Cooley

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On September 23, 2013, the United States Food and Drug Administration ("FDA") issued long awaited guidance titled, *Mobile Medical Applications: Guidance for Industry and Food and Drug Administration Staff* ("Final Guidance"). The Final Guidance replaces draft guidance on the topic that was issued on July 21, 2011. Additional information regarding the FDA's regulation of mobile medical applications is available here.

The FDA stated in the Final Guidance that it recognizes the "extensive variety" and "rapid pace of innovation" of mobile applications ("mobile apps"). Thus, the FDA intends to exercise its regulatory authority only for those mobile apps (i) that are medical devices, and (ii) whose functionality could pose a risk to a patient's safety if the mobile app failed to function as intended. This Client Alert includes an overview of key definitions used by the FDA in the Final Guidance, describes the regulatory framework established by the FDA, and discusses examples of mobile apps that the FDA intends to regulate.

Key definitions

Mobile application or **mobile app** is defined 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."

Mobile medical application or **mobile medical app** is defined as "a mobile app that meets the definition of a device" under § 201(h) of the Federal Food, Drug, and Cosmetic Act ("FDCA") that is intended (i) "to be used as an accessory to a regulated medical device"; or (ii) "to transform a mobile platform into a regulated medical device." The FDCA defines a "device" as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory" that is "intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease … or intended to affect the structure or any function of the body …" The intended use of the mobile app determines whether it is a "device", and is based on the labeling claims, advertising matter, oral or written statements, and/or other knowledge of the manufacturer.

Mobile medical app manufacturer is defined as "any person or entity that manufactures mobile medical apps in accordance with the definitions of manufacturer in 21 CFR parts 803, 806, 807, and 820." This includes, by way of example, an individual or entity that creates, designs, re-labels, remanufactures, modifies, or creates a mobile medical app, or initiates specifications or requirements for mobile medical apps (i.e., "author" of the mobile app). Examples of an individual or entity that does not qualify as a mobile medical app manufacturer include entities that exclusively distribute mobile medical apps (e.g., iTunes app store, Android market); mobile platform manufacturers; tools, services or infrastructure providers; health care professionals ("HCP") who manufacture or alter a mobile medical app solely for use in their professional practice and do not label or promote the mobile medical app to be generally used by other HCPs; and manufacturers of mobile medical apps used solely in research, teaching or analysis that are not introduced into commercial distribution.[1]

Mobile platform is defined as "commercial off-the-shelf (COTS) computing platforms, with or without wireless connectivity, that are handheld in nature." This includes, by way of example, smart phones, tablet computers and other portable computers.

Regulated medical device is a product that meets the definition of device under the FDCA and has been cleared, approved or otherwise classified by the FDA.

Overview of regulatory framework

Figure 1 below shows the FDA's regulatory framework for mobile apps. Generally, the FDA intends to regulate only those mobile medical apps that pose the same or similar potential risks to the public health as currently regulated devices if they fail to function as intended. The FDA stated, however, that all mobile medical app manufacturers should follow the Quality System regulation[2] in design and development, and implement prompt corrections to mobile medical apps, when appropriate.

Examples of mobile applications that are not subject to FDA regulation

The FDA provided several examples of mobile apps that are not medical devices and, thus, not subject to FDA regulation. This includes:

- Mobile apps that are intended to provide access to an electronic copy of a medical textbook or other reference material.
- Mobile apps that are intended for HCPs to use as educational tools for medical training, such as surgical training videos and interactive anatomy diagrams.
- Mobile apps that are intended for general patient education, such as training videos on how to administer first-aid and CPR.
- Mobile apps that automate general office operations in health care settings, such as insurance claims data collection and processing.
- Mobile apps that are generic aids or general purpose products not intended for medical use, such as mobile apps that provide maps and turn-by-turn directions to medical facilities.

In the Frequently Asked Questions ("FAQ") section of the Final Guidance, the FDA further stated that a digital version of medical device labeling or instructions for use that are provided through a mobile app are not considered a medical device. Rather, these items are considered part of the medical device's labeling and are subject to relevant regulatory labeling requirements.

The FDA further stated in the FAQs that mobile apps used for data collection in clinical studies are not mobile medical apps. However, manufacturers of these mobile apps should be aware of the FDA's guidance titled, *Electronic Source Data in Clinical Investigations,* released in September 2013.

Examples of mobile medical applications for which the FDA does not intend to pursue enforcement action under the FDCA

Generally, these are mobile medical apps that help a patient self-manage his/her disease or condition(s) or automate simple tasks for HCPs. The specific categories provided by the FDA are as follows:

- Mobile apps that provide or facilitate supplemental clinical care to help patients manage their health. This includes, by way of example, mobile apps that help individuals with obesity or diabetes to maintain a healthy lifestyle, including exercise and nutrition.
- Mobile apps that provide patients with simple tools to organize and track their health information. This includes, by way of example, mobile apps that allow an individual with high blood pressure to track daily blood pressure measurements.
- Mobile apps that provide easy access to information related to a patient's health conditions or treatments. These are mobile apps that are more than an electronic copy of a medical reference. This includes, by way of example, mobile apps with drug-drug interaction look-up tools.
- Mobile apps that are specifically marketed to help patients document, show, or communicate potential medical conditions to HCPs. This includes, by way of example, mobile apps that are a videoconferencing portal between a patient and his/her HCP.
- Mobile apps that perform simple calculations routinely used in clinical practice, such as APGAR score.
- Mobile apps that enable individuals and HCPs to interact with electronic health records and personal health records systems.

Mobile medical apps falling in this category should maintain documentation that describes the rationale used to determine this categorization. This documentation should be revisited if the intended use of the mobile medical app changes or if the FDA revises its approach to enforcement jurisdiction in this area.

Examples of mobile medical applications that are the

focus of FDA's regulatory oversight

The FDA provided the following examples in the Final Guidance of mobile medical apps that are its focus:

- Mobile apps that are an extension of one or more medical devices by connecting to such devices for the purpose of controlling the device or displaying, storing, analyzing, or transmitting patient-specific medical device data. This includes, by way of example, a mobile app designed to control the delivery of insulin on an insulin pump.
- Mobile apps that transform the mobile platform in to a regulated medical device by using attachments, display screens or sensors or by including functionalities similar to those of currently regulated products. This includes, by way of example, attachment of a blood glucose strip reader to a mobile platform to function as a glucose meter.
- Mobile apps that become a regulated medical device by performing patient-specific analysis and providing patient-specific diagnosis or treatment recommendations. This includes, by way of example, a mobile app that uses patient-specific parameters to create a dosage plan for radiation therapy.

Mobile medical app manufacturers creating mobile medical apps that are the focus of the FDA's regulatory oversight will need to determine whether the mobile medical app is a Class I device subject to General Controls; Class II device subject to General Controls, Special Controls and Premarket Notification; or Class III device subject to General Controls and Premarket Approval.[3] In the Final Guidance, the FDA encourages mobile medical app manufacturers to contact it for assistance.

For questions about the implications of the Final Guidance for your organization, please contact one of the attorneys listed above or the Cooley attorney that generally handles your matters.

Notes

1. These products may be subject to investigation device exemption regulations, however. See 21 CFR § 807.65(f) and 21 CFR § 812.1.
2. See 21 CFR part 820.
3. Information regarding the classification of medical devices is available here. The Product Classification and 510(k) Premarket Notification databases all provide assistance with classification.

Key Contacts

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