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FDA's Strategy For Interoperable Medical Device Regulation

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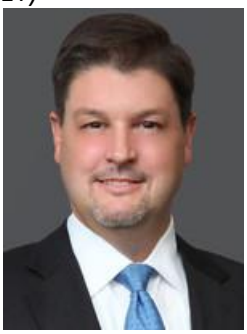
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This week, the Food and Drug Administration issued draft guidance entitled Design Considerations and Premarket Submission Recommendations for Interoperable Medical Devices. The FDA issues such documents to provide the agency's "current thinking" on a matter of concern to regulators and stakeholders. This particular guidance provides FDA's views on issues that device makers should consider when designing interoperable medical devices. In addition, FDA's draft guidance discusses how device makers should prepare a premarket submission, which is a form of application for permission to market a medical device. Many companies are likely to take an interest in this proceeding given its potential to affect an array of sectors in addition to the health care sector, including communications and Internet technology companies, wireless device manufacturers and communications infrastructure providers. The FDA seeks comment on the draft guidance on or before April 28, 2016.

Background

In the context of health information technology (HIT), the term "interoperable" refers to the ability of different information technology systems and software applications to communicate, exchange and use data seamlessly. The new interoperability guidance discussed below is another step in the FDA's efforts to implement the recent mandate set forth in the Food and Drug Administration Safety Innovation Act. In 2012, Congress tasked three agencies — the FDA, the Federal Communications Commission and the Office of the National Coordinator for Health Information Technology (ONC) (an agency within the Department of Health and Human Services) — with producing recommendations for a new HIT regulatory framework that would balance the goals of promoting innovation, protecting patient safety and avoiding regulatory duplication. Interoperability would be a critical component of such a new regulatory scheme.

The FDA states that, "[i]nteroperability in health care has the potential to encourage innovation and facilitate new models of health care delivery by promoting the availability and sharing of information across systems even when products from different manufacturers are used. However, one of the more controversial aspects of this multiagency effort has been the goal of ensuring interoperability among medical devices. In theory, interoperable medical devices would improve the efficiency of health care delivery by, for example, enabling providers in different specialties located at different institutions to share patient information quickly, thus facilitating faster treatment based on more complete information. At the same time, given the health care context, medical device interoperability has raised concerns about safety, and privacy concerns have become particularly acute given heightened sensitivity to cybersecurity threats.

The new interoperability guidance is divided into two principal sections; the first addresses design and the second addresses premarket submissions.

Design Considerations for Interoperable Medical Devices

The FDA guidance provides detailed information and recommendations for device design and stresses the critical importance of ensuring safety. To that end, the FDA states that device makers should perform a risk analysis and conduct appropriate testing that considers risks associated with the proposed technology, such as failures or malfunctions resulting from improper connection of devices or invalid commands. The FDA suggests that clear labeling regarding the functional, performance and interface requirements of the proposed device, as well as its limitations, would promote safe use. More specifically, the FDA provides detailed recommendations on six prime considerations for device design including (1) the purpose of the interface, (2) the anticipated users, (3) risk analysis and management, (4) verification and validation testing, (5) thoroughness and specificity of labeling and (6) the use of consensus standards. With regard to consensus standards, the FDA acknowledges the benefits of designing medical devices that incorporate published consensus standards in general and particularly in the context of interoperable medical devices. Further, the FDA explains that these benefits are maximized when not only medical device makers but all stakeholders, including health care organizations and providers, medical system designers and integrators and IT professionals, take part in the standards-setting process. Consider: In this regard, the FDA cites the CDRH Recognized Consensus Standards Database, a data collection maintained by its Center for Devices and Radiological Health, as a source for identifying potential interoperability standards.

Recommendations for Premarket Submissions

As a threshold matter, the FDA recognizes that "not all interoperable medical devices may require premarket submission." For those that do, however, the FDA suggests that sponsors should "consider any other appropriate guidances or special controls applicable to the device." The FDA next provides detailed recommendations on four main issues germane to the preparation of premarket submissions, which overlap considerably with the interoperability design considerations. The FDA requests that premarket submissions include (1) the device description, (2) risk analysis, (3) verification and validation and (4) labeling. With regard to labeling, the FDA provides lengthy, proscriptive requirements, which include discussing the purpose for the medical device and the data, describing interface specifications and providing a testing summary, citing the standards followed, explaining the limitations of the device, recommending steps for ease of use and writing proposed instructions for IT personnel.

Conclusion

The FDA's guidance concludes by stating that "the use and development of standards that support interoperability of medical devices is vital to creating interoperable systems that are reliable and safe," which illustrates the agency's view that developing and implementing consensus-based standards is essential to achieving a modern, efficient HIT regulatory framework. At the same time, the FDA acknowledges the competing priorities of developing new and innovative interoperable medical devices and protecting patient safety and privacy. As such, the FDA should conduct a fact-based technical analysis to assess the costs and potential burdens for medical device manufacturers and others in the HIT marketplace of developing interoperable medical devices that meet applicable standards for safeguarding patient information. The FDA has authority to regulate medical devices for safety and efficacy, and to that end to mandate specific requirements for such matters as labeling, testing and validation. But the FDA cannot compel interoperability itself, any specific design or function related to interoperability, or require specific standards for interoperability. The draft guidance did not mention activities of or coordination with other agencies that may be involved in that process such as the FCC and ONC. This area may be fertile ground for inquiry by stakeholders during the comment process.

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