FAQ: Unique Device Identification Final Rule

October 2013

Key Changes from Proposed Rule

- A separate UDI is not required for devices within a convenience kit, regardless of Class designation, so long as the label of the kit bears a UDI.
- Single-use devices within multi-packs (i.e., all of a single version or model, intended to be stored in that device package until removed for use, and which are not intended for individual commercial distribution), regardless of class designation, will only be required to print the UDI on the multi-pack (i.e., the next higher level of packaging) and not on the individual device label.
- Inventories of medical devices manufactured prior to the final rule will be allowed to be sold without UDIs for a period of three years from the compliance date of the device.
- Class I devices that are sold via retail may use the device’s Universal Product Code (UPC) as its UDI on both the device label and highest level of packaging.
- Combination products may use the product’s National Drug Code (NDC) as its UDI on both the product label and the next highest level of packaging.
- The elimination of the requirement for direct marking of the UDI on implantable devices, allowing the code to be printed on the lowest level of packaging rather than the device.
- FDA may grant one-year extensions for specific Class III devices if it is deemed to be in the best interest of the public health.

UDI Labeling Requirements for Medical Devices

**Who is considered a labeler (i.e., ultimately responsible for the placement of a UDI) under the final rule?** The FDA defines a labeler as someone who causes a label to be applied to a device or causes the label to replaced or modified, with the intent that the device will be commercially distributed.

**How does the UDI requirement impact wholesale distributors?** The adoption of UDI by wholesale distributors is not required by the FDA regulation; however, wholesale distributors that engage in relabeling (i.e., private labeling), reprocessing and/or kitting of their medical devices at receipt will bear the responsibility of placing a UDI on a device label, its packaging, or directly marked on the device itself.

**Which devices are required to be directly marked with a UDI?** Any medical device, with the exception of implantable devices, intended to be used more than once and reprocessed (i.e., cleansed, disinfected, or sterilized) between or before each use must be directly marked (i.e., permanently marked) with a UDI on the device itself.

**Are there any exemptions for medical devices under the final rule?** Yes, there are a number of exemptions under the final rule.

- Class I devices do not need to include production identifiers in the UDI; the UDI only needs to contain a device identifier.

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- Class I devices that are exempt under the FDA's good manufacturing practice are completely exempt from UDI requirements.
- All packaged single-use devices (i.e., all of a single version or model, intended to be stored in that device package until removed for use, and which are not intended for individual commercial distribution) are not required to have a UDI on the individual device itself; however, the UDI is required to be printed on the multi-pack.
- Implantable medical devices are not required to be directly marked with a UDI; however, the UDI is required to be on the lowest unit of use packaging.
- Class I devices labeled with a Universal Product Code (UPC) number may use the UPC number as their UDI number on both their device label and package; Class I device labeled with a UPC do not have to have an additional UDI on their device label and package; however, a UDI/UPC is required on both the device label and the highest level of packaging.
- Combination products that have a properly labeled National Drug Code (NDC) may use the NDC number as their UDI number on the highest level of packaging. Combination products labeled with a NDC do not need to have an additional UDI on their product package; however, unless the combination product is a single entity, a UDI number is required on the device constituents.

**What medical devices are subject to the UDI labeling requirements?** Generally, all medical devices subject to FDA oversight are subject to some aspect of UDI labeling requirements (i.e., UDI directly marked on a device or UDI required on next higher level of packaging; or UDI required on both the device and the next higher level of packaging both scenarios), unless they have received an exemption as noted above.

**How are convenience kits treated under the final rule?** A separate UDI is not required for devices within a convenience kit, regardless of Class designation, so long as the label of the kit bears a UDI. Convenience kits not already classified as Class I, II, or III devices are required to have a UDI based on the compliance date associated with the highest class of device in the kit (e.g., if the kit contains a Class II device the kit would have to meet the September 24, 2016 compliance date).

**How are Single Use Devices (SUDs) treated under the final rule?** Single use medical devices (i.e., all of a single version or model, distributed together in a single device package and not intended for individual sale), regardless of class designation, are not required to have a separate UDI on the device label; however, a UDI and/or UPC number is required on the next highest level of packaging.

**How are Class I and Over-the-Counter devices treated under the final rule?** Class I devices labeled with a Universal Product Code number may use the UPC number as their UDI number; Class I devices labeled with a UPC do not have to have an additional UDI on their label.

**How does the final rule treat combination products?** All combination products much bear a UDI; however, there are some exceptions.
- If a combination product has a National Drug Code number, then it is exempt from UDI requirement on the highest level of packaging. The NDC on the highest level of packaging will serve as the product’s UDI; however, the device constituent parts must have their own UDI unless...
- A combination product is a single entity (i.e., combination products where the device constituent parts are physically, chemically, or otherwise combined in way that you cannot separate those or use the device separately from the combination product) a separate UDI is not required on the device constituent parts and is only required on the highest level of packaging.

**How are devices intended to be used more than once and reprocessed (i.e., cleansed, disinfected, or sterilized) between or before each use treated under the final rule?** Any medical device, with the exception of implantable devices,
that is intended for more than one use and intended to be reprocessed before each use must bear a permanent marking providing the UDI on the device itself.

**How are implantable devices treated under the final rule?** Implantable devices do not have to be directly marked with a UDI; however, a UDI is required at the lowest level of packaging.

**Which devices will need to be directly marked with a UDI?** Any medical device, with the exception of implantable devices, is intended for more than one use and intended to be reprocessed before each use must bear a permanent marking providing the UDI on the device itself.

**Are there any exceptions to the direct marking requirement?** Yes, an exception will be granted if a manufacturer determines that:

- Direct marking would interfere with the safety or effectiveness of the device;
- Direct marking is not technologically feasible;
- The device is a reprocessed single-use device;
- The device has been previously marked.

Any manufacturer who determines that they cannot directly mark their product needs to note that in the design history file of their device.

**How is stand-alone software treated under the final rule?** Stand-alone software has to be able to make the UDI available to the user in plain text when started (e.g., in a help screen or an about screen). If the software is distributed in packaged form, it may use the same UDI for both the package and display screen. The compliance dates for stand-alone software are the same as the class compliance dates.

**Compliance Dates**

**When will the UDI system be implemented?** The UDI system will be implemented in phases over seven years, initially focusing on high-risk medical devices and devices licensed under the Public Health Service Act (e.g., implantable, life-supporting, and life sustaining devices).

- **September 24, 2014** - Class III medical device and/or a devices licensed under the Public Health Service Act
- **September 24, 2015** - Any implantable, life supporting, or life sustaining device not designated by the FDA as Class III
- **September 24, 2016** - Class II medical devices
- **September 24, 2018** - Class I medical devices
- **September 24, 2018** - Any other device not classified into Class I, II, or III
- **September 24, 2020** – Class I devices, and devices that have not been classified into Class I, Class II, or Class III that are required to be labeled with a UDI must bear a UDI as a permanent marking on the device itself if the device is intended to be used more than once and intended to be reprocessed before each use.

**Are there any exceptions to the compliance dates?** Yes, exceptions include:

- The FDA may grant a one-year extension to the compliance date for Class III devices or devices licensed under the Public Health Service Act if it is determined to be in the best interest of the public health.

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• Finished devices that are manufactured and labeled prior to the compliance date may be distributed for an additional three years after the existing compliance date associate with the finished device.

UDI Framework

**What is a Unique Device Identifier (UDI)?** A UDI is an alpha-numeric or numeric code, on a device label, its packaging, or directly marked on the device itself. The UDI must be represented in both plain text (i.e., human readable) and machine-readable format (e.g., codes, linear or two-dimensional, or RFID technology). Once fully implemented, the system is poised to help facilitate product recalls and assist in adverse event reporting.

**What will the UDI consist of?** There are two parts to the UDI: 1) the Device Identifier, which is specific to a particular version or model of the device and the labeler of the device (e.g., the person who causes the label to be applied to the device) and; 2) the Production Identifiers, which are control mechanisms currently used on a label or device itself (i.e., lot or batch numbers, serial numbers, manufacturing dates, and expiration dates). The UDI will be created and maintained by the device manufacturer; the manufacturer will also create the device identifiers and the production identifiers for their devices.

**What does the UDI final rule require?** Generally, the label and package (i.e., lowest level of packaging) of every medical device, unless otherwise excluded, must contain a unique number assigned by the manufacturer by the compliance date established for the device. Some devices require direct marking. Once a medical device becomes subject to UDI requirements, medical device labelers are required to update the information reported on the device via the FDA’s Global Unique Device Identification Database (GUDID) whenever the information changes.

**Will any proprietary information be captured in the public side of the Global Unique Device Identification Database (GUDID)?** The public side of the GUDID database will not contain any individual contact information, except for optional customer-service information if the submitting company chooses to provide individual contact information for that purpose. HIDA has prepared a separate document outlining the key components of the FDA’s draft guidance on the Global Unique Device Identification Database.

**Does the final rule require a particular production identifier be used?** No, the UDI rule does not require any particular production identifier. The production identifiers currently on a device or on the label of a device can be used in the UDI.

**Does the FDA identify any specific technology that can or cannot be used?** The FDA has taken a “technology-neutral” approach and does not identify any specific technology. Any form of automatic identification technology (e.g., codes, linear or two-dimensional, or RFID technology) is acceptable.

**What type of standards organization may apply for accreditation?** Any private organization (e.g., GS1, HIBCC, ICCBBA) may apply for accreditation as an issuing agency. A manufacturer will choose to work with one of these issuing agencies and will develop a UDI according to the standard of those organizations.

Definitions

**Automatic identification and data capture (AIDC):** means any technology that conveys the unique device identifier or the device identifier of a device in a form that can be entered into an electronic patient record or other computer system via an automated process. Expiration date means the date by which the label of a device states the device must or should be used.

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**Finished device:** means any device or accessory to any device that is suitable for use or capable of functioning. Global Unique Device Identification Database (GUDID) means the database that serves as a repository of information to facilitate the identification of medical devices through their distribution and use.

**Lot or batch:** means one finished device or more that consist of a single type, model, class, size, composition, or software version that are manufactured under essentially the same conditions and that are intended to have uniform characteristics and quality within specified limits.

**Label:** means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this Act that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper.

**Labeler:** means (1) Any person who causes a label to be applied to a device with the intent that the device will be commercially distributed without any subsequent replacement or modification of the label; and (2) Any person who causes the label of a device to be replaced or modified with the intent that the device will be commercially distributed without any subsequent replacement or modification of the label, except that the addition of the name of, and contact information for, a person who distributes the device, without making any other changes to the label, is not a modification for the purposes of determining whether a person is a labeler.

**Shipping container:** means a container used during the shipment or transportation of devices, and whose contents may vary from one shipment to another.

**Unique device identifier (UDI):** means an identifier that adequately identifies a device through its distribution and use. A UDI is composed of: (1) A device identifier--a mandatory, fixed portion of a UDI that identifies the specific version or model of a device and the labeler of that device; and (2) A production identifier--a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of the device:

- The lot or batch within which a device was manufactured;
- The serial number of a specific device;
- The expiration date of a specific device;
- The date a specific device was manufactured.
- For an HCT/P regulated as a device, the distinct identification code.

**Universal Product Code (UPC):** means the product identifier used to identify an item sold at retail in the United States.

**Version or model:** means all devices that have specifications, performance, size, and composition, within limits set by the labeler.

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