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FDA gives blessing to Baltimore company's diabetes system

WellDoc uses Internet and cell phone technology to help manage disease

By Robert Rand | Staff Writer
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A Baltimore company has won a key federal regulatory approval for its diabetes management software system, which it plans to start marketing early next year.

"This is a big milestone," said Christopher Bergstrom, chief strategy and commercial development officer for WellDoc, in an interview Monday.

WellDoc, which also has offices in Wilmington, Del., and Bangalore, India, said Monday that it has received what's known as 501(k) clearance from the Food and Drug Administration for its DiabetesManager System. The system is designed to provide patients who have type 2 diabetes and their physicians and other providers with real-time data about blood-sugar levels and other indicators, along with immediate nutritional and other guidelines to manage the disease.

There are other diabetes systems available, but WellDoc's goes further than they do, Bergstrom said.

"A lot of great solutions and companies are out there, but some don't have FDA clearance," Bergstrom said. "Many just collect data and push it and report it. But we analyze it and turn it into knowledge based on clinical guidelines."

For example, according to a presentation on WellDoc's website, a diabetes patient might test his blood in the morning. The data are fed into the WellDoc Internet and cell phone system, which immediately gives him feedback on what he should eat for breakfast.

"It's like having a GPS in your car that just says there's a traffic jam ahead" but doesn't give the driver directions to avoid the jam, Bergstrom said of other diabetes software systems. "Today's monitors just give a number. We provide what to do with that information in real time."

In a clinical study involving 30 patients with type 2 diabetes, patients who used the WellDoc system had a 2.0 decrease in A1c, indicating better control of blood sugar, versus 0.7 percent among the control group. Also, 84 percent of the patients who used the system had their medication adjusted, compared with 23 percent of the control group patients.

Privately held WellDoc, founded in 2005, is funded by angel investors, Bergstrom said. Its revenues have grown "significantly three years in row," he said, without disclosing specifics. The company already works with some large pharmaceutical companies on cell-phone programs on medication adherence and "virtual coaching."

The company has between 50 and 100 employees, twice what it had a year ago, he said, with plans to hire 10 more in Baltimore during the next six months.

"We have four starting today," Bergstrom said. Clinicians make up about half of its work force, with most of the other employees developing software and behavior techniques.

With other nations often relying on FDA approval as "benchmark" for licensing medical devices, the company is eyeing international markets, he said.

"Our president is overseas today," talking with government and other officials about marketing DiabetesManager abroad, Bergstrom said.

With about 20 million Americans with type 2 diabetes, the market potential is significant.

"With type 2 diabetes reaching epidemic rates and limited time for care, healthcare providers need new tools to more efficiently engage their patients between and during office visits," said Dr. Richard Bergenstal, executive director of the International Diabetes Center at Park Nicollet and president of the American Diabetes Association, in a statement. "WellDoc's System addresses this need by delivering real-time, evidence-based education and behavioral coaching. This enhanced engagement and communication is intended to enable providers to support positive patient behavior and improved health."

WellDoc officials foresee applying the technology to helping manage other chronic conditions that involve medication adherence or behavior changes, Bergstrom said, including cardiac heart failure, oncology and asthma.

He pointed to last week's announcement by the FDA and Federal Trade Commission of their joint support for combining medical and wireless technologies to manage disease.

"Here we are at the beginning of a tsunami," Bergstrom said. "WellDoc is well-positioned at the crux of that storm."