

New FDA Draft Guidance on Mobile Medical Apps

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July 2011

Top-Level Points

- The FDA issued guidance on mobile apps for medical use
- The FDA has established a two-part definition of a mobile medical app
- The FDA classifies three specific subsets of mobile medical apps (based strongly on the app's intended use) as medical devices
- Mobile medical apps that classify as medical devices should follow FDA guidance and regulations for medical devices
- The agency has listed specific types of mobile apps it will not be monitoring
- The FDA realizes these new guidelines may cause some confusion, and it encourages manufacturers of mobile medical apps to contact the Agency to determine the classification of their mobile app
- If needed, the FDA will expand its current definition of a mobile medical app and apply regulations per this new definition
- In future guidelines, the FDA will be addressing issues of wireless safety, quality systems and clinical decision support

Summary

On July 19, 2011, the U.S. Food and Drug Administration (FDA) issued a new draft guidance detailing how the regulatory body defines, classifies and regulates "mobile medical apps." The new guidance expands upon the FDA's previous definition of a medical device to include what the FDA defines as mobile medical apps. The FDA believes these mobile medical apps, which are increasingly common, pose the same risks to patients as those posed by medical devices (e.g. EEG and MRI) and that the FDA is therefore required to regulate mobile medical apps.¹ As with all FDA draft guidances, these guidelines do not establish legally enforceable responsibilities but rather describe the regulatory agency's current thinking and recommendations on the subject matter. Nevertheless, these guidelines should be taken seriously.

Key Information

The FDA's "Draft Guidance for Industry and Food and Drug Administration Staff – Mobile Medical Applications" can be summarized into three main sections that state the FDA's position on:

- Definition of a Mobile Medical App
- Scope of FDA Regulation Over Mobile Medical Apps
- FDA Mobile Medical App Regulations and Controls

In the new documentation, the FDA provides its definition of a mobile application (mobile app) as "a software application that can be executed (run) on a mobile platform, or a web-based software application that is tailored to a mobile platform but is executed on a server." With this broad app definition in place, the FDA then lays out a **two-part definition for a "mobile medical app"** that it will use to evaluate what apps fall under its oversight.

1. The mobile medical app must meet the FDA definition of a device: "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent... intended for use in the diagnosis or the cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man."²
2. The mobile medical app must be either "used as an accessory to a regulated medical device" or "transform a mobile platform into a regulated medical device."³

Most mobile apps will meet the first definitional requirement, as the FDA already considers application software a form of device. Therefore, **the real qualifier will be the mobile app's intended use**, which the FDA states can be found in the app's labeling claims, advertising materials, or in oral or written statements by manufacturers or their representatives.

However, the **FDA will only be applying its regulatory oversight to three types of mobile medical apps**, because it believes these apps pose the same or similar risk to the public health as currently regulated medical devices. The three types of apps, listed below, are based on the app's intended use.

¹ "Draft Guidance for Industry and Food and Drug Administration Staff – Mobile Medical Applications" (page 5)

² "Federal Food, Drug and Cosmetic Act (FD&C Act)" - Section 201(h)

³ "Draft Guidance for Industry and Food and Drug Administration Staff – Mobile Medical Applications" (page 7)



1. Apps that connect to a medical device for the purpose of A) controlling the device, or B) displaying, storing, analyzing or transmitting patient-specific medical device data (e.g. an app that controls the delivery of insulin on an insulin pump by transmitting signals to the pump)
2. Apps that transform the mobile platform into a medical device by using attachments, display screens or sensors or by including functionalities similar to those of currently regulated medical devices (e.g. an app that allows doctors to monitor brain activity by attaching EEG sensors to a mobile device)
3. Apps that allow the user to input patient-specific information and — using formulae or processing algorithms — output a patient-specific result, diagnosis or treatment recommendation to be used in clinical practice or to assist in making clinical decisions (e.g. an app that provides a questionnaire for collecting patient-specific lab results and computes the prognosis of a particular condition)

If a mobile medical app falls into one of the above categories, its manufacturers are required to follow the medical device regulations established by the FDA. These medical device regulations and controls are broken up into three classifications (Class I, Class II and Class III). A mobile medical app's classification will determine, among other things, the type of pre-marketing submission/application required for FDA clearance to market.

In addition to stating the definition of a mobile medical app and what types of mobile medical apps it will regulate, the **FDA has also defined categories of mobile apps it does not consider mobile medical apps** and that are therefore not subject to draft guidance. This list includes apps that:

- Are electronic "copies" of medical textbooks, teaching aids, or reference materials (e.g. an electronic version of the *Physician's Desk Reference* or reference flash cards or slideshows of common conditions)
- Are solely used to log, record, track, evaluate or make decisions or suggestions related to general health, lifestyle and wellness (e.g. dietary tracking logs, appointment reminders, exercise suggestions, etc.)
- Automate general office operations with functionalities that include billing, inventory, appointments or insurance transactions (e.g. apps that determine billing codes or automate functions such as collecting patient histories or that enable insurance claims data collection)
- Are generic aids that assist users but are not commercially marketed for a specific medical indication (e.g. apps that use the mobile platform for recording audio or note-taking)
- Perform the functionality of an electronic health record system or personal health record system

Implications and Action Items

- **Apps Already in Market:** Review the FDA draft guidance closely. Determine if your app meets the FDA mobile medical app definition. If it does, work with your legal and regulatory teams to determine if it falls under the FDA's regulatory oversight as a medical device and will need to follow the medical device regulations established by the FDA.
- **Apps Currently in Development:** Review the FDA draft guidance closely. Discuss with your regulatory and legal departments the potential impact these new regulations may have on your app with a particular eye to timelines, budget and functionality.
- **Planning an App:** Review the FDA draft guidance closely. Ascertain if your proposed app meets the FDA mobile medical app definition. If it will be under the FDA's regulatory oversight, then follow the medical device regulations established by the FDA.
- **Potential for More Guidelines:** While the FDA has been very specific with its definition of what is and isn't a mobile medical app, in the draft guidance the Agency will continue to monitor the performance of other mobile apps that are outside this guidance and determine whether additional or different actions are necessary to protect the public health.

For more insights into applying FDA regulations to digital marketing, see: <http://rtcrm.com/whitepapers/>

