

In February 2015, the Food and Drug Administration published guidance pertaining to mobile medical applications (or apps). Although guidance does not establish legally enforceable responsibilities, this document reflects FDA's current thinking and recommendations regarding mobile medical apps.

FDA applies regulatory oversight only to those mobile apps that represent medical devices and that could pose a risk to a patient's safety should the mobile app malfunction. FDA refers to this subset of mobile apps as *mobile medical apps*.

The guidance defines a *mobile platform* as a commercial, off-the-shelf computing platform, with or without wireless connectivity, that is handheld in nature—for example, smart phones, tablet computers, or other portable computers.

A *mobile app* is defined as either

- a software application that can be run on a mobile platform
- or a web-based software application that is tailored to a mobile platform but is executed on a server

A *mobile medical app* is a mobile app that meets the Food, Drug, and Cosmetic (or FD&C) Act's definition of a device and is intended either

- to be used as an accessory to a regulated medical device
- or to transform a mobile platform into a regulated medical device

The *intended use* of a mobile app determines whether it meets the definition of a device. Intended use may be shown by labeling claims, advertising materials, or oral or written statements by manufacturers or their representatives. A mobile app is considered a device when its intended use is

- for the diagnosis of a disease or condition, or the cure, mitigation, treatment, or prevention of disease
- or to affect the structure or any function of the human body

The guidance defines a *regulated medical device* as a product that meets the FD&C Act's definition of a device and that has been cleared or approved by the FDA review of a premarket submission or otherwise classified by the FDA.

Categories of mobile apps the FDA considers mobile medical apps subject to regulatory oversight include those

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- that are an extension of one or more medical devices by connecting (physically or wirelessly) to a device for purposes of controlling the device or for use in active patient monitoring or analysis of medical device data
- that transform a mobile platform into a regulated medical device by using attachments, display screens, or sensors, or by including functionalities similar to those of currently regulated medical devices
- and that become a regulated medical device by performing patient-specific analysis and providing patient-specific diagnosis or treatment recommendations; these types of mobile medical apps are similar to or perform the same function as those types of software devices that FDA has already cleared or approved

Examples of mobile apps that FDA does not consider mobile medical apps, and are therefore not subject to FDA regulation, include apps

- that are intended to provide access to electronic copies (such as electronic or audio books) of medical textbooks or other reference materials with generic text search capabilities
- that are intended for health care providers to use as educational tools for medical training or to reinforce past training
- that are intended for general patient education and that facilitate patient access to commonly used reference information.
- that automate general office operations in a health care setting and that are not intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease
- and that are generic aids or general-purpose products, such as apps that function generally as magnifying glasses or audio recording devices

FDA exercises enforcement discretion over mobile apps that pose low risk to patients. The term *enforcement discretion* means that even if the medical app may meet the definition of a medical device, the FDA can choose to not enforce its requirements because the risk to patients is low. Such apps include those that

- help patients self-manage their conditions without providing specific treatment or treatment suggestions;
- provide patients with simple tools to organize and track their health information;
- provide easy access to information related to patients' conditions or treatments;
- help patients document, show, or communicate potential medical conditions to health care providers;
- automate simple tasks for health care providers;

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- enable patients or providers to interact with Personal Health Record or Electronic Health Record systems; or
- are intended to transfer, store, convert format, and display medical device data in its original format from a medical device

Examples of types of mobile apps over which FDA exercises enforcement discretion (meaning FDA will not regulate) include

- apps that coach patients with conditions such as cardiovascular disease, hypertension, diabetes or obesity, and promote strategies for maintaining a healthy weight, getting optimal nutrition, exercising and staying fit, managing salt intake, or adhering to pre-determined medication dosing schedules by simple prompting
- and apps that help patients with diagnosed psychiatric conditions (such as post-traumatic stress disorder, depression, anxiety, or obsessive compulsive disorder) maintain their behavioral coping skills by providing a “skill of the day” behavioral technique or audio messages that users can access when experiencing increased anxiety.

eResearch section 7.2-2 asks researchers whether their research tests or utilizes a health-related mobile software application that meets FDA’s definition of a mobile app. Depending on the response, eResearch then guides researchers to further application sections, as applicable to their study.

Contact the IRB for more information about mobile medical apps.

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