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Shuren: FDA Making 'Pre-Cert Simulator' To 'Test Drive' Regulatory Frameworks For Digital Health Tech

Device center director also ponders whether the agency's Pre-Cert Program could cover a wider array of products in the future

by Shawn M. Schmitt

US FDA device center director Jeff Shuren said on 6 October that the agency is developing a "precertification simulator" that will allow it to assess different regulatory frameworks in the digital health space.

The director of the US Food and Drug Administration's device center says it's making a "precertification simulator" that will allow it to assess different regulatory frameworks in the digital health space without the need to cobble together physical pilot programs.

"We're … building today, under the auspices of the [FDA's new Digital Health] Center of Excellence, a precertification simulator so we in the digitized space can test drive different regulatory paradigms [to] see what the impact may be before, rather than going ahead and implementing or doing a full-blown physical pilot," Center for Devices and Radiological Health (CDRH) director Jeff Shuren said on 6 October at AdvaMed's Virtual MedTech Conference.

The FDA launched its Digital Health Center of Excellence (DHCOE) last month in an effort to help the agency gain a better understanding of the myriad policy and regulatory issues around digital health tech, including Software as a Medical Device (SaMD). (Also see "*Head Of New Digital Health Center Looking For A Few Good FDA Staff*" - Medtech Insight, 29 Sep, 2020.)

Shuren said the DHCOE will "serve as an innovation hub for test driving different approaches – different regulatory paradigms – to digital health technologies, because we do need more approaches. We need agile frameworks in place."

Once developed, Shuren said the pre-cert simulator will allow the CDRH to "be a lot smarter about our choices, and ultimately inform … regulatory actions – and maybe even legislative actions – that should be taken in the future."

> ***There are "things we can test drive [with the simulator] by modeling them out, that really would better inform what we do in the physical space." – Jeff Shuren***

The FDA is currently testing out a Precertification (Pre-Cert) Pilot Program for SaMD; the idea is for the agency to have such an abundance of confidence in particular software manufacturers, that their products can get to market faster. Pilot participants are appraised by the FDA on the principles of product quality, patient safety, clinical responsibility, cybersecurity responsibility and a proactive culture. (Also see "*FDA Readies Digital Health Pre-Cert Program For Lift Off*" - Medtech Insight, 26 Apr, 2018.)

"The Pre-Cert pilot has been incredibly informative, and *even had to take a bit of a twist during COVID-19 because we couldn't go out there to do appraisals*, and we've been doing some of that work remotely," Shuren said. Now, "I don't see us giving up on that physical kind of pilot, but [there are] things we can test drive [with the simulator] by modeling them out, that really would better inform what we do in the physical space that might then be for a continued pilot, or to ultimately build out a program."

Shuren pointed out that the FDA would "require a change in the law" if it wanted to apply the Pre-Cert Program more broadly. And, he said, if that must be done, then the device center would consider whether to push for the program to cover a wider array of products.

"If we really want to make this a program, the law would have to change, and quite frankly, if it would give more flexibility, should we do something that's just purely tailored to digital health technologies, or should we think more expansively on what we should do with medtech?" he asked. "Because lots of emerging technologies currently pose a challenge for us to provide the optimal kind of oversight to assure we've got advancements in innovation, but also good patient safeguards.

"So those kinds of changes maybe are things we want to think about more broadly, not just for digital health."

Experts have questioned whether the FDA has the legal authority to go ahead with the Pre-Cert program. The agency has said it's developing the program based on the congressional authority it has, but acknowledges that it may need more authorities to expand the program. (Also see "*US FDA's Software Pre-Cert Program: Is The Authority On The Books?*" - Medtech Insight, 31 Jul, 2018.)

At last year's MedTech Conference, Shuren noted the medtech industry is moving at a rapid pace with more complex science and technologies coming to the forefront. He argued this means the industry is moving a lot faster than the current regulatory framework allows for, and floated the concept of "regulatory Legos" to give the agency broader authorities. (Also see "*US FDA Toying With Idea Of 'Regulatory Legos' In MDUFA V*" - Medtech Insight, 1 Oct, 2019.)

Ferdous Al-Faruque contributed to this report.