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App Makers Have Mixed Reactions to Draft FDA Regulations

Makers of healthcare mobile applications (apps) are raising questions about whether the U.S. Food and Drug Administration (FDA) overstepped its boundaries by developing a draft guidance document that regulates certain apps, while others are welcoming the agency's action as an important development in healthcare.

"The FDA has drawn a line in the sand and signaled that mobile health doesn't get a special pass," says Chris Bergstrom, chief strategy and commercial officer for WellDoc, a Baltimore, MD manufacturer of mobile medical products. "Their actions underscore how serious they are taking mobile health."
The FDA plans to regulate only a small subset of apps which are either used as an accessory to a medical device or transform a mobile platform into a regulated device.

Examples include an app that controls an insulin pump, and a product placed on a mobile device to turn it into a blood glucose reader, the guidance document reads.

Apps that don't meet the definition include electronic copies of reference materials and apps that perform the functionality of an electronic health record, the guidance document reads.

Some are skeptical about the agency's definition of regulated apps.

"A number of apps the FDA mentions are probably not medical devices," says David Albert, president of AliveCor, an Oklahoma City, OK, manufacturer who is working on a device and app which turns an iPhone or iPad into an electrocardiogram monitor. "I think the FDA reached a little beyond where they have a clear domain."

No companies interviewed think the document will severely affect their business. AliveCor has always assumed that the hardware and app would require FDA clearance, Albert says.

WellDoc has a quality system in place and received FDA approval last year for a mobile health solution called DiabetesManager. Bergstrom says the document may "give our customers the confidence to know that the agency is regulating products with the intent to ensure patient safety."

The FDA is holding a comment period until Oct. 19. For more information, visit http://1.usa.gov/p7EVYH.

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