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MOBILE MEDICAL APPS: LIMITED FDA INTERVENTION

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In September, the FDA issued its final guidance to "inform manufacturers, distributors, and other entities" about how it intends to exercise its regulatory authority in relation to applications or "apps" intended for use on mobile platforms, e.g., cell phones, tablets and other mobile communications devices. While the guidance is not specifically intended for the medical community, understanding the FDA's regulatory position on mobile apps is important, especially as apps for use by both health care providers and patients proliferate. This article briefly explores the FDA's division of mobile apps into three subcategories for regulatory purposes, and provides links to useful resources that should be consulted before an app is used or recommended for use.

The FDA has divided mobile apps into three categories:

1. Mobile Medical Apps (MMAs). An MMA is a mobile app that meets the definition of device in section 201(h) of the Federal Food, Drug and Cosmetic Act[1] and is either: (1) intended to be

[1] Section 201(h) of the Federal Food, Drug and Cosmetic Act provides:

The term "device" (except when used in paragraph (n) of this section and in sections 331(i), 343(f), 352(c), and 362(c) of this title) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is--
(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
(3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.
21 U.S.C. § 321

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used as an accessory to a regulated medical device; or (2) intended to transform a mobile platform into a regulated device;

2. Mobile Apps for which the FDA intends to exercise enforcement discretion, i.e., mobile apps that may, under certain circumstances, be regulated; and
3. Mobile Apps that will not be subject to regulation.

In determining the category into which a mobile app fits, and whether regulation is necessary, the FDA has indicated that it intends to take a "functional" rather than "platform" approach to mobile apps, basing its decision to regulate on the intended use of the app.[2] Under a functional approach, the FDA will examine what the app does and will only regulate those apps that are "medical devices" and pose a risk to patient safety.

The FDA guidance provides three generic types of MMA that are subject to FDA regulations:

- Apps that make the mobile platform an extension of a medical device. This includes apps that connect to medical devices for purposes of controlling the device or to display, store, analyze or transmit patient specific medical data. For example, apps that permit the remote display of patient bedside monitors would qualify as MMAs and would be subject to FDA regulation. Apps that permit users to alter the settings of an infusion pump or calibrate a cochlear implant are also deemed to be MMAs;
- Apps that transform the mobile platform into a regulated medical device. For

[2] The FDA Guidance indicates that the apps intended use will be determined by looking at the app's labeling, advertising material and statements or claims made by manufacturers

example, apps that use a sensor or lead connected to the mobile platform to monitor the patient. Another example is apps which use the mobile platform's audio capabilities to create an electronic stethoscope and apps that display radiological images for diagnosis[3]; and

- Apps that 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 and Computer Aided Detection software.

Apps for which the FDA will exercise enforcement discretion, i.e., those apps that may, but generally will not be subject to regulation, include apps that:

- Help patients to self-manage diseases or conditions without providing specific treatment suggestions, e.g. apps that prompt patients to exercise or provide periodic encouragement to help them improve their lifestyles by stopping smoking;
- Provide simple tools for patients to organize and track health information, e.g., recording blood glucose levels;
- Provide easy access to information related to health conditions or treatments. The FDA does not include general reference materials in this category, rather it intends to capture context specific information, e.g., apps that use a specific patient's diagnosis to provide clinicians with guidelines on best practices, and apps that provide information regarding specific drug interactions;
- Help a patient to document his or her health condition and communicate with his/her health care provider about those conditions. This would include apps

[3] The FDA guidance notes that apps that display radiologic images may present a particular risk because of the small size of the image, the low contrast and differences in the ambient light when images are viewed.

that provide videoconferencing portals and apps that allow patients to transmit pictures of wounds to their health care provider to supplement oral discussions;

- Automate simple tasks for health care providers, including apps that assist with calculations that are done routinely and are based on standard formulae, for example, calculating BMI, mean arterial pressures, Glascow Coma Scale scores, Apgar scores and NIH Stroke Scale scores; and
- Enable patients or providers to interact with personal health records or electronic health record systems.

Apps that are not subject to regulation include:

- Apps that provide electronic copies of medical textbooks or reference materials with generic search capabilities;
- Apps intended to be used as educational tools for training. For example, apps that contain interactive anatomical diagrams or surgical training videos or apps that use games to simulate medical emergencies;
- Apps intended for general patient education, including apps that facilitate access to reference information, intended to increase patient awareness and support patient centered care;
- Apps that automate general office operations in health care settings and are not intended to be used in the diagnoses of disease or other conditions, or in the cure, mitigation, or prevention of disease. For example, apps that help assign billing codes, apps that collect and process insurance information and apps that permit electronic check in at health care facilities; and
- Apps that are generic aids or general purpose products including apps that provide email and apps that allow dictation of notes.

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As the number of medical apps proliferates, it is important that health care providers stay abreast of the developments in the relevant mobile app market, including knowledge not only of the available apps, but also which apps are subject to FDA regulation. Use and/or recommendation of a mobile medical app that is subject to regulation, but has not been FDA approved could be a violation of the standard of care. As such, if a healthcare provider plans to purchase and use an app that may qualify as a mobile medical app then he/she should contact the manufacturer and/or consult the FDA website to confirm that all regulations have been properly followed.

While medical apps are undoubtedly useful and will help both providers and patients, the FDA's guidance ought to be borne in mind. The FDA guidance should not only direct a health care provider's decision regarding the use of mobile apps, but should also inform the advice and recommendations he/she gives to patients about which apps to use and when the use of apps is appropriate.

Useful links:

The FDA's Guidance:

http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf

Examples of Mobile Medical Apps:

http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ConnectedHealth/MobileMedicalApplications/ucm368743.htm

Examples of apps for which the FDA will exercise enforcement discretion:

http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ConnectedHealth/MobileMedicalApplications/ucm368744.htm

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