Cooley

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The Food and Drug Administration (FDA) on February 6th, finalized guidance on certain medical devices that store and transfer data, opting for a very light regulatory touch. In its guidance, the FDA states that it doesn't intend to regulate Medical Device Data Systems (MDDS) (either hardware or software) that receive, transmit, store or display data from medical devices. In its rationale, the FDA points to "the low risk they pose to patients and the importance they play in advancing digital health" as a reason for opting out of regulating these devices. MDDS covered by this guidance cannot modify data, do not control any other connected devices and do not include any devices involved in active patient monitoring. Examples of covered MDDS include:

- The electronic transfer or exchange of medical device data. For example, this would include software that collects output from a ventilator about a patient's CO2 level and transmits the information to a central patient data repository.
- The electronic storage and retrieval of medical device data. For example, software that stores historical blood pressure information for later review by a healthcare provider.
- The electronic conversion of medical device data from one format to another in accordance with a preset specification. For example, software that converts digital data generated by a pulse oximeter into a digital format that can be printed.
- The electronic display of medical device data. For example, software that displays a previously stored electrocardiogram for a particular patient

Covered MDDS will not be subject to FDA regulatory compliance requirements, including "registration and listing, premarket review, postmarket reporting, and quality system regulation for manufacturers of these types of devices."

The FDA has scheduled a webinar for February 24th to "give an overview of FDA's approach to regulating MDDS and to help stakeholders understand the draft policies described in the general wellness and medical device accessories guidance documents and solicit comments." The webinar will cover the MDSS guidance as well as recently released guidance on mobile medical apps (MMA), general wellness policy for low risk devices and medical device accessories. During the webinar the FDA will make a brief presentation and then respond to question on all four guidance documents.

Its important to point out that the FDA's thinking on digital health is evolving. As the guidance states, it is intended to "describe the [FDA's] current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited." Moreover, Congress is actively engaged in the regulation of digital health as can be seen from the House of Representatives, Energy and Commerce Committee's 21st Century Cures Initiative and the Senate Health, Education, Labor and Pensions Committee's "Innovation for Heathier Americans" report. Clearly, the future of digital health is top of mind for policymakers across Washington and there could be significant changes to "what and how" it is regulated going forward.



# Key Contacts

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