

The FDA Proposes New Rule on Unique Medical Device Identification and Marking Requirements

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The United States Food and Drug Administration (FDA) has proposed a rule establishing a unique device identification system for medical devices and requiring a unique device identifier (UDI) to be placed on medical devices and device packages. *See* 77 FR 40736 (July 10, 2012). The FDA intends the unique device identification system to reduce medical errors, create greater accuracy in adverse event reporting and post-marketing surveillance, and facilitate recalls. The proposed rule, which was promulgated in accordance with the Food and Drug Amendments Act of 2007, is the result of pilot testing and public input. The UDI requirements, process, and implementation schedule are of particular interest to medical device and instrument manufacturers, and will have an impact on manufacturing and supply chain operations. Comments on the proposed rule may be submitted to the FDA by November 7, 2012.

Goals of the UDI System

In its 164-page proposal, the FDA enumerated several benefits that the UDI rule is intended to achieve. Once implemented, the FDA expects the proposed rule to facilitate rapid and accurate identification of medical devices, thereby improving safety and effectiveness of use. Establishing a set of common identifiers for medical devices may reduce confusion that can lead to inappropriate use of a device and decrease medical errors. The inclusion of UDIs for reference in adverse event reports may enable manufacturers and FDA to detect and analyze issues with particular devices more quickly, isolate underlying issues, and fashion solutions. Finally, the proposed rule is expected to allow manufacturers, distributors, and healthcare facilities to manage medical device inventory and recalls by improving ease of tracking a particular device, post-marketing surveillance studies, and identification among other products.

UDI Marking Requirements

Each UDI must include two numeric or alphanumeric identifiers: 1) a *device* identifier specifying the version or model of a device and its labeler; and 2) a *production* identifier providing variable information such as: lot or batch information; the serial number of a specific device; the expiration date of a specific device; and the date on which a device was manufactured. The proposed rule also requires that dates on medical device labels conform to a standard format, *i.e.*, Month, Day, Year (e.g., JAN 1, 2012), to ensure that dates are unambiguous.

The UDI must be provided in a plain-text version and in a form that uses automatic-identification and data capture (AIDC) technology. UDIs must be issued under a system operated by FDA or an FDA-accredited issuing agency and conform to international standards.

The UDI is not structured to provide direct information concerning a device; the device identifier is a reference number that will allow users to find data concerning the device in an FDA database, the Global Unique Device Identification Database (GUDID). This database, which will be available to manufacturers as well as the general public, will contain information about devices labeled with a UDI, but will not include patient information.

Certain types of devices must be directly marked with a UDI. Direct marking will allow accurate identification of devices without the need to reference labels, inserts, or packaging. Direct marking will be required on implantable devices, devices intended to be used more than once and which require sterilization before each use, and stand-alone software, as these devices are more likely to be separated from their labels.

The FDA states in its proposal that direct marking will not always be appropriate or feasible; accordingly, direct marking will not be required when implementation of a label would interfere with the safe and effective use of the device or is not technologically feasible. Labelers who determine that a device qualifies for an exemption will be required to document the basis of that decision in the design history file and send a notice to FDA.

The FDA seeks comment on whether flexibility in the direct marking requirement will achieve an appropriate balance. For an example of the marking system, click [here](#).

Retail and Class I Exemptions

Some devices will be exempt from the UDI requirements. The FDA proposed an exception for devices, other than prescription devices, which are sold at retail establishments. Examples include automatic external defibrillators, insulin syringes, glucometers, tampons, thermometers, toothbrushes, and bandages. In addition, certain class I medical devices, investigational devices, and devices intended for export will not be required to bear UDIs.

Implementation Schedule

The proposed rule includes tiered effective dates, which will result in a phased-in implementation of the rule:

- > Class III medical devices and devices licensed under the Public Health Service Act must be marked with a UDI within one year of the publication of the final rule;
- > Class II medical devices that are covered by the rule must bear a UDI within three years of the publication of the final rule; and
- > Class I medical devices and devices not otherwise classified that are covered by the rule must bear a UDI within five years of the publication of the final rule.

By implementing the rule in stages, the FDA asserts that it will have time to address unforeseen weaknesses or problems with the UDI system and take corrective action. Manufacturers must understand the marking system and be prepared to establish a marking system according to the tiered, phased-in schedule. The feasibility of marking must be considered on a device-by-device, and the responsibility rests with manufacturers to request an exemption or develop an operation protocol for each device that satisfies the UDI substance and marking requirements of the rule.

Costs are Borne by Labelers

The majority of the costs associated with implementation of the rule are expected to be borne by labelers of medical devices. The Eastern Research Group, Inc. (ERG) prepared cost analyses for the FDA concerning the implementation of the proposed rule. For domestic labelers, ERG projects that the total present value cost over ten years will be about \$500 million, and the total annualized costs will be about \$65 million over the same period.

Comments are Due by November 7, 2012

The FDA requests feedback on its proposed rule, and comments may be submitted by November 7, 2012. The text of the proposed rule is available [here](#). Additional information about the proposed rule, including the FDA's press release and the ability to sign up for electronic updates, is available on the FDA's website [here](#).

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