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FDA tightens up digital health oversight

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Software-enabled medical devices pose unique challenges to regulators, and the US agency is getting serious about meeting them.

The FDA has been grappling with the challenges of regulating digital health products for some time now, notably through its precertification initiative, designed to regulate a product's developer rather than the technology itself. It has now taken another step, with the formation of a dedicated centre within the agency intended to provide expertise and help formulate digital health policy.

The Digital Health Center of Excellence will focus on mobile health devices, wearable medical devices, software as a medical device and technologies used to study medical products. It appears that the DHCE will have some responsibility for oversight, but the formation of a specific regulatory path for digital products does not appear to be on the agenda.

The DHCE will be housed within the Center for Devices and Radiological Health (CDRH), the FDA body that oversees approval and clearance of medical devices. It will help the agency reimagine digital health oversight – a tricky prospect, as Richard Devereaux Phillips, director of healthcare policy at the Association of British Healthcare Industries, told *Evaluate Vantage*.

"Digital technologies always freak regulators out," he says, "because while devices iterate over 12 or 18 months … algorithms based on deep learning iterate instantaneously with every piece of information that goes into them. You're going to have to think differently about how you regulate those, and the producers of those."

Strategic priorities

The FDA has stopped short of tasking the DHCE with making actual approval decisions – it will not regulate digital products in the same way the CBER regulates biologicals, for instance. Neither will there be a separate regulatory pathway. But it will have some supervisory power.

Dreamed up in 2017, the precertification pilot programme is intended to allow software-based medical products on to the market faster by pre-evaluating the technology's developer. The first product submitted via this programme was Pear Therapeutics' Somryst app for insomnia and depression; it is not known how many others have followed this route (*Digital therapeutics have potential but commercial success unproven, August 15, 2019*).

The precertification initiative now appears to be one of the "strategic priorities and programmes" of the DHCE. This suggests that the DHCE will be the body checking over the healthcare IT companies that use this programme. If it gives the OK, their technologies will be on course to gain relatively swift approval or clearance

from the CDRH.

The DHCE's other strategic priorities and programmes cover cybersecurity, artificial intelligence and machine learning in software as a medical device, and wireless medical devices. Other than that, the new unit's roles are still somewhat ill-defined: the FDA stated that "there are many aspects of the Digital Health Center of Excellence that are still under development".

Establishing a unit dedicated to examining the regulatory difficulties posed by computerised health technologies, and seeking the best ways to solve them, is a notable advance for the FDA. And products such as disease management apps and wearable monitors are of particular use at a time when physically travelling to doctors' offices or hospitals is discouraged thanks to Covid-19, underlining the importance of new regulatory initiatives.

But the formation of the DHCE is more of an iterative step than a major change to governance of digital health. There might be more concrete moves to come in the future.