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Health Care Flash

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FDA announces the launch of the Digital Health Software Pre-certification Pilot Program

Applications accepted Aug. 1, 2017

In recent years, the Food and Drug Administration (FDA) has taken several steps to streamline and refine the regulatory approval process for health technology, an effort that accelerated substantially following the appointment of Dr. Scott Gottlieb as FDA Commissioner. As a next step in the process, the FDA recently announced that applications for a new Software Pre-certification (PreCert) Pilot Program are being accepted beginning Aug. 1, with a planned program launch date of Sept. 1, 2017. The goal of the PreCert program is to evaluate new approaches for regulatory approval of health focused software products, and the creation of a pre-certification program for companies that perform high-quality software design and testing.

The FDA is seeking input from volunteers to help design a regulatory framework that is responsive to the faster development and innovation cycles for health technology software devices, with the goal of improving patient access to new software technology. The outcome of this PreCert program may reduce the time and cost of market entry for software developers who are determined to be reliable manufacturers of high-quality, safe and effective digital health products.

The FDA plans to select up to nine participants, who best meet the following criteria:

1. The company must be developing or planning to develop a software product that meets the definition of a device in section 201(h) of the Federal Food, Drug, and Cosmetic Act.
2. The company has an existing track record in developing, testing and maintaining software products demonstrating a culture of quality and organizational excellence measured and tracked by certain Key Performance Indicators (KPIs) or other similar measures.
3. While participating in the pilot, the company must agree to:
    a. Provide access to measures described in #2;
    b. Collect real-world postmarket performance data and provide it to the FDA;
    c. Be available for real-time consultation with the FDA;
    d. Be available for site visits from FDA officials; and
    e. Provide information about the company's quality management system.

PreCert represents the next step in the FDA's efforts to address the regulatory pathway for health technology, following recent guidance from the FDA indicating that general wellness apps and devices are not subject to FDA review. For innovative companies interested in shaping the regulatory framework for health technology, participation in the PreCert program presents a unique opportunity.

If you are interested in submitting your company for consideration, please contact Jed Roher at 608.284.2269 or jroher@gklaw.com or review the Federal Register notice. We will continue to monitor new FDA developments and apprise our clients of the enhancements the administration is making in its approach to digital health technologies.

The information in this article is based on a summary of legal principles. It is not to be construed as legal advice. Individuals should consult with legal counsel before taking any action based on these principles to ensure their applicability in a given situation.

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