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Articles

Digital Health and Telehealth: Navigating the Current Legal Framework

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The commercialization of digital health and medtech products has significantly increased over the past several years, in part accelerated by the COVID-19 Public Health Emergency (PHE). However, the regulatory waters for many of medtech companies remain murky and the ways in which companies get reimbursed for these services is uncertain and changing. In many instances, digital products are not squarely regulated by the US Food and Drug Administration (FDA) or by the Department of Health and Human Services (HHS) Office of Civil Rights (OCR), which enforces the Health Insurance Portability and Accountability Act (HIPAA). Instead, a patchwork of various state data privacy and security laws may apply, in addition to consumer protection laws. Should a federal framework exist? Or should digital health technology be permitted to flourish with fewer regulatory hurdles?

In an article for the *ABA Health eSource*, Julia Kadish, Allison Fulton, Arushi Pandya and Ana Anvari of Sheppard Mullin's Digital Health Industry Team, explored these questions, along with the current regulatory regime, and recent rise of industry and non-profits groups working on frameworks and open-access resources to guide medtech companies to the right regulatory path.

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