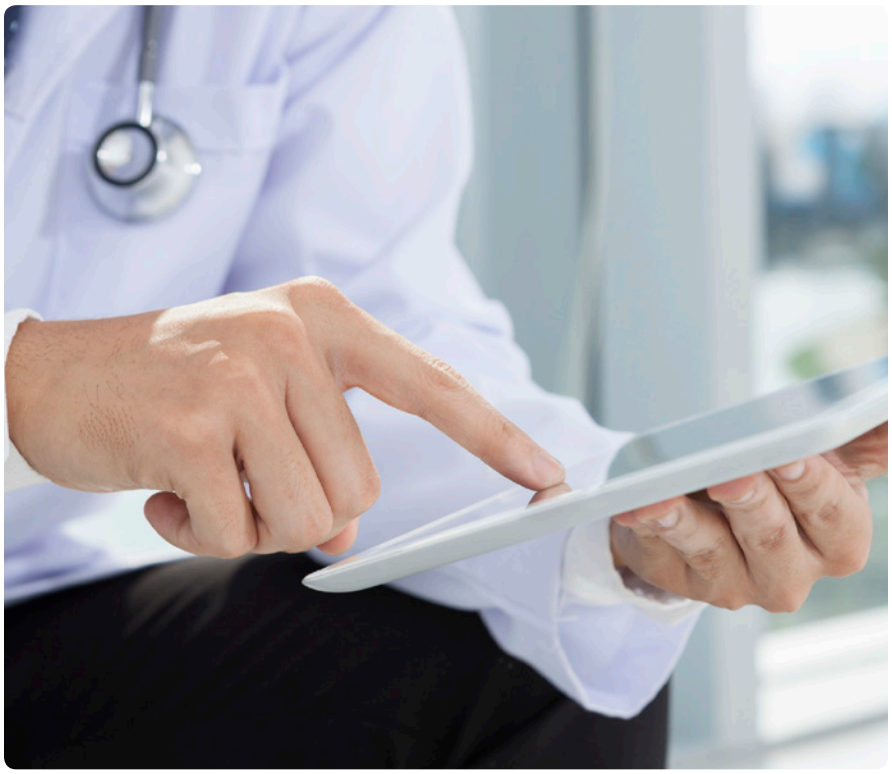
Keeping Up with Progress in Mobile Medical Apps

Patients with diabetes can already use smartphones to monitor the level of sugar in their blood, and doctors can whip out their tablets to read X-rays and perform ultrasounds or electrocardiograms.



Those functions represent just the tip of the iceberg in a coming revolution in mobile medical applications, or "apps," intended for use on mobile phones and tablets. The Food and Drug Administration (FDA) encourages innovation and is excited about the prospects that mobile medical apps offer for providing better care and greater patient involvement in their own health.

At the same time, FDA wants to ensure the safety and effectiveness of the small percentage of mobile medical apps that could be harmful if they didn't work properly.

FDA has issued a guidance document to give mobile app creators a clear and predictable roadmap to help them determine whether or not their products will be the focus of FDA's oversight. To protect consumers and encourage innovation, while at the same time providing the same level of confidence consumers have with other medical devices, the guidance document states that FDA will focus its oversight on medical mobile apps that meet the definition of device in the Federal Food, Drug, and Cosmetic Act and are intended to:

- transform a mobile device into a medical device regulated by FDA; or
- be used as an accessory to a medical device regulated by the FDA.

FDA intends to exercise enforcement discretion for other mobile apps. This focuses FDA's regulatory priorities on the small subset of mobile medical apps that could present a greater risk to health.

Examples Offer Clarity

Here is an example that demonstrates how this plays out in the real world: FDA oversees software medical devices that calculate the amount of radiation that should be given to a cancer patient. If the device were to give the wrong dose recommendation, it clearly would threaten the patient's health. Logically, a mobile medical app that calculates radiation dosage should have the same FDA oversight as the traditional device.

The draft guidance for mobile medical apps, published in July 2011, elicited more than 130 public comments that the FDA reviewed and considered when writing the final guidance.

"Most were positive; people gen-

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erally liked the draft proposal and understood which types of mobile medical apps we would regulate," says Bakul Patel, M.S., MBA, senior policy advisor to the director of FDA's Center for Devices and Radiological Health. However, some who commented asked for more examples of what would not fall within the focus of FDA's regulatory oversight—a suggestion incorporated in the final guidance just issued.

Patel explained, for example, that FDA would regulate a mobile medical app that helps measure blood pressure by controlling the inflation and deflation of a blood pressure cuff (a blood pressure monitor), just as it regulates traditional devices that measure blood pressure. A false reading by either blood pressure device would deliver a false diagnosis and perhaps even lead to treatment that could endanger patients.

However, although a mobile app that doctors or patients use to log and track trends with their blood pressure or insulin dose is a medical device, as explained in the final mobile medical app guidance, such mobile apps would not fall within the current focus of FDA's regulatory oversight. Similarly, mobile medical apps that recommend calorie or carbohydrate intakes to people who track what they eat also are not within the current focus of FDA's regulatory oversight. While such mobile apps may have health implications, FDA believes the risks posed by these devices are low and such apps can empower patients to be more engaged in their health care.

In the final mobile medical apps guidance, FDA clarifies that its mobile medical apps policy does not apply to the use of smartphones or tablets themselves. Providers of mobile medical apps, such as the iTunes app store, would not be treated as medical device manufacturers.

A Growing Trend

The mobile app market is anticipated to grow 25 percent annually for some time, according to the market research firm Kalorama Information; companies are investing record amounts in developing new health apps. Consumers will be finding more and more options from which to choose.

FDA intends to stay current with the expertise needed to evaluate mobile medical apps for which safe use and accuracy are critical to public health by hiring additional skilled engineers, including software engineers, and medical officers with device expertise. FDA also works closely with experts in academia and is now reviewing its current practices involved in evaluating software used in mobile medical apps.

So far, FDA has cleared nearly 100 mobile medical apps. These mobile medical apps include blood pressure monitors, apps that send real-time readings of electrocardiographs to your doctor, and apps that access vital signs for use in emergency cardiac care. Despite the growth of mobile medical apps, consumers should still talk to their health care providers about decisions related to their health care.

"Mobile apps are unleashing amazing creativity, and we intend to encourage these exciting innovations," says Patel. "At the same time, we have set risk-based priorities and are focusing FDA's oversight on mobile apps that are devices for which safety and effectiveness are critical." FDA

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