FDA Regulation of Mobile Medical Apps

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Healthcare professionals and patients alike are embracing mobile medical applications for smartphones. Experts project that, by 2015, 500 million smartphone users will be using medical apps. A 2011 press release [1] from the U.S. Food and Drug Administration indicates the FDA's plan to regulate some smartphone medical apps, a decision that has been met by both positive and negative reviews.

The FDA claims it will seek to regulate only those mobile apps that are an auxiliary to already-regulated devices or that allow the smartphone to be transformed into a sort of medical device when using the app. Proponents of the FDA's regulation of apps such as these argue that regulation will keep app makers honest about what their product really does and enable users, whether doctors or patients, to be able to trust approved apps for accuracy. User confidence and peace-of-mind are the primary goals.

The FDA's guidelines do not indicate that every health-related app will require FDA approval. For instance, a calorie-counting or healthy-eating app may not need approval from the FDA. Only true "medical apps", where inaccuracies or bugs could cause great economic and personal loss, would need to seek FDA approval to be sold. An example of a medical app is an ECG regulator used by doctors in hospitals or remotely by patients at home. The new regulation process is consistent with the FDA's current medical software regulations and would liken itself to pre-existing medical device regulation protocols.

Not surprisingly, many application makers oppose the bill. Some question how the apps would fit into the framework of other governmental departments, such as the Centers for Medicare and Medicaid, and restrictions given to devices under certain state constitutions. Treating apps like medical devices also submits them to a long wait (up to three years) and high expenses (up to $75 million) for approval. An app also may be subject to the 2.3% medical device tax before it can enter the market. Many smartphone app developers cannot afford the time and upfront costs required for approval and argue that FDA regulation will greatly restrict medical software innovation.

Some app developers have proposed new protocols strictly for medical mobile apps, instead of aligning them with pre-existing medical device regulations. The FDA is slated to make its decision by the end of the year. In the meantime, it has begun approving apps to those who have applied and met criteria.

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