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There's an App for That! The FDA Offers a Framework for Regulating Mobile Health

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This article appears in the September 1, 2011 issue of *Managed Care Outlook*, Volume 24, Number 17, and has been reprinted, with changes, with permission from Aspen Publishers.

Those in the Health Care Space Should Expect the mHealth Market to Continue to Grow

Doctors are using iPads to enter data into a patient's electronic medical record during the patient's visit, patients are using their smartphones to monitor their caloric intake or to find doctors who accept their insurance policies,[1] and veterans who have post-traumatic stress disorder (PTSD) are consulting the PTSD Coach to learn about PTSD, conduct a self-assessment, and find support networks.[2] Health care organizations increasingly are integrating smartphones and tablets into their health care infrastructure and daily use. At the same time, individuals are taking advantage of the health care tools that are location-independent and available at the click of a button. A 2010 Pew Research study found that out of the 85 percent of adults that use a cell phone, 17 percent have used it to look up health-related information, and 9 percent have health-related software applications (*i.e.*, an "app") on their phones.[3]

GROWTH OF MOBILE HEALTH

The federal government is encouraging this growth in mobile health ("mHealth"). In 2010, for example, the National Institutes of Health awarded about 150 grants for mobile phone-related research.[4] Stakeholders see mobile technology as a means to save money on the management of chronic diseases, to educate the population, and to more easily reach individuals in chronically underserved areas. For example, one study recently found that individuals who used a diabetes management app experienced a decrease in hemoglobin A1C levels. Specifically, the researchers found that over a 12-month period, patients using the app had an average decline in A1C levels of 1.9 percent compared with a 0.7 percent decrease among those patients who did not use the app.[5]

The private sector is also investing heavily with the anticipated growth in the mHealth market. As reported by the New York Times, "[a] report by Parks Associates in February estimated that in the United States alone, revenue from digital health technology and services would exceed $5.7 billion in 2015, compared with $1.7 billion in 2010, fueled by devices that monitor chronic conditions like hypertension and diabetes and by wellness and fitness applications and programs."[6]

As those who use smartphones and tablets well know, however, to access these mHealth tools, users must download and install an application (*i.e.*, an "app") into their mobile device. As of August 2011, the Apple App Store had over 425,000 apps, and the Android Market had close to 250,000 available for purchase or free download. The data on the number of health care-related apps available varies.

The New York Times recently reported that as of November 2010, there were more than 17,000 mobile health apps available.[7] While it does appear that the majority of the apps currently available are not health care related, the issue is nonetheless important enough that the Food and Drug Administration (FDA) feels compelled to step in and offer some clarification on its intention to regulate health care apps.

The Proposed Regulation

On July 21, 2011, the FDA published its two-page draft guidance document on Mobile Medical Applications (the "FDA guidance") in the *Federal Register*.[8] The FDA issued the "draft guidance to inform manufacturers, distributors, and other entities about how the FDA intends to apply its regulatory authorities to select software applications intended for use on mobile platforms (mobile applications or 'mobile apps')." While the guidance document, once finalized, will reflect the "FDA's current thinking on mobile medical applications," it is not binding on the FDA and does not confer any rights on any party.

For the time being, the FDA is limiting its regulatory authority to a subset of mobile apps that it is calling mobile medical apps, which are defined as mobile apps that meet the "device" definition in §201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).[9] Products "that are built with or consist of computer and/or software components or applications are subject to [FDA] regulation as devices when they meet the definition of a device in section 201(h) of the FD&C Act."[10] In pertinent part, the FD&C Act defines device as: "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent [that is] *intended for use in* the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man [or] intended to affect the structure or any function of the body of man or other animals[.]"[11]

In addition to meeting the definition of device, the mobile app also must be "used as an accessory to a regulated medical device or [t]ransform[] a mobile platform into a regulated medical device."[12]

The FDA's goal is to limit the regulation to "a subset of mobile apps that either have traditionally been considered medical devices or affect the performance or functionality of a currently regulated medical device."[13] In that respect, the FDA is narrowly tailoring its approach.

The FDA makes clear that it "intends to exercise enforcement discretion" toward mobile apps that do not meet the definition of mobile medical app but nonetheless meet the "device" definition of the FD&C Act. "This means that FDA intends to exercise its discretion ***to decline to pursue enforcement actions*** for violations of the FD&C Act and applicable regulations by a manufacturer of a mobile medical app, as specified in this guidance."[14]

Concluding Comments

The FDA guidance makes clear that the FDA is taking a limited regulatory approach to mobile health technologies. This reflects

the understanding that the market and the technology are relatively new. Conversely, the mere fact that the FDA is regulating these types of technologies at all reflects that the FDA recognizes that mobile medical apps can pose risks to public health. As the FDA explains:

> [M]obile medical apps may pose additional or different risks [compared to traditional medical devices] due to the unique characteristics of the [mobile] platform. For example, the interpretation of radiological images on a mobile device could be adversely affected by the smaller screen size, lower contrast ratio, and uncontrolled ambient light of the mobile platform[.]

Despite the concerns raised by the FDA and others in the industry, those in the health care space should expect the mHealth market to continue to grow as organizations take advantage of this new method of engaging their customers.

Endnotes:

1. *See e.g.*, BlueCross BlueShield Association, Blue National Doctor and Hospital Finder App, www.bcbs.com/mobile/ (last visited Aug. 1, 2011).
2. The PTSD Coach is an app that was created by a joint effort of the Office of Veteran's Affairs and the Department of Defense. *See* Office of Veteran's Affairs, VantagePoint Blog, Mobile App Helps Veterans with PTSD, www.blogs.va.gov/VAntage/?p=2241 (last visited Aug. 1, 2011).
3. Pew Research Center, Mobile Health 2010 (Oct. 2010), *available at* www.pewinternet.org/~/media//Files/Reports/2010/PIP_Mobile_Health_2010.pdf.
4. *See* Francis S. Collins, *Mobile Technology and Health Care*, 5 NIH Medline Plus 2 (2011), *available at* www.nlm.nih.gov/medlineplus/magazine/issues/winter11/articles/winter11pg2-3.html.
5. *See* Charlene C. Quinn et al, *Cluster-Randomized Trial of a Mobile Phone Personalized Behavioral Intervention for Blood Glucose Control*, Diabetes Care (2011) (published online before print). *But see* Justine Baron & Stanton Newman, A Systematic Review of the Effectiveness of Mobile Health Interventions for the Management of Diabetes, Int'l J. Integrated Care (2011) (The authors reviewed several studies and found that the results on the effectiveness of mobile health with respect to managing diabetes was inconclusive. They attributed this finding, in part, to a low number of studies).
6. Sonia Kolesnikov-Jessop, *Do-It-Yourself Health Care With Smartphones*, NYTimes.com, Feb. 28, 2011, www.nytimes.com/2011/03/01/technology/01iht-srhealth01.html?_r=2&scp=8&sq=health%20mobile%20app&st=cse.
7. Sonia Kolesnikov-Jessop, *Do-It-Yourself Health Care With Smartphones*, NYTimes.com, Feb. 28, 2011, www.nytimes.com/2011/03/01/technology/01iht-srhealth01.html?_r=2&scp=8&sq=health%20mobile%20app&st=cse (relying on a November 2010 report from research2guidance). *See also*, Brian Dolan, *3 Million Downloads for Android Health Apps*, MobiHealthNews.com, Mar. 11, 2010, mobihealthnews.com/6908/3-million-downloads-for-android-health-apps/.
8. *See* FDA, Draft Guidance for Industry and Food and Drug Administration Staff; Mobile Medical Applications; Availability, 76 FR 43689 (July 21, 2011) [hereinafter, the "guidance"].
9. *See* 21 U.S.C. § 321.
10. Guidance at fn. 1.
11. *Id*. (emphasis added).
12. *Id*.
13. *Id*.
14. Guidance at fn. 2 (emphasis added).

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