

Reproduced with permission from Health IT Law & Industry Report, 08 HITR 35, 8/29/16. Copyright © 2016 by The Bureau of National Affairs, Inc. (800-372-1033) <http://www.bna.com>

## Oversight

### **Digital Health Industry Uncertain About Limits of Federal Oversight**

**F**ederal regulators will test the limits of their authority to oversee digital health technologies over the next year, Albert Cacoza, a partner in the life sciences practices of the Washington office of Ropes & Gray, told Bloomberg BNA.

While the Food and Drug Administration has signaled it won't regulate consumer health tools like fitness trackers, other federal agencies are taking an active role in overseeing the digital health space, Cacoza said. The Federal Trade Commission in particular is being aggressive in asserting its jurisdiction in the industry, he said Aug. 24.

"The FTC seems to want to take a more aggressive role," Cacoza said.

---

**"The FTC seems to want to take a more aggressive role."**

ALBERT CACOZZA, ROPES & GRAY

---

Facing scrutiny from multiple agencies has left many companies in the digital health space uncertain about how their products are regulated by the federal government, Cacoza said.

Three agencies primarily oversee the digital health industry: the FDA, the FTC and the Department of Health and Human Services Office for Civil Rights. Digital health encompasses a broad swath of technologies, from electronic health records to fitness trackers and mobile health apps.

Additionally, state attorneys general and other regional regulators are taking an interest in digital health, Cacoza said.

The FDA in July released guidance clarifying that the agency won't enforce its oversight rules over products that are intended only for general wellness, such as tools for weight management, physical fitness or mental acuity (*see previous article*).

**Agency Authorities.** The guidance included a number of examples of technologies the FDA considers to be general wellness products, drawing a clear distinction for digital health technology developers, Cacoza said.

However, the OCR has broad authority to enforce the privacy and security rules of the Health Insurance Portability and Accountability Act (HIPAA), he said.

The line between which companies are covered by HIPAA and which aren't can be unclear, Cacoza said. HIPAA rules apply to health-care organizations and their business associates, which can be companies that manage data or develop software.

But, digital health tools are regularly being used by health-care organizations, which can make the companies that create those tools business associates of health-care company clients, Cacoza said.

The OCR will soon begin auditing business associates of HIPAA-covered entities, the agency announced in July.

These audits are likely to test the OCR's ability to identify business associates and its authority to investigate their privacy and security practices. Some health attorneys have warned that most business associates don't work exclusively for health-care companies or even count health care companies among their top clients, meaning their data security procedures are probably not focused on HIPAA compliance (*see previous article*).

Similarly, the FTC has the authority to investigate unfair and deceptive trade practices under the FTC Act, Cacoza said. The agency has used its FTC Act authorities to take action against companies it believes have lax data security practices, he said.

In a July opinion against the medical testing company LabMD Inc., the FTC held that poor data security leading to a breach is enough on its own to show unfair business practices.

However, LabMD is appealing the ruling and challenging the FTC's authority to take action against a company for actions that could cause harm (*see previous article*).

The case could provide some much-needed insight into the FTC's authorities over health companies, Ca-cozza said.

BY ALEX RUOFF

To contact the reporter on this story: Alex Ruoff in Washington at [aruoff@bna.com](mailto:aruoff@bna.com)

To contact the editor responsible for this story: Kendra Casey Plank at [kcasey@bna.com](mailto:kcasey@bna.com)