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Final Rule on the Unique Device Identification System to be Published Next Week

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The **U.S. Food and Drug Administration** (**FDA**) issued a final rule regarding requirements for a unique device identification system. The final rule will be published in the Federal Register on September 24, 2013, and FDA has posted a draft guidance regarding the requirements on its website. FDA's rule requires labels of medical devices to include a unique device identifier (UDI). Labelers of medical devices will be required to submit product information to FDA's Global Unique Device Identification Database (GUDID).

The UDI system is intended to allow the health care community and the public to identify any device through its UDI appearing on the label and package of the device. The system is intended to improve adverse event reporting, and allow for more effective management of medical device recalls. For medical devices intended to be used more than once and reprocessed before each use, the UDI must also be directly marked on the device itself. UDIs are required to appear in both plain-text format and a format readable by a bar code scanner or other automatic identification and data capture (AIDC) technology.

Implementation of the rule is staggered based on product risk, with the medical devices presenting the highest risk being subject to the rule first:

Compliance Date	**Requirement**
One year after publication of the final rule	The labels and packages of class III medical devices and devices licensed under the Public Health Service Act (PHS Act) must bear a UDI, and data must be submitted to the GUDID database.
Two years after publication of the final rule	The labels and packages of implantable, life-supporting, and life-sustaining devices must bear a UDI, and data must be submitted to the GUDID database. Devices that are life-supporting or life-sustaining, intended to be used more than once, and intended to be reprocessed before each use must bear a UDI as a permanent marking on the device itself.

Compliance Date	Requirement
Three years after publication of the final rule	The labels and packages of class II medical devices must bear a UDI, and data must be submitted to the GUDID database. Class III devices intended to be used more than once and intended to be reprocessed before each use must bear a UDI as a permanent marking on the device itself.
Five years after publication of the final rule	The labels and packages of class I medical devices and devices that have not been classified into class I, class II, or class III must bear a UDI, and data must be submitted to the GUDID database. Class II devices intended to be used more than once and intended to be reprocessed before each use must bear a UDI as a permanent marking on the device itself.
Seven years after publication of the final rule	Class I devices, and devices that have not been classified into class I, class II, or class III intended to be used more than once and intended to be reprocessed before each use must a bear a UDI as a permanent marking on the device itself.

The UDI functions as the key that can be used to obtain critical information from the GUDID about the medical product. The UDI is a unique numeric or alphanumeric code that consists of two parts:

- a device identifier (DI), a mandatory, fixed portion of a UDI that identifies the labeler and the specific version or model of a device, and
- a production identifier (PI), a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of a device:
- the lot or batch number within which a device was manufactured;
- the serial number of a specific device;
- the date a specific device was manufactured; and
- the distinct identification code required for human cell, tissue, or cellular and tissue-based products (HCT/P) regulated as a device.

Only the DI will be used in the GUDID, and the GUDID will include only information that is important to the identification of devices. For example, the GUDID will not include any information that would identify a patient.

Based on the draft guidance issued by FDA, information submitted to the GUDID may require the use of Structured Product Labeling (SPL). SPL is a HL7 standard for the exchange of product information using extensible markup language (XML). It is the same format currently used by FDA for listing drug products. Preparation and submission of SPL files requires knowledge in programming, although some web-based tools have been provided for preparing drug registration and listing SPL files.

It is recommended that all medical device manufacturers prepare an action plan for implementing the requirements of the unique device identification system rule.

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