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CLIENT ALERT

FDA Conforms Regulations to Exclude Certain Software Functions from the Definition of Device

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The Food and Drug Administration (FDA) Final Rule amending certain classification regulations to reflect changes to the Federal Food, Drug, and Cosmetic Act (FD&C Act) made by the 21st Century Cures Act (Cures Act) became effective April 19, 2021. The Final Rule amends eight classification regulations to conform to the medical software provisions of the Cures Act, eliminating from medical device regulations certain software intended to transfer, store, or display clinical laboratory tests and software that encourages a "healthy lifestyle."

See the Final Rule, *available at* https://www.federalregister.gov/documents/2021/04/19/2021-07860/medical-devices-medical-device-classification-regulations-to-conform-to-medical-software-provisions

The Cures Act, enacted on December 13, 2016, amended the FD&C Act to state that the term "device" does **not** include software functions excluded pursuant to section 520(o)(1) of the FD&C Act. In particular, Section 520(o)(1) of the FD&C Act excludes functions that are intended for (1) administrative support of a healthcare facility; (2) maintaining or encouraging a healthy lifestyle and are unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition; (3) serving as electronic patient records to the extent that such records are intended to transfer, store, convert formats, or display the equivalent of a paper medical chart; (4) transferring, storing, converting formats, or displaying clinical laboratory test or other device data and results, findings by a healthcare professional (unless such function is intended to interpret or analyze clinical laboratory test or other device data, results, or findings); or (5) unless the function is intended to acquire, process, or analyze a medical image or a signal from an in vitro diagnostic device or a pattern or signal from a signal acquisition system for the purpose of: (a) displaying, analyzing, or printing medical information about a patient or other medical information; (b) supporting or providing recommendations to a healthcare professional about prevention, diagnosis, or treatment of a disease or condition; and (c) enabling such healthcare professional to independently review the basis for such recommendations that such software presents so that they are not primarily relying on the device's recommendations to make a diagnosis or treatment decision. The regulatory status of device hardware intended to transfer, store, convert formats, and display medical data and results remains unchanged and continues to be regulated by the FDA.

The Final Rule conforms the FD&C Act to reflect these exclusions. The Final Rule also amends classification regulations to conform the "identification" description with the device definition under the FD&C Act:

- Clinical use “identification” description amended to remove non-device software functions that maintain and retrieve laboratory data (21 CFR 862.2100);
- Continuous glucose monitor (CGM) secondary display “identification” description amended to remove receive-and-display software functions, and amends the title of the CGM secondary display regulation to “Continuous Glucose Monitor (CGM) Secondary Alarm System” (21 CFR 862.1350);
- Automated indirect immunofluorescence microscope and software-assisted system device “identification” description amended to replace the first use of the word “software” with “device,” and both hardware and software functions that use fluorescent signal acquisition and processing software, data storage, and transferring mechanisms, or assay specific algorithms to interpret or analyze results, are devices (21 CFR 866.4750);
- Medical device data systems (MDDS) “identification” description amended to remove non-device software functions intended for transferring, storing, converting formats, or displaying clinical laboratory test or other device data and results (21 CFR 880.6310);
- Home uterine activity monitor (HUAM) “identification” description amended to remove non-device software functions intended for transmitting, receiving, and displaying data (21 CFR 884.2730);
- Medical image storage device “identification” description amended to remove non-device software functions intended for storing and retrieving so that a medical image storage device is a hardware device that provides electronic storage and retrieval functions for medical images (21 CFR 892.2010);
- Medical image communications device “identification” description amended to include software functions intended for medical image processing and manipulation (21 CFR 892.2020); and
- Picture archiving and communications system “identification” description (1) amended to remove non-device software functions intended for storing and displaying medical images, and (2) revised to clarify that the regulation includes software and hardware functions intended for medical image management and processing (21 CFR 892.2050).

With this Final Rule, the FDA conforms these classification regulations to the medical software provisions of the Cures Act and reflects the Agency’s current statutory authority.

We note that government orders on the local, state, and federal level are changing every day, and the information contained herein is accurate only as of the date set forth above.

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