Mobile Medical Applications - Guidance for Industry and Food and Drug Administration Staff (Final Guidance)

Explains the FDA’s thinking on the regulation of mobile medical apps as devices and its focus on apps whose failure would present significant risk to patients.

**Updated last June 2, 2017**
for the 02/09/2015 Final Guidance

**WHAT IT DOES**

On February 9th, 2015 the Food and Drug Administration (FDA) issued final guidance (Guidance for Industry and Food and Drug Administration Staff) on mobile medical applications (apps). Mobile medical apps are mobile apps that meet the definition of a “device” under section 201(h) of the Federal Food, Drug and Cosmetic Act (FDCA 21 U.S.C. 321(h)) and are intended either:

1. To be used as an accessory to a regulated medical device; or
2. To transform a mobile platform into a regulated medical device.

Thus, categorization as a mobile medical app is determined by the intended use of the mobile app, regardless of the hardware or platform involved. The FDA will also consider the potential risk of mobile apps that meet the above criteria, focusing on those “whose functionality could pose a risk to a patient’s safety if the mobile app were to not function as intended.” For lower risk devices, the FDA intends to not enforce requirements under the FDCA (enforcement discretion).

The document states that “when the intended use of a 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, the mobile app is a device.” FDA oversight focus will be targeted toward mobile apps that:

1. Serve as an extension of one or more medical devices by connecting to such device(s) for purposes of controlling the device(s) or for use in active patient monitoring or analyzing medical device data.
2. 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.
3. Perform patient-specific analysis and provide patient-specific diagnosis, or treatment recommendations.

Appendix C of the final guidance provides a list of mobile medical app examples which will fall under FDA oversight.

Mobile apps for which the FDA intends to exercise enforcement discretion include those that:

1. Provide or facilitate supplemental clinical care, by coaching or prompting, to help patients manage their health in their daily environment.
2. Provide patients with simple tools to organize and track their health information without providing recommendations to alter or change a previously prescribed treatment or therapy.
3. Provide easy access to information related to patients’ health conditions or treatments (beyond providing an electronic “copy” of a medical reference). Apps that provide and contextually-relevant information to users by matching patient-specific information to reference information routinely used in clinical practice to facilitate a user’s assessment of a specific patient.
4. Help patients document, show, or communicate to providers potential medical conditions, and are not labelled or promoted for medical use.
5. Perform simple calculations generally tailored for clinical use, but retain functionality that is similar to simple general purpose tools such as paper charts, spread sheets, timers or generic mathematical calculators.
Enable patients and providers with mobile access (view or download) to Personal Health Record (PHR) systems or Electronic Health Record (EHR) systems.

Meet the definition of Medical Device Data Systems (MDDS) as defined in the classification regulation (21 CFR 880.6310).

Appendix B of the final guidance provides a list of examples of mobile apps for which the FDA intends to exercise enforcement discretion.

Mobile medical apps that fall within a medical device classification are subject to the related requirements. The associated controls for each class of device are outlined below.

1. Class I Devices: General Controls, including:
   - Establishment registration, and Medical Device listing (21 CFR Part 807);
   - Quality System (QS) regulation (21 CFR Part 820);
   - Labeling requirements (21 CFR Part 801);
   - Medical Device Reporting (21 CFR Part 803);
   - Premarket notification (21 CFR Part 807 Subpart E);
   - Reporting Corrections and Removals (21 CFR Part 806)
   - Investigational Device Exemption (IDE) requirements for clinical studies of investigational devices (21 CFR Part 812).

2. Class II devices: General Controls (as described for Class I), Special Controls, and (for most Class II devices) Premarket Notification (i.e., 510(k)).

3. Class III devices: General Controls (as described for Class I), and Premarket Approval (21 CFR Part 814).

Overall, Class I devices are the least regulated and Class III devices have the most stringent regulations. Appendix D of the final guidance provides examples of medical devices and their regulatory classification, while Appendix E further describes the general controls listed above. Of note, the FDA “strongly recommends” that manufacturers follow the Quality System regulation (including Good Manufacturing Practice) during design and development of all mobile apps that might qualify as a device, presumably to help ensure compliance from the beginning. The FDA views this as important because “the majority of software-related device failures are due to design errors,” which could be identified and corrected during development with the proper regulatory oversight.

Some of the other resources provided by the FDA to guide the industry include:

- FDA cleared or approved mobile medical apps
- Mobile medical apps that are NOT Medical Devices
- The FDA’s database of existing classification of mobile medical apps

This guidance is nonbinding and does not establish legally enforceable responsibilities.

RELEVANT SCIENCE

Some examples of neurologically-focused mobile medical apps include:

- An app used to control a transcutaneous electrical nerve stimulator (TENS), which is a Class II medical device. A TENS is a pain relief device that uses electrodes placed on the skin to send low level electronic currents that presumably affect underlying nerve pathways.
- An app used to control a surgically implanted medical device that mediates spinal cord or peripheral nerve stimulation (Class III or II, respectively). The spinal cord is a part of the central nervous system, which controls the body’s activities. The central nervous system controls muscles and organs through the peripheral nervous system. Spinal cord and peripheral nerve stimulation sends a low level electrical current into nerve pathways to disrupt pain signals.
- An app that controls or monitors a neurosurgical nerve locator, which is a Class II medical device. This device is a surgery tool used to locate or monitor the function of nerves during neurosurgery, in order to prevent damage, identify nonfunctional nerves,
and facilitate less invasive surgeries.

Genomics-focused mobile apps have largely avoided being classified as medical devices by limiting their diagnostic potential. For instance, Face2Gene is a facial-recognition software produced by FDNA that can scan faces for telltale features associated with genetic disorders. However, it is purposely not a diagnostic tool: instead of giving a diagnosis, it points physicians towards a diagnosis that then requires confirmation, often through genetic testing.

On the other hand, the Atlas of Human Malformation Syndromes in Diverse Populations is working to develop facial-recognition software for use as a genetic disorder diagnostic tool. It remains to be seen how such software would be regulated if manufactured as a mobile medical application.

Other examples of potential mobile medical apps would be those that allow mobile phones to be turned into point-of-care diagnostic testing devices, which can conduct diagnostic tests outside of a laboratory setting. For example, scientists have been able to use mobile phones to capture microscope images for pathology analysis and DNA mutation analysis. These technologies could eventually become medical devices used in the diagnosis and treatment of diseases and disorders, and might require mobile medical apps for their operation.

RELEVANT EXPERTS

**Ryan J. Shaw**, PhD, RN, Associate Professor at the Duke School of Nursing and in the School of Medicine’s Center for Applied Genomics and Precision Medicine. Dr. Shaw is a pioneer in mobile health—the collection and dissemination of information using mobile and wireless devices. He works with faculty at Duke’s Schools of Engineering and Medicine to integrate mobile technologies into first-generation care delivery systems.

“The growth of mobile medical applications and their availability to consumers and integration into healthcare systems, has led to an evolving regulatory landscape with needed guidance. The FDA now provides this guidance that helps stakeholders evaluate whether their mobile medical app requires regulatory oversight or falls within the agency’s category in which it intends to exercise enforcement discretion.”

Relevant publications:


**Dori M. Steinberg**, PhD, RD: Assistant Research Professor, Duke Global health Institute; Associate Director, Duke Global Digital Health Science Center. Dr. Steinberg’s research focuses primarily on technology-based interventions for weight control, dietary change, and chronic disease management among adults. In particular, how we can leverage connected mobile devices to improve adherence to self-monitoring behaviors.

Relevant publications:


ENDORSEMENTS & OPPOSITION

Endorsements:
Healthcare IT, "an expansive document that truly seeks to deregulate our nimble and innovative industry, while ensuring patient safety."

Opposition:

At present, there have not been any publicly reported opposition to this action.

STATUS

Guidance issued February 9th, 2015. This guidance supersedes “Mobile Medical Applications: Guidance for Food and Drug Administration Staff” issued on September 25, 2013.

RELATED POLICIES

Food and Drug Administration Safety and Innovation Act, Public Law 112-144

Medical Devices Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices

A mobile medical app may also be subject to other general regulations or device-specific regulations. For example, the FDA has implemented regulations applicable to wireless medical devices which address considerations regarding radio frequency issues. Other FDA regulations cover medical devices intended for home use, which include consumer usability issues. Ultimately, these and other requirements applicable to a given mobile medical app will depend on the app’s intended use or specific configuration with other medical devices.

To learn when the Federal Trade Commission (FTC), FDA or Office of Civil Rights (OCR) regulations apply to a mobile health app please refer to this FTC Mobile Health App Interactive Tool.

POLICY HISTORY

In 2011, the FDA issued the first draft of the guidance. Based on the extensive public comments received from various stakeholders the final draft was issued in 2013. The final draft was later updated in 2015, so it is consistent with “Medical Devices Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices” guidance document released that year which addresses similar themes.

Public comments on the current 2015 guidelines can be accessed here.

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