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New FDA Law Paves Way For mHealth Regulations

By letting FDA proceed with developing regulations for mobile health apps, Congress assures mHealth industry that clarity is on the horizon

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By Ken Terry

The mobile health software industry breathed a sigh of relief after President Obama on July 9 signed new legislation that gave the FDA a green light to continue developing mHealth regulations.

Joseph Smith, chief medical and science officer for the West Wireless Health Institute, told *InformationWeek Healthcare* that software vendors believe the uncertainty about the FDA's regulatory stance has hampered their growth. "Regulatory clarity is always essential in rapidly growing areas so you can attract sufficient capital and people know what the rules of the game are," he said.

Earlier in the legislative process, it appeared that a provision in the bill might require the FDA to suspend work on its guidance while the Department of Health and Human Services (HHS) wrote a report on the issues involved. But in the House-Senate conference on the measure, it was decided that the FDA could go forward while HHS developed the report on a "regulatory framework for health information technology, including mobile medical applications, that promotes innovation, protects patient safety and avoids regular duplication."

Last summer, the FDA published draft guidance on how it might regulate certain types of mobile health applications. Although the agency made clear that the regulations would cover only a small portion of mHealth apps, they included categories that would affect many software developers. Among the classifications that the FDA proposed regulating to protect patient safety were:

-- Mobile apps that allow the remote use of one or more medical devices by controlling them or displaying, storing, analyzing, or transmitting patient-specific medical device data. This would apply, for example, to remote displays of data from bedside monitors, ECG waveforms, and medical images generated by picture archiving and communication systems (PACS).

-- Software that transforms the mobile platform into a medical device by using attachments, display screens, or sensors, or by including functions similar to those of currently regulated medical devices. Examples include apps that turn mobile devices into electronic stethoscopes, glucose meters, or accelerometers for capturing sleep data.

-- Mobile apps that can be used to provide clinical decision support after users input patient data. According to the FDA draft guidance, this would specifically apply to programs such as those that help clinicians reach a diagnosis or calculate a dosage for a medication. But observers said it could also apply to certain kinds of consumer mHealth apps.

According to Smith, whose organization has provided input to the FDA on its mHealth guidance, the FDA probably will issue a separate guidance on regulations pertaining to clinical decision support applications. Besides letting the FDA move forward on its regulatory work, the new law speeds up the process for FDA approval of mHealth solutions that include or function as devices. In the past, Smith noted, the FDA first

had to decide whether the system was similar to another approved device on the market before it would review the application. But the legislation allows the FDA to consider the product as "de novo" if the vendor attests that there's nothing else like it.

During the process of developing its guidance, Smith said, "The FDA has been responsive to stakeholders in providing clarity and a light regulatory policy." The key to the agency's attitude, he said, is that it seems to regard mHealth apps as a low-risk area.

Nevertheless, the FDA has required some vendors to go through a rigorous review to obtain clearance for their applications. Among the products that have obtained FDA 510 (k) clearance—usually applied to medical devices—are WellDoc's Diabetes Manager, Airstrip Technologies' RPM, Proteus Biomedical's Raisin skin patch, and Corventis' Nuvant wireless heart monitor technology.