FDA Issues Guidance for Mobile Medical Applications

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The number of mobile medical applications for use on smartphones and tablets is growing rapidly as more and more app developers release new products in this area. However, until recently, the regulatory status of many of these mobile applications has been unclear.

Some of the uncertainty will be eliminated by FDA's issuance of a nonbinding final guidance document concerning mobile medical apps on September 25, 2013. A copy of the guidance document can be accessed online at http://www.fda.gov/downloads/MedicalDevices/.../UCM263366.pdf.

Bakul Patel, M.S., MBA, senior policy advisor to the director of FDA's Center for Devices and Radiological Health, explained that FDA wants to clarify to developers which types of apps will be regulated as medical devices and emphasized that most mobile apps will not be subject to FDA oversight. "Mobile apps are unleashing amazing creativity, and we intend to encourage these exciting innovations," said Patel in an FDA Consumer Update. "At the same time, we have set risk-based priorities and are focusing FDA's oversight on mobile apps that are devices for which safety and effectiveness are critical."

Which Mobile Apps Will Be Subject to FDA Oversight?

The guidance document reveals that FDA's focus is on the function of the app, stating that FDA only intends to regulate those mobile apps "that are medical devices and whose functionality could pose a risk to a patient's safety if the mobile app were not to function as intended." FDA calls these types of apps mobile medical apps. Not all categories of mobile medical apps will be regulated at this time, but only those apps that are meant: "(1) to be used as an accessory to a regulated medical device; or (2) to transform a mobile platform [commercial off-the-shelf computing platforms, with or without wireless connectivity, that are handheld in nature] into a regulated medical device."

Categories of Mobile Apps That Will Be Subject to FDA Oversight at This Time

Section V(A) of the FDA guidance document provides more information regarding which categories of mobile apps will be regulated. The guidance document states that these mobile apps have met "the definition of a medical device in the FD&C Act" and that "their functionality poses a risk to a patient's safety if the mobile app were to not function as intended."

The following specific categories of mobile apps *are* the focus of FDA's regulatory oversight:

1. Mobile apps that are an extension of one or more medical devices by connecting to such device(s) for the purposes of controlling the device(s) or displaying, storing, analyzing, or transmitting patient-specific medical device data

   Examples provided include apps that merely display patient data, such as those that provide remote display of data from bedside monitors or display previously stored EEG waveforms, as well as mobile apps that actually control a medical device such as those that provide the ability to inflate or deflate a blood pressure cuff through a mobile platform and mobile apps that control the delivery of insulin on an insulin pump.

2. Mobile 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 device

Examples of these types of devices include mobile medical apps that use an existing part of the mobile platform for a medical function such as mobile apps that use the built in accelerometer on a mobile platform to collect motion information for monitoring sleep apnea, or a mobile app that uses sensors on a mobile platform for creating an electronic stethoscope function.

3. Mobile apps that become a regulated medical device (software) by performing patient-specific analysis and providing patient-specific diagnosis, or treatment recommendation

   Examples of mobile medical apps in this category include apps that use "patient-specific" information to calculate dosage or create dosage plans, such as for radiation therapy, Computer Aided Detection (CAD) software, or image processing software.

Appendix C provides further specific examples of mobile apps that will be regulated, including:

- apps that use a sensor or lead that is connected to a mobile platform to measure and display electrical signals produced by the heart;
- apps which use a sensor or electrode attached to a mobile platform to electronically amplify and project sounds associated with internal organs;
- apps which use a sensor or electrode attached to the mobile platform to measure physiological parameters during CPR and give feedback about the quality of CPR being delivered;
- apps that use tools within the mobile platforms such as speakers to produce controlled levels of test tones and signals intended for use in conducting diagnostic hearing evaluations; and
- mobile apps that present donor history questions to a potential blood donor and record/transmit the responses to a blood collection facility to use in determining blood donor eligibility.

Categories of Mobile Apps that Will Not be Subject to FDA Oversight at This Time

As further described in Appendix A of the guidance document, FDA has decided to apply its regulatory discretion for other categories of mobile applications, including some which may be considered mobile medical apps or medical devices. The following specific categories of mobile apps *are not* currently the target of FDA's regulatory oversight:

1. Mobile apps that provide or facilitate supplemental clinical care, by coaching or prompting, to help patient's manage their health in their daily environment
2. Mobile apps that provide patients with simple tools to organize and track their health information
3. Mobile apps that provide easy access to information related to patients' health conditions or treatments (beyond providing an electronic "copy" of a medical reference)
4. Mobile apps that are specifically marketed to help patients document, show, or communicate to providers potential medical conditions
5. Mobile apps that perform simple calculations routinely used in clinical practice
6. Mobile apps that enable individuals to interact with PHR systems or EHR systems

Appendix B of the guidance document provides more specific examples of mobile apps that may be considered medical devices, but that FDA has chosen not to regulate at this time.

FDA has also provided examples of certain mobile apps that are not considered medical devices and *will not* be subject to oversight. These include the following categories of mobile apps:

1. Mobile apps that are intended to provide access to electronic copies of medical textbooks or other reference materials with generic text search capabilities
2. Mobile apps that are intended for health care providers to use as educational tools for medical training
3. Mobile apps that are intended for general patient education and facilitate patient access to commonly used reference information
4. Mobile apps that automate general office operations in a health care setting and are not intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease
5. Mobile apps that are generic aids or general purpose products (such as audio recorders or flashlights apps)

Mobile Medical App Manufacturers

One final category addressed in the guidance document is mobile app manufacturers. FDA clarifies that providers of mobile medical apps, such as the iTunes store or the Google Play store, will not be treated as medical device manufacturers. Similarly, licensed physicians who create or modify mobile apps for use in their own professional practice and do not promote the apps to be generally used by other practitioners will also not be treated as medical device manufacturers.

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