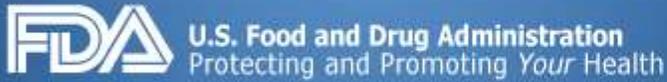


Wednesday June 2, 2016



## **FDA Categorization of Investigational Device Exemption (IDE) Devices to Assist the Centers for Medicare and Medicaid Services (CMS) with Coverage Decisions - Draft Guidance for Sponsors, Clinical Investigators, Industry, Institutional Review Boards and Food and Drug Administration Staff**

Today the FDA issued a [draft guidance](#) “Food and Drug Administration Categorization of Investigational Device Exemption Devices to Assist the Centers for Medicare and Medicaid Services (CMS) with Coverage Decisions.” This draft guidance, when final, modifies FDA’s current policy on categorization of IDE devices. This categorization assists CMS in determining whether or not an IDE device should be covered (reimbursed by CMS). Currently, devices with an approved Investigational Device Exemption (IDE) are categorized into one of two categories by FDA Experimental/Investigational (Category A) devices or Non-experimental/Investigational (Category B) devices based on our understanding of the risks and benefits of the device.

On December 2, 2015, FDA’s Center for Devices and Radiological Health (CDRH) and CMS’s Coverage and Analysis Group (CAG) executed a Memorandum of Understanding (MOU) to streamline and facilitate the efficient categorization of investigational medical devices to support CMS’s ability to make Medicare coverage (reimbursement) determinations for those investigational devices. The MOU noted the need for FDA and CMS to revise their shared understanding regarding categorization. This guidance document will facilitate categorization by further explaining the framework that FDA intends to use to help determine appropriate categorization for an IDE in which the device will be studied.

On July 14, 2016 from 2:00 – 3:30 PM, Eastern Time we will hold a Clinical Trials Update webinar. During the webinar we will:

- Update you on CDRH’s Clinical Trials Program
- Provide an overview of the CMS categorization draft guidance document
- Discuss the Early Feasibility Program for medical devices

During the webinar, participants will be given the opportunity to interact with subject matter experts and ask questions about any of these topics. Additional details about this webinar will be available on the [CDRH Webinar](#) website prior to July 14.

