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Medical Technology Alert

FDA Issues Draft Guidance Easing Compliance for Medical Device Data and Image Systems

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In what has been an active couple of months of released guidance documents, the FDA issued another draft guidance on June 20, 2014 entitled, “Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices.” See guidance here. The primary purpose of this draft guidance is to inform manufacturers, distributors and other entities that the FDA will not enforce compliance with the regulatory controls that apply to medical device data systems (MDDS), medical image storage devices, and medical image communications devices, due to the “low risk that they pose to patients and the importance they play in advancing digital health.”

MDDS are defined as hardware or software products that transfer, store, convert formats, and display medical device data. They are not used in active patient monitoring and do not modify data or control the functions or parameters of any connected medical devices. Medical image storage devices are defined as devices that provide electronic storage and retrieval functions for medical images. Medical image communications devices are defined as devices that provide electronic transfer of medical image data between medical devices. Although the FDA considers all three types of entities to be subject to its jurisdiction over medical devices, devices that meet these definitions will be subject to FDA’s enforcement discretion and not be required to comply with regulatory controls that would otherwise have applied, such as premarket review, registration and listing, post-market reporting and quality system regulation.

The FDA will receive comments regarding the draft for 60 days after its availability is published in the *Federal Register*. When finalized, the draft guidance will amend the Mobile Medical Applications guidance document published on September 25, 2013, in a manner set forth in the draft guidance.

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