FDA Provides Update on Pre-Cert Program and Launches Digital Health Center of Excellence

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You'd be forgiven in the current climate of coronavirus and election season, to name just a couple hot issues of the day, for missing two recent announcements from the FDA about its digital health program. On September 14, 2020, FDA published "**Developing the Software Precertification Program: Summary of Learnings and Ongoing Activities**" and the following week, on September 22, launched the **Digital Health Center of Excellence**.

Regular readers of this blog will recall that **FDA's Pre-Cert program for digital health** (and potentially other medical products) would reimagine the FDA's evaluation of software, putting an emphasis on the software developer's culture of quality and operational excellence as well as postmarket monitoring of software once deployed. FDA shared in its September 14 update that it is continuing to evaluate the Pre-Cert program through mock excellence appraisals and parallel review of software both through the proposed Pre-Cert model and under the existing statutory framework (i.e., through 510(k) and De Novo submissions). The work ranges from specific activities like "defin[ing] structured data models for the information and objective evidence needed to make key decisions at each stage of the product lifecycle under the future Pre-Cert Program" to more general activities like "identify[ing] infrastructure needs for statutory authority."

In its September 22 announcement, FDA shared with stakeholders that it had launched the Digital Health Center of Excellence (DHCoE), which is envisioned to "provide centralized expertise and serve as a resource for digital health technologies and policy for digital health innovators, the public, and FDA staff." The DHCoE will also continue work to "modernize digital health policies and regulatory approaches" that has been going on within FDA's Center for Devices and Radiological Health (CDRH), and it will "provide efficient access to highly specialized expertise, knowledge, and tools to accelerate access to safe and effective digital health technology."

Digital health, of course, is not limited to medical devices. We are seeing digital applications in pharmaceuticals and biologics (e.g., "smart" pills with sensors), as well digital applications in how those products are developed and evaluated (e.g., using artificial intelligence). What is curious about the newly announced DHCoE, then, is that it will be housed within CDRH and not at a level above or on par with the medical product centers, a la the Oncology Center of Excellence **created in January 2017** and authorized by the **21st Century Cures Act**.

Considering its organizational placement, we will be paying close attention to how FDA is able to achieve the goals of the DHCoE. For example, the device center is often regarded as less conservative than either the drug or biologics centers, so when there are digital health policies that put the medical product centers at odds, who will arbitrate between them to reach a final decision? FDA Deputy Commissioner Amy Abernethy has been a champion of digital health reform, though her tenure at FDA may be interrupted early next year by a new administration.

Given all the momentum and activity in this area, look for digital health to be a focus area in the upcoming **user fee reauthorization process**. DHCoE will need funding to hire the "highly specialized expertise" it promises to bring to the agency's expanded digital health program. The Pre-Cert update included an explicit mention of needing new statutory authority. These items would not be inappropriate for the agency to push for in discussions with Congress (for needed authorities) and industry (for funding).

Further, CDRH Director Jeff Shuren continues to push for a wholesale reevaluation of how FDA reviews medical devices. At a recent medtech conference, Dr. Shuren said, referring to flexibility in how the agency has been reviewing COVID-19 products: "The level of regulatory flexibility has been unprecedented and could serve as a model in the future." Studying CDRH's activities over the past decade or so, it is not difficult to imagine the future Dr. Shuren envisions: flexible premarket reviews relying in part on an evaluation of the product developer, in part on an evaluation of the product, and relying heavily on postmarket surveillance and analysis to identify and quickly address problems. How quickly these ideas are implemented, and whether they are implemented just for medical devices or more broadly, depends in large part on whether a potentially new administration in 2021 will support them and whether Congress will provide needed authority and funding.

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