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The FDA wants to know what you intend to do with that mHealth mobile app.

In 2007 there were no smartphones and no apps. Now there are millions, and 50,000 of those are health and fitness apps available for download to mobile devices. The market for health- related apps has grown to more than four million downloads per day.

The numbers continue to build, and it is projected in three years, half of all smartphone users will have downloaded mobile health software programs. They can help patients save money, allow better communication between health services and individuals, and profoundly affect our health. Mobile health is staged to become part of our lives, but *what is an app*?

Two types of mobile apps

There are two classifications of mobile applications: a **native app** (operating system specific), one that must be pre-installed on the device or downloaded from a Web site, or a **web app** (operable on any device) that resides on a server and is accessed via the Internet for performing specific tasks.

A mobile application can be simple, a "lifestyle" app like an appointment reminder, task scheduler, data logger. It can be complex, comparable to a patient monitoring or disease diagnosis tool – a highly specific app that could affect health outcomes.

As it stands, app developers can make significant claims and there is no way to be sure their handiwork performs as advertised. Eventually it will be sorted out, but for now there are questions whether or not apps belong in healthcare's clinical workflow.

Widespread usage

A 2012 Healthcare Information and Management Systems Society (HIMSS) survey showed that 80% of physicians routinely use mobile health technology to provide patient care. Understandably, hospital IT and those responsible for a healthcare organization's health policy are unwilling to incorporate unsecure or controversial tech into their network. HIPAA legislation (patient privacy), EHR and Meaningful Use requirements (Electronic Health Records), and security are their top concerns.

Three categories

The three general categories of mobile apps which require oversight are those that:

1) act as "an extension of one or more medical devices by connecting to such a device for purposes of controlling the device or displaying, storing, analyzing, or transmitting patient-specific medical-device data."

2) "transform a mobile platform into a medical device by using attachments, display screens, or sensors, or by including functionalities similar to those of currently regulated medical devices."

3) "allow the user to input patient-specific information and - using formulae or processing algorithms - output a patient-specific result, diagnosis, or treatment recommendation to be used in clinical practice."

The FDA position

The US-FDA has elected to exercise "enforced discretion" for the majority of mobile medical apps, as they pose minimal risk to

consumers, and focus their regulatory oversight on the subset that present a greater risk to patients if they do not work correctly. The FDA has the intent to protect patients and at the same time, "encourage innovation".

The mobile medical apps that will not require premarket review or registration with the FDA are those that:

- Help patients manage their disease or condition without providing specific treatment suggestions.
- Provide patients with tools to access, document, organize, and track their health information.
- Automate simple tasks for health care providers, or enable patients to interact with Personal Health Records or Electronic Health Record systems.

The FDA is focusing its oversight on mobile medical apps which:

- Are intended to be used as an accessory to a regulated medical device. An example is an application that allows a medical professional to make a diagnosis by viewing a medical image (eg. and ultrasound, MRI, mammogram, or PET scan, etc.) from a picture archiving and communication system (PACS) on a smartphone or tablet.
- Transforms a mobile platform into a regulated medical device like an ECG.

The FDA does not regulate the sale or general consumer use of smartphones and tablets, or non-medical apps. Mobile medical apps that are reviewed by the FDA will be assessed with the same regulatory standards and risk-based approach that they have applied to other medical devices.

Future of healthcare

Physicians and patients who use smartphones, tablets, and laptops, are exploring new ways of collecting and communicating health data. Presently there are unresolved questions of what to do with this information and generally, how is this all going to work?

According to Leslie Saxon, M.D., a professor of clinical medicine at the University of Southern California Keck School of Medicine (USC), and director of the USC Center for Body Computing, mobile apps will be "a large part of the future" of health care and that issues of regulation and standardization are "surmountable."

Ron Sully is the Director of Marketing
at Omnica Corporation. He can be reached at:
rons@omnica.com