Center for Connected Health Policy
The National Telehealth Policy Resource Center

The FDA and Mobile Medical Applications

On September 25, 2013, the Food and Drug Administration (FDA) issued ***Mobile Medical Applications: Guidance for Industry and Food and Drug Administration Staff (The Guidance). The Guidance*** is meant to provide clarity and predictability for mobile medical application (app) manufacturers and other interested parties. It does not create or confer rights, nor does it bind either the FDA or the public. It merely provides the FDA's current thinking on the topic, and should be looked upon as recommendations.

The FDA intends to apply its oversight to those medical apps that are medical devices, and whose functionality could pose a risk to the patient's safety if the mobile app did not function as intended.[1]

What is a mobile medical app subject to FDA regulations?

The Guidance's definition of "mobile medical app" is one that:

- Meets the definition of a device in section 201(h) of the Food, Drug, and Cosmetic Act; and
  - Is intended to be used as an accessory to a regulated medical device; or
  - Transforms a mobile platform into a regulated medical device.[2]

If the intended use of the mobile app is for the diagnosis of disease or other conditions; or the cure, mitigation, treatment, or prevention of disease; or is intended to affect the structure or any function of the body of man; it is subject to FDA regulations. The intended use is determined through examining labeling claims, advertising materials, or oral or written statements by manufacturers or representatives. **The platform for the mobile app (e.g., an iPad or Android smartphone) is irrelevant.**[3]

How does the FDA enforce regulatory requirements regarding medical apps?

The FDA decided to only oversee mobile apps that fall under the medical device definition, and whose functionality could pose a risk to a patient's safety if it did not perform as intended. This subset will be the focus of the FDA's regulatory oversight, and devices in this subset need to comply with the FDA's classification procedures.

The FDA will exercise "enforcement discretion" on other mobile medical apps because they pose a low risk to patients. This means that they retain the right to enforce the requirements under the Food, Drug and Cosmetic Act on these apps, but are not doing so at this time. See Chart 1 for examples of what medical apps will be regulated, and on what the FDA will exercise enforcement discretion.

CENTER FOR CONNECTED HEALTH POLICY

The Center for Connected Health Policy (CCHP) is a public interest nonprofit organization that develops and advances telehealth policy solutions to promote improvements in health and health care systems.

Telehealth expands access, particularly among underserved communities, and improves the efficiency and cost effectiveness of health care systems. With these benefits in mind, CCHP:

- Promotes policies that expand telehealth program adoption;
- Conducts objective research and policy analysis;
- Develops nonpartisan policy recommendations;
- Serves as a state and national resource on telehealth policy issues.

In its work as the federally designated National Telehealth Policy Resource Center (NTRC-P), CCHP provides technical assistance to twelve regional telehealth resource centers (TRCs) nationwide. The NTRC-P project is made possible by Grant #G22RH24746 from the Office of the Advancement of Telehealth, Health Resources and Services Administration, Department of Health and Human Services.

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What FDA regulatory requirements do manufacturers need to follow if their device falls into the subset of devices under FDA oversight?

The FDA classifies mobile medical device according to their current medical device classification procedures (Class I-III). Mobile medical app manufactures should determine the class under which their product falls, and follow the associated procedures. (See Chart II).

Definitions[4]

Mobile Platform: Hand-held commercial off-the-shelf (COTS) computing platforms, with or without wireless connectivity. Examples include smart phones, tablet computers, or other portable computers.

Mobile Application (Mobile App): A software application that can be executed (run) on a mobile platform, or a web-based and server-run software application that is tailored to a mobile platform. Many mobile apps are not medical devices, and FDA does not regulate them.

Regulated Medical Device: A *medical device* is "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, that is... intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man... or... intended to affect the structure or any function of the body of man or other animals," (Section 201(h) of the Federal Food, Drug and Cosmetic Act). To be *regulated*, the medical device must have been cleared or approved by the FDA review of a premarket submission, or otherwise classified by the FDA.

Mobile Medical Application (Mobile Medical App): A product that meets the above definition of a medical device and is either intended as an accessory to a regulated medical device, or transforms a mobile platform into a regulated medical device.

Mobile App Manufacturer: A person or entity that manufactures mobile medical apps. It does not include entities which distribute mobile medical apps, such as Google play or the iTunes App store.

[1] Food and Drug Administration, *Mobile Medical Applications: Guidance for Industry and Food and Drug Administration Staff*; September 25, 2013; p. 4.
[2] Ibid, p. 7.
[3] Ibid, p. 8.
[4] Ibid.

Chart 1: FDA Regulatory Enforcement of Medical Apps

Subject to FDA Oversight	FDA Will Use Discretion	Not a Medical Device
Mobile apps that are an extension of one or more medical devices by connecting to such device(s) for purposes of controlling the device(s); or displaying, storing, analyzing, or transmitting patient-specific medical device data. **Example:** Apps that provide control to inflate and deflate a blood pressure cuff.	Mobile apps that help patients self-manage their disease. **Example:** Apps that help asthmatics track inhaler usage, asthma episodes experienced, location of user at the time of an attack, or environmental triggers of asthma attacks.	Mobile apps that are intended to provide access to electronic "copies" (e.g., e-books, audio books) of medical textbooks or other reference materials with generic text search capabilities.
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 devices. **Example:** Apps that use attachment of blood glucose strip reader to function as a glucose meter.	Mobile apps that help patients organize and track health information. **Example:** Apps that help patients with specific diseases log, track, or trend their events or measurements.	Mobile apps that are intended for health care providers to use as educational tools for medical training. **Example:** Medical flash cards, surgical training videos, and medical board certification preparation materials.
Mobile apps that become a regulated medical device by performing patient-specific analysis, and providing patient-specific diagnosis or treatment recommendations. These types of mobile medical apps are similar to, or perform the same function as, those types of software devices that have been previously cleared or approved. **Example:** Apps that use patient-specific parameters, and calculate dosage and dosage plan for radiation therapy.	Mobile apps that provide easy access to information related to patients' health conditions or treatments. **Example:** A drug-drug interaction, or drug-allergy look-up tool.	Mobile apps that are intended for general patient education, and facilitate patient access to commonly used reference information. **Example:** A portal to distribute medical material, or app to provide information, on gluten-free products.

Chart 1: FDA Regulatory Enforcement of Medical Apps

Subject to FDA Oversight	FDA Will Use Discretion	Not a Medical Device
	Mobile apps that help patients document, show, or communicate potential medical conditions to a health care provider. **Example:** Apps that enable video conferencing with a provider, or allow a patient or caregiver to send an emergency notification to first responders.	Apps that automate general office operations. **Example:** Apps that determine billing codes, analyze insurance claims for fraud, or generate reminders for appointments.
	Mobile apps that perform simple calculations routinely used in clinical practice.	Mobile apps that are generic aids or general purpose products. **Example:** Mobile platforms that allow for note-taking, or a magnifying glass not specifically intended for medical purposes.
	Mobile apps that enable individuals to interact with health record systems.	

Chart 2: Medical Device Classifications and Requirements

Class I

A device is in Class I if (i) general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, or (ii) there is insufficient information from which to determine that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, or to establish special controls to provide such assurance, but the device is not life-supporting or life-sustaining or for a use which is of substantial importance in preventing impairment of human health, and which does not present a potential unreasonable risk of illness or injury.

Requirements

- **Establishment Registration and Medical Device Listing:** Manufacturers of medical devices are required to annually register their establishments with FDA, and provide a list of the devices they market.
- **Quality System (QS) Regulation:** Provides a framework for all manufacturers to develop and follow to help ensure that their products consistently meet applicable requirements and specifications. Manufacturers should develop requirements for their products that will result in devices that are safe and effective, and establish methods and procedures to design, produce, and distribute their devices.
- **Labeling Requirements:** Medical device manufacturers are required to comply with applicable labeling regulations for medical devices and in-vitro diagnostic products.
- **Medical Device Reporting:** The Medical Device Reporting (MDR) regulation requires manufacturers and importers of medical devices to submit reports to the FDA whenever they receive, or otherwise become aware of, information from any source that reasonably suggests that a device they market may have caused or contributed to a death or serious injury, or has malfunctioned, and the device or a similar device that they market would be likely to cause or contribute to a reportable death or serious injury if the malfunction were to recur.
- **Premarket Notification:** Mobile medical app manufacturers should identify the current classification covering their mobile medical app. Manufacturers are required to prepare and submit to the FDA an appropriate premarket submission as required for their device classification.
- **Reporting Corrections and Removals:** A mobile medical app manufacturer may voluntarily take action at any time, or may be requested to take action by the FDA, to correct problems. Voluntary action is usually taken by device manufacturers.
- **Investigational Device Exemption (IDE) Requirements for Clinical Studies of Investigational Devices:** An IDE allows an investigational device to be used in a clinical study in order to collect safety and effectiveness data required to support a Premarket Approval (PMA) application or a Premarket Notification 510(k) submission to FDA. Clinical studies with devices of significant risk must be approved by FDA and by an Institutional Review Board (IRB) before the study can begin. Studies with devices of non-significant risk must be approved by the IRB only before the study can begin.

Chart 2: Medical Device Classifications and Requirements

Class II

A device is in Class II if general controls alone are insufficient to provide reasonable assurance of its safety and effectiveness, and there is sufficient information to establish special controls, including the promulgation of performance standards, post market surveillance, patient registries, development and dissemination of guidance documents (including guidance on the submission of clinical data in premarket notification submissions in accordance with section 510(k) of the act), recommendations, and other appropriate actions as the Commissioner deems necessary to provide such assurance. For a device that is purported or represented to be for use in supporting or sustaining human life, the Commissioner shall examine and identify the special controls, if any, that are necessary to provide adequate assurance of safety and effectiveness, and describe how such controls provide such assurance.

Requirements

- **General Controls** (as described in class I)
- **Special Controls**
- **Premarket Notification** (for most Class II devices)

Class III

A device is in Class III if insufficient information exists to determine that general controls are sufficient to provide reasonable assurance of its safety and effectiveness, or that application of special controls would provide such assurance, and if, in addition, the device is life-supporting or life-sustaining, or for a use which is of substantial importance in preventing impairment of human health, or if the device presents a potential unreasonable risk of illness or injury.

Requirements

- **General Controls** (as described in class 1)
- **Premarket Approval**