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CLIENT ALERT

FDA Issues Final Guidance on Mobile Medical Apps

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On September 23, 2013, the U.S. Food and Drug Administration (FDA) issued a final guidance for developers of mobile medical applications. Mobile applications, or apps, are user-friendly software programs that run on mobile communication devices, such as smartphones and tablet computers. In releasing the new guidance, the agency acknowledged that "[m]obile apps have the potential to transform health care by allowing doctors to diagnose patients with potentially life-threatening conditions outside of traditional settings, help consumers manage their own health and wellness, and also gain access to useful information whenever and wherever they need it."

Many apps developed for mobile platforms meet the definition of a medical device under the Federal Food, Drug, and Cosmetic Act (FDCA). That is, the developers of the apps intend them "for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease." In the final guidance, however, FDA draws a distinction between what it calls "mobile medical apps" – apps that "could pose a risk to a patient's safety" if they fail to function as intended – and other apps that pose only a low risk to consumers.

FDA says it will exercise enforcement discretion for apps that fall in the latter category and will not enforce the requirements ordinarily imposed on medical device makers by the FDCA. It will, however, regulate mobile medical apps as medical devices.

FDA described several types of apps it considers mobile medical apps including:

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1. **Apps that cause the mobile platform to become an extension of one or more medical devices by connecting to such device(s) for purposes of controlling the device(s) or displaying, storing, analyzing, or transmitting patient-specific medical device data.**

   Examples include apps that display data from bedside monitors; apps that control inflation and deflation of blood pressure cuffs through a mobile platform; and apps that control the delivery of insulin on insulin pumps by transmitting control signals to the pumps from the mobile platform.

2. **Apps that transform the 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.**

   Examples include apps that function as glucose meters when blood glucose strip readers are attached to the mobile platform; and apps that measure, store, and display electrocardiograph (ECG) signals when ECG electrodes are attached to the mobile platform.

3. **Apps that become a regulated medical device (software) by performing patient-specific analysis and providing patient-specific diagnosis, or treatment recommendations.**

   Examples include apps that use patient-specific parameters and calculate dosage or create a dosage plan for radiation therapy; Computer Aided Detection software; image processing software; and radiation therapy treatment planning software.

In contrast to the foregoing, FDA said it intends to exercise enforcement discretion for mobile apps that:

- **help patients self-manage their disease or 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' health conditions or treatments;**
- **help patients document, show, or communicate potential medical conditions to health care providers;**
- **automate simple tasks for health care providers; or**
- **enable patients or providers to interact with Personal Health Record (PHR) or Electronic Health Record (EHR) systems.**

FDA intends to limit enforcement to "manufacturers" of mobile medical apps, which it defines as "anyone who initiates specifications, designs, labels, or creates a software system or application for a regulated medical device in whole or from multiple software components." FDA does not include in this definition persons who exclusively distribute mobile medical apps without engaging in manufacturing functions. Thus, the owners and operators of "Google play," the "iTunes App store," and "Blackberry App World" are not required to comply with the the medical device regulations even if they distribute mobile medical apps. FDA also expressly excluded manufacturers and distributors of mobile platforms (i.e., smartphone and tablet makers) who solely distribute or market their platforms and do not intend them (by marketing claims) to be used for medical device functions.

For more information, please contact the professional(s) listed below, or your regular Crowell & Moring contact.

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