Draft
Mobile Medical Applications Guidance

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Center for Devices and Radiological Health
CDRH

Agenda

- Definitions
- Regulatory Approach for MMAs
- Questions

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Defining Mobile Medical Applications (MMAs)

Related Definitions:

- Device
- Mobile Platform
- Mobile Application
- Regulated Medical Device
- MMA Manufacturer

Definition of Device

SEC. 201. [321] For the purposes of this Act –

(h) The term "device" … means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is--

(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

(3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

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Definition of Device

Includes Software

(Always has)

Mobile Platform

Handheld off-the-shelf computers, such as smart phones and tablets

Mobile Application

Software that is designed to be accessed with a mobile platform

Regulated Medical Device

A product that:

1. Meets the definition of a medical device AND
2. FDA has classified or reviewed

Mobile Medical App (MMA)

A Mobile App that has a medical device intended use and:

- Is used with a regulated medical device OR
- Transforms the mobile platform hardware into regulated medical device hardware

MMA Manufacturer

- The MMA developer or the person/company who hires the developer

  - *Not* the company that makes the commercial off-the-shelf mobile platform
  - *Not* the owner of the “App Store” or distribution network
  - *Not* the phone company or the internet service provider

Scope

This guidance does not specifically address wireless safety considerations, classification and submission requirements related to clinical decision support software, or the application of quality systems to software. The FDA intends to address these topics through separate guidance documents.

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Regulatory Approach

FDA proposed to actively oversee only certain types of mobile apps:

- Apps that meet the definition of an "MMA"

  - *Not* apps that don't meet that definition
  - *Not* apps that may meet the definition but are specifically identified as under enforcement discretion

Apps that, if medical devices, are under enforcement discretion

- Automate common medical knowledge available in the medical literature
- Allow individuals to self-manage their disease or condition
- Automate common clinician's diagnostic and treatment tasks using simple general purpose tools, including spreadsheets, timers, or other general computer applications, by performing logging and tracking

Apps that, if medical devices, are under enforcement discretion

- Log, track, and graph manually-entered (keyed in) data that lead to reminders or alarms
- Act as data viewers for patient education
- Organize, store, and display personal health data, such as lab results, doctor visits, dosages, calories consumed, etc.
- Use drug labeling to provide information that is typically available on a drug label, e.g., acetaminophen dosage for children and adults

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Questions?

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