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Client Alert

FDA & Life Sciences Practice Group

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FDA Issues Proposed Unique Device Identifier Rule
UDIs Will Be Required on Most Device Labels and Packages

On July 10, 2012, the Food and Drug Administration (FDA or "the Agency") published a proposed rule entitled Unique Device Identification System.[1] In the Food and Drug Administration Amendments Act of 2007 (FDAAA), Congress directed FDA to issue regulations to implement a unique device identifier (UDI) system. Following four pilot programs and input from industry, healthcare professionals, hospitals, payors, and patients, FDA drafted and promulgated the proposed rule.

In its press release regarding the UDI proposed rule, FDA lists the benefits that the Agency believes will result from implementation of a UDI system.[2] These benefits are: (1) more accurate reporting, reviewing, and analyzing of adverse events, leading to quicker corrective actions; (2) reduced medical errors through more rapid and precise identification of a device and its characteristics; (3) consistency in the way medical devices are referenced in electronic health records and clinical information systems; (4) more effective management of recalls through standardized identifiers; and (5) a foundation for a secure global distribution chain, thereby helping to address counterfeiting, diversion, and emergencies. The preamble to the proposed rule provides further detail on what FDA believes are the benefits of its proposed rule. The Agency recognizes that the full benefits of the proposed UDI system will not be realized until healthcare facilities adopt or modify information technology systems that can store and access UDI information across administrative, clinical (including electronic health records), and payment systems. Under the proposed rule, however, these facilities are not required to modify their existing systems or to adopt new ones.

The proposed rule creates new sections in FDA's regulations in 21 C.F.R.: Section 801.3 contains definitions relevant to UDI labeling; Subpart B in Part 801 contains labeling requirements for unique device identification; and Part 830 addresses the mechanics of obtaining a unique device identifier and the information that must be submitted to FDA in connection with unique device identifiers. The proposed rule also adds conforming amendments to existing FDA regulations, including Part 803 (medical device reporting), Part 806 (reports of corrections and removals), Part 810 (mandatory recalls), Part 814 (premarket approvals), Part 820 (Quality System regulation (QSR)), and Part 822 (postmarket surveillance).

Comments on the proposed rule must be submitted to docket number FDA-2011-N-0090 by November 7, 2012.

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The Unique Device Identifier (UDI)

The UDI is an alpha-numeric code assigned by an FDA-accredited issuing agency that allows healthcare professionals, patients, and other users to access basic identifying information about a specific version or model of a medical device via an FDA-run database, the Global Unique Device Identification Database (GUDID). The UDI must be provided in both plain text format and a second format that can be read by automatic identification and data capture (AIDC) technology, such as a bar code, radiofrequency identification (RFID) tag, or near field communication (NFC). The UDI is not decodable in the manner that a National Drug Code (NDC) number is; rather, the UDI only serves as a reference number for accessing information in the GUDID.

The UDI consists of two parts: the *device identifier* and the *production identifier*. The device identifier links to the specific version or model of a device and the name and contact information for the labeler (typically the manufacturer, as explained below). The production identifier contains the following additional information, but only if that information already appears on the device label: lot or batch number, serial number, expiration date, and/or date of manufacture. The UDI proposed rule does not require the inclusion of any of this information on device labels, but if the information does appear on the label, then it must be part of the production identifier. Class I devices are not required to have a production identifier in their UDIs.

Labeling with the UDI

The proposed rule requires the UDI to be provided on the device label and the device package both in plain text and an AIDC format. When AIDC technology is not visible (*e.g.*, RFID tag), the UDI label on the device label and package must include a symbol that provides notice of the AIDC technology.

Certain devices that are used for extended periods of time and are likely to be separated from their labels must also be directly marked with a UDI on the device itself. The three categories of these direct marking devices are: implantable devices intended to be used for at least thirty days, devices intended for sterilization and reuse, and stand-alone software. For implantable devices and reusable sterile devices, the direct marking must be provided by either easily-readable plain text, AIDC technology or alternative technology that allows for identification of the device, or both. For stand-alone software, the direct marking must be provided by a plain text statement that is displayed when the software is started or in response to a menu command. FDA proposes some exceptions from the direct marking requirement, such as when it is not technologically feasible (*e.g.*, marking bone cement), the capital investment for direct marking greatly exceeds the benefit of the direct marking, the device has been previously directly marked, or the device is sold at retail and has a Universal Product Code (UPC).

The *labeler* is responsible for ensuring that each device meets the UDI requirements. The labeler will typically be the manufacturer of the device, but specifications developers, reprocessors, convenience kit assemblers, repackagers, and relabelers may also be considered labelers for the purpose of the UDI rule. FDA defines labeler as "[a]ny person who causes a label to be applied to a device [or who causes the label to be modified] with the intent that the device will be introduced into interstate commerce without any intended subsequent replacement or modification of the label." Distributors that add the name of and contact information for the distributor, but that do not otherwise modify the label, are not considered labelers.

Labelers will be required to keep records linking UDIs to the associated device version or model for three years from the date the version or model is no longer marketed.

Exceptions from the UDI Requirement

Proposed 21 C.F.R. § 801.30 contains twelve exceptions from the UDI requirement. The following categories of devices would not need to be labeled with a UDI:

- Over-the-counter devices sold at retail establishments. This exception also would apply to these same devices when provided directly to healthcare facilities.
- Class I devices that are QSR-exempt. This exception includes Class I devices that are subject to 21 C.F.R. § 820.180 (recordkeeping requirements) and § 820.198 (complaint files) if they are exempt from the remainder of the QSR.
- Individual Class I, single-use devices that are distributed together in a single package, with generally-known uses, and that are not intended for individual sale (*e.g.*, box of patient examination gloves, box of adhesive bandages). The device package must contain a UDI label but the individual devices do not need to be separately labeled. Under the proposed rule, labelers of Class II devices that would fit this exception if they were Class I devices can request an exception from FDA.
- Devices "used solely for research, teaching, or chemical analysis, and not intended for any clinical use."
- Custom devices.
- Investigational devices.
- Veterinary medical devices not intended for human use.
- Devices intended for export.
- Devices held by the Strategic National Stockpile (a federal stockpile authorized under the Public Health Service Act to provide rapid access to large quantities of medical products, including medical devices, in the event of an act of terrorism or natural disaster).
- Devices that FDA excludes in the future from the UDI requirement, in conjunction with a recognized performance standard.
- Constituent parts of combination products that can only be used as part of the combination product (described below).
- Single use devices packaged in a convenience kit (described below).

In addition, shipping containers in which medical devices or packages of medical devices are shipped do not need to be labeled with UDIs, although the devices and packages of devices within the container do need to be so labeled. Additionally, as discussed above, Class I devices do not need to be labeled with a production identifier; they only need a device identifier. Finally, the proposed rule provides FDA the authority to grant case-by-case exceptions and alternative labeling requirements.

The Global Unique Device Identification Database (GUDID)

The Global Unique Device Identification Database (GUDID) will contain the information regarding the medical devices identified by UDIs. The GUDID will be available to the general public through FDA's website. FDA will not require submission of any information that would constitute a trade secret, confidential commercial information, or protected privacy information (*e.g.*, patients' names or other identifiers).

The labeler will be responsible for submitting the information to the GUDID for any device required to carry a UDI. The following information will be available in the GUDID and must be reported by the labeler:

- Device identifier portion of the UDI (the specific version or model of a device and the name and contact information for the labeler).
- Any previously-used device identifiers for the particular medical device.
- For devices with direct marking UDIs: either (i) a statement that the device identifier on the device is identical to the device identifier on the label or (ii) a copy of the unique device identifier that is on the device if it is different from the device identifier on the label.
- Proprietary, trade, or brand name of the device.
- Version or model number.
- For devices labeled as sterile, a statement that the device is labeled as sterile.
- For devices labeled as containing latex, a statement that the device contains latex.
- Size of the device, with the unit of measure, if the device is available in more than one size.
- Type of production identifiers, if any (*e.g.*, lot/batch number, manufacturing date, expiration date, serial number). The GUDID does not have to provide the specific information for the production identifiers; it must only state which types of production identifiers are printed on the label and/or package.
- Premarket submission number for approved or cleared devices.
- FDA listing number assigned to the device (this will not be visible to the public).
- Global Medical Device Nomenclature (GMDN) generic descriptor for the device, but only if GMDN data are available to the public at no cost when the rule is finalized. The purpose of GMDN descriptors is to provide a single naming system for types of devices to facilitate the exchange of safety data between regulatory agencies.
- Total number of devices in the package.

FDA may also allow labelers to submit "ancillary information" if the labeler so wishes. The ancillary information that FDA will accept for inclusion in the GUDID will be listed on the GUDID website[3] and may change periodically.

Assigning a UDI

All UDIs must be issued by an FDA-accredited issuing agency, either a state agency or a private non-profit organization. The proposed rule provides the criteria and application process for selection as an accredited issuing agency. FDA has not yet selected any such agencies. Under certain circumstances, FDA will act as the issuing agency, specifically, when there are no FDA-accredited issuing agencies or if FDA determines that small businesses would be substantially and adversely affected by the fees charged by accredited issuing agencies. FDA would not charge any fees when acting as an issuing agency.

Special Situations: Combination Products, Convenience Kits, Multi-Packs

Combination Products

According to the proposed rule, if a combination product's primary mode of action is as a device, then the combination product must be labeled with a UDI and the device constituent part must also be labeled with a separate UDI. On the other hand, if a combination product's primary mode of action is as a drug, the package for the combination product would not need a UDI label, but the device constituent part must nevertheless be labeled with a UDI. However, if a device constituent part of a combination product can only be used as part of the combination product because it is physically, chemically, or otherwise combined with the other constituent part(s) (*e.g.*, a drug eluting stent), then the device constituent part would not need a UDI.

Convenience Kits

As defined in the proposed UDI regulations, a convenience kit contains two or more different devices packaged together for the convenience of a user. The convenience kit itself would need to be labeled with a UDI. Each device within the kit would also need a distinct UDI, if a UDI would be required if the device were packaged separately. Single use devices included in a convenience kit would not need to be labeled with a separate UDI.

Multi-Packs

Under the proposed rule, when multiple devices are packaged together within one package, the package must contain a UDI and each individual device must be labeled with a UDI as well. This would apply to any package that contains a fixed quantity of devices, including packages that contain other packages. Shipping containers, however, would not need UDI labels because they often have variable contents and quantities. FDA provides the following example:

> [I]f a device is sold in individual device packages, which are sold in boxes of five device packages, which are sold in cartons that contain ten boxes of five device packages, a UDI would be required to appear on the individual device package, on the box of five packages (which is itself a 'device package' . . . because it contains a fixed number of devices), and on the carton of ten boxes of five device packages (again, because the carton is a 'device package.')

Timeline for UDI Labeling

The elements of the UDI rule, once final, will be implemented in a staged process, over the course of several years. Class III devices and devices licensed under the Public Health Service Act would be the first devices to which the rule would apply, beginning one year after FDA publishes the final rule. Class II devices would need to be labeled with UDIs beginning three years after the final rule is published, followed by Class I devices and devices not classified into Class I, II, or III, five years after publication of the final rule. The GUDID data reporting requirements begin at the same time as the UDI labeling requirements for each group of devices. The requirement for direct marking of certain devices (described above) goes into effect two years after the UDI label requirements go into effect for the type of device that must be directly marked.

Consistent Date Format

The proposed rule also standardizes the format for all dates (*e.g.*, dates of manufacture, expiration dates) provided on medical device labels. Beginning one year following publication of the final rule, all dates should appear in Month Day, Year format, using a three-letter abbreviation for the month (*e.g.*, JAN 1, 2012).

Other Uses of the UDI

Medical Device Reporting

FDA is proposing to revise the MDR regulations in 21 C.F.R. Part 803 to require manufacturers, user facilities, and importers to include UDIs on MDRs filed with the Agency. FDA also proposes to require UDI information to be provided with adverse events reported by user facilities in annual reports.

Recalls

In the proposed rule, FDA would revise 21 C.F.R. Part 806 to add UDIs to the information that must be provided to the Agency when reporting a correction or removal under Part 806. Additionally, FDA is proposing to revise the regulations in Part 810 so that FDA will include UDIs when providing a cease distribution and notification order pursuant to the Agency's mandatory recall authority.

Premarket Approval Applications

FDA is also proposing to use UDIs in PMA reporting. Specifically, the Agency proposes that each periodic report for Class III devices shall include information on all UDIs in effect at the time that the report is filed and on any UDIs discontinued since the previous periodic report.

Quality System Regulation

The proposed rule modifies the QSR in multiple places to incorporate the use of UDIs. FDA proposes that device labeling not be released for storage or use until the accuracy of the UDI has been inspected. The proposed rule would also require UDIs to be added to device history records, complaint files, and service reports.

Medical Device Tracking

FDA would revise the medical device tracking regulations in Part 821 to require the use of UDIs in tracking systems for medical devices that are subject to tracking requirements.

Postmarket Surveillance

The UDI proposed rule would amend the postmarket surveillance regulations at 21 C.F.R. Part 822 to require the use of UDIs in postmarket surveillance plans submitted to FDA when such postmarket surveillance is required.

Inclusion on Informational and Educational Materials

FDA suggests that the UDI can be included on informational and educational materials that accompany or supplement the device. This is not required, but the Agency believes it could be beneficial and could "provide a quick and useful means for patients and health care professionals to obtain additional information concerning a device, without having to provide that information in the document. This could allow the document to focus on its important core messages without the distraction of greater complexity, while a reader who wants those additional details could use the UDI to obtain information from the GUDID." FDA does not state what type of additional information could be accessed via the GUDID regarding a device, but presumably FDA is referring only to the required elements for the GUDID (listed above) and any ancillary information that the Agency may allow in the future.

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Please contact us if you have questions regarding the potential implications of the proposed rule or if you would like assistance in developing comments to the docket or preparing for implementation of the UDI requirements.

[1] 77 Fed. Reg. 40736 (July 10, 2012).
[2] FDA News Release, "FDA proposes unique device identification system for medical devices," July 3, 2012, *available at* www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm310505.htm.
[3] www.fda.gov/udi