguards), is especially important for technologies covered through the TCET pathway.

Upon the opening of an NCD analysis, CMS strongly encourages these organizations to provide specific feedback on the state of the evidence and their suggested approaches to best practices for the emerging technologies under review. While CMS prefers to have this information during the initial public comment period upon opening the NCD, we realize that in many cases it may take longer for these organizations to provide their collective perspectives to CMS since these technologies will have only recently received FDA market authorization. Since CMS may consider any information provided that is in the public domain while undertaking an NCD, CMS encourages these organizations to publicly post on their website any additional feedback, including relevant practice guidelines, within 90 days of CMS' opening of the NCD. These organizations are encouraged to notify CMS when recommendations have been posted. All information considered by CMS to develop the proposed TCET NCD will become part of the NCD record and will be reflected in the bibliography as is typical for NCDs.

c. Coverage of Similar Devices

FDA market-authorized Breakthrough Devices are often followed by similar devices that other manufacturers develop. We believe that it is important to let physicians and their patients make decisions about the best available treatment depending upon the patient's individual situation. Rather than extending privileged coverage status only to the first device that achieves FDA market authorization, we are seeking comments on whether coverage of similar devices using CED would establish a level playing field and avoid delays in access that would occur if a separate NCD were required to ensure coverage. To be eligible for coverage under a TCET NCD, similar devices will be subject to the same coverage conditions, including a requirement to propose an EDP. Elements of the approved EDPs for similar devices, specifically the non-proprietary information, will be posted on the CMS website. In some cases, studies under the EDP may continue beyond the pre-specified NCD reconsideration date. In this case, CMS strongly encourages manufacturers to complete these studies even if further evidence development is voluntary. CMS seeks public comments on its approach for providing coverage for similar devices under the TCET pathway.

d. Duration of Coverage Under the TCET Pathway

The duration of transitional coverage through the TCET pathway will be tied to the CMS and AHRQ approved EDP. The review date specified in the EDP will provide one additional year after study completion to allow manufacturers to complete their analysis, draft one or more reports, and submit them for peer-reviewed publication. Given the short timeframes in the TCET pathway, an unpublished publication draft that a journal has accepted may also be acceptable. In general, we anticipate this transitional coverage period would last for a period of 3 to 5 years as evidence is generated to address evidence gaps identified in the Evidence Preview. However, CMS retains the right to reconsider an NCD at any point in time.

3. Transition to Post-TCET Coverage

TCET provides time-limited coverage for devices with the potential to deliver improved outcomes to the Medicare population but do not yet meet the reasonable and necessary standard for coverage under section 1862(a)(1)(A) of the Act. Consequently, TCET coverage is conditioned on further evidence development as agreed in a CMS and AHRQ approved EDP.

a. Updated Evidence Review

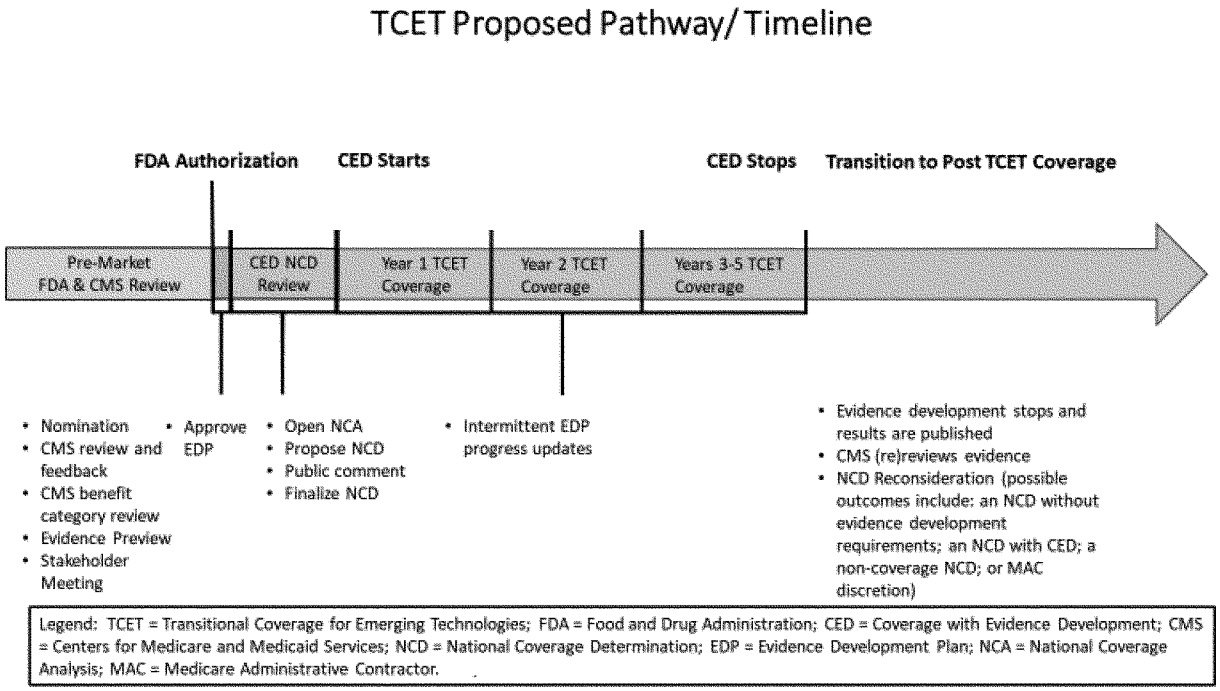
CMS intends to conduct an updated evidence review within 6 calendar months of the review date specified in

the EDP. To conduct the review, CMS intends to engage a third-party contractor to conduct a systematic literature review using detailed requirements that CMS developed in collaboration with AHRQ. The contractor will then perform a qualitative evidence synthesis and compare those findings against the benchmarks for each outcome specified in the original NCD. After conducting quality assurance on the contractor review, CMS will assess whether the evidence is sufficient to reach the reasonable and necessary standard. CMS will also review applicable practice guidelines and consensus statements and consider whether the conditions of coverage remain appropriate. CMS will collaborate with AHRQ and FDA as appropriate as the updated Evidence Review is conducted and will share the updated review with them.

b. NCD Reconsideration

Based upon the updated evidence review and consideration of any applicable practice guidelines, CMS, when appropriate, will open an NCD reconsideration by posting a proposed decision which proposes one of the following outcomes: (1) an NCD without evidence development requirements; (2) an NCD with continued evidence development requirements; (3) a non-coverage NCD; or (4) permitting local MAC discretion to make a decision under section 1862(a)(1)(A) of the Act. Neither an FDA market authorization nor a CMS approval of an Evidence Development Plan guarantees a favorable coverage decision. Standard NCD processes and timelines will continue to apply, and following a 30-day public comment period, CMS will have 60 days to finalize the NCD reconsideration.

The steps previously described for the TCET process follows with the applicable estimated timelines for obtaining a CMS coverage determination are illustrated in the diagram:



E. Roles

CMS has outlined the general roles of each participant in the TCET pathway.

1. Manufacturer

The manufacturer initiates consideration for TCET by voluntarily submitting a complete nomination as outlined previously under ''1. Nomination,'' of section II.D of this document entitled ''Procedures for the TCET Pathway.'' In the interest of expediting CMS decision making, the manufacturer should be prepared to quickly and completely respond to all issues and requests for information raised by the CMS reviewers. If CMS does not receive information from manufacturers in a timely fashion, CMS review timelines will be lengthened, potentially significantly. Manufacturers are encouraged to submit any materials they plan to present during meetings with CMS at least 7 days in advance of the scheduled meeting. Manufacturers should be prepared with the resources and skills to successfully develop, conduct, and complete the studies included in the EDP.

2. CMS

CMS will provide a secure and confidential nomination and review process as outlined previously in section II.C. of this document. CMS will initiate review of nominations for the TCET pathway by retrieving applications from the secure mailbox, and communicating with FDA regarding Breakthrough Devices seeking coverage under the TCET pathway. Throughout all stages of the TCET pathway, CMS intends to maintain open communication channels with FDA, AHRQ and the relevant manufacturer and fulfill its statutory obligations concerning the NCD process.

3. FDA

FDA will keep open lines of communication with CMS on Breakthrough Devices seeking coverage under the TCET pathway as resources permit. Participation in the TCET pathway does not change the review standards for FDA market authorization of a device, which are separate and distinct from the standards governing a CMS NCD.

4. AHRQ

Currently, AHRQ reviews all CED NCDs established under section

1862(a)(1)(E) of the Act. Consistent with section 1142 of the Act, AHRQ collaborates with CMS to define standards for clinical research studies to address the CED questions and meet the general standards for CED studies (*https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development*). Since we anticipate that many of the NCDs conducted under the TCET pathway will result in CED decisions, AHRQ will continue to review all CED NCDs consistent with current practice. Additionally, AHRQ will collaborate with CMS as resources allow to evaluate the Evidence Preview and EDP and will have opportunities to offer feedback throughout the process that will be shared with manufacturers. AHRQ will be a partner with CMS as the Evidence Preview and EDP are being developed and approvals for these documents will be a joint CMS–AHRQ decision.

F. TCET and Parallel Review

While the TCET pathway will be limited to Breakthrough Devices, other potential expedited coverage mechanisms, such as Parallel Review, remain available. Eligibility for the Parallel Review program is broader than for the TCET pathway and could facilitate expedited CMS review of non-Breakthrough Devices. To achieve greater efficiency and to simplify the coverage process generally, CMS intends to work with FDA to consider updates to the Parallel Review program and other initiatives to align procedures, as appropriate.

G. Prioritizing Requests

CMS intends to review TCET pathway nominations and respond within 30 days after receipt of the email. At present, CMS anticipates accepting up to five TCET candidates annually due to CMS resource constraints. CMS intends to prioritize innovative medical devices that, as determined by CMS, have the potential to benefit the greatest number of individuals with Medicare.

III. Collection of Information Requirements

Based on our initial assessment of Breakthrough Devices applying the characteristics we list in II.C. of this notice with comment period regarding appropriate candidates for the TCET pathway, we anticipate that we will receive approximately eight nominations for the TCET pathway per year. Due to current CMS resource constraints, we do not anticipate the TCET pathway will accept more than five candidates per year. Since we estimate fewer than 10 respondents, the information collection requirements are exempt in accordance with the implementing regulations of the Paperwork Reduction Act (PRA) at 5 CFR 1320.3(c). As we gain experience with the TCET pathway, if we receive a higher number of respondents than anticipated, we will provide an updated analysis.

IV. 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 notice, and, when we proceed with a subsequent document, we will respond to the comments in that document.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on June 20, 2023.

Dated: June 21, 2023.

Xavier Becerra,

Secretary, Department of Health and Human Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Proposed Information Collection Activity, Temporary Assistance for Needy Families (TANF) Data Reporting for Work Participation (Office of Management and Budget #0970–0338)

AGENCY: Office of Family Assistance, Administration for Children and Families, United States Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Administration for Children and Families (ACF) is requesting to extend approval of the Temporary Assistance for Needy Families (TANF) Data Reporting for Work Participation, with proposed revisions. Revisions are intended to improve the clarity of the instructions, streamline reporting, and ensure all instructions are up-to-date.

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: You can obtain copies of the proposed collection of information and submit comments by emailing *infocollection@acf.hhs.gov.* Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: This request includes the following information collections: work verification procedures, the Caseload Reduction Documentation Process, the TANF Data Report, the Separate State Program (SSP)-Maintenance of Effort (MOE) Data Report, and TANF sampling instructions. The data and information from these reports and processes are used—and will continue to be used—for program analysis and oversight, including the calculation and administration of the work participation rate and associated penalties. Congress provides federal funds to operate TANF programs in the states, the District of Columbia, Guam, Puerto Rico, the U.S. Virgin Islands, and for approved federally recognized tribes and Alaskan Native Villages. We are proposing to continue the same information collections with only changes to instructions to improve clarity and eliminate data elements and guidance that are no longer relevant. The Work Verification Plan Guidance has been updated to incorporate further guidance that was published in 2006. The TANF and SSP–MOE Data Report instructions were revised to streamline the data collection, reduce the burden on respondents by eliminating unnecessary data elements, and clarify confusing data elements. The TANF and SSP–MOE Data Report layouts were also updated to reflect the streamlined instructions. The TANF Sample Manual was revised to eliminate outdated and unused sections.

Respondents: The 50 states of the U.S., the District of Columbia, Guam, Puerto Rico, and the U.S. Virgin Islands.