

(4) Reimburse the Forest Service in a timely manner for the cost of abating an emergency.

(b) *Compliance Officer determination of material noncompliance.* When determining whether an operator or lessee has failed or refused to comply in a material respect with reclamation requirements or other requirements or standards identified in paragraph (a) of this section, the Compliance Officer shall:

(1) Inform the operator or lessee by certified mail of the authorized Forest Service officer's material noncompliance referral and the Compliance Officer's intent to proceed with a material noncompliance review.

(2) Inform the operator or lessee of the opportunity to submit a written response to the referral and/or to request an oral presentation with the Compliance Officer within 30 calendar days of receipt of the certified letter.

(3) Ensure that:

(i) Opportunities for corrective action according to § 228.112(b) have been pursued;

(ii) Consideration is given to the status of any noncompliance referrals sent to the Bureau of Land Management for action per § 228.112(e); and

(iii) Consideration is given to the seriousness of the effects caused by the operator's failure or refusal to comply.

(4) Consider any pending judicial or administrative appeals involving the operator, including those within the purview of the Bureau of Land Management.

(5) Notify the operator or lessee by certified mail of the outcome of the material noncompliance referral review. If material noncompliance was determined, the notice shall state that the Bureau of Land Management will be advised to not issue a lease or approve the assignment of any lease to the entity. The notification shall also state that the decision is the final administrative determination of the Department of Agriculture.

(c) *Notifying the Bureau of Land Management.* Upon completion of a material noncompliance review, the Compliance Officer shall notify the Bureau of Land Management in writing of the outcome of the review. When an entity has been found to be in material noncompliance, the Forest Service shall advise the Bureau of Land Management not to issue or approve the assignment of any lease to the entity determined to be in material noncompliance.

(d) *Notification that material compliance has occurred.* If an entity found to be in material noncompliance subsequently comes into material compliance with reclamation

requirements or other requirements or standards identified in paragraph (a) of this section, the Compliance Officer shall advise the Bureau of Land Management that the entity has come into material compliance.

#### § 228.114 Posting requirements.

The affected National Forest or Grassland ranger district office shall promptly post notices provided by the Bureau of Land Management of:

(a) Competitive lease sales which the Bureau of Land Management plans to conduct that include National Forest System lands. These must be posted for a minimum of 45 days prior to the sale;

(b) Substantial modifications in the terms which the Bureau of Land Management proposes to make for leases on National Forest System lands (43 CFR 3101.1–4). These must be posted for a minimum of 30 days prior to the sale; and,

(c) Applications for Permits to Drill which the Bureau has received involving leases or agreements located on National Forest System lands according to provisions of Onshore Order 1. These must be posted for a minimum of 30 days.

#### § 228.115 Information collection requirements.

The Office of Management and Budget reviewed and approved the information collection requirements contained in this subpart and assigned OMB Control No. 0596–0101. The collection of information allows the Forest Service to approve or take other appropriate actions on surface use plans of operations; requests to waive, except, or modify lease stipulations; requests for reduction in reclamation liability; noncompliance issues; and notices of cessation of operations. The information collection requirements of this subpart are supplemental to the Bureau of Land Management's various OMB information collection approvals for issuing and managing Federal oil and gas leases, but primarily to the following: OMB Control No. 1004–0134 for 43 CFR 3162.3; and OMB Control No. 1004–0136 for Form 3160–3, Application for Permit to Drill.

### PART 261—PROHIBITIONS

■ 5. The authority citation for part 261 continues to read as follows:

**Authority:** 7 U.S.C. 1011(f); 16 U.S.C. 4601–6d, 472, 551, 620(f), 1133(c)—(d)(1), 1246(i).

■ 6. Amend § 261.2 by revising the definition for “Operating plan” to read as follows:

#### § 261.2 Definitions.

\* \* \* \* \*

*Operating plan* means the following documents, providing that the document has been issued or approved by the Forest Service: A plan of operations as provided for in 36 CFR part 228, subparts A and D, and 36 CFR part 292, subparts C and G; a supplemental plan of operations as provided for in 36 CFR part 228, subpart A, and 36 CFR part 292, subpart G; an operating plan as provided for in 36 CFR part 228, subpart C, and 36 CFR part 292, subpart G; an amended operating plan and a reclamation plan as provided for in 36 CFR part 292, subpart G; a surface use plan of operations as provided for in 36 CFR part 228, subpart E; a surface use portion of a sundry notice as provided for in 36 CFR part 228, subpart E; a permit as provided for in 36 CFR 251.15; and an operating plan and a letter of authorization as provided for in 36 CFR part 292, subpart D.

\* \* \* \* \*

**James E. Hubbard,**

*Under Secretary, Natural Resources and Environment.*

[FR Doc. 2020–18518 Filed 8–31–20; 8:45 am]

**BILLING CODE 3411–15–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

#### 42 CFR Part 405

[CMS–3372–P]

RIN 0938–AT88

### Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of “Reasonable and Necessary”

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Proposed rule.

**SUMMARY:** This proposed rule would establish a Medicare coverage pathway to provide Medicare beneficiaries nationwide with faster access to new, innovative medical devices designated as breakthrough by the Food and Drug Administration (FDA). After the final rule is effective, the Medicare Coverage of Innovative Technology (MCIT) pathway would begin national Medicare coverage on the date of FDA market authorization and would continue for 4 years. We are also proposing 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 Part A and Part B.

**DATES:** To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on November 2, 2020.

**ADDRESSES:** In commenting, please refer to file code CMS-3372-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of 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-P, 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-P, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

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

**FOR FURTHER INFORMATION CONTACT:** Linda Gousis or JoAnna Baldwin, (410) 786-2281 or [CAGInquiries@cms.hhs.gov](mailto:CAGInquiries@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.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday

through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

### I. Background

The Administration is committed to ensuring Medicare beneficiaries have access to new cures and technologies that improve health outcomes. Section 6 of the October 3, 2019 Executive Order 13890 (E.O. 13890) “Executive Order on Protecting and Improving Medicare for Our Nation’s Seniors,”<sup>1</sup> directs the Secretary to “propose regulatory and sub-regulatory changes to the Medicare program to encourage innovation for patients” including by “streamlining the approval, coverage, and coding process.”<sup>2</sup> The E.O. 13890 explicitly includes making coverage of breakthrough medical devices “widely available, consistent with the principles of patient safety, market-based policies, and value for patients.”<sup>3</sup> The E.O. also directs the Secretary to “clarify the application of coverage standards.”<sup>4</sup>

We are responding directly to these directives by proposing a definition of the term “reasonable and necessary” to clarify coverage standards and proposing the Medicare Coverage of Innovative Technology (MCIT) pathway to accelerate the coverage of new, innovative breakthrough devices to Medicare beneficiaries. To date, the factors used in making “reasonable and necessary” determinations based on section 1862(a)(1)(A) of the Act have not been established in regulations for Medicare coverage purposes. The Secretary has authority to determine whether a particular medical item or service is “reasonable and necessary” under section 1862(a)(1)(A) of the Act. (See *Heckler v. Ringer*, 466 U.S. 602, 617 (1984).) When making coverage determinations, our policies have long considered whether the item or service is safe and effective, not experimental or investigational, and appropriate. (For more information see the January 30, 1989 notice of proposed rulemaking (54 FR 4307)). These factors are found in Chapter 13 of the Medicare Program Integrity Manual (PIM) at section 13.5.4—*Reasonable and Necessary Provisions in LCDs* as instructions for Medicare contractors. We are proposing to codify in regulations the Program Integrity Manual definition of

“reasonable and necessary” with modifications, including to add a reference to Medicare patients and a reference to commercial health insurer coverage policies. We propose that an item or service would be considered “reasonable and necessary” if it is—(1) safe and effective; (2) not experimental or investigational; and (3) appropriate for Medicare patients, including the duration and frequency that is considered appropriate for the item or service, in terms of whether it is—

- Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient’s condition or to improve the function of a malformed body member;
- Furnished in a setting appropriate to the patient’s medical needs and condition;
- Ordered and furnished by qualified personnel;
- One that meets, but does not exceed, the patient’s medical need; and
- At least as beneficial as an existing and available medically appropriate alternative.

We also propose that an item or service would be “appropriate for Medicare patients” under (3) if it is covered in the commercial insurance market, except where evidence supports that there are clinically relevant differences between Medicare beneficiaries and commercially insured individuals. An item or service deemed appropriate for Medicare coverage based on commercial coverage would be covered on that basis without also having to satisfy the bullets listed above. We believe this definition is a significant step in meeting the E.O.’s directive to bring clarity to coverage standards. Stakeholders have expressed interest in codifying a definition of “reasonable and necessary” for many years. This proposed definition is familiar and functional, can satisfy that interest and meet the E.O.’s ask, while also aligning with the goals of MCIT by providing clarity and predictability for innovation, including for beneficiaries and innovators.

The proposed MCIT coverage pathway is specifically for Medicare coverage of devices that are designated as part of the Food and Drug Administration’s (FDA) Breakthrough Devices Program (hereafter referred to as “breakthrough devices”) and are FDA market authorized. The MCIT pathway would be voluntary and device manufacturers would notify CMS if they want to utilize this coverage option.

We propose that national Medicare coverage under the MCIT pathway would begin immediately upon the date of FDA market authorization (that is, the

<sup>1</sup> Executive Order on Protecting and Improving Medicare for Our Nation’s Seniors, available at <https://www.whitehouse.gov/presidential-actions/executive-order-protecting-improving-medicare-nations-seniors/>.

<sup>2</sup> *Id.*

<sup>3</sup> *Id.*

<sup>4</sup> *Id.*

date the medical device receives Premarket Approval (PMA); 510(k) clearance; or the granting of a De Novo classification request) for the breakthrough device. This coverage would occur unless the device does not have a Medicare benefit category or is otherwise excluded from coverage by statute (that is, the Medicare statute does not allow for coverage of the particular device.) This coverage pathway delivers on the Administration's commitment to give Medicare beneficiaries access to the newest innovations on the market, consistent with the statutory definitions of Medicare benefits. Because Medicare is a defined benefit program, devices that do not fit within the statutory definitions may not be considered for MCIT. As an example, medical equipment for home use by the beneficiary must be durable (that is, withstand repeated use) for it to be coverable by Medicare (as defined in statutes and regulations by the Secretary). At this time, we are limiting MCIT to medical devices because that is a category of products explicitly identified in E.O. 13890, and we have identified that breakthrough devices can experience variable coverage across the nation shortly after market authorization.

We propose this MCIT pathway because the prescribed statutory timeframes for the National Coverage Determination (NCD) process limit CMS' ability to institute immediate national coverage policies for new, innovative medical devices. NCDs and Local Coverage Determinations (LCD) take, on average, 9 to 12 months to finalize. Because of this length of time, there may be coverage uncertainty between the period of FDA market authorization and CMS finalization of an NCD or a Medicare Administrative Contractor's (MACs) finalization of an LCD. During this time period shortly after market authorization, MACs make coverage determinations on a case-by-case (individual beneficiary) basis, but those decisions do not usually establish agency policies for future claims because a case-by-case decision is for a particular beneficiary and their health circumstances.

Over the past few years, CMS has heard concerns from stakeholders that breakthrough devices are not automatically covered nationally by Medicare once they are FDA market authorized. Variation in coverage from one jurisdiction to another is also a concern. To date, 16 breakthrough devices have also been market authorized. The majority of these breakthrough devices (10 devices)

experience variability in coverage for two reasons. One reason is because the breakthrough devices are coverable at MAC discretion, like many other item and services, on a case-by-case basis (that is, the breakthrough device may be covered for one patient, but not for another within the same jurisdiction). The other reason is because breakthrough devices are used by a hospital or other provider that operates under a bundled payment system (such as a diagnosis related group (DRG) system), so there may be no separate coverage policy for each item or service that may be included in the bundled payment. Another example of variable coverage is for one breakthrough device that is non-covered by a local policy in Florida, but coverable at MAC discretion on a case-by-case basis in other jurisdictions. One breakthrough device has national coverage through an NCD. One breakthrough device has uniform coverage because the same LCD has been adopted in all jurisdictions. There are three breakthrough devices that do not have a Medicare benefit category (for example, certain wearable devices); therefore, those breakthrough devices cannot be covered by the Medicare program.

In contrast to varied local coverage, the proposed MCIT would create a pathway for immediate national Medicare coverage of any FDA-market authorized breakthrough device if the device meets criteria outlined in this proposal.

#### A. Statutory Authority

We are also proposing to establish in regulations the factors we have historically used in making "reasonable and necessary" determinations under section 1862(a)(1)(A) of the Act, with some modification. To summarize, this section explains that Medicare payment may be made under part A or part B for any expenses incurred 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. Thus, with some exceptions, section 1862(a)(1)(A) of the Act requires that an item or service be "reasonable and necessary" to be covered by Medicare. The courts have recognized that the Secretary has significant authority to determine whether a particular item or service is "reasonable and necessary." (*Heckler v. Ringer*, 466 U.S. 602, 617 (1984). *See also*, *Yale-New Haven Hospital v. Leavitt*, 470 F.3d 71, 84 (2d Cir. 2006); *Kort v. Burwell*, 209 F. Supp. 3d 98, 110 (D.C. 2016) (The statute vests substantial authority in the Secretary.)) So even though section

1862(a)(1)(A) of the Act limits the scope of Medicare coverage, the Secretary has discretion to revise his/her interpretation of the statute in order to ensure adequate coverage for items and services under Part A and Part B.

This proposal would provide national Medicare coverage for breakthrough devices that are FDA market-authorized and used consistent with the FDA approved or cleared indication for use (also referred to as the "FDA-required labeling").<sup>5</sup> This device coverage under the MCIT pathway is reasonable and necessary under section 1862(a)(1)(A) of the Act because the device has met the unique criteria of the FDA Breakthrough Devices Program.

#### B. FDA Breakthrough Devices Program

Under the proposed MCIT coverage pathway, CMS would coordinate with FDA and manufacturers as medical devices move through the FDA regulatory process for Breakthrough Devices to ensure seamless Medicare coverage on the date of FDA market authorization unless CMS determines those devices do not have a Medicare benefit category. The Breakthrough Devices Program is an evolution of the Expedited Access Pathway Program and the Priority Review Program (section 515B of the Federal Food, Drug, and Cosmetic Act (FD&C Act)), 21 U.S.C. 360e-3; see also final guidance for industry entitled, "Breakthrough Devices Program," <https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM581664.pdf>.

The FDA's Breakthrough Devices Program is not for all new medical devices; rather, it is only for those that the FDA determines meet the standards for breakthrough device designation. In accordance with section 3051 of the 21st Century Cures Act (21 U.S.C. 360e-3),<sup>6</sup> the Breakthrough Devices Program is for medical devices and device-led combination products that meet two criteria. The first criterion is that the device provide 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

<sup>5</sup> FDA Guidance for Industry, "Medical Product Communications That Are Consistent With the FDA-Required Labeling—Questions and Answers," available at <https://www.fda.gov/media/133619/download>.

<sup>6</sup> 21st Century Cures Act, available at <https://www.congress.gov/114/plaws/publ255/PLAW-114publ255.pdf>; see FDA Guidance for Industry and Food and Drug Administration Staff, Breakthrough Devices Program available at <https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program>.

represents a breakthrough technology; no approved or cleared alternatives exist; it offers significant advantages over existing approved or cleared alternatives, including additional considerations outlined in the statute; 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 among all other medical devices.<sup>7</sup> The parameters of the breakthrough devices program focus on innovations for patients, in turn, MCIT, focuses on these breakthrough devices consistent with E.O. 13890 and in order to streamline coverage of innovative medical devices.

### C. Current Medicare Coverage Pathways

Currently, we utilize several coverage pathways for items and services, which includes medical devices. None of the coverage pathways described in this section offer immediate, predictable coverage concurrently with FDA market authorization like the proposed MCIT pathway would do. We summarize the other coverage pathways here to provide context for MCIT.

- **National Coverage Determinations (NCDs):** Section 1862(l)(6)(A) of the Act defines the term national coverage determination as “a determination by the Secretary with respect to whether or not a particular item or service is covered nationally under this title.” In general, NCDs are national policy statements published to identify the circumstances under which particular items and services will be considered covered by Medicare. 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, and includes a determination that the item or service under consideration has a Medicare benefit category. The NCD pathway, which has statutorily prescribed timeframes, generally takes 9 to 12 months to complete.<sup>8</sup>

- **Local Coverage Determinations (LCDs):** Medicare contractors develop LCDs based on section 1862(a)(1)(A) of the Act that apply only within their

geographic jurisdictions. (Sections 1862(l)(6)(B) and 1869(f)(2)(B) of the Act.) MACs will not need to develop LCDs for breakthrough devices when they are nationally covered through MCIT.

The MACs follow specific guidance for developing LCDs for Medicare coverage in the CMS Program Integrity Manual, and in some instances, an LCD can also take 9 to 12 months to develop (MACs must finalize proposed LCDs within 365 days from opening per Chapter 13—Local Coverage Determinations of the (PIM) 13.5.1). We note that the MCIT pathway will not alter the existing coverage standards in Chapter 13—Local Coverage Determinations of the PIM.<sup>9</sup> That chapter will continue to be used in making determinations under section 1862(a)(1)(A) of the Act for other items and services at the local level.

- **Claim-by-claim Adjudication:** In the absence of an NCD or LCD, MACs would make coverage decisions under section 1862(a)(1)(A) of the Act and may cover or not cover items and services on a claim-by-claim basis. The majority of claims are handled through the claim adjudication process.

- **Clinical Trial Policy (CTP) NCD 310.1:** The CTP pathway can be used for coverage of 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 pathway was developed in 2000.<sup>10</sup> This coverage pathway has not generally been utilized by device manufacturers because they usually seek coverage of the device, which is not included in this pathway.

- **Parallel Review:** Parallel Review is a mechanism for FDA and CMS to simultaneously review the submitted clinical data to help decrease the time between FDA’s approval of a premarket application or granting of a de novo classification and the subsequent CMS NCD. Parallel Review has two stages: (1) FDA and CMS meet with the manufacturer to provide feedback on the proposed pivotal clinical trial within the FDA pre-submission process; and (2) FDA and CMS concurrently review (“in parallel”) the clinical trial results submitted in the PMA, 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 is most successful for devices that have a significant amount of clinical evidence. (Candidates for parallel review would not be appropriate for simultaneous MCIT consideration.)

Even though CMS has multiple coverage pathways, at this time none are readily available to provide immediate national coverage for new breakthrough devices with a Medicare benefit category at the same time as FDA market authorization. Further, some of these new breakthrough devices are likely to have limited or developing bodies of clinical evidence because of the newness of the device; therefore, the MCIT pathway can support manufacturers that are interested in combining coverage with their own clinical study to augment clinical evidence of improved health outcomes, particularly for Medicare patients.

Given this summary of existing coverage pathways, we seek comment from the public regarding if any of these existing pathways should be modified to achieve the goals set out by E.O. 13890.

### D. MCIT Pathway

We propose that the MCIT pathway would provide immediate national coverage for breakthrough devices beginning on the date of FDA market authorization and continue for up to 4 years, unless we determine the device does not have a Medicare benefit category as determined by us as part of the MCIT pathway process. The MCIT pathway is voluntary (that is, manufacturers would affirmatively opt-in), and would be initiated when a manufacturer notifies CMS of its intention to utilize the MCIT pathway. (This notification process is described further in section III. of this proposed rule.) We would subsequently coordinate with the manufacturer regarding steps that need to be taken for MCIT implementation purposes. The frequency of subsequent engagement will be largely driven by whether the manufacturer has questions for CMS, or CMS and FDA. The timing of coverage will depend upon the timing of the FDA’s market authorization decision. Engagements can take place in the form of in-person meetings, phone calls, emails, etc. We intend to put devices that are covered through the MCIT pathway on the CMS website so that all stakeholders will be aware of what is covered through the MCIT pathway. Manufacturers of breakthrough devices will not be obligated or mandated by CMS to conduct clinical studies during

<sup>7</sup> FDA does not publish a list of breakthrough designated or breakthrough designated and subsequently market authorized devices. However if a breakthrough device gains market authorization through a PMA only, then the summary of safety and effectiveness data (SSED) will contain a reference for the breakthrough designation. This is not true for De Novos which have been granted or cleared 510(k)’s. In consideration of that approach, this notice of public rulemaking does not contain such lists.

<sup>8</sup> Section 1869(f)(4) of the Act.

<sup>9</sup> CMS Program Integrity Manual, Chapter 13 Local Coverage Determinations, available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/pim83c13.pdf>

<sup>10</sup> 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>.

coverage under the proposed MCIT pathway. However, we seek comment as to whether CMS should require or incentivize manufacturers to provide data about outcomes or should be obligated to enter into a clinical study similar to CMS's Coverage with Evidence Development (CED) paradigm.<sup>11</sup> We are aware some manufacturers may be required by the FDA to conduct post market data collection as a condition of market authorization, and nothing in this proposed rule would alter that FDA requirement. Manufacturers are encouraged to develop the clinical evidence base needed for one of the other coverage pathways after the MCIT pathway ends. This evidence is encouraged not only for CMS and private commercial health insurer coverage policies but also to better inform the clinical community and the public generally about the risks and benefits of treatment. CMS encourages early manufacturer engagement, both before and after FDA market authorization, for manufacturers to receive feedback from CMS on potential clinical study designs and clinical endpoints that may produce the evidence needed for a definitive coverage determination after MCIT. This feedback would not involve CMS predicting specific coverage or non-coverage.

In order to further the goals of E.O. 13890, CMS proposes to rely on FDA's breakthrough device designation and market authorization of those devices to define the universe of devices eligible for MCIT, except for those particular devices CMS determines do not have a Medicare benefit category or are statutorily excluded from coverage under Part A or Part B. In order to provide immediate national coverage to innovative medical devices, we propose to establish a time limit on how long a breakthrough device can be eligible for MCIT (that is, considered a breakthrough device for coverage purposes). MCIT has a time limit on newness similar to our New Technology Add-on Payment (NTAP) policy. Eligibility for the NTAP is also time limited and this time limit applies to all new technologies, including breakthrough devices, for which an application for additional payment is submitted. Additionally, the time-limited characteristic of MCIT will drive some manufacturers to leverage this

period of coverage to demonstrate the value of their device in the competitive marketplace. The 4-year coverage period is particularly important for manufacturers of breakthrough devices that choose to further develop the clinical evidence basis on which the FDA granted marketing authorization. From our experience with clinical studies conducted as part of an NCD, 4 years is approximately the amount of time it takes to complete a study.

At the end of the 4-year MCIT pathway, coverage of the breakthrough device would be subject to one of these possible outcomes: (1) NCD (affirmative coverage, which may include facility or patient criteria); (2) NCD (non-coverage); or (3) MAC discretion (claim-by-claim adjudication or LCD). Manufacturers that are interested in a NCD are encouraged to submit a NCD request during the third year of MCIT to allow for sufficient time for NCD development. We seek public comment on whether CMS should open a national coverage analysis if a MAC has not issued an LCD for a breakthrough device within 6 months of the expiration date of the 4-year MCIT period.

In our analysis of the current coverage landscape to determine opportunities for innovation and efficiencies, we also considered modifying the coverage process for non-breakthrough devices (for example, PMAs because they are also new to the market), but ultimately determined that it was the unique characteristics of FDA designated breakthrough devices and their ability to serve unmet needs that resonated most with the E.O.'s direction to encourage innovation for patients. We also considered expedited coverage of newly market authorized and breakthrough devices when used in a clinical study.

We seek public comment on the proposed MCIT pathway, the considerations described, whether any of the existing coverage pathways should be modified to achieve the goals set out by the E.O., and alternatives to these proposals. We specifically seek public comment on whether the MCIT pathway should also include diagnostics, drugs and/or biologics that utilize breakthrough or expedited approaches at the FDA (for example, Breakthrough Therapy, Fast Track, Priority Review, Accelerated Approval)<sup>12</sup> or all diagnostics, drugs and/or biologics. We seek data to support including these additional item categories in the MCIT pathway. Also,

we specifically seek manufacturer input on whether an opt-in or opt-out approach would work best for utilizing the MCIT pathway. We believe manufacturers will welcome this new coverage pathway. We want to preserve manufacturers' business judgment and not assume which Medicare coverage pathway a given manufacturer of a breakthrough device would prefer (if any). Therefore, we have proposed an opt-in approach with an email to CMS to indicate affirmative interest in coverage. We are interested in whether an opt-out approach would be less burdensome for stakeholders. If so, we encourage public comment on a process for stakeholders to opt-out of MCIT that would not be burdensome. Also, we seek public comment on whether, once a manufacturer has opted-out of coverage, it can subsequently opt-in to MCIT.

## II. Provision of Proposed Regulations

### A. Defining "Reasonable and Necessary"

As described in section I. of this proposed rule, the Secretary has authority to determine the meaning of "reasonable and necessary" under section 1862(a)(1)(A) of the Act. We are proposing to codify the longstanding Program Integrity Manual definition of "reasonable and necessary" into our regulations at 42 CFR 405.201(b), with modification. Under the current definition, an item or service is considered "reasonable and necessary" if it is (1) safe and effective; (2) not experimental or investigational; and (3) appropriate, including the duration and frequency that is considered appropriate for the item or service, in terms of whether it is—

- Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;
- Furnished in a setting appropriate to the patient's medical needs and condition;
- Ordered and furnished by qualified personnel;
- One that meets, but does not exceed, the patient's medical need; and
- At least as beneficial as an existing and available medically appropriate alternative.

In addition to codifying the above criteria, we propose to include a separate basis under which an item or service would be appropriate under (3) above that is based on commercial health insurers' coverage policies (that is, non-governmental entities that sponsor health insurance plans). The

<sup>11</sup> 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>.

<sup>12</sup> Fast Track, Breakthrough Therapy, Accelerated Approval, Priority Review, available at <https://www.fda.gov/patients/learn-about-drug-and-device-approvals/fast-track-breakthrough-therapy-accelerated-approval-priority-review>.

commercial market analysis would be initiated if an item/service fails to fulfill the existing factor (3) criteria defining appropriate for Medicare patients but fulfills (1) safe and effective and (2) not experimental or investigational. By considering commercial health insurer coverage policies, CMS would bring together the expertise of private payers and CMS. For example, in a recent NCD on acupuncture for chronic low back pain, CMS considered the technology assessments and coverage criteria among commercial health insurer coverage policies.<sup>13</sup> We believe that this approach would be in line with E.O. 13890 that directs us to make technologies “widely available, consistent with the principles of patient safety, market-based policies, and value for patients.” Under this separate basis, we propose that an item or service would satisfy factor (3) if it is covered under a plan(s) coverage policy if offered in the commercial insurance market, unless evidence supports that differences between Medicare beneficiaries and commercially insured individuals are clinically relevant. Under our proposal, we would exclude Medicaid managed care, Medicare Advantage, and other government administered healthcare coverage programs from the types of coverage CMS would consider, as these enrollees are not in the commercial market. In the following paragraphs, we seek comment on this proposal and on how best to implement this mechanism.

We solicit comments on sources of data that could be used to implement this policy, and whether CMS should make this information public and transparent. We seek public comment on the most appropriate source(s) for these coverage policies and the best way to determine which commercial plan(s) we would rely on for Medicare coverage.

We seek comment on whether beneficiaries, providers, innovators, or others wishing to gain coverage for an item or service demonstrate that the item or service is covered by at least one commercial insurance plan policy. If they can provide CMS with evidence of commercial coverage or if CMS or its MACs identify such coverage from its review of compilations of health insurance offerings or data from other sources, CMS would consider factor (3) to be satisfied.

We solicit comment on whether we should limit our consideration of

commercial plan offerings or covered lives to a subset of the commercial market in the interest of simplicity, including looking at geographic subsets, subsets based on number of enrollees, subsets based on plan type (HMO, PPO, etc.), or other subsets of plans—including utilizing a singular plan. We also seek comment on whether, given considerations such the variation and distribution of coverage policies and access to innovations, we should only cover an item or service if it is covered for a majority, or a different proportion such as a plurality, of covered lives amongst plans or a majority, plurality, or some other proportion of plan offerings in the commercial market. (A plan offering is a contract an insurer offers to its enrollees, and a single insurance company may provide many different offerings.)

We also recognize that plan offerings may impose certain coverage restrictions on an item or service, *e.g.* related to clinical criteria, disease stage, or number and frequency of treatment. As greater access to innovative treatments provides beneficiaries with more opportunity to improve health and drive decisions, we would, when coverage is afforded on the basis of commercial coverage, adopt the least restrictive coverage policy for the item or service amongst the offerings we examine. However, given potential unreasonable or unnecessary utilization, we also solicit comment on whether we should instead adopt the most restrictive coverage policy. We are further considering, as another variation, that if coverage restrictions are largely similar and present across the majority of offerings, CMS would adopt these in its coverage policies. We note that such coverage restrictions include the basic requirement for medical necessity at the level of individual patients. Medicare will still only pay for an item or service received by a beneficiary if it is medically necessary for the beneficiary. We seek comment on whether, if we were to take this approach, we should instead use a proportion other than a majority, as low as any offering and as high as all offerings, as a sufficient threshold. As a final variation, we could defer, in the absence of an NCD or national policy, to the MACs to tailor the restrictions on coverage based on what they observe in the commercial market, just as we rely on MACs with regards to the current definition.

We further solicit comment on whether to grant coverage for an item or service to the extent it meets the first and second factors and the commercial coverage basis for the third factor.

Under this approach, we would only use the current definition of “appropriate” from the current PIM when the exception for clinically relevant differences between Medicare beneficiaries and commercially insured individuals applies (or if the commercial coverage basis is determined by a proportion like a majority and there is insufficient commercial coverage information available). We note that referring to commercial coverage in this way may expand or narrow the circumstances under which we will cover a particular item or service and therefore solicit comment on whether, under such an approach, we should grandfather our current coverage policies for items and services. We also emphasize that the MACs will continue to make judgements in evaluating individual claims for reimbursement, such that a decision by CMS that an item or service is reasonable and necessary in general does not mean that it is reasonable and necessary in all circumstances with respect to individual claims for reimbursement.

We seek public comment on the most appropriate source(s) for these coverage policies. Further, under our proposal, each MAC would be responsible for reviewing commercial offerings to inform their LCDs or claim by claim decisions, which would include individual medical necessity decisions. We may also allow the MACs to develop approaches to address any or all of the considerations outlined above, parallel to their current practice of making coverage decisions in the absence of an NCD or national policy. We solicit comment on the best role of the MACs, along these lines or otherwise. We also solicit comment on whether the discretion to use the current criteria in the PIM when there is evidence to believe Medicare beneficiaries have different clinical needs should be exercised through the NCD process or in other ways, as well as what quantum of evidence should be sufficient.

In sum, we are proposing to define the term “reasonable and necessary” based on the factors currently found in the PIM, plus an alternative basis for meeting factor (3) based on any coverage in the commercial market. We are also soliciting comment on an alternative under whether an item or service satisfies the commercial coverage basis for factor (3) is determined by how it is treated across a majority of covered lives amongst commercial plan offerings, as well as an alternative whereby an item or service would be appropriate for Medicare patients to the extent it is covered in the commercial market.

<sup>13</sup>CMS, Decision Memorandum for Acupuncture for Chronic Low Back Pain, available at <https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=295#:~:text=Decision,of%20the%20Social%20Security%20Act.>

When evidence supports that differences between Medicare beneficiaries and commercially insured individuals are clinically relevant, we would rely on the criteria in the current PIM. We would continue relying on local administration of the program by MACs (including coverage on a claim by claim basis and LCDs) and maintain our discretion to issue NCDs based on the final rule.

We solicit comment on this proposed definition of reasonable and necessary, and alternatives outlined above, as well as other mechanisms or definitions we could establish for the term “reasonable and necessary”, and the merits and drawbacks associated with each, including the potential impact on Medicare program expenses or complexity. We may finalize any variation or outgrowth of the policies described in this proposal, or some combination of these options in lieu of or in conjunction with our proposed definition.

#### *B. Application of the “Reasonable and Necessary” Standard to the MCIT Pathway*

We are proposing that, under the proposed MCIT pathway, an item or service that receives a breakthrough device designation from the FDA would be considered “reasonable and necessary” under section 1862(a)(1)(A) of the Act because breakthrough devices have met the FDA’s unique breakthrough devices criteria, and they are innovations that serve unmet needs. While other devices are still considered new to the market, for example, PMAs and even some 510(k)s, the devices designated by the FDA as breakthrough are representative of true innovations in the marketplace. This application of the “reasonable and necessary” standard in this way would ensure that the MCIT pathway can provide a fast-track to Medicare coverage of innovative devices that may more effectively treat or diagnose life-threatening or irreversibly debilitating human disease or conditions.

MCIT would improve healthcare for Medicare beneficiaries by providing national Medicare coverage for devices receiving the FDA breakthrough device designation, which are FDA market-authorized and used consistent with the FDA approved or cleared indication for use (also referred to as the “FDA required labeling”),<sup>14</sup> so long as the breakthrough device is described in an

appropriate Medicare benefit category under Part A or Part B and is not specifically excluded by statute. We believe the criteria for qualification as a breakthrough device, as defined in section 515B(b) of the Food, Drug and Cosmetic Act (21 U.S.C. 360e–3(b)) is sufficient to satisfy the elements of the “reasonable and necessary” standard. The first breakthrough device designation criterion is that a device must “provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions” (21 U.S.C. 360e–3(b)(1)). The second criterion is that the device must satisfy one of the following elements: It represents a breakthrough technology; there are no approved or cleared alternatives; it offers significant advantages over existing approved or cleared alternatives, including additional considerations outlined in the statute; or availability of the device is in the best interest of patients (21 U.S.C. 360e–3(b)(2)). Thus, breakthrough devices are those that HHS has determined may provide better health outcomes for patients facing life-threatening or irreversibly debilitating human disease or conditions. We believe that a device meeting these criteria, once also FDA market authorized, is “reasonable and necessary” for purposes of Medicare coverage.

This proposed rule recognizes that the FDA market authorization of breakthrough devices warrants immediate coverage under the “reasonable and necessary” clause in section 1862(a)(1)(A) of the Act. We previously stated that FDA determinations were not controlling determinations for Medicare coverage purposes under section 1862(a)(1)(A) of the Act. (For more information see the January 30, 1989 **Federal Register** (54 FR 4307) (“FDA approval for the marketing of a medical device will not necessarily lead to a favorable coverage recommendation . . .”) and the August 7, 2013 **Federal Register** (78 FR 48165) (“However, FDA approval or clearance alone does not entitle that technology to Medicare coverage.”) Under the Secretary’s broad authority to interpret section 1862(a)(1)(A) of the Act (*supra* section I.A.), we are revising our interpretation of the statute because of the practical concerns that our current standards have delayed access to a unique set of innovative devices that FDA has found to be safe and effective, and we believe are “reasonable and necessary” for purposes of Medicare coverage.

In light of E.O. 13890, the Secretary has determined that application of the

current standards for making “reasonable and necessary” determinations may take too long following FDA market authorization of breakthrough devices. More importantly, the existing standard has not always provided Medicare beneficiaries adequate access to certain breakthrough medical devices when needed to improve health outcomes. We are proposing that breakthrough devices per se meet the reasonable and necessary standard in order to increase access and to reduce the delay from FDA market authorization to Medicare coverage.

#### *C. MCIT Pathway*

We are proposing the MCIT pathway to deliver on the Administration’s commitment to provide access to breakthrough devices to Medicare beneficiaries. The MCIT pathway provides up to 4 years of national coverage to newly FDA market authorized breakthrough devices. We are aware that this coverage may also facilitate evidence development on devices for the Medicare population because manufacturers can gather additional data on utilization of the device during the MCIT coverage period.

##### 1. Definitions

In § 405.601(a) we are proposing that the MCIT pathway is voluntary. Operationally, we propose that manufacturers of breakthrough devices notify CMS of their intention to elect MCIT shortly after receiving notice from the FDA of being granted the breakthrough device designation. Ideally, this notification would be sent to CMS within 2 weeks of receiving breakthrough designation. However, entities would not be penalized for notifying CMS after that time. Alternatively, submitting a notification to CMS shortly before or concurrently with the date of the FDA marketing submission should also afford CMS sufficient time to operationalize MCIT for the device. The CMS Coverage and Analysis Group would establish an email box for these inquires. This notification alerts CMS to offer guidance to manufacturers about the MCIT pathway and point to resources for coding and payment, which are key conversations to effectuate coverage upon FDA market authorization. We intend to utilize the existing coverage implementation processes to be prepared to offer coverage immediately upon the FDA market authorization.

In § 405.601(b), we propose the following definitions for the purposes of 42 CFR part 405. We propose to define

<sup>14</sup> FDA Guidance for Industry, “Medical Product Communications That Are Consistent with the FDA—Required Labeling—Questions and Answers”, available at <https://www.fda.gov/medial/133619/download>.

“breakthrough device” as a medical device that receives such designation by the FDA (section 515B(d)(1) of the FD&C Act (21 U.S.C. 360e–3(d)(1))). We also propose to define, for the sake of clarity in the rule, that the acronym MCIT stands for Medicare Coverage of Innovative Technology.

## 2. MCIT Pathway Device Eligibility

In § 405.603(a) we propose that the pathway is available to devices that meet the definitions proposed in § 405.601. Based on the explicit mention of devices in E.O. 13890 and our interaction and feedback from stakeholders who expressed their concern that there is more uncertainty of coverage for devices than for other items and services (for example, diagnostics, drugs and biologics), this proposed policy is for devices only.

We propose in § 405.603(b) that the breakthrough devices that received FDA market authorization no more than 2 calendar years prior to the effective date of this subpart (the date the final rule is finalized) and thereafter will be eligible for coverage for claims submitted on or after the effective date of this rule. Claims for breakthrough devices with dates of service that occurred before the effective date of this rule would not be covered through MCIT. For example, a hypothetical breakthrough device that was FDA market authorized on October 1, 2018, and utilized on January 1, 2020 would not be eligible for coverage under MCIT because on January 1, 2020, the date of service, the final MCIT rule was not yet legally in effect. In contrast, a claim for utilization of the same hypothetical breakthrough device with a date of service on January 1, 2021 might be eligible for coverage if the claim occurred after the effective date of the rule (assuming that the effective date of the rule was prior to January 1, 2021). Breakthrough devices market authorized prior to the effective date of this rule will not be eligible for all 4 years of coverage. The 4-year period starts on the date of FDA market authorization. For example, a breakthrough device market authorized on October 1, 2018 would have claims covered through MCIT from the effective date of the final rule until October 1, 2022. If a manufacturer initially chooses to not utilize the MCIT pathway, and then chooses to do so some time after the breakthrough device’s market authorization, coverage still only lasts 4 years from the date of FDA market authorization. We seek comment on this eligibility criterion for devices and specifically the 2 year lookback.

We propose in § 405.603(c) that to be part of the MCIT pathway, the device

must be used according to its FDA approved or cleared indication for use. We propose that the device is only covered for use consistent with its FDA approved or cleared indication for use because that is the indication and conditions for use that were reviewed by the FDA and authorized for marketing. Data are unlikely to be available to support extending beyond the FDA required labeling for breakthrough devices on the date of marketing authorization. Use of the device for a condition or population that is not labeled (“off-label”) will not be covered as that use would not be FDA authorized. We specifically seek comment on whether off-label use of breakthrough devices should be covered and, if so, under what specific circumstances and/or evidentiary support.

In § 405.603(d) and (e), we additionally propose limitations to what is coverable under the Act. In § 405.603(e), we are proposing that if CMS has issued an NCD on a particular breakthrough device, that breakthrough device is not eligible for MCIT. We are proposing this because, once the device has been reviewed by CMS for the FDA required approved or cleared indication for use; CMS has made a coverage determination based on the available evidence for that technology. We believe this would happen rarely because breakthrough devices are new technologies that are not likely to have been previously reviewed through the NCD process. In § 405.603(f), we acknowledge that devices in the MCIT pathway may be excluded due to statute or regulation (for example, 42 CFR 411.15, Particular services excluded from coverage) and, like other items and services coverable by Medicare, the device must fall within the scope of a Medicare benefit category under section 1861 of the Act and the implementing regulations. If the device does not fall within a Medicare benefit category as outlined in the statute and implementing regulations, the device is not eligible for Medicare coverage; therefore, the device would not be eligible for the MCIT pathway.

## 3. General Coverage of Items and Services under the MCIT Pathway

We propose in § 405.605 that devices covered under the MCIT pathway are covered no differently from devices that are covered outside of MCIT. In other words, provided the items and services are otherwise coverable (that is, not specifically excluded and not found by CMS to be outside the scope of a Medicare benefit category), covered items and services could include the

device, reasonable and necessary surgery to implant the device, if implantable, related care and services costs of the device (for example, replacing reasonable and necessary parts of the device such as a battery), and coverage of any reasonable and necessary treatments due to complications arising from use of the device. What the MCIT pathway offers compared to other pathways is predictable national coverage simultaneous with FDA market authorization that will generally last for a set time period.

The proposed MCIT pathway would support and accelerate beneficiary access to certain innovative devices. CMS encourages manufacturers that have breakthrough devices covered under MCIT to develop additional data for the healthcare community.

## 4. MCIT Pathway for Breakthrough Devices: 4 Years of Coverage

In § 405.607(a), we propose that the MCIT pathway for coverage would begin on the same date the device receives FDA market authorization. We propose this point in time to ensure there is no gap between Medicare coverage and FDA market authorization. This supports the MCIT pathway’s focus of ensuring beneficiaries have a predictable access to new devices.

We propose in § 405.607(b)(1) that the MCIT pathway for breakthrough devices ends 4 years from the date the device received FDA market authorization. We propose this 4 year time period because it could allow manufacturers to develop clinical evidence and data regarding the benefit of the use of their device in a real world setting. For example, we believe 4 years would allow most manufacturers sufficient time to complete FDA required post-approval or other real-world data collection studies that may have been a condition of FDA market authorization. This assumption is based upon our historical experience with studies conducted through coverage with evidence development (CED). Further, this time period allows Medicare to support manufacturers that, whether required by the FDA or not, have an interest in better understanding the health outcomes of their device in the Medicare population, including impacts on patient-reported and longer-term outcomes.

Further, § 405.607(b) proposes reasons that the MCIT pathway may end prior to 4 years. This includes circumstances whereby the device becomes subject to an NCD, regulation, statute, or if the device can no longer be lawfully marketed.

*D. Summary*

In summary, the MCIT pathway would provide immediate Medicare coverage of newly FDA market authorized breakthrough devices for 4 years. We seek public comment on all of our proposals. In particular, we seek feedback on whether the proposed 4 year coverage period is sufficient. We also look to stakeholders and the public to determine the level of interest and expected use of the proposed MCIT pathway so the agency can begin to estimate the level of needed resources to support successful implementation. We are also seeking public comments on our proposal to codify in regulations the standards we have historically used in making reasonable and necessary decisions under Part A and Part B under section 1862(a)(1)(A) of the Act. After considering public comments we would prepare a final rule that we expect

would be effective 60 days after publication of the final rule.

**III. Collection of Information Requirements**

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.

- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of the section 3506(c)(2)(A)-required issues for the following sections of this document that contain information collection requirements (ICRs).

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2018 National Occupational Employment and Wage Estimates for all salary estimates (<https://www.bls.gov/oes/current/oes131041.htm>, released May 2019). In this regard, the table that follows presents the mean hourly wage, the cost of fringe benefits (calculated at 100 percent of salary), and the adjusted hourly wage.

TABLE 1—NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES FOR MCIT

Occupation title	Occupation code	Mean hourly wage (\$/hr)	Fringe benefit (\$/hr)	Adjusted hourly wage (\$/hr)
Compliance Officer .....	13-1041	34.86	34.86	69.72

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer. Nonetheless, there is no practical alternative and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

This proposed coverage pathway allows for a voluntary participation and therefore necessitates that manufacturers of breakthrough devices notify CMS of their intent to enter the MCIT pathway. Therefore, the burden associated with notifying CMS is the time and effort it would take for each of the organizations to send CMS an email or letter. We anticipate two MCIT pathway participants in the first year based upon the number of medical devices that received FY2020 NTAP and were non-covered in at least one MAC jurisdiction by LCDs and related articles.

We estimate notifying CMS of intent to participate in MCIT would involve 15 minutes at \$69.72 per hour by a compliance officer. In this regard, we estimate 15 mins per notification at a cost of \$17.43 per organization (0.25 hours × \$69.72). In aggregate, we estimate 0.5 hours (0.25 hours × 2

submissions) at \$34.86 (\$17.43 × 2 submissions).

After the anticipated initial 2 submitters, over the next 3 years we expect 3 submitters in year 2, 4 submitters in year 3, and 5 submitters in year 4 to notify CMS of interested in the MCIT pathway. We expect this increase in submitters each year to level off at this point. In this regard, we estimate the same 0.25 hours per submission at a cost of \$17.43 per organization. Similarly, in aggregate, we estimate, for year 2 (0.75 hours at \$52.29 an hour), for year 3 (1.0 hour at \$69.72 an hour), and for year 4 (1.25 hours at \$87.15 an hour).

The proposed requirements and burden will be submitted to OMB under control number 0938-NEW.

We are requesting public comments on these information collection and recordkeeping requirements.

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule; or
2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget,

*Attention:* CMS Desk Officer, CMS-3372-P, Fax: (202) 395-6974; or Email: [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov).

Comments must be received on/by November 2, 2020.

**IV. Regulatory Impact Statement**

This proposed rule makes Medicare coverage policy updates pursuant to the authority at section 1862(a)(1)(A) of the Act. We are using regulatory action per the October 3, 2019 “Executive Order on Protecting and Improving Medicare for Our Nation’s Seniors” to address the increasing need for a swift Medicare coverage mechanism to allow beneficiaries across the nation to access breakthrough devices faster after FDA market authorization. This proposed rule addresses that need by establishing a coverage pathway that will allow immediate beneficiary access to FDA market authorized breakthrough devices.

We have examined the impact of this proposed 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). This proposed rule does reach the economic threshold and thus is considered a major rule.

Regulatory alternatives to this proposed rule were to combine Medicare coverage with clinical evidence development under section 1862(a)(1)(E) of the Act, to take no regulatory action at this time, or to adjust the duration of the MCIT pathway. Combining coverage with clinical evidence development would have met the E.O. 13890 overarching goal of beneficiary access to breakthrough devices. However, this alternative did not meet the other E.O. 13890 aims of minimizing time between FDA market authorization and Medicare coverage and wide availability. The timing of coverage would depend upon the manufacturer being able to initiate a clinical study and the wide availability of coverage could be an issue if providers did not have the infrastructure necessary to participate in the clinical study. CMS chose to not to pursue combining coverage with evidence development for breakthrough devices because we wanted to meet the timing and wide availability aims of E.O. 13890. CMS also considered taking no regulatory action and trying to leverage the existing Medicare coverage pathways or proposing sub-regulatory policies to achieve the streamlined coverage process described in E.O. 13890. Taking no action would not have resulted in the desired national coverage and access envisioned in E.O. 13890 because, as described in this preamble, the existing coverage pathways do not consistently provide swift, national beneficiary access to innovative devices. As discussed elsewhere in the preamble, the nature of the problem being addressed by this proposed regulation is a potential delay between a milestone such as FDA market authorization and CMS coverage; as such, we request comment on a policy option of

shortening of the duration of the MCIT pathway from the proposed 4 years to 1 year.

In addition to the alternatives just discussed, there are various possibilities regarding how to change the definition of “reasonable and necessary”—for example, whether to include a new aspect of the proposed definition that focuses on commercial insurance coverage practices. As noted earlier in the preamble, the goal of this revision is to expand coverage. However, the nuances of the definition would affect the magnitude of the impact and we request comment that would facilitate quantification of effects and comparison of alternatives at the final rule stage.

The impact of implementing the MCIT pathway is difficult to determine without knowing the specific technologies that would be covered. In addition, many of these technologies would be eligible for coverage in the absence of this rule, such as through a local or national coverage determination, so the impact for certain items may be the acceleration of coverage or adoption 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 innovative technologies would not otherwise be eligible for coverage in the absence of this rule. Because it is not known how these new technologies would otherwise come to market and be reimbursed, it is not possible to develop a point estimate of the impact. In general, we believe 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 is voluntary for the manufacturer. Because manufacturers typically join the Medicare coverage pathway that is most beneficial to them, this would 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.

In order to demonstrate the potential impact on Medicare spending, the CMS Office of the Actuary (OACT) developed

three hypothetical scenarios that illustrate the impact of implementing the proposed MCIT pathway. Scenarios two and three assume that the device would not have been eligible for coverage in the absence of this 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**.<sup>15</sup> 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 the proposed rule. If the devices received 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 number of anticipated devices in the pathway ( $\$2,044 \times 2,322 \times 2 = \$ 9.5$  million). For the third scenario, the high-cost scenario, we assumed the new technologies would receive the maximum add-on payment from the FY 2020 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 ( $\$22,425 \times 6,500 \text{ patients} \times 2 = \$ 291.5$  million). For subsequent years, we increased the number of anticipated devices in the pathway by three, four, and five in the last two scenarios until 2024.<sup>16</sup> In addition to

<sup>15</sup> 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).

<sup>16</sup> 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

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 will elect MCIT coverage, we have 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 is a range of potential impacts of the proposed MCIT coverage pathway 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.

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

	Costs (in millions)			
	FY 2021	FY 2022	FY 2023	FY 2024
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

We believe the assumptions used in the three scenarios are reasonable to show the possible wide range of impacts for implementing this proposed pathway, in particular for a technology that would not have otherwise been eligible for coverage.

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. 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.<sup>17</sup> We determined that small businesses potentially impacted may 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). During the first 4 years of MCIT, we anticipate approximately 14 surgical and medical instrument manufacturers may participate, and based off of U.S. Census data, the majority of this businesses type are small businesses with less than 1,000 employees (968 out of 1,093 businesses have less than 500 employees).<sup>18</sup> As such, this proposed rule would impact less than 5 percent of these businesses, and the revenue impact, if any, would not be negative. Rather, it would be a positive impact because MCIT would provide Medicare coverage (and subsequent payment) to providers who purchase the devices from these manufacturers. For Offices of Physicians (except Mental Health Specialists) and Freestanding Ambulatory Surgical and Emergency Centers that may be providing the breakthrough devices, the majority are small businesses with less than 1,000 employees (4,060 out of 4,385 and 160, 367 out of 161, 286 have less than 500 employees, respectively).<sup>19</sup> Given that we estimate, at most in the high-cost scenario, that 6,500 beneficiaries would utilize breakthrough devices through MCIT per year, and even if each beneficiary were to access services at only one of these small businesses (that is, no two beneficiaries used the same office or center), still less than 5 percent of these small businesses would be

impacted by MCIT. As such, the revenue impact, if any, would not be negative, rather, it would be a positive impact because MCIT would provide Medicare coverage (and subsequent payment) to providers. Overall, this proposed rule results in a payment, not a reduction in revenue. We are not preparing a further analysis for the RFA because we have determined, and the Secretary certifies, that this proposed 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 through this proposed rule. Rather, for small entities that develop or provide breakthrough devices to patients, this proposed rule is a means for the device to be covered through the Medicare program, which does not detract from revenue and could be viewed as a positive economic impact. With the limited information we had to base this estimate, we solicit public comment on improvements to this estimate for the final rule.

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

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 proposed 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.

<sup>17</sup> Small Business Administration, Table of Small Business Size Standards Matched to North American Industry Classification System (NAICS) Codes, available at [https://www.sba.gov/sites/default/files/2019-08/SBA%20Table%20of%20Size%20Standards\\_Effective%20Aug%202019%2C%202019\\_Rev.pdf](https://www.sba.gov/sites/default/files/2019-08/SBA%20Table%20of%20Size%20Standards_Effective%20Aug%202019%2C%202019_Rev.pdf).

<sup>18</sup> 2017 County Business Patterns and 2017 Economic Census. Number of Firms, Number of Establishments, Employment, Annual Payroll, and Preliminary Receipts by Enterprise Employment Size for the United States, All Industries: 2017 (release date: May 6, 2020).

<sup>19</sup> *Id.*

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 this proposed 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 through this proposed rule. 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 is a means for the device to be 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 2020, that threshold was approximately \$156 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 regulation does not impose any costs on State or local governments, the requirements of Executive Order 13132 are not applicable.

Executive Order 13771 (E.O. 13771), titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017. This proposed rule, if finalized as proposed, is expected to impose no more than *de minimis* costs and thus be neither an E.O. 13771 regulatory action nor an E.O. 13771 deregulatory action.

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

## 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.

### 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 chapter IV 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).

■ 2. Section 405.201 is amended in paragraph (b) by adding the definition of “Reasonable and necessary” in alphabetical order to read as follows:

### § 405.201 Scope of subpart and definitions.

\* \* \* \* \*

(b) \* \* \*

*Reasonable and necessary* means that an item or service is considered—

- (1) Safe and effective;
- (2) Except as set forth in § 411.15(o) of this chapter, not experimental or investigational; and
- (3) Appropriate for Medicare patients, including the duration and frequency that is considered appropriate for the item or service, in terms of whether it (i) Meets all of the following criteria:

(A) Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient’s condition or to improve the function of a malformed body member;

(B) Furnished in a setting appropriate to the patient’s medical needs and condition;

(C) Ordered and furnished by qualified personnel;

(D) One that meets, but does not exceed, the patient’s medical need; and

(E) At least as beneficial as an existing and available medically appropriate alternative; or

(ii) Is covered by commercial insurers, unless evidence supports that differences between Medicare

beneficiaries and commercially insured individuals are clinically relevant.

\* \* \* \* \*

■ 3. Subpart F, consisting of §§ 405.601–405.607, is added to read as follows:

### Subpart F—Medicare Coverage of Innovative Technology

Sec.

- 405.601 Medicare coverage of innovative technology.  
405.603 Medical device eligibility.  
405.605 Coverage of items and services.  
405.607 Coverage period.

### Subpart F—Medicare Coverage of Innovative Technology

#### § 405.601 Medicare coverage of innovative technology.

(a) *Basis and scope.* Medicare coverage of innovative technology (MCIT) is a program that provides national, time-limited coverage under section 1862(a)(1)(A) of the Act for certain breakthrough medical devices. Manufacturer participation in the pathway for breakthrough device coverage is voluntary.

(b) *Definitions.* For the purposes of this subpart, the following definitions are applicable:

*Breakthrough device* means a device that receives such designation by the Food and Drug Administration (FDA) (section 515B(d)(1) of the FD&C Act (21 U.S.C. 360e–3(d)(1)).

*MCIT* stands for Medicare coverage of innovative technology.

#### § 405.603 Medical device eligibility.

The MCIT pathway is available only to medical devices that meet all of the following:

- (a) That are FDA-designated breakthrough devices.
- (b) That are FDA market authorized at most [date 2 years prior to effective date of final rule] and thereafter.
- (c) That are used according to their FDA approved or cleared indication for use.
- (d) That are within a Medicare benefit category.
- (e) That are not the subject of a Medicare national coverage determination.
- (f) That are not otherwise excluded from coverage through law or regulation.

#### § 405.605 Coverage of items and services.

Covered items and services furnished within the MCIT pathway may include any of the following, if not otherwise excluded from coverage:

- (a) The breakthrough device.
- (b) Any reasonable and necessary procedures to implant the breakthrough device.

(c) Reasonable and necessary costs to maintain the breakthrough device.

(d) Related care and services for the breakthrough device.

(e) Reasonable and necessary services to treat complications arising from use of the breakthrough device.

#### § 405.607 Coverage period.

(a) *Start of the period.* The MCIT pathway begins on the date the breakthrough device receives FDA market authorization.

(b) *End of the period.* The MCIT pathway for a breakthrough device ends as follows:

(1) No later than 4 years from the date the breakthrough device received FDA market authorization.

(2) Prior to 4 years if a manufacturer withdraws the breakthrough device from the MCIT pathway.

(3) Prior to 4 years if the breakthrough device becomes the subject of a national coverage determination or otherwise becomes uncovered through law or regulation.

Dated: May 4, 2020.

**Seema Verma,**

*Administrator, Centers for Medicare & Medicaid Services.*

Dated: June 11, 2020.

**Alex M. Azar II,**

*Secretary, Department of Health and Human Services.*

[FR Doc. 2020-19289 Filed 8-31-20; 8:45 am]

BILLING CODE 4120-01-P

## DEPARTMENT OF THE INTERIOR

### Fish and Wildlife Service

#### 50 CFR Part 17

[FF09E21000 FXES11110900000 201]

### Endangered and Threatened Wildlife and Plants; Two Species Not Warranted for Listing as Endangered or Threatened Species

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Notice of findings.

**SUMMARY:** We, the U.S. Fish and Wildlife Service (Service), announce 12-month findings on petitions to add Big Cypress epidendrum (*Epidendrum strobiliferum*) and Cape Sable orchid (*Trichocentrum undulatum*) to the List of Endangered and Threatened Plants under the Endangered Species Act of 1973, as amended (Act). After a thorough review of the best available scientific and commercial information, we find that it is not warranted at this time to list the Big Cypress epidendrum

or Cape Sable orchid. However, we ask the public to submit to us at any time any new information relevant to the status of either of the species mentioned above or their habitats.

**DATES:** The findings in this document were made on September 1, 2020.

**ADDRESSES:** Detailed descriptions of the basis for these findings are available on the internet at <http://www.regulations.gov> under the following docket numbers:

Species	Docket No.
Big Cypress epidendrum	FWS-R4-ES-2020-0043.
Cape Sable orchid .....	FWS-R4-ES-2020-0044.

Please submit any new information, materials, comments, or questions concerning this finding to the person specified under **FOR FURTHER INFORMATION CONTACT.**

**FOR FURTHER INFORMATION CONTACT:** Roxanna Hinzman, Field Supervisor, U.S. Fish and Wildlife Service, South Florida Ecological Services Field Office, email: [roxanna\\_hinzman@fws.gov](mailto:roxanna_hinzman@fws.gov), telephone: 772-469-4309. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service at 800-877-8339.

#### SUPPLEMENTARY INFORMATION:

##### Background

Under section 4(b)(3)(B) of the Act (16 U.S.C. 1531 *et seq.*), we are required to make a finding whether or not a petitioned action is warranted within 12 months after receiving any petition that we have determined contains substantial scientific or commercial information indicating that the petitioned action may be warranted (“12-month finding”). We must make a finding that the petitioned action is: (1) Not warranted; (2) warranted; or (3) warranted but precluded. We must publish a notice of these 12-month findings in the **Federal Register**.

##### Summary of Information Pertaining to the Five Factors

Section 4 of the Act (16 U.S.C. 1533) and the implementing regulations at part 424 of title 50 of the Code of Federal Regulations (50 CFR part 424) set forth procedures for adding species to, removing species from, or reclassifying species on the Lists of Endangered and Threatened Wildlife and Plants (Lists). The Act defines “species” as any subspecies of fish or wildlife or plants, and any distinct population segment of any species of vertebrate fish or wildlife which interbreeds when mature. The Act defines “endangered species” as any species that is in danger of extinction

throughout all or a significant portion of its range (16 U.S.C. 1532(6)), and “threatened species” as any species that is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range (16 U.S.C. 1532(20)). Under section 4(a)(1) of the Act, a species may be determined to be an endangered species or a threatened species because of any of the following five factors:

(A) The present or threatened destruction, modification, or curtailment of its habitat or range;

(B) Overutilization for commercial, recreational, scientific, or educational purposes;

(C) Disease or predation;

(D) The inadequacy of existing regulatory mechanisms; or

(E) Other natural or manmade factors affecting its continued existence.

These factors represent broad categories of natural or human-caused actions or conditions that could have an effect on a species’ continued existence. In evaluating these actions and conditions, we look for those that may have a negative effect on individuals of the species, as well as other actions or conditions that may ameliorate any negative effects or may have positive effects.

We use the term “threat” to refer in general to actions or conditions that are known to or are reasonably likely to negatively affect individuals of a species. The term “threat” includes actions or conditions that have a direct impact on individuals (direct impacts), as well as those that affect individuals through alteration of their habitat or required resources (stressors). The term “threat” may encompass—either together or separately—the source of the action or condition or the action or condition itself. However, the mere identification of any threat(s) does not necessarily mean that the species meets the statutory definition of an “endangered species” or a “threatened species.” In determining whether a species meets either definition, we must evaluate all identified threats by considering the expected response by the species, and the effects of the threats—in light of those actions and conditions that will ameliorate the threats—on an individual, population, and species level. We evaluate each threat and its expected effects on the species, then analyze the cumulative effect of all of the threats on the species as a whole. We also consider the cumulative effect of the threats in light of those actions and conditions that will have positive effects on the species, such as any existing regulatory mechanisms or conservation efforts. The