Hogan Lovells

FDA Unveils Software Pre-Certification Pilot Program to Foster Digital Health Innovation

August 1, 2017

Following promises in June for a new regulatory paradigm to address regulation of medical software, FDA released a Digital Health Innovation Action Plan on July 27, 2017, including a pilot software Pre-Certification (PreCert) program. The Digital Health Innovation Action Plan announces details for future implementation of several outstanding items from the 21st Century Cures Act, as well as additional innovations, like the PreCert program, that FDA hopes will foster innovation in the digital health sector.

Digital Health Innovation Action Plan

The Digital Health Innovation Action Plan sketches out details and timelines for FDA's approach to digital health technology. The action plan highlights a number of activities that FDA has taken in the past years and months, including releasing the Mobile Medical Apps Guidance, issuing several cybersecurity guidance documents, and working with other government agencies on the FDASIA Health IT Report, among others. The plan then turns to specific guidance documents that the Agency plans to issue to assist in implementation of the 21st Century Cures Act software provisions. These include the following:

- General 21st Century Cures Implementation Guidance (draft by end of 2017) addressing the effect of the 21st Century Cures Act on pre-existing FDA policy related to mobile medical applications, medical device data systems, medical image storage devices, medical image communication devices, general wellness products and laboratory workflow;
- Clinical Decision Support Software Guidance (draft by 1st quarter 2018) explaining the scope of the Agency's purview over clinical decision support products;
- Multifunctionality Guidance (draft by 1st quarter 2018) addressing regulatory oversight for products that mix regulated and unregulated functionality;
- *Deciding When to Submit a 510(k) for a Software Change to an Existing Device* (finalize current draft by end of 2017);
- International Medical Device Regulators Forum (IMDRF) *Software as a Medical Device (SaMD): Clinical Evaluation* (finalize after IMDRF issues final version in September 2017).

Perhaps most notable among these planned guidance document is the Agency's proposed guidance on clinical decision support (CDS), which has been promised by the Agency for a number of years, but has never been released, even in draft form.

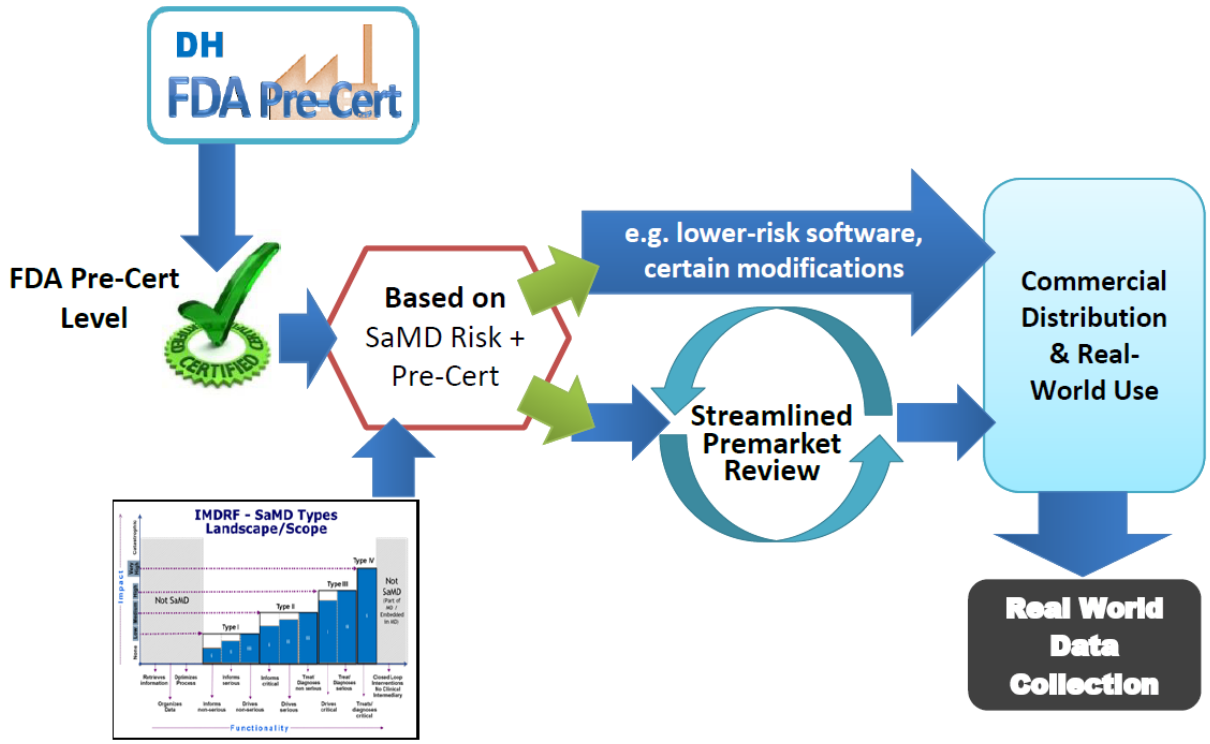
The Action Plan also includes information on the Agency's efforts to enhance internal expertise on digital health issues through hiring, including a planned Entrepreneurs in Residence program.

FDA's PreCert Program Pilot

Central to the Agency's Action Plan is the proposed launch of a Digital Health Software Pre-Certification (PreCert) Program, with the stated purpose of reducing the time and cost of market entry for digital health software companies with a track record of developing and testing quality products in order to allow for greater patient access to digital health technologies. The Agency explains that the traditional approach to hardware-based medical devices of moderate or high risks is not suited for software products, which have faster iteration of design, development, and validation. In order to reduce burden on both the Agency and industry, the proposed program would shift focus to certification of the developers in place of the traditional focus on product clearance or approval.

Specifically, FDA would "pre-certify" software companies who "demonstrate a culture of quality and organizational excellence based on objective criteria, for example, that they can and do excel in software design, development and validation (testing)." Once pre-certified, developers could market low-risk devices and software without FDA review, or through a more streamlined premarket review with reduced submission content and faster review. In addition, pre-certified firms could collect postmarket data to affirm the regulatory status of the product, as well as to support new product functions. Companies may be able to take advantage of the National Evaluation System for Health Technology (NEST) to generate better evidence for medical device evaluation throughout the device innovation cycle. FDA is also considering third party certification.

Figure 1: High level concept of the reimagined approach using FDA Pre-Cert for Software



However, that is really where the details of the program obligations and benefits stop. FDA's goal appears to be partnership with up to nine companies who would participate in the pilot program and help to shape the future full scale PreCert program, including defining criteria that FDA would then use for assessing other companies for pre-certification in the future. The specific benefits that those companies would obtain through participation in the program are not fully detailed. Thus, companies joining the program would do so without certainty about the future benefits. Nonetheless, given the opportunity to play a role in shaping a regulatory paradigm shift, many companies may welcome the opportunity.

FDA notes that various sizes and types of companies that develop both high and low risk products will be selected to participate. This will be key to ensuring that the final program represents the viewpoints of the many different stakeholders that make up the regulated software industry.

FDA is planning to begin accepting applications for the program on August 1st taking into account the following criteria:

- The company must be in the process of developing or planning to develop a software product that meets the definition of a medical device;
- The company must have an existing track record in developing, testing, and maintaining software products and demonstrating a culture of quality and organizational excellence measures that are tracked by Key Performance Indicators (KPI) or other similar measures; and
- During participation of the pilot, companies must agree to:
    - Provide access to measures for developing, testing and maintaining software products and demonstrating a culture of quality and organizational excellence measures by KPI;
    - 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.

FDA plans to evaluate submissions and select companies during the month of August. Companies considering submitting an application should consider their development stage and status of their internal quality system. Because the benefits of the program are as yet unknown, companies who elect to participate should carefully consider the additional information that may require disclosure to FDA in evaluating the potential pros and cons of participation.

A webinar outlining the details of this pilot program will also be held on August 1st. Further, FDA will hold a public workshop in January 2018 to report on and review the initial experience of the pilot program, in order to help inform development programs underway outside of the pilot.

Contacts

Jennifer Agraz Henderson
Partner, Washington, D.C.
Tel +1 202 637 5783
jennifer.henderson@hoganlovells.com

Janice M. Hogan
Partner, Philadelphia,
Washington, D.C.
Tel +1 267 675 4611
(Philadelphia)
Tel +1 202 637 5600
(Washington, D.C.)
janice.hogan@hoganlovells.com

Jonathan S. Kahan
Partner, Washington, D.C.
Tel +1 202 637 5794
jonathan.kahan@hoganlovells.com

Yarmela Pavlovic
Partner, San Francisco
Tel +1 415 374 2336
yarmela.pavlovic@hoganlovells.com

Lina R. Kontos
Counsel, Washington, D.C.
Tel +1 202 637 5713
lina.kontos@hoganlovells.com

Erkang Ai, Ph.D.
Associate, Philadelphia PA
Tel +1 267 675 4631
erkang.ai@hoganlovells.com