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Mobile Medical Applications: FDA's Guidance for Industry and FDA Staff

On September 23, 2013, the Food and Drug Administration (FDA) released its final guidance on mobile medical applications (apps) entitled, *Mobile Medical Applications: Guidance for Industry and Food and Drug Administration Staff*. The guidance informs manufacturers, distributors and other entities about how the FDA intends to apply its regulatory authorities on select mobile medical apps. Click here to view the guidance.

DEFINITION

The FDA considers a mobile app to be a medical device if its function is intended for the diagnosis of disease or other conditions; or the cure, mitigation, treatment or prevention of disease; and if its intended use is:

- As an accessory to a regulated medical device; or
- To transform a mobile platform into a medical device.

SCOPE OF OVERSIGHT

The FDA's scope of regulatory oversight is determined by two aspects: (1) the functionality and intended use of the mobile app and (2) the risk posed by the app if it does not function as intended. Using these principles, the FDA sorts mobile medical apps into two groups:

Group 1**:** For mobile apps that may meet the definition of a medical device but pose a low risk to the public, the FDA intends to exercise enforcement discretion. This means the FDA will NOT enforce requirements under the Federal Food, Drug, and Cosmetic Act (FD&C Act).

Group 2: For mobile apps that are medical devices and whose functionality could pose a risk to the patient's safety if the app were to not function as intended, the FDA intends to apply regulatory oversight.

The FDA will not regulate:

- Mobile apps that are not defined as medical devices.
- The sale or consumer use of smartphones or tablets.
- Mobile platforms that solely provide market access to mobile medical apps (i.e. iTunes App Store, Google Play, and BlackBerry App World).

RESPONSIBILITY

The responsibility of adhering to FDA's regulatory requirements is directed to the manufacturer of mobile medical apps. This includes the persons or entities that initiate the specifications, or design, label, modify or create a mobile medical software system in whole or from multiple components. This does not include app manufacturers who are not the original author of the app.

WHAT IS REGULATED & WHAT MIGHT NOT BE REGULATED

The tables below do not reflect the complete list of FDA's considerations; they are only intended to provide clarity and assistance in identifying the mobile apps that will and will not be subject to FDA's regulatory requirements at this time.

Group 1. What might not be regulated: Mobile apps for which FDA intends to exercise enforcement discretion.

These are mobile medical apps that are determined to pose a low risk to the public. The apps are divided into six functionality categories:

1) **Self-management tools**
   - Apps used to coach patients with conditions such as asthma, cardiovascular disease, hypertension, diabetes or obesity.
   - Apps used to promote health strategies.

   Examples: Apps that assist in maintaining a healthy weight & general fitness, getting optimal nutrition or adhering to medication dosing schedules.

2) **Organize & Track health information** (without providing recommendations to alter or change a previously prescribed treatment)
   - Apps that provide patients with chronic disease or specific conditions tools to log, track or trend their events or measurements.

   Examples: Apps to track blood pressure measurements, drug intake times, diet, daily routine or emotional states.

3) **Education**
   - Apps for clinicians to provide best practice treatment guidelines.
   - Apps for reminders or to provide guidance for patients.
   - Apps that inform of drug-drug interaction or provide drug-allergy look-up tools.

   Examples: Apps that provide guidance for smoking cessation, guidance for pregnant women or apps that provide a reference for possible drug or allergy interactions.

4) **Tools for patients to communicate potential medical conditions**
   - Apps that use a mobile camera for documenting or transmitting pictures and videoconferencing portals.

5) **Automate Simple Calculations for Clinical Use**

   Examples: Apps to calculate Body Mass Index (BMI), Mean Arterial Pressure, or APGAR Scores

6) **Interact with Personal Health Record (PHR) or Electronic Health Record (EHR) systems**
   - Apps that provide patients and providers with mobile access to health record systems to view or download EHR data.

Group 2. What will be regulated: The subset of apps that are the focus of FDA's regulatory oversight.

These are mobile medical apps that can pose significant harm if the app were to not function as intended. The list includes apps with the intended purpose of:

1) Controlling medical devices • Includes apps that are an extension of a medical device by connecting to such device(s) or by transmitting control signals. *Examples: an app that controls the delivery of insulin on an insulin pump or an app that provides the ability to control inflation and deflation of a blood pressure cuff.*
2) Displaying, analyzing, or transmitting patient-specific medical device data • Apps that display medical device data to perform patient monitoring. • Apps that are intended to display or store medical device data without controlling or altering the functions or parameters of any connected medical device. *Examples: An app that provides remote display of data from bedside monitors or an app that displays electrocardiograph (ECG) waveforms.*
3) Transforming a mobile platform into a medical device • Apps that use a mobile platform for medical device functions by using attachments, display screens, or sensors. *Examples: the attachment of electrocardiograph (ECG) electrodes to a mobile platform to measure, store and display ECG signals or a app that uses sensors on a mobile platform for creating electronic stethoscope function.*
4) Interpreting patient-specific data • Apps that perform patient-specific analysis and interpret data to provide diagnosis or treatment recommendations. *FDA recommends manufacturers of these types of apps to contact FDA to discuss what regulatory requirements may apply. *Examples: Apps that calculate dosage and create a dosage plan or apps that use Computer Aided Detection (CAD) software.*

REGULATORY REQUIREMENTS

Mobile medical app manufacturers are subject to meet the regulatory requirements if their mobile app falls into the following three FDA medical device classifications:

- Class I – Devices that have only general controls. Most Class I devices are exempt from Premarket Notification.
- Class II – Devices that have special controls in addition to general controls. Most Class II devices require Premarket Notification.
- Class III – Devices that pose a significant risk of illness or injury. Most Class III devices need Premarket Approval.

FDA encourages mobile medical app manufacturers to search FDA's public databases, such as the "Product Classification" database and the "510(k) Premarket Notification" database, to determine the level of regulation for a given device and for the most up-to-date information about the relevant regulatory requirements. These databases can be accessed through the following links:

(http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm) and (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm).

The guidance also includes additional examples of current regulations and a brief description of certain device regulatory requirements in Appendix D & E. A list of FAQs is included in Appendix F.

CONTACT

After reviewing the guidance, the FDA encourages mobile app manufacturers to contact the Agency to obtain more information using one of the following ways:

- Phone or e-mail - For general regulatory information, contact the Division of Small Manufacturers, International and Consumer Assistance (DSMICA). Email: dsmica@fda.hhs.gov; phone: 301-796-7100 or 800-638-2041.

FUTURE GUIDANCE FROM FDA

In January 2014, FDA is expected to release a report to Congress on a risk-based approach to the regulation of Health IT and mHealth products with insight from the FDA Safety and Innovation Act (FDASIA) workgroups. In this report, the FDA will provide guidance on Clinical Decision Support (CDS) software.

For inquiries about this eHealth Initiative overview of the FDA Mobile Medical App Guidance, please contact Nadeen Siddiqui at nadeen.siddiqui@ehidc.org.