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FDA Gives Its Final Word on Mobile Medical Apps

It's been more than two years in the making, but this week saw the release of the U.S. Food and Drug Administration's (FDA) final guidance on mobile medical apps. The agency says it intends to regulate a subset of apps that present a greater risk to patients if they do not work as intended, using a tailored, risk-based approach.

"Some mobile apps carry minimal risks to consumer or patients, but others can carry significant risks if they do not operate correctly. The FDA's tailored policy protects patients while encouraging innovation," said Jeffrey Shuren, MD, director of the FDA's Center for Devices and Radiological Health.

According to the document, the agency will focus on apps that either are intended to be used as an accessory to a regulated medical device, or can transform a mobile platform into a regulated medical device—for example, one that can change a smartphone into an electrocardiography machine to detect abnormal heart rhythms. Another example would be a mobile app that uses an attachment to the mobile platform to measure blood glucose levels.

The FDA lists a number of apps which it says "may meet the definition of medical device," but "will not be subject to regulatory requirements at this time." The agency uses the term "enforcement discretion" to describe its approach to such apps, which include those that use video games to help patients with physical therapy exercises, as well as those that try to motivate smokers trying to quit or patients recovering from addiction..

The agency, in its guidance document, also lists apps that "are not considered medical devices" and would not be regulated by it. Such apps include those that offer medical dictionaries, surgical training videos, quizzes, and help in locating a healthcare facility.

The guidance also includes a list of frequently asked questions, the first of which asks what a developer should do if its app is not listed. According to the document, those companies are urged to contact the agency for more information.

To read the guidance, click here (pdf).

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