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# Health Policy Brief

DECEMBER 5, 2013

## **mHealth and FDA Guidance.** As the market for mobile health applications continues to grow, developers look to the FDA for guidance on what will be regulated and how.

### WHAT'S THE ISSUE?

Mobile health, or mHealth, refers to the use of smartphones, tablets, and other mobile and wireless devices in both public health and health care. One of the most commonly understood forms of mHealth includes software applications, most commonly called “apps,” which are designed to provide a health-related service for the user. The apps are sometimes called mHealth apps, medical apps, mobile medical apps, or similar permutations. Consumers may use mHealth apps to monitor their own health; doctors or other health care providers similarly can use the apps to engage patients in the tracking of their health.

For consumers, the apps may allow for a greater personal control in health management, from tracking exercise to scheduling doctor appointments. For physicians and other care providers, apps can assist in day-to-day medical care, as well as allow for health-related tasks in remote areas without access to traditional health care infrastructure.

New mHealth apps enter the marketplace daily, and they will continue to do so, particularly as mobile devices become more common and as the technology behind mobile hardware and software advances. Such technology allows for increasingly sophisticated mHealth

applications and may even transform a smartphone or a tablet into a medical device. Unlike a tracking mechanism that merely captures data, medical devices are instruments that help diagnose, prevent, or treat an illness or condition.

Both the relative newness of the mHealth market and the influx of applications pose challenges to the federal agencies responsible for regulating health-related products. This is particularly true for the Food and Drug Administration (FDA). Part of the FDA's mission is to protect the public by making sure drugs, medical devices, and other health-related products are both safe and effective. To continue this mission in the mHealth sphere, the agency must ensure that certain mobile health apps—specifically those considered to be medical devices—are demonstratively safe and that the apps do as the companies who make them claim.

It is also the FDA's mission to advance public health by moving lifesaving technologies through regulation, both to ensure products' safety and to help them come to market. With this in mind, it is also important that the FDA provide guidance to the companies that make and sell mHealth apps, so that the companies know when regulations apply and how to comply while making new products available to consumers.

**“The FDA intends to apply its regulatory oversight to only those mobile apps that are medical devices and whose functionality could pose a risk to a patient’s safety if the mobile app were to not function as intended.”**

### WHAT’S THE BACKGROUND?

There are two main types of mHealth apps that concern general consumers: consumer-operated apps (most of which will not be FDA-regulated) and health care–operated apps (which may or may not be FDA-regulated depending on each app’s function).

Consumer-operated apps may track personal fitness, such as miles walked or calories consumed or burned; provide doctor appointment reminders or drug dosing schedules; display reference material about prescription drugs or from medical textbooks; or save and display certain personal health records.

Health care–operated apps are used by clinicians and other health care providers and may do anything from making patients’ electronic medical records easily accessible and shareable (between clinicians) to tracking vital signs to transforming a mobile device into a diagnostic tool.

The mHealth field is young—its first devices came to market in the late 2000s. These were simply off-the-shelf pieces of hardware that had been adapted to connect to a mobile device, such as heart rate sensors, blood pressure cuffs, and glucose monitors. In just five years the landscape has changed. Forecasters predict that the market and the number of apps will continue to grow at a rate of 25 percent each year for the foreseeable future. Industry experts suggest that 500 million consumers and health care providers will use a mobile health app within the next two years; by 2018, the experts assert, half of the 3.4 billion mobile device users worldwide will download a health app.

In addition to native mHealth apps—those that have been developed specifically for mobile devices rather than adapted to them—smartphones and tablets may now transform into an x-ray reader, ultrasound scanner, or electrocardiogram device. It is possible to imagine a time in the near future when mHealth devices go a step further to assist with remote drug delivery, where a sensor implanted in a patient’s body indicates when the blood levels of a vital drug are running low. Doctors could intervene, providing a patient with a new dose from afar, keeping the drug at more stable levels compared to what happens when a patient takes—and sometimes forgets to take—a pill.

Such complicated mobile medical devices are a prime example of why certain mHealth apps require FDA oversight, and regulation will become more important as mobile devices become even more robust and ubiquitous. Already, the FDA receives thousands of medical devices to review each year—between fiscal years 2008 and 2010, for example, the agency received more than 13,600 devices for review. New mobile medical devices will add to that burden.

The FDA has cleared more than 100 mobile health apps during the past 10 years, 40 of which came through during the past two. As the market grows, more people engage with mHealth apps, and new technologies lead to increasingly sophisticated devices, new regulatory concerns emerge.

### WHAT’S THE LAW?

The FDA carries out its mission through three means: laws, regulations, and guidance documents. Laws are congressionally mandated, whereas regulations are rules published directly by the FDA. Guidance documents outline the agency’s policy on a variety of topics, and they serve an educational purpose.

In July 2011 the FDA issued draft guidance on mHealth applications, which was then opened to outside comment. The document garnered comments from more than 130 outside individuals and organizations. On September 25, 2013, the FDA issued its final guidance on mHealth apps, which is not significantly different from the 2011 draft, although it does include substantial new language clarifying how the agency will regulate specific mHealth apps, in part based on the outside comments.

The majority of the outside comments to the July 2011 draft guidance supported a hands-off, risk-based approach, which focuses on the types of apps that pose the greatest risk to consumers and patients.

According to the final guidance: “The FDA intends to apply its regulatory oversight to only those mobile apps that are medical devices and whose functionality could pose a risk to a patient’s safety if the mobile app were to not function as intended.” By using its enforcement discretion to provide oversight to a small subset of health apps, the FDA hopes to strike a balance, ensuring patient safety without stifling innovation.

# 25%

## Growth rate

Forecasters predict that the market and the number of apps will continue to grow at a rate of 25 percent each year for the foreseeable future.

**“The FDA’s enforcement discretion approach may stir more debate in the future.”**

The FDA will not regulate consumer-operated apps that track general health or health care–operated apps that monitor health records or medical appointments. Nor will it regulate any that make available reference materials such as prescription drug directories or medical texts or are otherwise used for educational purposes. These types of mHealth apps are not typically considered to be medical devices and pose a minimum risk to consumers and patients.

The FDA will not regulate as manufacturers those companies that sell mobile apps through services such as Apple’s iTunes Store and Google Play. Neither will it be involved in regulating sales or general use of smartphones, tablets, or other mobile devices.

The FDA will, however, regulate apps that are classified as medical devices, either working together with existing medical equipment or turning a mobile device into a medical device. In either case, this means that the device is intended to diagnose, treat, or cure specific health problems. If such apps were to malfunction, they pose a risk to consumers and patients. The FDA’s decision to regulate such apps is in line with the agency’s role in the oversight of medical devices in general. Mobile health apps that require FDA oversight will go through the same stringent reviews already required for medical equipment.

Additionally, some apps that meet the definition of a *medical device* may nevertheless go unregulated by the FDA because they pose low risk. These include consumer-operated apps that provide diagnoses or treatment recommendations, such as apps that provide GPS coordinates of locations with potential environmental health threats—for example, badly polluted regions that may pose a risk to people with asthma. Other examples include apps that provide health information to smokers, pregnant women, addicts, or people with psychiatric conditions; apps that provide information on potential herb and drug interactions; apps that communicate with first responders; and apps that track or share personal medical records.

Guidance, however, is not a formal law or regulation. To date, there is no congressional law on mHealth apps, although lawmakers introduced one bill on the topic. On December 3, 2012, Rep. Michael Honda (D-CA) introduced H.R. 6626, the Health Care Innovation and Marketplace Technologies Act of 2012, and on June 13, 2013, he reintroduced it as H.R. 2363,

the Health Care Innovation and Marketplace Technologies Act of 2013. The most recent version of the bill was assigned to the following congressional committees: the House Energy and Commerce Subcommittee on Health, the House Small Business Committee, and the House Ways and Means Committee. The bill is not expected to pass the committees.

At a November 2013 hearing of the House Energy and Commerce Committee, Jeffrey E. Shuren, director of the FDA’s Center for Devices and Radiological Health, did not endorse the push for additional legislation at a time when the technology continues to rapidly evolve. “Once you draw lines and they’re chiseled in stone, we’re sort of locked in for a long period of time,” Shuren testified, according to *CQ Health Beat*. “We are not saying that there isn’t going to be a need for legislation at some point. There may well be. We just think that, at the present time, it’s just simply premature.”

As for regulations, they are in the works. The FDA’s Safety and Innovation Act requires the FDA, working with the Office of the National Coordinator for Health Information Technology, and the Federal Communications Commission to help develop a broad risk-based regulatory framework for health information technology (IT). It is intended to include mobile medical applications. A report outlining this framework must be submitted to Congress by January 2014.

## WHAT’S THE DEBATE?

The FDA’s final September 2013 guidance specifically on mobile medical applications followed contentious disagreement between two major industry groups as to whether the guidance should have been published at all. On one side of the debate was the mHealth Regulatory Coalition, a policy group that represents industry stakeholders, which wanted the FDA to publish guidance as soon as possible to make the path clearer to the companies that develop mHealth apps. Although pleased with the guidance’s publication in September, the group says that the guidance did not go far enough, failing to provide a formal definition of *FDA-regulated apps* and other key explanations.

On the other side of the debate was a group of 140 health care stakeholders, including two dozen consumer groups, 18 medical societies and physician groups, and six hospitals. The stakeholders were led by Athena Health, a company that provides electronic practice

management and medical records services. The group had pressed the FDA to withhold formal guidance until the broader, congressionally mandated health IT framework was submitted in January 2014.

In a separate issue, the final guidance, while similar to the July 2011 draft guidance, does introduce information and language that has not yet gone through a public vetting. As with the draft guidance and the many outside comments it drew, some industry experts have said that portions of the final guidance are not entirely clear, which could lead to conflicting interpretations, although these are peripheral issues.

### WHAT'S NEXT?

The FDA's report outlining a broad framework for health IT regulation must be submitted to

Congress by January 2014. Among many topics, it is expected outline how mobile health regulation will work in practice.

If the agency follows the FDASIA workgroup's final recommendations, the framework will emphasize innovation, patient safety, and efficient regulation. The latter requirement will focus on preventing duplicative regulation, which would drag down the process and make it more difficult for mHealth applications to come to market. The January framework will also likely help the FDA and other agencies formulate guidance for clinical decision support application software and other details that the agency left out of its final guidance in September. ■

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Health Policy Briefs are produced under a partnership of *Health Affairs* and the Robert Wood Johnson Foundation.

Cite as:  
"Health Policy Brief: mHealth and FDA Guidance," *Health Affairs*, December 5, 2013.

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