# FDA's Software Pre-Cert Program: More Details Revealed

9 August 2017

In follow up to the U.S. Food and Drug Administration's (FDA) late July announcement of the Digital Health Innovation Action Plan and the pilot Software Precertification (Pre-Cert) program, the Agency held an August 1, 2017, webinar to further explain the Pre-Cert program. The webinar reiterated many of the points covered in the written materials, but further expanded on the scope of the future Pre-Cert program, the goals for the pilot program, and roles for pilot participants. Consistent with the initial program announcement, the webinar emphasized that the Pre-Cert program, once fully developed and implemented, would be designed to streamline the premarket FDA review process for manufacturers of Software as a Medical Device (SaMD) that demonstrate a "Culture of Quality and Organizational Excellence (CQOE)." However, the webinar also made clear that the purpose of the pilot program is to educate FDA and benefits to be realized by pilot participants have not yet been fully defined.

The webinar further emphasized that the future Pre-Cert program, as well as the pilot program, would be available only for SaMD developers where the company's products would be actively regulated by FDA. The Agency is adopting a definition of SaMD proposed by the International Medical Device Regulators Forum (IMDRF) as follows: "Software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device." The Pre-Cert program would not include software carved out of FDA's jurisdiction by the 21st Century Cures Act and likely would not be relevant for developers of software that is not actively regulated by FDA at this time (e.g., general wellness software). FDA does plan to update its regulations and guidance in the coming months to conform to the software provisions of the 21st Century Cures Act providing further clarity on how the agency will regulate software going forward.

In a regulatory paradigm shift for FDA, the Pre-Cert program would emphasize the processes and practices of the companies developing such products, rather than the products themselves. Based on those processes and practices, FDA could grant one of several levels of pre-certification, which would then provide companies with a streamlined premarket review process for individual products. The precertification level coupled with the risk presented by the SaMD would dictate whether the product could go straight to commercial distribution and real world use or whether it would be subject to a streamlined premarket review by FDA. The levels of pre-certification and the associated premarket review benefits have not been fully defined at this time.

The purpose of the proposed pilot program is for FDA to gather information about how companies in this space currently operate and for the Agency to better understand how such companies measure and assure quality. Based on preliminary work, FDA indicated that potential

measurements for assessing CQOE could include whether a company shows commitment towards (a) providing safe patient experience, (b) being clinically responsible, (c) delivering highest product quality, (d) being cybersecurity responsible, and (e) being proactive versus reactive. These elements would be measured by key performance indicators (KPI), which FDA hopes to develop through the pilot program. Examples of potential KPI include:

– Organizational resource: KPI that demonstrates outcome measures in leadership, employee training, organizational support, infrastructure, employee empowerment, etc.
– Customer: KPI that demonstrates outcome measures in revenue, marketing, support, etc. Learning and growth KPI that demonstrates outcome measures in product support, innovation, employee training, stakeholder engagement, etc.
– Internal process: KPI that demonstrates outcome measures in product engineering, management support, risk management commitment, efficiency, revenue, etc.

The pilot program will enroll up to nine companies on a phased basis, with the first 3 companies (to be chosen this month) participating beginning in September 2017 and the final participants completing the program by September 2018. Interested companies may apply at any time throughout the pilot program. FDA hopes to enroll companies of various sizes and types that develop both high and low risk products to ensure that the metrics developed are appropriate for the full range of SaMD products. FDA's goal is to enroll both medtech and non-traditional medical device companies (e.g., tech companies entering the medical industry).

Pilot participants will assist FDA in the development of criteria and metrics to be used for the future Pre-Cert program and would be expected to dedicate resources to partner with FDA staff, provide access to KPIs or similar measures employed at their companies, and engage in sharing their experiences with the Pre-Cert pilot to improve the program. Participants will also:

– Collect real-world post-market data and provide it to FDA;
– Meet with FDA for real-time consultation;
– Be available for site visits from FDA officials; and
– Provide information about the firm's quality management system.

During the webinar, FDA noted that initial pilot participants can expect 3 to 4 onsite visits by the Agency, though less visits may be required for later participants. FDA emphasized that the pilot program is about learning and not compliance, though notably, when asked the agency did not rule out the possibility of enforcement action (e.g., for identified noncompliance with current regulatory requirements) as a result of on-site visits and company interactions.

Companies interested in participating in the pilot program should email a statement of interest to FDAPre-CertPilot@fda.hhs.gov, with a subject line "Pre-Cert Pilot: statement of interest". FDA began accepting Statements of Interest for the program on August 1. During the webinar, FDA commented that a successful Statement of Interest would highlight the ways in which a candidate company is currently achieving excellence through managing, developing and validating software products, information on KPIs employed at the company, and the company's use and plans for real world data collection. Additionally, information about the company's products currently in development would be helpful.

While the Pre-Cert program will hopefully be a very helpful step in the right direction to minimize the regulatory burdens on low risk software in the medical device space, the benefits of the full

program have not yet been defined. In addition, beyond contributing to the future Pre-Cert program development, the benefits for companies participating in the pilot program are unclear at this time. Given that the program would impact many different types of programs (e.g., traditional medtech, small software developers, etc.), having a variety of viewpoints included in the pilot will be key to the success of the future program. Even if a company decides not to participate in the pilot program or is not chosen, the Agency welcomes input and comments from all stakeholders.

The webinar also noted the Agency's planned development of a Regulatory Development Kit (RDK). The goal would be to provide a toolkit for digital health developers similar to the concept of a Software Development Kit. The kit will be interactive rather than a traditional paper-only guidance document or checklist, and will address regulatory intent, expectations and principles across the SaMD lifecycle. Further details are not available at this time.

The slides for the Agency's webinar are available on FDA's [website](). Companies interested in the program can also reach out to their Hogan Lovells point of contact.

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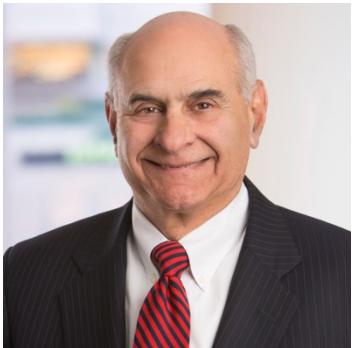**Janice M. Hogan**
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