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Streamlined Regulation of Healthcare Software Platforms

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Healthcare software as a service ("SaaS") platforms continue to be attractive targets for private equity sponsors and their portfolio companies. The U.S. Food and Drug Administration ("FDA") is developing a new program to facilitate the development and life cycle management of certain healthcare SaaS platforms that meet the statutory definition of a "device,"[1] commonly referred to as software as a medical device ("SaMD").

In January 2019, the FDA outlined the implementation of the Software Precertification Program, under which SaMD manufacturers that demonstrate a robust culture of quality and organizational excellence and are committed to monitoring real-world performance are eligible for streamlined review and approval/clearance of their products.[2]

In determining whether an SaMD manufacturer is eligible for precertification, the FDA will evaluate the manufacturer's demonstration of excellence in the following:

- Development, testing and maintenance necessary to deliver SaMD products at the highest level of quality;
- Providing a safe patient experience and emphasizing patient safety as a critical factor in all decision-making;
- Responsibly conducting clinical evaluation and ensuring patient-centric issues are appropriately addressed;
- Protecting and addressing cybersecurity issues through active engagement with stakeholders and peers; and
- Utilizing a proactive approach to surveillance, assessment of user needs and continuous learning.

As currently envisioned, the Software Precertification Program presents an opportunity for private equity sponsors and their portfolio companies expanding into the SaMD space. Acquiring an SaMD manufacturer that meets the precertification requirements will facilitate the development and release of new SaMD products and overall growth. In addition, the robust internal quality, regulatory and compliance infrastructures required for such manufacturers will help ensure compliance with applicable FDA regulatory requirements and can be leveraged for more general and data privacy compliance matters. For those interested in this space, it will be important to monitor the continued development of the Software Precertification Program.

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1. 21 U.S.C. § 321(h). ↩

2. See FDA, "Developing a Software Precertification Program: A Working Model" (Jan. 2019); see also FDA, "Software Precertification Program: Regulatory Framework for Conducting the Pilot Program within Current Authorities" (Jan. 2019); FDA, "Software Precertification Program: 2019 Test Plan" (Jan. 2019). ↩

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