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Apple's IPhone Health Tool May Get Same FDA Scrutiny as Stents

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By Anna Edney

Applications for smartphones that check on blood sugar or allergies may face the same scrutiny from U.S. regulators as heart stents and defibrillators.

The Food and Drug Administration plans to issue draft guidelines this year classifying mobile health tools for handheld computers such as Apple Inc.'s iPhone as medical devices, said Bakul Patel, a policy adviser for the agency's device center, in an interview. Chips that Qualcomm Corp. makes to power smartphones may have to adhere to medical-device quality standards the FDA sets for phone applications.

The effort would establish ground rules for a market that will climb ninefold to $6 billion in 2015 -- with 1.4 billion downloads of medical applications -- from $664 million last year, said Ilkka Korhonen, a former senior manager of Nokia Corp.'s wellness business program. Makers may winnow offerings because analysts estimate the cost to get FDA approval for a device can exceed $30 million.

"You'll have to be much more serious about pursuing an application to get it on the market," said Bradley Merrill Thompson, co-founder of the mHealth Regulatory Coalition whose members include AT&T Inc., Roche Holding AG and Boston Scientific Corp. "It's going to require much more work, be more expensive. It will shrink the number of apps on the market for sure."

'Sign of Trust'

Regulatory clearance for a low- to moderate-risk medical device -- such as a pump to administer intravenous fluids -- costs an average of $31 million, according to a Stanford University study of 204 companies released in November. The agency requires makers to have systems to ensure the product produces consistent results, said Thompson, a lawyer at Epstein Becker & Green in Washington.

"In the marketplace, FDA clearance is a big differentiator," said Chris Bergstrom, chief strategy and commercial officer at WellDoc Inc., a technology company in Baltimore. "It's a sign of trust."

The FDA defines medical devices as any tool that diagnoses or treats a disease or condition. Some makers of health applications that fall under the definition have voluntarily sought the agency's approval.

Less than a dozen mobile health applications have FDA clearance, said Erica Jefferson, an agency spokeswoman. The online Apple store features 20,000 to 30,000 wellness apps, said Dane Stout, executive director of the connected health practice at the regulatory consulting firm Anson Group in Indianapolis who co-founded mHealth with Thompson.

Trudy Muller, a spokeswoman for Apple, declined to comment.

Smoking Tool

The FDA is trying to decide whether to group products that generally address wellness issues with applications that are designed for specific medical tasks, such as helping diabetics manage blood-glucose levels.

Current law doesn't clarify whether a health tool that that tracks tobacco use or alerts a family member of an allergic reaction falls into the medical-device category, Thompson said.

"As I look at it there are quite a few people out there with apps that will require FDA clearance," he said.

WellDoc received FDA clearance for its DiabetesManager System in August, a two-year process Bergstrom said could have been shortened by a year if the company was more familiar with the application process and FDA was more experienced with emerging mobile-health technology.

Venture Capital

"There were a lot of things that we had to learn together because we were really breaking new ground," he said.

DiabetesManager works through an algorithm downloaded onto a user's phone. Users enter a glucose level and other personal information and the application gives instructions on how to avoid spikes or plummets.

WellDoc formed a partnership with AT&T, based in Dallas, in October for the communications company to offer DiabetesManager to its employees.

WellDoc relied on venture capital to help get through the FDA approval process. Liz Boehm, a principal analyst at Forrester Research, said many small companies will need to acquire similar backing.

She said regulation's expense may lead to "fewer frivolous health apps that don't drive toward healthy lifestyle" being created."

Companies that make wireless hardware and software may also be affected by new regulatory standards. Undecided is whether the FDA will decide to treat smartphones as accessories to medical devices.

Operating System Testing

"We are not literally in the health-care industry and we play a part in it because we enable the connectivity of some medical devices," said Robert Jarrin, senior director of government affairs in Washington at Qualcomm, the digital wireless communications company based in San Diego.

Companies also are awaiting guidance on whether the FDA will require testing on each smartphone's operating system. Google Inc.'s Android platform can run on three different phones, Stout said.

The agency has dealt with new technology before, Patel said, though this time is more difficult.

"This is different in terms of the scale and the amorphousness of the scale," he said.