FINAL FDA GUIDANCE ON INTEROPERABLE MEDICAL DEVICES

On September 6, 2017, the U.S. Food and Drug Administration ("FDA") published final guidance ("Guidance") summarizing its recommendations for medical devices that are connected to each other and to other technology ("interoperable medical devices"). The Guidance finalizes preliminary guidance from January 2016 and is intended to encourage rapid innovation in the marketplace by allowing effective exchange and use of information by and between devices and information technology systems while ensuring safety for patients and users. The goal, according to Bakul Patel, Associate Director for Digital Health in FDA's Center for Devices and Radiological Health, is to support interoperability that allows "devices talk to each other in a safe and effective way enabling smarter care."

The Guidance notes that device manufacturers must ensure appropriate safety concerns are considered and that reasonable precautions are taken when developing interoperable medical devices to avoid "unforeseen safety and effectiveness issues for the patient, operator, device or system." Examples of these types of safety considerations include the impact of communication failures, which could lead to the exchange of inaccurate, delayed and/or incorrect information, as well as device malfunction, which could lead to patient injury.

The Guidance provides specific recommendations for device design and premarket submissions for device manufacturers, including the following.

- Device labeling should clearly set forth the functional and performance requirements of electronic interfaces and data exchange to minimize risks associated with failure to exchange and/or use data as intended.

- Identification of anticipated users should help direct decisions regarding the electronic interface structure, device design and labeling, as different labeling may be appropriate for different user populations.

- Adequate risk management, verification and validation mechanisms should be included as part of the device design process.

Although FDA guidance is not binding, this Guidance gives insight as to the FDA's current stance on the submission requirements related to information exchange between interoperable medical devices and information technology systems. Patel noted that the FDA's guidance is a "good step towards safer devices, and [the FDA] will continue to work with all stakeholders to adapt along with the technology." This is an area of rapid development, and it is likely that the FDA's views on this subject will continue to change as more interoperable medical devices are developed and the FDA gains experience on the subject matter. We will continue to monitor and report on this topic as information becomes available.

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