

FDA approves WellDoc diabetes management system

By Emily Mullin Staff
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A Baltimore health technology company has been given a stamp of approval from the Food and Drug Administration to take its new diabetes management system to market.

WellDoc said it has received a 501(k) clearance from the FDA for its DiabetesManager System.

The mobile platform will work to improve chronic disease management outcomes and reduce health care costs for patients with type 2 diabetes by offering clinical coaching over the phone and Internet.

The system will connect patients to health care professionals so that doctors and other health care providers can extend their care beyond traditional office visits.

It's estimated that 23.6 million people in the U.S. — 7.8 percent of the population — have diabetes. Roughly 90 percent of those people have type 2 diabetes.

In development for more than five years, the DiabetesManager System tracks daily routines, including medications, exercise and nutrition. Based on blood glucose data, WellDoc recommends lifestyle adjustments to keep patients on track with their diabetes management.

Physicians will be able to access patient data using the technology, analyze it, tap into the WellDoc expert system for care guidelines, then make adjustments in patient care.

Mobile health regulation has become a much-debated topic at the federal level, and the FDA is in the process of defining which mobile health products should be considered as medical devices subject to regulation.

In July, the FDA and the Federal Communications Commission signed an agreement to implement clear regulations to bring broadband and wireless-enabled medical devices to market.

The company intends to commercially launch the WellDoc DiabetesManager System early next year. WellDoc also has offices in Wilmington, Del., and Bangalore, India.