Health Care

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FDA Draft Guidance Would Ease Regulatory Burdens for Certain mHealth Applications

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On August 1, 2014, the Food and Drug Administration (FDA) released draft guidance that would exempt from premarket 510(k) review many low-risk medical devices—including certain mobile applications that can convert a cell phone into a medical device, such as a thermometer or a stethoscope. Although the guidance is not yet legally enforceable, the FDA also announced its intention not to enforce compliance with premarket review requirements for these devices and noted that it did not expect manufacturers to submit 510(k)s for these devices prior to adoption of a final rule or order. The FDA's recognition that these devices are sufficiently well understood and do not present risks that require premarket review to ensure their safety and effectiveness—and its corollary decision to exercise enforcement discretion as to these devices—eases the regulatory burden on medical application developers and expands opportunities for continued development and dissemination of important mobile tools for improving patient care and physician practice.

I. Mobile Health Applications – Consumer Promise, Regulatory Challenge

Mobile applications are already changing consumers' approach to health care and empowering them to take a more active role in managing their health; one study found that, in 2013, there were approximately 31,000 health-related apps on the market.[1] Even Congress can agree on the promise of mobile health

[1] Michael Essany, Mobile Health Care Apps Growing Fast in Number, mHealthWatch (April 15, 2013).

applications. In the past year, both the House and the Senate introduced bills[2] to direct FDA oversight toward products that pose a potential risk to human safety, while limiting the regulatory authority over low-risk, information-based applications.

The promise that comes with this rapid technological development, however, has challenged regulators charged with protecting the health and safety of the public, as innovation has often outpaced their ability to issue timely policies and maintain appropriate oversight. This challenge is particularly demanding for regulators contemplating oversight of the thousands of mobile health applications flooding the Apple app store and similar marketplaces each month. Quick access and low cost are two driving factors behind mobile app success—two elements that do not align with a high regulatory approval threshold and long review periods.

The rate of innovation for mobile health applications has led the FDA to balance patient safety with encouraging innovation by "focus[ing] its regulatory priorities on the small subset of mobile medical apps that could present a greater risk to health."[3] For example, the FDA's April 2014 guidelines—issued jointly with the Office of the National Coordinator for Health Information Technology (ONC) and the Federal Communications Commission (FCC)—declared that health management IT functionalities were not the same as medical devices and FDA would not subject health IT applications to regulatory oversight.[4] Medical device health IT functionality, such as computer aided detection software, remote display or notification of real-time alarms from bedside monitors, and robotic surgical planning and control, would however garner the attention of the FDA since they generally pose greater risks to patient safety.[5] The FDA's new guidance extends this risk-based approach to regulating new mobile health technologies.

II. Development of FDA Regulation of Mobile Health Tools

Even before the recent explosion in health-related mobile applications, the rapid advance of computer-based health tools has historically posed a regulatory challenge for the FDA. Between 1989 and 2005, the FDA relied on a "Draft Software Policy" in identifying what computer-based products would be considered medical devices and how the agency would regulate these devices. Technological developments, however, outpaced regulators and the FDA withdrew this policy in 2005.[6] In July 2011, the FDA released its first draft guidance explicitly addressing mobile medical applications. Adopted in final form in September 2013, this guidance delineated the subset of mobile apps that met the definition of medical devices, and specified varying levels of enforcement for these apps based on the risks they presented to the health of the public.[7]

Specifically, looking to Section 201(h) of the Food, Drug and Cosmetic Act, the FDA defined as medical devices those mobile apps that are intended "to be used as an accessory to a regulated medical device; or

[2] A bipartisan group of House members introduced the Sensible Oversight for Technology which Advances Regulatory Efficiency (SOFTWARE) Act to amend Section 201 of the Federal Food, Drug and Cosmetic Act to provide guidance to the FDA regarding mobile medical application regulation. Similarly, the Senate proposed the Preventing Regulatory Overreach To Enhance Care Technology (PROTECT) Act of 2014 which also proposed revisions to Section 201, citing a global market for mobile health and significant job creation potential. Both bills would have clarified the term "device" to specifically exclude clinical software or health software.

[3] *"Keeping Up with Progress in Mobile Medical Apps"*, U.S. Food and Drug Administration, Consumer Updates (Sept. 23, 2013).

[4] *See*, FDASIA (Food and Drug Administration Safety and Innovation Act) Health IT Report – Proposed Strategy and Recommendations for a Risk-Based Framework, April 2014.

[5] *Id.* at 4.

[6] Annual Comprehensive List of Guidance Documents at the Food and Drug Administration (70 Fed. Reg. 824, 890) (Jan. 5, 2005).

[7] FDA, Mobile Medical Applications (Sept. 25, 2013).

to transform a mobile platform into a regulated medical device."[8] Consistent with its authorizing statute, the FDA distinguished between those mobile apps that are and are not medical devices based on each app's intended use. The agency noted that an app's intended use could "be shown by labeling claims, advertising materials, or oral or written statements by manufacturers or their representatives."[9]

The FDA then explained its intention "to focus its oversight on a subset of mobile apps."[10] Not only did the FDA clarify that it would *not* regulate mobile apps that did not meet the definition of a medical device, it announced its intention to exercise enforcement discretion as to mobile apps that pose a low risk to patients. The guidance made clear, however, that the FDA *did* intend to apply its regulatory oversight to mobile apps that "can transform a mobile platform into a regulated medical device by using attachments, display screens, sensors, or other such methods."[11]

For these apps, the FDA implied that its standard regulatory regime for medical devices would apply. Under this regime, medical devices are classified into three classes based on the level of risk they pose to the public. The lowest risk devices are classified as Class I and are usually subject only to general controls including establishment registration, medical device listing, quality system regulation, labeling requirements, and medical device reporting. In contrast, Class II devices are generally subject to 510(k) premarket notification requirements, from which most Class I devices are exempt.

A device subject to 510(k) requirements cannot be commercially distributed in the United States until the FDA issues a letter of substantial equivalence finding that the device is substantially equivalent either to a device legally in commercial distribution in the United States before May 28, 1976, or to a device that the FDA has already determined to be substantially equivalent. To obtain this clearance from the FDA, a manufacturer must submit evidence comparing its device to a device already legally marketed. The submitted evidence must show that the device either: (1) has the same intended use AND the same technological characteristics as a predicate device, or (2) has the same intended use as but different technological characteristics than the predicate, but does not raise new questions of safety and effectiveness and is at least as safe and effective as the predicate device. Gathering the required evidence may be arduous and the FDA takes an average of five months to issue its decision, resulting in added costs and lost time in bringing a new product to market.[12]

III. New Guidance and Unresolved Challenges

The FDA's new guidance, however, may smooth the path to market for many medical mobile apps that the FDA's 2013 guidance suggested would be subject to premarket approval requirements. By exempting certain additional categories of medical mobile apps from premarket approval, the new guidance allows faster innovation and incentivizes development of products that pose little risk to patients, while raising the quality and efficiency of the care patients receive. Nevertheless, regulatory challenges may be daunting for any app developer wishing to market a product that may be considered a medical device. For instance, certain FDA regulatory requirements apply to *all* medical devices, even those exempted from premarket review.

[8] *Id.* at 5.
[9] *Id.* at 6.
[10] *Id.* at 12.
[11] *Id.* at 13.
[12] *See* Emergo Group, How Long Does it Take for a 510(k) Submission to be Cleared by the U.S. FDA? (February 2014).

Further, all app developers should consider whether their products may face other government oversight or legal challenges. In particular, health information privacy and security is an important aspect of health technology and protection against cyber threats and attacks is crucial. A digitized medical environment, while improving care and access, can be readily exploited by opportunistic hackers. Players in the health IT space should be highly cognizant of this risk and take steps necessary to limit risks to patient safety and the company's bottom line. Although the new guidance removes some regulatory obstacles to innovation, informed legal counsel remains central to success in this quickly evolving regulatory sphere.

Public comment on the FDA draft guidance will be solicited until September 30, 2014, as outlined in 79 Fed. Reg. 44804 (Aug. 1, 2014). The draft guidance is available for here for review.

If you have any questions about the content of this alert, please contact the Pillsbury attorney with whom you regularly work, or the authors below.

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