Morgan Lewis

June 2013 Update: Software and Mobile Medical Apps Regulation

Congressional Hearing

The year began with discussions and controversy related to the application of the medical device tax (which became effective on January 1, 2013) to mobile applications (apps) and platforms, such as smartphones and tablets. These discussions led to a three-day congressional hearing by the House Energy and Commerce Committee in March. While the purpose of the hearing was somewhat unclear and may have related more to political issues arising from the device tax, it provided an opportunity for the Food and Drug Administration (FDA) to clarify several issues and announce its deadline for the release of its final guidance on mobile medical apps. Specifically, Christy Foreman, Director of the Center for Devices and Radiological Health's Office of Device Evaluation, noted the following:

- FDA does not intend to regulate the sale or general consumer use of smartphones or tablets, nor does it consider the entities that exclusively distribute mobile medical apps through app stores, such as iTunes, to be medical device manufacturers.
- FDA intends to adopt a "narrowly tailored" and "risk based" approach to the regulation of mobile medical apps.
- FDA intends to release the final guidance on mobile medical apps by the end of its fiscal year on October 1, 2013.

Implementation of Section 618 of the Food and Drug Administration Safety and Innovation Act

At the end of April, the Health IT Policy Committee's Food and Drug Administration Safety and Innovation Act (FDASIA) Workgroup held its kickoff meeting to begin working on the preparation of a report on strategies and recommendations for the regulation of health IT, as mandated by FDASIA. The FDASIA Workgroup is a subcommittee of the Health IT Policy Committee, a federal advisory committee that advises the National Coordinator for Health Information Technology on a policy framework for the development and adoption of a nationwide health information infrastructure. The FDASIA Workgroup includes representatives from the Office of the National Coordinator for Health Information Technology, FDA, and the Federal Communications Commission, as well as representatives from industry, academia, and health-related institutions.

Notably, at this first meeting, FDA signaled its intent to take a risk-based approach to the regulation of health IT, which it characterized as "smart regulation." Dr. Shuren, Director of FDA's Center for Devices and Radiological Health, stated that FDA would employ "selective use of regulatory tools appropriate for [the] technology" and cited its focus on only a small subset of mobile medical apps as an example of how FDA intended to encourage innovation in the mobile health area.

The FDASIA Workgroup held additional meetings in May, and subgroups were created on safety, innovation, and regulations. These subgroups provided presentations at a meeting held in Washington, D.C., on May 30 and 31. The meetings will continue throughout the month of June. In addition, the FDA's Office of the National Coordinator for Health Information Technology and the Federal Communications Commission issued a notice in the *Federal Register* on May 30, 2013, requesting comments on elements that the FDASIA Workgroup should consider in developing its report on recommendations for a risk-based regulatory framework for health IT. Comments may be submitted until 11:59 p.m. on August 31, 2013.

FDA Enforcement Efforts

On May 21, in one of its first enforcement actions against an app developer, FDA posted on its website an "It Has Come to Our Attention" letter to Biosense Technologies.[1] Biosense was marketing the "uChek Urine analyzer" app, which allowed a mobile phone to analyze various urine dipsticks regulated as Class II medical devices. According to FDA, the phone and device, as a whole, functioned as an automated strip reader. FDA has

1. View the letter at http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/ucm353513.htm.

requested that BioSense provide FDA, within 30 days, either (i) the FDA clearance number for the uChek Urine analyzer or (ii) a basis for a determination that FDA clearance is not required.

Interestingly, FDA chose to issue this correspondence as an "It Has Come to Our Attention" letter and not a warning letter. Because regulation of mobile medical apps is still unclear to industry, FDA is not taking a heavy-handed approach but has given the company an opportunity to respond before it takes more formal enforcement action. Nevertheless, the app under discussion in this case does not fall into a "gray area," as many mobile medical apps do.[2] Biosense's app is promoted as an accessory to urine dipsticks, which are Class II devices, and, in its letter, FDA identified a cleared 510(k) for another urine analyzer intended for use with urine dipsticks.

2. For more information on FDA's enforcement efforts, see Law360's article "FDA Shows Deft Touch With 1st Mobile App Enforcement," which contains commentary from associate Michele Buenafe and is available at http://www.morganlewis.com/pubs/Law360_FDAShowsDeftTouchWithMobileAppEnforcement_22may13.pdf.