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FDA reviews medical device risks

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Health tools for smart phones that monitor blood-sugar levels or work as stethoscopes may face the same scrutiny from regulators as heart stents or ultrasound machines.

These mobile medical applications pose a potential risk and may have to meet Food and Drug Administration medical device-quality standards before they can be sold for use with smart phones, such as Apple's iPhone, according to draft guidelines issued Tuesday.

The FDA is focusing on applications that directly diagnose or treat conditions like diabetes or that transform the smart phone into a medical device. The regulations mark the first ground rules for a market that Ilkka Korhonen, a former senior manager of Nokia Corp.'s wellness business program, estimates may climb ninefold to $6 billion in 2015.

"This area is growing exponentially," said Bakul Patel, a policy adviser with the FDA's device center. "We're looking at the mobile applications that would pose a risk for patients if they didn't work as intended."

Regulators propose to standardize the design, production and distribution of the applications to ensure the products are safe and effective. Stents and ultrasound machines typically must undergo a review that requires manufacturers to demonstrate products are at least as safe and effective as legally marketed devices for the same use, Patel said.

Most applications will be subjected to the lightest class of FDA regulation and won't have to meet oversight such as the pre-market review, known as a 510(k) program, Patel said.

Some manufacturers may still face costs of about $31 million to gain FDA clearance to market a device, according to a Stanford University analysis of 204 companies released in November.

The guidelines don't affect design specifications for companies like Apple and Verizon Communications that provide smart phones, or makers of operating systems such as Google's Android platform, which powers Motorola Mobility Holding's Droid handset.

The public has 90 days to comment on the proposed guidelines.

The government has already cleared as many as a half-dozen applications, Patel said. These include an ultrasound product and health tools letting doctors view X-rays and other images on iPhones or iPads, according to the agency.

WellDoc in Baltimore won clearance in August 2010 for its DiabetesManager System after undergoing a two-year evaluation, according to Chris Bergstrom, the company's chief strategy and commercial officer.

DiabetesManager tells patients how to avoid sudden spikes or drops in blood sugar based on data provided by the user.

“We are finding the types of manufacturers of mobile apps vary from really small folks to really large companies,” said Patel. “Even traditional manufacturers of medical devices are getting into the mobile app area.”