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Gottlieb Announces New Regulatory Paradigm for Digital Health Software

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The development of medical software products presents the opportunity to notably improve a number of healthcare issues in the U.S. today, such as facilitating greater consumer involvement in their own healthcare and enhancing the speed of clinical decision-making. At the same time, these opportunities are driving rapid development, with the number of products increasing exponentially. Recognizing both the opportunities and the potential regulatory challenges presented by such rapid development, the FDA – under the leadership of recently confirmed Commissioner Scott Gottlieb – is spearheading a new "Digital Health Innovation Plan" intended to encourage innovation in the digital health technology space while continuing to ensure that products brought to market are safe and effective. Dr. Gottlieb emphasized in a recent FDA blog post[1] that the Agency's policies must be clearly communicated to avoid creating uncertainty, noting in particular that industry should not need to seek FDA's position "on every individual technological change or iterative software development."

FDA's Center for Devices and Radiological Health (CDRH) has begun working to implement the software-related provisions of the 21st Century Cures Act, which for the first time formally exclude certain types of software from regulation as a medical device.[2] New FDA guidance, promised in the next few months, will further clarify how these statutory provisions will be applied in practice, and how this law and its implementing regulations will affect pre-existing FDA policies on medical software. FDA is also slated to announce additional technologies that, while not addressed in the Act, are similarly low risk and thus will not be subjected to certain premarket regulatory requirements.

More broadly, FDA has been developing a new regulatory framework for software as a medical device (SaMD) that is designed to foster a more efficient, risk-based approach to overseeing these products. A key part of this pilot effort, which the Agency plans to roll out in the fall of 2017, is creation of a third party certification program through which lower-risk digital health products could be marketed without FDA premarket review and higher-risk digital health products could be marketed with a more streamlined FDA premarket review. The idea is to allow for pre-certification of companies that have consistently shown high-quality design, testing/validation, and

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[1] *See* Dr. Gottlieb's post on the FDA blog, "Fostering Medical Innovation: A Plan for Digital Health Devices" (June 15, 2017), at: https://blogs.fda.gov/fdavoice/index.php/2017/06/fostering-medical-innovation-a-plan-for-digital-health-devices/?source=govdelivery&utm_medium=email&utm_source=govdelivery

[2] *See* our prior Client Alert on this subject from December 16, 2016, at https://www.hoganlovells.com/en/publications/president-obama-signs-21st-century-cures-act-into-law-exempting-certain-types-of-medical-software-from-fda-regulation

maintenance of their software devices. Such companies would then be permitted to make use of a more efficient pre-market review process, either by avoiding review altogether or by leveraging a more expedited review, with the objective of reducing the time and cost of market entry and, in turn, enhancing incentives for investing in the digital health industry. Dr. Jeffrey Shuren, CDRH Director, has likened the concept to the Transportation Security Administration's Pre-check program that offers selected travelers expedited security screening.[3] Pre-certified companies would still be subject to post-market controls.

FDA's new approach to medical software may further enable a shift of the regulatory burden from pre- to post-market by allowing real-world data collected on marketed products to support new or evolving product functions and expansion of indications for use. This goal will be facilitated through an independent National Evaluation System for Health Technology (NEST) – strongly supported by FDA – which will coordinate diverse players and bring together various data sources for evidence generation. NEST is expected to launch as a fully operational system by the end of 2019.

While many of the details of FDA's new approach to medical software regulation remain to be finalized and are expected to be announced over the coming months, given Dr. Gottlieb's general views on the importance of transparency and predictability for industry, we expect to see potentially notable changes over the next few years in FDA's approach to the regulation of digital health – changes that could positively impact the ability of companies to bring digital health technologies to market. With all of these developments in the works, stakeholders are encouraged to be vocal with their comments in order to help shape FDA's future policy in this important area.

Hogan Lovells will continue to monitor and report on developments in the digital health space as they transpire. Please contact any of the authors of this alert or the Hogan Lovells attorney with whom you regularly work for further information.

[3] *See* "FDA Eyes Plan to Lessen Review Burden for Software Updates" (Sept. 28, 2016), at: https://www.healthdatamanagement.com/news/fda-eyes-plan-to-lessen-review-burden-for-software-updates?tag=00000153-f735-d9ec-a7f7-fffffe9d0000

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