

# Client Alert

July 2012

## **FDA Proposes Unique Device Identification System for Medical Devices**

On July 3, 2012, the Food and Drug Administration (“FDA” or “Agency”) released a proposed rule requiring that most medical devices marketed in the United States carry a unique device identifier (“UDI”). The proposed rule would implement Section 519(f) of the Federal Food, Drug, and Cosmetic Act (“FD&C Act” or “Act”), which was added to the Act by Section 226 of the Food and Drug Administration Amendments Act of 2007, and directs the FDA to promulgate regulations establishing a unique device identification system for medical devices.

The proposed rule would require the label of medical devices and device packages to include a UDI, except where the rule provides for alternative placement of the UDI or for an exception for a particular device or type of device. The UDI would be required to be directly marked on the device itself for certain categories of devices, such as implantable devices, devices that are intended to be reused and sterilized before each use, and stand-alone software. The UDI would consist of two elements: 1) a “device identifier,” which identifies the particular version or model of a device and its labeler; and 2) a “production identifier,” which includes the current production information for that device, such as the lot or batch number, the serial number, expiration date or date of manufacture. Each UDI would be required to be provided in both a plain-text version and a form that uses automatic identification and data capture (“AIDC”) technology. Device labels and packages would also be required to bear dates presented in a standard format.

For devices subject to the UDI requirements, the labeler would be required to submit information about the device to the FDA to facilitate the rapid identification of the device and its labeler, and to provide links to other FDA data. The labeler would be required to submit this information no later than the date on which the label of the device must bear a UDI, and to update the information when changes occur. The Agency would make this information publicly available through a variety of channels, including a new database, the Global Unique Device Identification Database (“GUDID”). The GUDID would not include patient information.

Under the proposed rule, UDIs would be issued under a system operated by an FDA-accredited issuing agency and would conform to certain international standards. The proposed rule provides a process through which an applicant could seek such accreditation.

A final UDI rule would become effective in several phases over a total period of seven years. The requirement that the label of devices and device packages subject to the proposed rule bear a UDI would become effective five years after publication of a final rule.

Interested persons may submit comments on the proposed rule within 120 days after its publication in the Federal Register, which is expected to occur on Tuesday, July 10.

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