PUBLICATION

FDA Flexes Mobile App Enforcement Muscles (Gently) [Ober|Kaler]

2013: Issue 13 - Focus on HIPAA/Privacy

The FDA was granted authority to regulate mobile health care applications (apps) as part of the Food and Drug Administration and Innovation Act. (*For a detailed discussion of the FDA's authority, see "FDA Safety and Innovation Act Includes Important Provision Regarding Mobile Health Care Technology."*)

The grant followed the FDA's own issuance of draft guidance on the subject. While the draft guidance has not been finalized, the FDA has taken steps to review certain applications, clearing approximately 100 health-care-related applications in recent months. Until very recently, however, no steps had been taken to require mobile app developers to work with the FDA with regard to the health-related apps. The FDA's recent letter to Biosense Technologies, however, makes it clear that the FDA does intend to require mobile app developers to seek clearance before marketing their health care apps.

Biosense developed and markets the "uCheck Urine Analyzer" app which allows users to photograph specialized urinalysis test strips with their phone or other mobile device and have the results analyzed by the app to report on levels of glucose, urobilinogen, pH, ketone, blood, protein, bilirubin, nitrite, leukocyte, and specific gravity. The app was first tested in India but it was promoted at the February 2013 Technology, Entertainment, Design (TED) conference. The developer's decision not to seek out FDA clearance before marketing in the United States had been a subject of industry speculation for some time – a speculation settled by the FDA's letter.

The enforcement route chosen by the FDA, however, reflects countervailing pressures on the agency to avoid stifling innovation. The FDA elected to send an "It Has Come To Our Attention" letter that provided Biosense a generous 30-day response period. (As of this article's drafting, Biosense has not publicly responded.) Notably as well, the agency identified a similar device system and directed Biosense to the data used to support its clearance – information that Biosense can use to seek fast-track approval for a substantially similar device.

Ober|Kaler's Comments

Providers who use, and those who develop, mobile health care apps should stay apprised of the FDA's enforcement actions with Biosense (and, as applicable, other, similarly situated entities). In the absence of finalized agency guidance, the manner in which developers like Biosense are treated will help provide guideposts to other developers as to when FDA clearance will be expected and how vigorously the agency will pursue its mandate to supervise the mobile app space. It is a positive sign, however, that the agency has chosen to act with restraint, encouraging developers to pursue potentially transformative apps like Ucheck while also ensuring that patient safety and a level industry playing field will be ensured.

* *Joshua J. Freemire is a former member of Ober|Kaler's Health Law Group*