FDA Clears WellDoc for Diabetes Management

By Brian Dolan
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The United States Food and Drug Administration (FDA) has granted WellDoc 510(k) clearance to market its WellDoc DiabetesManager System to care providers and adult patients with type 2 diabetes. Next: WellDoc plans to commercially launch the WellDoc DiabetesManager System in early 2011.

Five years in the making, WellDoc's offering as a mobile health (mHealth) system built on automated clinical coaching and behavioral algorithms driven by real-time patient data, according to the company. WellDoc's software aims to enable care providers to extend their care beyond traditional office visits by utilizing mobile phones and the Internet. The DiabetesManagement system specifically features a medication adherence program and secure capture, storage, and real-time transmission of blood glucose data.

WellDoc's service doesn't just help users track their biometrics, the company also runs the data through its own proprietary Automated Expert Analytics System, which identifies trends and delivers relevant educational and behavioral patient coaching based on the data.

Just last week the FDA cleared AirStrip Technologies RPM product and earlier this year the FDA cleared Proteus Biomedical's wireless sensor "Raisin" patch as well as Corventis' Nuvant wireless heart monitor technology.

In an interview this morning with MobiHealthNews, WellDoc's Founder and CEO Ryan Sysko noted that the recent FDA clearances and the increased attention that regulatory bodies like the FDA and FCC have paid to mobile health are clear signs of maturation for the nascent industry. Regulation for mobile health devices and services is more complex than other devices reviewed by the FDA because mHealth often includes a hybrid of software and biotech, Sysko said.

"As you know there are thousands of mobile health apps available today, but only a very small percentage of them have FDA approval," Sysko said. "This is a critical differentiator for [WellDoc]."

Sysko also noted that other markets look to the US for regulatory clearance. WellDoc is eyeing the mobile health opportunity in the Middle East, Asia and Europe.

WellDoc has announced pilots with a number of care providers like the US Air Force and other nontraditional health services providers, including GreatCall's Jitterbug mobile phone service for seniors. One of WellDoc's clinical trials was funded by Sprint and Johnson & Johnson company LifeScan: The pilot was conducted with CareFirst and The University of Maryland School of Medicine.

Sysko described the FDA clearance as really just the first milestone for the regulatory process ahead of WellDoc. As a Class II medical device, WellDoc can expect to get audited at some point by the FDA to ensure the quality of its services and manufacturing processes.

“Without question, after our very first meeting with the FDA it was clear very clear that our service would require FDA approval before we could [commercially] bring it to market,” Sysko said. “In the next three to six months you can expect us to announce a number of launches.”