FDA's Health Software Precertification Program Aims to Foster Innovation, Reduce Time/Cost of Market Entry

By Neil Issar | November 8, 2017

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The American healthcare industry is ripe for technological disruption, but it has been slow to embrace true digital health reform. Certain government agencies, however, finally appear to be embracing digital health technology. Most recently, the FDA's Center for Devices and Radiological Health ("CDRH") announced a Digital Health Innovation Action Plan.[1]

The action plan lays out the agency's vision for fostering digital health innovation while continuing to protect and promote the public health with an appropriate level of regulation. Specifically, the plan is the first step towards creating a regulatory framework that accommodates the clinical promise and unique user interfaces of digital health technologies, as well as the industry's compressed timelines for new product introductions. Towards this end, it will involve:

- Issuing new and revised guidance to provide clarity on the medical software provisions of the 21st Century Cures Act, including policies pertaining to clinical decision support software, mobile medical applications, medical image storage and communications devices, and low-risk general wellness products[2]
- Developing a new approach to digital health technology oversight, including a pilot precertification program that will give software developers that meet certain criteria access to streamlined approval processes[3]
- Augmenting the FDA's staff and expertise of the CDRH's digital health unit[4]

The plan's Digital Health Software Precertification ("PreCert") Program is a voluntary, risk-based pilot program in which the FDA will focus on the developers of Software-as-a-Medical Device ("SaMD"),[5] rather than primarily on their products, to reduce their time and cost of market entry. The PreCert program was conceived after the FDA recognized that its "traditional approach to moderate and higher risk hardware-based medical devices is not well suited for the faster iterative design, development, and type of validation used for software products."[6]

After receiving more than 100 applications for participation in the first phase of the program, the FDA recently announced the selection of nine participants, including Apple, Johnson & Johnson and Roche, to name a few.[7]

As participants, these companies will provide access to measures they currently use to develop, test, and maintain their software products, including ways they collect post-market data. Participants also agreed to be available for site visits from FDA staff and to provide information about their quality management systems. The FDA will use the information to explore whether and how precertified companies—which will have demonstrated a culture of quality, patient safety, and organizational excellence—can bring certain types of digital health products to market without FDA premarket review or through a more streamlined FDA premarket review. The streamlined review may include reduced submission content, faster review of that content by CDRH staff, or both.

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To support and help develop the PreCert program, the FDA also launched a Digital Health Entrepreneurs-in-Residence ("EIR") Program, which brings together world-class entrepreneurs and innovators to work with the CDRH digital health unit staff for a minimum of six months to iteratively develop and test key conceptual elements of the program. The FDA just completed accepting applications for EIR Program participation, and will share public updates about it and the PreCert pilot program online as well as through stakeholder meetings, including a January 2018 workshop.

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[1] U.S. Food & Drug Admin., Digital Health Innovation Action Plan (July 27, 2017).

[2] *Id.*

[3] *See* 32 Fed. Reg. 35,216 (July 28, 2017).

[4] U.S. Food & Drug Admin., *supra* note 1.

[5] For the PreCert program, the FDA will initially use the SaMD definition and framework outlined by the International Medical Device Regulators Forum (IMDRF), a voluntary group of medical device regulators from around the world. The IMDRF defines SaMD as "software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device." Examples of SaMD include smartphone apps used for diagnosis of medical conditions, medical image-processing software intended to run on a computer, and in-vitro diagnostic software.

[6] 32 Fed. Reg. at 35,216.

[7] Press Release, U.S. Food & Drug Admin., FDA selects participants for new digital health software precertification pilot program (Sept. 26, 2017).

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