Device Software Functions Including Mobile Medical Applications

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

Software functions that meet the definition of a device may be deployed on mobile platforms, other general-purpose computing platforms, or in the function or control of a hardware device. The FDA's policies are independent of the platform on which they might run, are function-specific, and apply across platforms. The term "software functions" includes mobile applications (apps).

Mobile 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 (https://research2guidance.com/product/mhealth-economics-2017-current-status-and-future-trends-in-mobile-health/) ⬀ (http://www.fda.gov/about-fda/website-policies/website-disclaimer) in 2017, 325,000 health care applications were available on smartphones, which equates to an expected 3.7 billion mobile health application downloads that year by smartphone users worldwide. Users include health care professionals, consumers, and patients.

The FDA encourages the development of mobile medical apps (MMAs) 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 Policy for Device Software Functions and Mobile Medical Applications Guidance (/regulatory-information/search-fda-guidance-documents/policy-device-software-functions-and-mobile-medical-applications), first issued in 2013 as "Mobile Medical Applications" (MMA guidance) and updated in 2015 and 2019, explains the agency's oversight of device software functions, including mobile medical apps, as devices and our focus only on the software that presents a greater risk to patients if it doesn't work as intended and on software that causes smartphones, computers, or other mobile platforms to impact the functionality or performance of traditional medical devices. In 2019, the FDA updated the guidance to reflect changes to the device definition in accordance with Section 3060 of the 21st Century Cures Act, which created a function-specific definition for device. The functions excluded from the device definition are independent of the platform on which they might run. Also, the FDA clarified that the policies for software are function-specific and apply across platforms. Therefore, instances of "mobile

application" in the guidance and on this webpage have been changed to "software function." Accordingly, the FDA updated the title of the guidance to "Policy for Device Software Functions and Mobile Medical Applications."

On this page:

- What are mobile medical apps?

- How does the FDA regulate device software functions?

- Device software functions that are the focus of FDA oversight

- Software functions for which the FDA intends to exercise enforcement discretion

- Does the FDA regulate mobile devices, such as smartphones or tablets, and mobile app stores?

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.

How does the FDA regulate device software functions?

The FDA applies the same risk-based approach to device software functions as the agency uses to assure safety and effectiveness for other medical devices. This guidance document (/regulatory-information/search-fda-guidance-documents/policy-device-software-functions-

and-mobile-medical-applications) provides examples of how the FDA might regulate certain moderate-risk (Class II) and high-risk (Class III) device software functions. The guidance also provides examples of software functions that:

- are not medical devices,
- are medical devices, but for which the FDA intends to exercise enforcement discretion, and
- are medical devices and are the focus of FDA oversight.

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

Device software functions that are the focus of FDA oversight

The FDA is taking a tailored, risk-based approach that focuses on the subset of software functions that meet the regulatory definition of "device." Software functions span a wide range of health functions. While some software carries minimal risk, those that can pose a greater risk to patients will require FDA review.

For more information, please see examples of premarket submissions of MMAs that are cleared or approved by the FDA (/medical-devices/device-software-functions-including-mobile-medical-applications/examples-premarket-submissions-include-mmas-cleared-or-approved-fda) and examples of device software functions the FDA regulates (/medical-devices/device-software-functions-including-mobile-medical-applications/examples-device-software-functions-fda-regulates) for a detailed list of examples of software that are medical devices and would require FDA review.

For a list of what is considered a device software function, manufacturers and developers can search the FDA's public database of existing classification (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/PCDSimpleSearch.cfm) by type of software (for example, diagnostic). Approved/cleared device software functions will also be listed in the 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).

The FDA's device software functions and mobile medical apps policy does **not** require software developers to seek FDA re-evaluation for minor, iterative product changes.

Software functions for which the FDA intends to exercise enforcement discretion

For many software functions that meet the regulatory definition of a "device" but pose minimal risk to patients and consumers, the FDA will exercise enforcement discretion and will not expect manufacturers to submit premarket review applications or to register and list their software with the FDA. This includes device software functions that:

- Help patients/users self-manage their disease or condition without providing specific treatment suggestions; or

- Automate simple tasks for health care providers.

For a more detailed list of examples of these types of device software functions that are not the focus of FDA's oversight, please see examples of software functions for which the FDA will exercise enforcement discretion (/medical-devices/device-software-functions-including-mobile-medical-applications/examples-software-functions-which-fda-will-exercise-enforcement-discretion).

Does the FDA regulate mobile devices, such as smartphones or tablets, and mobile app stores?

The FDA's mobile medical apps policy does **not** regulate the sale or general consumer use of smartphones or tablets. The 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. The 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 the FDA.

Resources

- Policy for Device Software Functions and Mobile Medical Applications - Guidance (/regulatory-information/search-fda-guidance-documents/policy-device-software-functions-and-mobile-medical-applications)

- Ask a Question About Digital Health Regulatory Policies (/medical-devices/digital-health/ask-question-about-digital-health-regulatory-policies)