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ALERT

FDA Clarifies Which mHealth Apps Require Pre-Market Notification as Medical Devices

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On September 25, 2013, the U.S. Food and Drug Administration (FDA) issued its much-anticipated Final Guidance for Industry on Mobile Medical Applications (mobile apps), in which it clarifies the subset of mobile apps it will regulate as medical devices under the Food, Drug, and Cosmetic Act. The FDA will exercise its discretion not to regulate apps that may satisfy the medical device definition but pose little risk to the public. Indeed, the FDA unequivocally stated that it does not consider entities that exclusively distribute mobile medical apps—*e.g.*, app stores like iTunes and the Android Play Store—to be medical device manufacturers simply because their platforms may be used to access a mobile medical app.

Rather, the FDA intends to focus its regulatory oversight on those mobile apps that are medical devices and whose functionality could pose a risk to a patient's safety. The FDA indicated it will focus its regulatory oversight on mobile medical apps that:

- Connect to a medical device for purposes of "controlling the device(s) or displaying, storing, analyzing or transmitting patient-specific medical device data or convert patient-specific medical device data."
- 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."
- Become a regulated medical device (software) "by performing patient-specific analysis and providing patient-specific diagnosis, or treatment recommendations."

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Many wireless carriers, device manufacturers, and software developers are currently exploring healthcare technology solutions that connect clinicians, patients, and critical information in a manner which may meet these outlined parameters for regulatory oversight. Companies developing products and offerings that fall within the categories outlined above will need to file a 510(k) Pre-Market Notification and secure FDA clearance before marketing or selling their product to consumers.

Please note that the Final Guidance is nonbinding on the FDA and industry. Should a public health issue or crisis arise due to improper use of any of the mobile apps the FDA has elected not to regulate, the FDA could withdraw its regulatory forbearance and treat the offending app as a medical device.