Mobile Medical Applications

(mailto:mobilemedicalapps@fda.hhs.gov)

Email MMA Questions to the FDA

The widespread adoption and use of mobile technologies is opening new and innovative ways to improve health and health care delivery.

Mobile applications (apps) can help people manage their own health and wellness, promote healthy living, and gain access to useful information when and where they need it. These tools are being adopted almost as quickly as they can be developed. According to industry estimates, 500 million smartphone users worldwide will be using a health care application by 2015, and by 2018, 50 percent of the more than 3.4 billion smartphone and tablet users will have downloaded mobile health applications (http://www.research2guidance.com/500m-people-will -be-using-healthcare-mobile-applications-in-2015/ (http://www.research2guidance.com/500m-people-will-be-using-healthcare-mobile-applications-in-2015/)). These users include health care professionals, consumers, and patients.

The FDA encourages the development of mobile medical apps that improve health care and provide consumers and health care professionals with valuable health information. The FDA also has a public health responsibility to oversee the safety and effectiveness of medical devices – including mobile medical apps.

The FDA issued the **Mobile Medical Applications Guidance for Industry and Food and Drug Administration Staff (/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf)** (PDF - 269KB) on September 25, 2013, which explains the agency's oversight of mobile medical apps as devices and our focus only on the apps that present a greater risk to patients if they don't work as intended and on apps that cause smartphones or other mobile platforms to impact the functionality or performance of traditional medical devices.

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What are mobile medical apps?

Mobile apps are software programs that run on smartphones and other mobile communication devices. They can also be accessories that attach to a smartphone or other mobile communication devices, or a combination of accessories and software.

Mobile medical apps are medical devices that are mobile apps, meet the definition of a medical device and are an accessory to a regulated medical device or transform a mobile platform into a regulated medical device.

Consumers can use both mobile medical apps and mobile apps to manage their own health and wellness, such as to monitor their caloric intake for healthy weight maintenance. For example, the National Institutes of Health's LactMed app provides nursing mothers with information about the effects of medicines on breast milk and nursing infants.

Other apps aim to help health care professionals improve and facilitate patient care. The Radiation Emergency Medical Management (REMM) app gives health care providers guidance on diagnosing and treating radiation injuries. Some mobile

medical apps can diagnose cancer or heart rhythm abnormalities, or function as the "central command" for a glucose meter used by an insulin-dependent diabetic patient.

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How will the FDA regulate mobile medical apps?

The FDA will apply the same risk-based approach the agency uses to assure safety and effectiveness for other medical devices. The **guidance document (/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf)** (PDF - 269KB) provides examples of how the FDA might regulate certain moderate-risk (Class II) and high-risk (Class III) mobile medical apps. The guidance also provides examples of mobile apps that are not medical devices, mobile apps that the FDA intends to exercise enforcement discretion and mobile medical apps that the FDA will regulate in **Appendix A (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf#page=20)**, **Appendix B (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf#page=23)** and **Appendix C (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf#page=26)**.

We encourage app developers to **contact the FDA (mailto:mobilemedicalapps@fda.hhs.gov)** – as early as possible – if they have any questions about their mobile app, its level of risk, and whether a premarket application is required.

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Mobile medical apps that the FDA will regulate

The FDA is taking a tailored, risk-based approach that focuses on the small subset of mobile apps that meet the regulatory definition of "device" and that:

- are intended to be used as an accessory to a regulated medical device, or
- transform a mobile platform into a regulated medical device.

Mobile apps span a wide range of health functions. While many mobile apps carry minimal risk, those that can pose a greater risk to patients will require FDA review.

Please visit the **mobile medical apps example page (/MedicalDevices/DigitalHealth/MobileMedicalApplications/ucm368784.htm)** for a list of examples of mobile medical apps that have been cleared or approved by the FDA. Visit the **Examples of MMAs the FDA regulates (/MedicalDevices/DigitalHealth/MobileMedicalApplications/ucm368743.htm)** webpage for a more detailed list of examples of mobile apps that would require FDA review.

For a list of what is considered a mobile medical application, manufacturers and developers of mobile applications can search **FDA's database of existing classification (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/PCDSimpleSearch.cfm)** by type of mobile medical application (for example diagnostic). Approved/cleared mobile medical applications will also be listed in FDA's **510(k) (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm)** and **PMA (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm)** databases and on the FDA's **Registration & Listing Database (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm)**.

FDA's mobile medical apps policy does **not** require mobile medical app developers to seek Agency re-evaluation for minor, iterative product changes.

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Mobile apps for which the FDA intends to exercise enforcement discretion

For many mobile apps that meet the regulatory definition of a “device” but pose minimal risk to patients and consumers, the FDA will exercise enforcement discretions and will not expect manufacturers to submit premarket review applications or to register and list their apps with the FDA. This includes mobile medical apps that:

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

For a more detailed list of examples of these types of mobile medical apps that do not require FDA review, please visit the webpage **Examples of Mobile Apps for which the FDA will exercise enforcement discretion (/MedicalDevices/DigitalHealth/MobileMedicalApplications/ucm368744.htm)**.

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Does the FDA regulate mobile devices and mobile app stores?

FDA’s mobile medical apps policy does **not** regulate the sale or general consumer use of smartphones or tablets. FDA’s mobile medical apps policy does **not** consider entities that exclusively distribute mobile apps, such as the owners and operators of the “iTunes App store” or the “Google Play store,” to be medical device manufacturers. FDA’s mobile medical apps policy does **not** consider mobile platform manufacturers to be medical device manufacturers just because their mobile platform could be used to run a mobile medical app regulated by FDA.

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Does the guidance apply to electronic health records?

FDA’s mobile medical app policy does **not** apply to mobile apps that function as an electronic health record (EHR) system or personal health record system.

Additional Resources

- **Mobile Medical Applications - Guidance for Industry and Food and Drug Administration Staff (PDF - 1.3MB) (/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf)**

More in Mobile Medical Applications (/MedicalDevices/DigitalHealth/MobileMedicalApplications/default.htm)

Examples of MMAs the FDA Regulates (/MedicalDevices/DigitalHealth/MobileMedicalApplications/ucm368743.htm)

Examples of MMAs That Are NOT Medical Devices (/MedicalDevices/DigitalHealth/MobileMedicalApplications/ucm388746.htm)

Examples of Mobile Apps For Which the FDA Will Exercise Enforcement Discretion (/MedicalDevices/DigitalHealth/MobileMedicalApplications/ucm368744.htm)

Examples of Pre-Market Submissions that Include MMAs Cleared or Approved by FDA (/MedicalDevices/DigitalHealth/MobileMedicalApplications/ucm368784.htm)