Thank You Very Much, Mr. Roboto: FDA Announces New Digital Health Programs

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Scott Gottlieb, M.D., FDA's commissioner, recently announced new digital health initiatives that will aid the agency's push to regulate and support digital healthcare in the medical device space. [1] In a statement posted to FDA's blog, Dr. Gottlieb stated:

> FDA's traditional approach to medical devices is not well suited to these [digital] products. We need to make sure our approach to innovative products with continual updates and upgrades is efficient and that it fosters, not impedes, innovation. Recognizing this, and understanding that the potential of digital health is nothing short of revolutionary, we must work toward establishing an appropriate approach that's closely tailored to this new category of products.

The new initiatives include the Digital Health Innovation Action Plan and Software Precertification Program.

Digital Health Innovation Action Plan

FDA's Digital Health Innovation Action Plan is designed to change the way FDA oversees digital health technology to "help provide patients with timely access to high-quality, safe, and effective digital health products."[2] The goals of the program are to:

- enable a modern and tailored approach that allows software iterations and changes to occur in a timely fashion;
- ensure high quality medical product software throughout the life of the product by enabling companies to demonstrate their embedded culture of quality and organization excellence (CQOE); and
- be a program that learns and adapts and can adjust key elements and measures based on the effectiveness of the program.[3]

FDA has developed an Action Plan describing how it intends to accomplish these goals and generally redesign policies and processes to match the needs of digital health technology and implement and clarify the relevant portions of 21st Century Cures Act, which included provisions related to medical software. Actions will include issuing three draft guidances and finalizing a fourth:

- a general 21st Century Cures implementation draft guidance setting forth FDA's interpretations of some of the medical software provisions (expected by end of 2017);
- a draft guidance describing what clinical decision support software falls outside FDA's jurisdiction (expected in first quarter 2018);
- a draft guidance clarifying FDA's oversight of products with multifunctionality (products with both software functions falling under FDA's medical device oversight and functions that do not) (expected in first quarter 2018);
- final guidance on Deciding When to Submit a 510(k) for a Software Change to an Existing Device (expected by the end of 2017); and

1 https://blogs.fda.gov/fdavoice/index.php/2017/07/fda-announces-new-steps-to-empower-consumers-and-advance-digital-healthcare/ (last visited Aug. 21, 2017).
2 https://www.fda.gov/MedicalDevices/DigitalHealth/UCM567265 (last visited Aug. 21, 2017).
3 *Id.*

- finalize guidance on Software as a Medical Device (expected if the International Medical Device Regulators Forum adopts its proposal in September).[4]

Software Precertification Program

The Software Precertification Program is a voluntary pilot program that will "enable [FDA] to develop a tailored approach toward this [new] technology by looking first at the software developer or digital health technology developer, rather than primarily at the product."[5] FDA will take a firm-based, rather than product-based approach to regulating digital health products to evaluate whether a precertification program could replace the need for premarket submissions for certain products and for others, allow for reduced content and/or faster review.

The program will include up to nine software firms of various sizes, ranging from small startups to large companies that develop software products that are devices. Participants will be selected based on the following:

- 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.[6]

AGG Observations

- Some of what FDA announced was expected, especially given the content of the 21st Century Cures Act, and the existing enforcement discretion practice for certain digital devices.
- FDA will be growing its digital health expertise by hiring new staff in the Center for Devices and Radiological Health and is also launching an "Entrepreneurs in Residence" program this coming fall, which will seek input from thought leaders and others.[7]
- FDA's initiatives and proposed guidance documents signal a significant shift in the way FDA plans to oversee and regulate digital health products.
- Participants in the digital health marketplace should pay close attention, as FDA's proposed actions, as influenced by those in the marketplace, may dictate the contours of the regulated space for decades to come.
- FDA intends to hold a public workshop to discuss "reimagining the paradigm" in early 2018. Consider attending or submitting comments. Additional opportunities for comment will arise when the draft guidances are issued. We will keep you posted.

4 https://www.fda.gov/downloads/MedicalDevices/DigitalHealth/UCM568735.pdf (last visited August 21, 2017); Fostering Medical Innovation: A Plan for Digital Health Devices; Software Precertification Pilot Program, 82 Fed. Reg. 35216 (July 28, 2017).
5 https://blogs.fda.gov/fdavoice/index.php/2017/07/fda-announces-new-steps-to-empower-consumers-and-advance-digital-healthcare/ (last visited Aug. 21, 2017).
6 Fostering Medical Innovation: A Plan for Digital Health Devices; Software Precertification Pilot Program, 82 Fed. Reg. 35216 (July 28, 2017).
7 https://www.fda.gov/downloads/MedicalDevices/DigitalHealth/UCM568735.pdf?source=govdelivery&utm_medium=email&utm_source=govdelivery (last accessed Aug. 21, 2017).

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