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REPORT

Technology

Mobile Health Coalition Forming to Draft Proposed Guidance for FDA Regulation of HIT

Ambiguity about what mobile health technologies the Food and Drug Administration will regulate is prompting the formation of an industry coalition that will draft proposed guidance to the agency on the mobile health IT products that should and should not be under its regulatory purview.

Health care attorney Bradley Merrill Thompson, with Epstein Becker & Green PC, Washington, and health IT executive Dane Stout, with the consulting firm Anson Group, have begun inviting industry associations and IT companies to join the mHealth Regulatory Coalition, with the sole aim of developing the proposed guidance to FDA.

The group will meet for the first time July 8 in Washington, Thompson told BNA June 10. That meeting will be a combined initial business meeting as well as an informational meeting for associations and firms considering joining the effort.

''We've gotten a good response so far,'' Thompson said.

The concern for the mobile health IT industry, Thompson and Stout explained, is an overwhelming uncertainty about what mobile technologies FDA might regulate. That uncertainty, they said, is causing companies to put on pause plans to develop new mobile technology products for use in the health care market.

''One of the things we keep hearing is companies saying, you know we're interested in this mobile health space, but this whole concept that FDA might regulate [us] is so foreign to us that we don't know how to deal with it and so we're trying to stay way clear,'' Thompson said. ''The notion of FDA regulation scares them.''

However, Stout added, companies already developing and producing mobile health technologies or mobile technologies for use in the health industry may not be aware they could be regulated by FDA.

In both cases, Stout said, clarity for the industry is needed, but no guidance exists yet from FDA.

The ambiguity about FDA regulation is not around traditional medical devices such as blood glucose meters—which already are subject to FDA oversight—but the connectivity of those devices via cellphones, television set-top boxes, and other remote connections that allow providers to monitor patients in remote locations, including their homes and skilled nursing facilities, Thompson said.

''It's there that the ambiguity lies,'' he said.

Too Early to Define Guidance. Thompson said it is too early to say how the proposed guidance will look when it is ready for FDA because the content will be member-driven. He said there are a variety of companies in the mobile health IT market, including some health care companies that already have relationships with FDA and are comfortable with the agency and other consumer and technology companies that are more inclined to say with a broad brush that FDA regulation is too risky for their business models. Those disparate experiences will shape the guidance, he said.

Thompson said, though, that he expects the coalition's discussions to be at the ''roll-up-the-sleeves level,'' about specific technologies, not theories.

''We want to end up with a very useful document,'' Thompson said. ''We'll get very specific about the technology and the intended uses, I predict.''

He added that such level of specificity would be most useful to FDA as well.

Private Industry Only. Thompson said that while the coalition would communicate with FDA throughout the process of creating the proposal, it would not include an FDA representative.

''My expectation is that right at the beginning it will be a private sector meeting without specific government involvement, but I would also say that I would expect

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FDA would be very much a part of the communication from that point forward,'' Thompson said.

Thompson also said the guidance would propose what technologies should and should not be regulated, but not how those technologies should be regulated.

''That will be down the road for someone else,'' he said. ''We're just focused on the one issue of what.''

Also not in question is whether FDA has the authority to regulate in the mobile health space, but how it will exercise its authority, Thompson noted.

In April, Thompson said, Jeffrey Shuren, director of FDA's Center for Devices and Radiological Health, invited the health IT industry to take the first step in drafting guidance for how the agency might regulate mobile health IT because of FDA's limited resources.

Thompson said that while there are protocols in place for industry to recommend such guidance to FDA, often industry waits for the agency to develop guidance before getting involved in the process.

BY KENDRA CASEY PLANK

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