CDRH's Parallel Review & Other Payer Communication Opportunities

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What Are We Encouraging?

CDRH Review Team

Manufacturer

Payer

Create awareness

- ~~Provide~~ a process to enable manufacturers to include and engage payers during meetings with CDRH using the Pre-Submission program.

Payer Communication Task Force

- Facilitates communication between device manufacturers and payers
- https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHInnovation/ucm456149.htm

History of Parallel Review

Purpose: Reduce the time between FDA marketing approval and a coverage decision/patient access

Announced: 75 Fed. Reg. 57045 (Sept. 17, 2010)

Described: 76 Fed. Reg. 62808 (Oct. 11, 2011)

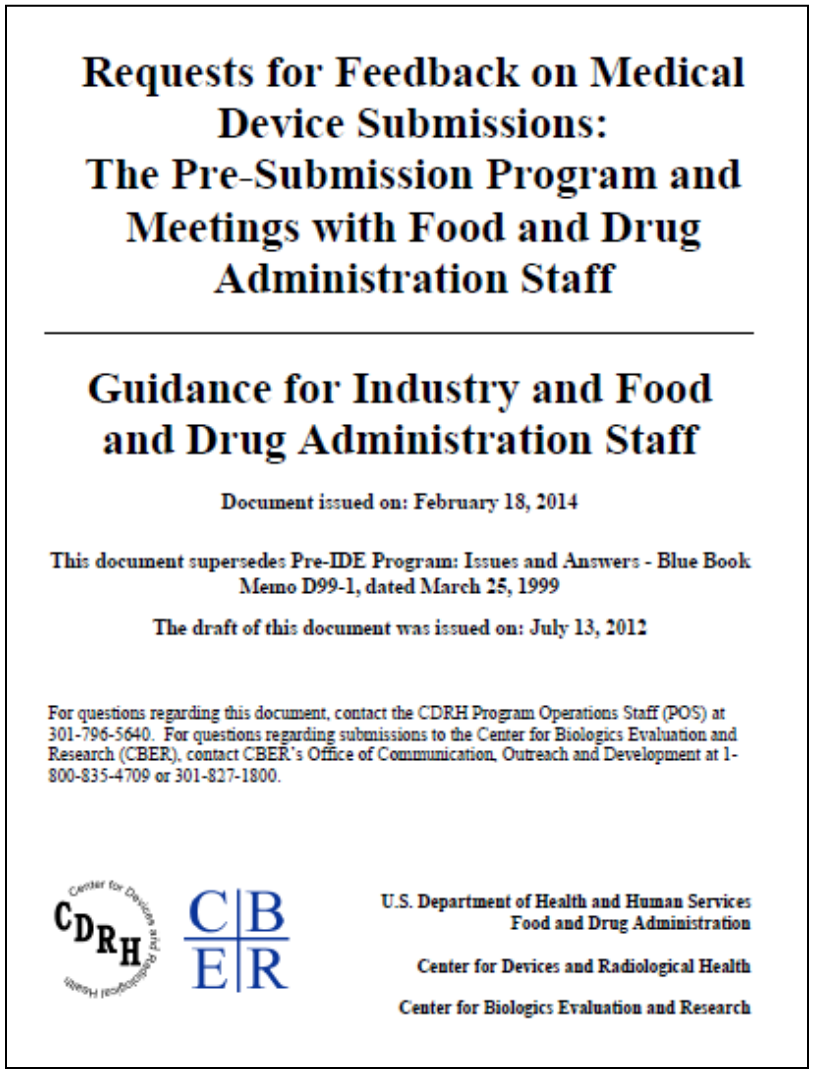
Extended: 78 Fed. Reg. 76628 (Dec. 18, 2013)

Extended: 81 Fed. Reg. 73113 (Oct. 24, 2016)

Parallel Review 101

- Manufacturer meets jointly with FDA and CMS using FDA's Pre-Submission program and incorporate feedback from both agencies in pivotal clinical trial
- Medical device requires an original or supplemental PMA or the granting of a de novo request
- Device isn't excluded by statute from Part A and/or Part B Medicare coverage
- Device addresses the needs of the Medicare population

CDRH Guidance



Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff

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Guidance for Industry and Food and Drug Administration Staff

Document issued on: February 18, 2014

This document supersedes Pre-IDE Program: Issues and Answers - Blue Book Memo D99-1, dated March 25, 1999

The draft of this document was issued on: July 13, 2012

For questions regarding this document, contact the CDRH Program Operations Staff (POS) at 301-796-5640. For questions regarding submissions to the Center for Biologics Evaluation and Research (CBER), contact CBER's Office of Communication, Outreach and Development at 1-800-835-4709 or 301-827-1800.

U.S. Department of Health and Human Services
Food and Drug Administration

Center for Devices and Radiological Health

Center for Biologics Evaluation and Research

Clear cover letter with your <u>CDRH</u> goal

<u>Concise</u> description and summary

Specific questions

<u>No</u> MDUFA user fees

Beneficial to FDA too

Parallel Review Lessons Learned

- Earlier interaction is more beneficial - good to have all parties present when planning the trial
- Agencies have different evidentiary requirements and may not always agree
- Agencies don't change evidentiary requirements by coordinating efforts

Private Payers

- Medicare/NCD is not appropriate for many devices
- Answer: Add Private Payers

Private Payer Program

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Notice

Request for Expressions of Interest From Coverage Organizations; Coverage Organizations Interested in Providing Input Regarding Private Payer Coverage to Medical Device Sponsors Who Request Their Participation in a Pre-Submission Meeting With the Food and Drug Administration

A Notice by the Food and Drug Administration on 02/24/2016

ACTION Notice; Request For Expressions Of Interest.

SUMMARY The Food and Drug Administration (FDA) is requesting expressions of interest from organizations that evaluate clinical evidence used to support private payer coverage decisions for medical devices (coverage organizations) that wish to provide input to medical device developers (sponsors) on clinical trial design or other plans for gathering clinical evidence needed to support positive coverage decisions. These

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Links

CDRH's Payer Communication Task Force

http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHInnovation/ucm456149.htm

CDRH's Pre-Submission Program

http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM311176.pdf

Private Payer Federal Register Notice

https://www.federalregister.gov/articles/2016/02/24/2016-03909/request-for-expressions-of-interest-from-coverage-organizations-coverage-organizations-interested-in

CMS Innovator's Guide to Navigating Medicare

https://www.cms.gov/Medicare/Coverage/CouncilonTechInnov/Downloads/Innovators-Guide-Master-7-23-15.pdf


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