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FDA Testing New Approaches for Review of Digital Health Device Applications

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by Claire H. Topp and Alex Stoflet

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On January 7, 2019, FDA Commissioner Scott Gottlieb announced significant updates to the FDA's pilot Software Pre-Certification Program, sometimes referred to more broadly as a Digital Health Pre-Certification Program ("Pre-Cert").

Pre-Cert was originally announced in 2017 as part of the FDA's Digital Health Innovation Action Plan. The FDA envisions the program as a streamlined process for bringing digital health technologies to market. More

specifically, the FDA hopes to develop Pre-Cert into a program by which certain digital health developers can become precertified as part of an "Excellence Appraisal." Excellence-appraised developers could then take advantage of streamlined premarket submission processes for their digital devices. To date, the FDA has been working with a variety of stakeholders, including nine companies "represent[ing] a wide range of companies and technology in the digital health sector," in developing the program.

In connection with the announcement earlier this week, the FDA issued "three documents that, together, launch us into the next phase of the agency's vision of Pre-Cert."

The first of the three documents is a Regulatory Framework for Conducting the Pilot Program within Current Authorities (the "Framework"). This document builds out the regulatory framework within which the FDA will implement Pre-Cert. Here are some highlights:

- At least to start, Pre-Cert is limited to software as a medical device ("SaMD"), defined as software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device. The FDA hopes eventually to expand the program to review all medical device software products, including software in a medical device ("SiMD") and other software that could be considered accessories to hardware medical devices.

- The FDA intends to utilize the De Novo classification process (section 513(f)(2) of the FD&C Act), an existing pathway for certain new types of low to moderate risk devices to obtain marketing authorization as a Class I or Class II device as opposed to automatic Class III designation, for the next phase of Pre-Cert. Here is an overview of the proposed process:

- Participants
  with a SaMD product may participate in an Excellence Appraisal, as well as an optional Review Determination Pre-Submission. When submitting a product for De Novo Review, an excellence-appraised developer would submit a streamlined "Pre-Cert De Novo Request," in which it would not need to re-submit information reviewed during the Excellence Appraisal or the optional Pre-Submission. Assuming premarket requirements are met, the FDA would classify the device by written order and, if the device is Class II, establish special controls, which may include Excellence Appraisal elements and postmarket data collection elements.

- Following
  a De Novo order, an excellence-appraised developer would also be able to take advantage of a streamlined "Pre-Cert 510(k)" process, in which the developer can again leverage submission requirements already documented during the Excellence Appraisal and optional Pre-Submission process. The FDA expects review of a Pre-Cert 510(k) to be more efficient than the review of a traditional 510(k). The Pre-Cert 510(k) can also be used for modifications to devices, assuming
  a 510(k) is required for the modification.

The second
document is a 2019
Test Plan (the "Test Plan"). The Test Plan lays out the scope and
approach of the Pre-Cert pilot in 2019. The
primary purpose of the Test Plan "is to assess whether the Excellence Appraisal and Streamlined Review components together produce an equivalent basis for determining reasonable assurance of safety and effectiveness for a SaMD product… as compared to the traditional paradigm." Here are some highlights:

- Consistent
  with the Framework, the scope of the Test Plan is limited to: (i) selected SaMD with De Novo Requests, and (ii) selected 510(k) submissions, which would be tested as if they were follow-on 510(k)s for devices classified through a Pre-Cert De Novo Request.

- The
  FDA plans to prioritize selection of submissions that will enable evaluation and testing of all four components (Excellence Appraisal, Review Pathway Determination, Streamlined Review, and Real-World Performance plan) outlined in the Working Model (discussed below), and to focus on cases representing a broad spectrum of software developers (e.g., small and large firms, low- and high-risk products, companies not traditionally considered medical device manufacturers).

- During
  the Test Plan, the FDA will apply both the proposed Pre-Cert pathway and the traditional review process to each test case, enabling it to refine Pre-Cert and confirm the validity of the overall program. Developers participating in the Pre-Cert pilot, after an Excellence Appraisal and optional Pre-Submission, will still need to submit full traditional marketing submissions. Internally, the FDA will then create a "mock Streamlined Review package" and review the submission on parallel paths, traditional and "mock Streamlined." Similarly, the FDA will also be internally conducting retrospective tests of SaMD regulatory submissions previously reviewed.

Finally, the
third document released is an updated Working
Model (currently v1.0). The Working Model, which has been updated over time with continuous public input, describes in greater detail the goal, vision, scope, and process for Pre-Cert. It also includes summaries of public comments that have been received and FDA responses to them.

Pre-Cert, if
implemented and successful in accomplishing FDA's stated goals, could have a significant impact on the healthcare industry beyond the software developers it promises to impact directly. Digital health is increasingly becoming an important tool for healthcare businesses. Streamlining processes for bringing digital health technology to market and modifying existing technology will in turn increase the rate at which providers are able to utilize updated digital health technologies in practice. As this technology continues to garner the focus and support of regulatory bodies, it will be important not only for developers to understand the FDA's streamlined approval process, but also for

providers to prepare for the potential transformative effect digital health tools can have on the care they provide.