FDA Proposes Rule Mandating Unique Device Identifiers for Medical Devices

Kristi L. Wolff

July 23, 2012

On July 10, 2012, the Food and Drug Administration ("FDA") published a proposed rule implementing Federal Food, Drug, and Cosmetic Act ("FD&C Act") provisions establishing a unique device identification system for medical devices. Section 226 of FDAAA amended the FD&C Act to add new section 519(f), which directs FDA to promulgate regulations establishing a unique device identification system for medical devices: "Unique Device Identification System. The Secretary shall promulgate regulations establishing a unique device identification system for medical devices requiring the label of devices to bear a unique identifier, unless the Secretary requires an alternative placement or provides an exception for a particular device or type of device. The unique identifier shall adequately identify the device through distribution and use, and may include information on the lot or serial number." The recently enacted[1] Food and Drug Administration Safety and Innovation Act ("FDASIA") reemphasized Congressional interest in developing a unique device identification system by directing FDA to issue a proposed rule for the system by December 31, 2012. The proposed rule would dovetail with § 605 of FDASIA which directs FDA to develop an improved device recall assessment program that would, at a minimum, identify:

1. Trends in the number and type of device recalls;
2. Which types of devices are most frequently subject to recall;
3. Underlying causes of device recalls.

The proposed unique identifier system is expected to capture the information necessary to allow FDA to fulfill this requirement.

New Rule Would Require Medical Devices in All Classes to Have Unique Identifiers, With Exceptions

The proposed rule would require medical device manufacturers—including a specification developer, a single-use device reprocessor, a convenience kit assembler, a repackager, a relabeler, or any other person who applies a label to or modifies a label on a device that will not be modified again before sale—to place a unique device identifier ("UDI") on the label and packaging of medical devices both in plain-text and also using automatic identification and data capture ("AIDC") technology. FDA intentionally did not identify the particular type of AIDC technology to be used. The proposed rule would leave the decision of whether to use technology like an advanced barcode or a radio frequency identifier (RFID) to the manufacturer allowing for flexibility and advancements in technology. Certain devices that may become separated from packaging and/or labels because the

product is intended for long term use, implantation, or the product is stand-alone software regulated as a medical device would have to be directly marked with a UDI.

The UDI would not actually hold any product identification information. Instead, the manufacturer must submit identifying information to the GUDID including inter alia:

1. The device model number,
2. The proprietary, trade, or brand name of the device as it appears on the label of the device,
3. If the device is labeled as sterile, requires sterilization for use or contains latex, a statement to that effect,
4. The FDA listing number assigned to the device,
5. The number of individual devices contained in each device package.

FDA would aggregate the manufacturer-provided information in a new Global Unique Device Identification Database ("GUDID"). This public database would allow a physician to scan or manually enter the UDI of a device at a patient's bedside and quickly access complete information regarding the device's key attributes and proper use instructions.

FDA Expects New Program Would Yield Many Benefits

The main public health driver of the proposed rule is reduction in medical errors. By aggregating device information, FDA also expects that safety and recall issues can be addressed more effectively and more quickly. The broad benefits that the agency expects from implementation of the UDI system are the following:

- **Reduce Medical Errors**. With one scan, any individual can reach critical device information including the specific model, whether it needs to be sterilized before use and whether the product is involved in a recall. This would ensure recalled devices are not accidentally used in patient care and that the specific device prescribed by the doctor and not one "like it" is used in caring for a particular patient.
- **Simplify the Integration of Device Use Information into Data Systems**. UDIs are intended to streamline physician ordering systems making it easier for doctors to identify the particular device they want to prescribe reducing confusion that could cause errors.
- **Provide for More Rapid Identification of Medical Devices With Adverse Events**. Including a UDI in adverse event reports are expected to increase accuracy in reporting which device or devices were involved in an adverse event.
- **Provide for More Rapid Development of Solutions to Reported Problems**. Manufacturers and FDA can more rapidly review, aggregate, and analyze related reports regarding a particular device, leading to more rapid isolation and identification of the underlying problems, and development of an appropriate solution to a particular concern.
- **Provide for More Rapid, More Efficient Resolution of Device Recalls**. A device labeled with a UDI can be identified rapidly and with great precision and the UDI, particularly when combined with AIDC technology, will hasten the identification of devices that are the subject of a recall. The more rapidly a recall is implemented and completed, the more rapidly the risks

presented are reduced and eliminated.

- **Better-Focused and More Effective FDA Safety Communication**. By citing UDIs, FDA would be able to more precisely focus safety alerts, public health notifications, or other communications, eliminating confusion with similar devices and allowing more rapid responsive action. This more tailored approach will also prevent other devices from being swept up in an overbroad recall.
- **Provide an Easily-Accessible Source of Definitive Device Identification Information**. Including UDIs in informational and educational materials, such as package inserts, training materials, educational materials, and other supplementary information, 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.
- **Additional Benefits**. Incorporating UDIs into electronic patient records would allow healthcare providers to capture important information regarding the use (including implantation) of a device on a patient. UDIs can also be used to identify similar products in the event of a shortage and could help detect counterfeit devices.

Benefits Would Require Buy-In from Health Care Stakeholders

The proposed rule was developed using industry pilot programs and public workshops with industry stakeholders including device manufacturers as well as hospitals and health care facilities. While the labeling and reporting requirements of the new UDI system would be mandatory for medical device manufacturers, use of the UDI system by health care facilities remains optional. The success of this new program relies in large part on hospitals and health care facilities voluntarily adopting technology and procedures necessary to use the UDI system. Changes would need to be made in administrative, clinical, and payment information systems to fully realize the benefits of the program. Some additional potential benefits for streamlining recalls would also require retailers and manufacturers to make IT system changes.

FDA Seeks to Increase Flexibility and Reduce Burden on Manufacturers by Leveraging Existing Labeling Systems

FDA has proposed a flexible system intended to limit the potential burden placed on medical device manufacturers by utilizing existing labeling systems while still incorporating international labeling standards. The proposed UDI system would incorporate by reference four international standards: International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 646:1991, Information technology--ISO 7-bit coded character set for information interchange; ISO/IEC 15459-4:2006(E), Information technology—Unique identifiers--Part 2: Registration procedures; ISO/IEC 15459-4:2008, Information technology-- Unique identifiers--Part 4: Individual items; and ISO/IEC 15459-6:2007, Information technology--Part 6: Unique identifier for product groupings. The UDI system would incorporate and leverage existing systems including the GS1 Global Trade Identification Number (GTIN); the Universal Product Code (UPC) system used to identify most items sold by retail establishments, and the Health Industry Bar Code (HIBC) system, so long as the administering organizations apply for and obtain FDA accreditation. Furthermore, individual manufacturers would not have to create each UDI. Rather, issuing agencies like the ones mentioned above would control the issuing of new UDIs. This is intended to reduce confusion and the likelihood of duplication. It is also intended to ensure that a UDI is not reused even when a product is

discontinued as the information may still be relevant.

Requirements Would Be Phased In Over Time to Reduce the Burden on Manufacturers

FDA intends to make the program flexible by phasing in the labeling requirements over a period of seven years in accordance with this chart published in the proposed rule:

One year after publication of a final rule	Dates on medical labels must be formatted as required by § 801.18.
	The label and package of class III medical devices and devices licensed under the Public Health Service Act must bear a UDI. § 801.20(b)(1).
	Data for class III devices and devices licensed under Public Health Service Act that are required to be labeled with a UDI must be submitted to the GUDID database. § 830.300.
Three years after publication of a final rule	Class III devices required to be labeled with a UDI must bear a UDI as a permanent marking on the device itself if the device is 1) an implantable device, 2) a device intended to be used more than once and intended to be sterilized before each use, or 3) stand-alone software regulated as a medical device. § 801.50.
	The label and package of class II medical devices must bear a UDI. § 801.20(b)(2).
	Data for class II devices that are required to be labeled with a UDI, must be submitted to the GUDID database. § 830.320.
Five years after publication of a final rule	Class II devices required to be labeled with a UDI must bear a UDI as a permanent marking on the device itself if the device is 1) an implantable device, 2) a device intended to be used more than one and intended to be sterilized before each use, or 3) stand-alone software regulated as a medical device. § 801.50.
	The label and package of class I medical devices and devices that have not been classified into class I, class II, or class III must bear a UDI. § 801.20(b)(3), (4).
	Data for 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 be submitted to the GUDID database. §830.320.
Seven years after publication of final rule	Class I devices and devices that have not been classified into class I, class II, or class III required to be labeled with a UDI must bear UDI as a

permanent marking on the device itself if the device is 1) an implantable device, 2) a device intended to be used more than once and intended to be sterilized before each use, or 3) stand-alone software regulated as a medical device. §801.50.

The phase-in schedule would prioritize identifying more specialized and higher risk devices in Class III as well as those necessitating direct labeling. Though the proposed rule would allow three years for implantation devices requiring direct labeling, the previously-mentioned Food and Drug Safety and Innovation Act passed on July 12, 2012, shortens the window of compliance to two years.[2] FDA is proposing to exempt Class I devices from having to provide production identifiers and proposing full exceptions from UDI labeling and data reporting for certain very low risk devices and other categories of devices.

Proposed Exemptions Could Offer Flexibility, Especially for Class I Devices

FDA acknowledged that there may be situations where a UDI is not necessary because the cost to the manufacturer would outweigh the benefit or would simply be impractical. The agency proposes that exceptions would apply to devices, other than prescription devices, that are sold at retail establishments, such as drug stores; devices sold directly to a hospital or other health care facility; devices used for teaching or research purposes with no clinical application; veterinary devices not intended for human use; and a wide range of devices available at retail, including automatic external defibrillators, insulin syringes, glucometers, tampons, thermometers, toothbrushes, bandages, and more. Because retail items like those listed are usually labeled with a UPC code that can substitute as a UDI, excluding these items is intended to reduce the overall burden of the proposed rule. Other exceptions would apply to any Class I device that FDA has by regulation exempted from the good manufacturing practice (GMP) requirements of part 820, the Quality Systems Regulation. Class I devices, however, are often subject to recalls which could make participation in the UDI system beneficial. FDA is also considering whether each item in a combination product or convenience kit would need its own label.

Manufacturers and small businesses that cannot afford AIDC technology necessary for labeling could apply for individual exemptions if the labeler can demonstrate that application of the standard UDI labeling requirements is not technologically feasible or that the objectives of this rule would be better served by application of an alternative approach. On the other hand, a manufacturer of an exempt product could voluntarily choose to use a UDI and submit product information to GUDID. FDA has indicated that input from industry stakeholders particularly related to cost, practicality and potential exemptions, is critical to the development and success of this program.

FDA Seeks Comments on Implementation of New UDI Program

The agency is particularly interested in receiving comment on the following items:

- **Timeline**: Do the proposed effective dates provide adequate time to prepare to meet the rule's requirements?
- **Use of AIDC Technology**: Should the type of AIDC be mandated? What are the potential costs to your manufacturing of adopting AIDC labeling technology? What types of AIDC manufacturers are likely to use?
- **Labeling Combination Products and Convenience Kits**: When is it most effective to label

all components in a package?

- **Direct Marking of Devices**: How practical and feasible is it to directly mark implantable or reusable devices and stand-alone software? Should the requirement be limited to certain types of implants? If so, how should we define which implantable devices meet that requirement? Are there good reasons to require direct marking for all devices intended for more than one use, regardless of whether the device must be sterilized before each use? Are there other types of devices that you believe would benefit from direct marking?

- **Exemptions**: To what extent should devices sold in retail establishments and other Class I devices be subject to or exempted from the requirements of this proposed rule? Are the categorical exemptions provided sufficient? Should other categorical exemptions apply? What are the potential costs of adapting manufacturing facilities to implement proper labeling systems?

All comments must be submitted by November 7, 2012.

Kelley Drye & Warren LLP

Kelley Drye's team of Food and Drug lawyers strives to integrate our clients' business strategies with FDA compliance and to help resolve regulatory enforcement matters when they arise. Working side-by-side with business development and marketing professionals, we provide comprehensive regulatory counseling and assist in developing products, labels, and promotional materials that achieve our clients' goals without running afoul of regulatory requirements. With close knowledge of FDA's enforcement priorities and deep experience with the FTC's regulation of advertising, our team can provide comprehensive legal advice with an eye towards giving clients a competitive edge.

For more information about this Client Advisory, please contact:

Kristi L. Wolff
(202) 342-8805
kwolff@kelleydrye.com

---

[1] The Food and Drug Administration Safety and Innovation Act was signed into law on July 9, 2012.

[2] Food and Drug Safety and Innovation Act of 2012, Pub. L. No. 112-144 § 614 (2012).