FISH & RICHARDSON

Regulatory

MOBILE MEDICAL APPS: FDA ISSUES FINAL GUIDANCE

On September 25, 2013 the Food & Drug Administration released final guidance on mobile medical apps. FDA announced it will apply its enforcement discretion and regulate only those mobile medical apps that are "medical devices" and whose functionality could pose a risk to a patient's safety if they do not function as intended.

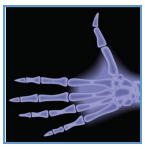
> *medical device* - anything, including software, intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man.

The "intended use" of software is therefore critical to determining if it is a regulated medical device.

Focus of FDA's Regulatory Oversight

FDA identified three categories of mobile medical apps as the focus of its oversight. This includes mobile apps that:

Connect to another device for purposes of **controlling** or **displaying, storing, analyzing, or transmitting patient-specific medical device data**. Examples include remote display of data from bedside monitors, display of previously stored EEG waveforms, or apps that provide the ability to control inflation and deflation of a blood pressure cuff through a mobile platform.



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 mobile apps that allow use of the attachment of electrocardiograph (ECG) electrodes to a mobile platform to measure, store, and display ECG signals.

Perform patient-specific analysis and provide patient-specific diagnosis or treatment recommendations. Examples include apps that use patient-specific parameters to calculate dosage or create a dosage plan for radiation therapy or image processing software.

Enforcement Discretion

Mobile apps for which FDA intends to use "enforcement discretion" and not regulate include apps that:

- Help users self-manage their diseases or conditions without providing specific treatment or treatment suggestions;
- Provide users with simple tools to organize and track their health information;
- Provide easy access to information related to users' health conditions or treatments;
- Help users document, show, or communicate potential medical conditions to health care providers;
- Automate simple tasks for health care providers; or
- Enable users or providers to interact with Personal Health Record (PHR) or Electronic Health Record (EHR) systems.

FDA also clarified that the following persons would not be regulated as medical device manufacturers:

Manufacturers or distributors of mobile platforms who do not specifically intend or market their products for medical device functions. Examples include smartphones or tablets.

Distributors of apps who are engaged only in providing an online market place where mobile medical apps may be available. Examples include "Google Play" and the "iTunes Store."

Licensed practitioners who manufacture a mobile medical app or alter a mobile medical app solely for use in their own professional practice. Examples include physicians, dentists, and optometrists.

Determining whether a particular mobile app is a regulated medical device can be tricky business. Trickier still is the FDA's regulatory maze, as the pathway to lawful marketing can vary depending on the risk of the device. Fish has assisted various manufacturers with obtaining FDA marketing authorization for software-based devices. Please contact us with any questions.

FDA's guidance can be read here: http://1.usa.gov/HuKjwg

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