

FDA OKs new Type of Diabetes-Monitoring System

August 3, 2010

In development for more than five years, WellDoc's DiabetesManager System has just received the U.S. Food and Drug Administration's 510(k) clearance to be marketed to health care providers and adult patients with type 2 diabetes, the company announced.

A mobile health system, DiabetesManager will offer automated clinical coaching based on real-time patient data, enabling patients and health care professionals to set parameters and manage the disease outside of office visits.

WellDoc announced that it intends to commercially launch the system in early 2011, and will be an exhibitor in the inaugural Mobile Health Pavilion at the annual meeting of the American Association of Diabetes Educators this week in San Antonio, Texas.



"With type 2 diabetes reaching epidemic rates and limited time for care, health care providers need new tools to more efficiently engage their patients between and during office visits," Richard Bergenstal, president of the American Diabetes Association, said in a statement. "WellDoc's System addresses this need by delivering real-time, evidence-based education and behavioral coaching."

And while DiabetesManager joins literally dozens of similar apps and online services for diabetes monitoring and management, a WellDoc representative said it is the first of its kind to receive FDA clearance:

This is the first of its kind in the sense that it actually provides real-time feedback to patients, in terms of what they should be doing with the input they're submitting. So if a patient enters in glucose in the morning, the system analyzes it and responds in real time, giving the patient an action as to what to do...Previous solutions have taken the data and stored it, but there has not been a system that analyzes it and provides real-time feedback.

The DiabetesManager System centers on medication adherence, the gathering and storing of blood glucose data, and the identification of trends based on this data so that patients can receive behavioral coaching to better manage diabetes.