By the time you read this article, it may well be outdated. And that's a good thing for digital health companies.

Changes in digital health policies have been coming at lightning speed from Congress and the U.S. Food and Drug Administration (FDA). With the continued explosion of software and software-controlled medical devices, including the growing use of machine learning and artificial intelligence to develop tools to support and even enhance the practice of medicine, the FDA has acknowledged that the existing framework for regulation of medical devices is not entirely suited to this new realm of products. As a consequence, the FDA, with the help of Congress, has been rapidly developing a new paradigm.

Yarmela Pavlovic, Kristin Zielinski Duggan, and Suzanne Levy Friedman of Hogan Lovells in this article review some of the recent FDA initiatives in this space, including the Precertification Program, the Medical Device Safety Action Plan and the FDA guidance on Multiple Function Device Products.

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