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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3180-N4]

Food and Drug Administration

[Docket No. FDA-2010-N-0308]

Program for Parallel Review of Medical Devices

AGENCY: Food and Drug Administration; Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) and the Centers for Medicare & Medicaid Services (CMS) (the Agencies) are informing the public that the Parallel Review of medical devices pilot program will be fully implemented and extended indefinitely. The Agencies are soliciting nominations from manufacturers of innovative medical devices to participate in the "Program for Parallel Review of Medical Devices." The Parallel Review program is a collaborative effort that is intended to reduce the time between FDA marketing approval or FDA's granting of a de novo request and Medicare coverage decisions through CMS's National Coverage Determination (NCD) process. This program is intended to ensure prompt and efficient patient access to safe and effective and appropriate medical devices for the Medicare population.

DATES: The program described in this document for parallel review for medical devices is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The program will be fully implemented as of the date of the publication of this document in the Federal Register.

FOR FURTHER INFORMATION CONTACT: For device manufacturers interested in Parallel Review and for general questions: Murray Sheldon, Center for Devices and Radiological Health, Food and Drug Administration, 301-796-5443, Parallel-Review@fda.hhs.gov. For questions related to devices reviewed by Center for Biologics Evaluation and Research: Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 7301, Silver Spring, MD 20993, 240-402-7911. For general questions about the NCD process: Tamara Syrek Jensen, Centers for Medicare and Medicaid Services, 410-786-3529, Tamara.SyrekJensen@cms.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

A. Parallel Review Pilot Program's History

As discussed in the September 17, 2010, Federal Register notice (75 FR 57045), the Agencies announced their intention to initiate a Parallel Review pilot program that would establish a process for overlapping evaluation of clinical evidence for premarket, FDA-regulated medical devices in order to reduce the time between FDA marketing approval or FDA's granting of a de novo request and a Medicare NCD. The Agencies piloted the program in an effort to increase quality of patient health care by facilitating earlier access to innovative medical technologies for Medicare beneficiaries.

In the October 11, 2011, Federal Register notice (76 FR 62808), the Agencies provided notice of the procedures for voluntary participation in the pilot program as well as the guiding principles they intended to follow during the program. In the December 18, 2013, Federal Register notice (78 FR 76628), the Agencies extended the duration of the pilot program for an additional 2 years.

Currently, the Agencies appreciate the full potential of the parallel review program and realize the positive impact of the pilot, and have now decided to transition into a permanent program.

B. Purpose of Parallel Review

Parallel Review allows both Agencies to review information about a medical device concurrently, rather than sequentially, while continuing to make their premarket review and coverage decisions consistent with their respective statutory authority. FDA works to ensure that only safe and effective medical devices are marketed in the United States. CMS makes coverage decisions for medical technologies, which are reasonable and necessary for the Medicare population. Neither FDA's premarket review criteria nor CMS's coverage processes criteria change when a medical device is accepted into the parallel review program.

C. Lessons Learned From the Parallel Review Pilot Program

The Agencies learned two primary lessons from the Parallel Review pilot program. First, they found that manufacturers benefit from engaging both Agencies at the pivotal clinical trial design phase. The feedback that manufacturers receive from both Agencies at the pivotal clinical trial design stage can assist manufacturers in designing pivotal trials that can answer both Agencies' evidentiary questions. Thus, it is more likely that manufacturers will only need to conduct a single pivotal clinical study rather than several pivotal clinical studies to satisfy both Agencies.

Second, concurrent review by the Agencies of clinical evidence can reduce the time from FDA premarket approval or the granting of a de novo request to an NCD. For example, on August 11, 2014, FDA approved a medical device that was part of the Parallel Review Pilot Program. On the same day, CMS initiated its national coverage analysis (NCA). CMS

published a favorable final NCD on October 9, 2014, less than 2 months after the medical device received its premarket approval and 7 months before the NCD statutory due date.

II. Parallel Review Program

Based on the positive experience from the Parallel Review Pilot Program, both Agencies have decided to extend the Parallel Review program indefinitely.

A. Parallel Review Process

The program has two stages: (1) The pivotal clinical trial design development stage, and (2) the concurrent evidentiary review stage. The manufacturer should submit a request for parallel review prior to the start of the first stage by sending an email to Parallel-Review@fda.hhs.gov, which indicates their interest in the program and includes the following information:

1. Nomination of manufacturer:
    - Name of the manufacturer and relevant contact information;
    - name of the product;
    - succinct description of the technology and disease or condition the device is intended to diagnose or treat; and
    - state of development of the technology (that is, in pre-clinical testing, in clinical trials, currently undergoing premarket review by FDA)

2. A statement that the manufacturer intends to meet jointly with FDA and CMS using FDA's Pre-Submission program (Ref. 1), or other mechanisms that allow for meetings of the three parties to gather and incorporate feedback from both Agencies about the design and analysis of their pivotal clinical trial, to support a marketing application and a National Coverage Determination.

3. A statement that the medical device will require an original or supplemental application for premarket approval (PMA) or the granting of an FDA de novo request;

4. The medical device is not excluded by statute from Part A and/or Part B Medicare coverage (and the request for parallel review includes a list of Part A and/or Part B Medicare benefit categories, as applicable, into which the manufacturer believes the medical device falls); and

5. A statement that the medical device addresses the public health needs of the Medicare population (and the request for parallel review includes an explanation of how).

Upon completion of the pivotal trial and submission of an original or supplemental PMA, or a de novo request, the Agencies intend to review the pivotal clinical trial evidence concurrently ("in parallel"). Both Agencies will independently review the data to determine whether it meets their respective Agency's standards and communicate with the manufacturer during their respective reviews.

Manufacturers and each Agency have the option to withdraw from the Parallel Review Program until CMS opens the NCD by posting a tracking sheet. For example, if the manufacturer would like to withdraw from the program after the pivotal trial, but before the NCA tracking sheet is posted, that would be acceptable. More information on the NCD process is set forth in the August 7, 2013 Federal Register notice (78 FR 48164). Once a tracking sheet is posted, CMS must complete the statutorily defined NCD process.

B. Candidate Prioritization

The Agencies intend to review Parallel Review requests and respond within 30 days after receipt of the email. The Agencies intend to prioritize innovative medical devices that will benefit from the efficiencies of the Parallel Review. Priority will also be given to medical

devices expected to have the most impact on the Medicare population. An FDA marketing approval does not guarantee a favorable coverage decision.

III. Paperwork Reduction Act of 1995

As stated in previous Federal Register notices related to the Parallel Review pilot, due to FDA and CMS resource issues, the permanent program will follow the same capacity limit by accepting no more than five candidates per year. As such, like the pilot program, this collection of information does not meet the definition of an information collection, as defined under 44 U.S.C. 3501-3520.

IV. References

The following references are on display in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at http://www.regulations.gov. FDA has verified the Web site addresses, as of the date this document publishes in the Federal Register, but Web sites are subject to change over time.

1. FDA Guidance, "Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff." Available at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM311176.pdf.

Dated: October 18, 2016.

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Leslie Kux,

Associate Commissioner for Policy,

Food and Drug Administration.

Dated: OCT 05 2016.

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Andy Slavitt,

Acting Administrator,

Centers for Medicare & Medicaid Services.

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