COVINGTON

COVINGTON & BURLING LLP

ADVISORY | Food & Drug

July 16, 2012

FDA ISSUES PROPOSED RULE TO ESTABLISH A UNIQUE DEVICE IDENTIFICATION SYSTEM FOR MEDICAL DEVICES

On July 11, 2012, the Food and Drug Administration (FDA) published in the Federal Register its long-awaited proposed rule to establish a unique device identification system for medical devices.[1] Comments on the proposed rule are due by November 7, 2012.

If finalized, the proposed rule would require the label of medical devices and device packages to bear a unique device identifier (UDI) provided in a plain-text version and in a form that uses automatic identification and data capture technology. In addition, some device types would require direct marking. FDA has also proposed to require the submission of information concerning each device to a new database, the Global Unique Device Identification Database (GUDID), that FDA intends to make public. The requirements of the proposed rule would be phased in over several years.

The proposed rule is significant, and the requirements and exceptions are complex. Key provisions of the proposal are described below.

BACKGROUND

Section 226 of the Food and Drug Administration Amendments Act of 2007 amended the Federal Food, Drug, and Cosmetic Act (FDCA) to add a new section 519(f) directing FDA to promulgate regulations establishing a UDI system for medical devices requiring the label of devices to bear a unique identifier that adequately identifies the device through distribution and use.[2] FDA held a public workshop in February 2009 to discuss issues relating to establishment of a UDI system and asked interested persons to submit comments.[3]

On July 9, 2012 the President signed into law the FDA Safety and Innovation Act, which amended section 519(f) of the FDCA to require the Secretary of Health and Human Services to issue proposed regulations establishing a UDI system by December 31, 2012, a deadline FDA met by the issuance of this proposed rule. The bill also amended the FDCA to require the Secretary to finalize the proposed regulation not later than 6 months after the close of the comment period on the proposed rule and to implement the final regulations with respect to devices that are implantable, life-saving, and life sustaining not later than two years after the regulations are finalized.[4]

---

[1] FDA, Unique Device Identification System, Proposed Rule, 77 Fed. Reg. 40736 (July 10, 2012). The proposed rule would principally amend 21 C.F.R. Part 801 and add new 21 C.F.R. Part 830. It would also amend Parts 803, 806, 810, 814, 820, 821, and 822.

[2] FDCA § 519(f), 21 U.S.C. § 360i(f).

[3] FDA, Unique Device Identification System, Public Workshop, Request for Comments, 74 Fed. Reg. 2601 (Jan. 15, 2009). In fact, FDA's efforts to develop a UDI system preceded FDAAA. The agency held public meetings in 2005 and 2006 and published a request for comments from stakeholders in 2006.

[4] FDA Safety and Innovation Act, S. 3187, 112th Cong., 2d Sess. § 614 (2012).

SUMMARY OF PROPOSED RULE

1. Who must comply with the rule?

The "labeler" of a device would be responsible for meeting the UDI labeling requirements.[5] FDA proposed to define "labeler" as any person who causes a label to be applied to a device, or who causes the label to be modified (except for the addition of the name and contact information of a distributor), with the intent that the device be introduced into interstate commerce without subsequent replacement or modification.[6] The labeler will ordinarily be the device manufacturer. However, the labeler could include a specifications developer, convenience kit assembler, repackager, or relabeler.

The term does not include persons who label a device on the instructions of the person who actually places the device into interstate commerce. Thus, a contractor who labels a device following the instructions of the specification developer or manufacturer would not be the labeler.[7]

2. To which devices would the rule apply?

The proposed rule would require the labels and packages of most class II and class III devices to bear a UDI, as well as class I devices that are subject to the good manufacturing practice requirements of the Quality System Regulation (QSR).[8]

The UDI requirement would apply to combination products for which the primary mode of action is that of a device, regardless of which FDA Center has been designated as having primary jurisdiction. In addition, the label of the device constituent part(s) of a combination product, regardless of the primary mode of action of the combination product, would be required to bear its own UDI, distinct from any UDI assigned to the combination product. However, the requirement to mark the device constituent part of a combination product does not apply if that device part is physically, chemically, or otherwise combined with other constituents such that it is not possible to use the device constituent except as part of the combination product.[9]

The UDI requirement would apply to the label and package of each convenience kit consisting of two or more different types of medical devices packaged together. Each device in a convenience kit would be required to bear its own UDI (distinct from the UDI of the convenience kit), unless the device is intended for a single use.[10]

All UDI labeling requirements would also apply to in vitro diagnostic devices.[11]

The following types of devices would be excepted from the UDI requirement:

- a device available for purchase at a retail establishment (other than a prescription device);

---

[5] 77 Fed. Reg. at 40747, 40774.
[6] *Id.* at 40768 (proposed 21 C.F.R. § 801.3).
[7] *Id.* at 40747.
[8] If a class I device is exempted from the good manufacturing practice requirements of the QSR, or remains subject to only the QSR requirements concerning recordkeeping (21 C.F.R. § 820.180) or complaint files (21 C.F.R. § 820.198), the device would qualify for an exception from the UDI labeling requirements. 77 Fed. Reg. at 40749, 40770.
[9] 77 Fed. Reg. at 40749, 40769 (proposed 21 C.F.R. §§ 801.25(a)-(b)).
[10] *Id.* (proposed 21 C.F.R. §§ 801.25(c)-(d)).
[11] *Id.* (proposed 21 C.F.R. § 801.119).

- class I single-use devices that are distributed together in a single package (that package is not exempt);
- a device used solely for research, teaching, or chemical analysis and not intended for any clinical use;
- a custom device;
- an investigational device;
- a veterinary medical device;
- a device intended for export outside the United States;
- a device held by the Strategic National Stockpile; and
- a device for which FDA has established a performance standard and has recognized an exception to the UDI requirement.[12]

Exempted devices may voluntarily include a UDI on the label of the device.[13]

3. What is the form and content of the proposed UDI?

The proposed rule would require a UDI to be composed of two parts: (1) a device identifier, and (2) a production identifier. A "device identifier" is a mandatory, fixed portion of a UDI that identifies the specific version or model of a device and the labeler of that device. A "production identifier" is 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, the serial number, the expiration date, or the date of manufacture.[14] FDA noted that the "UDI is not structured to provide direct information concerning a device; the device identifier is a reference number that allows you to find data concerning the device in an FDA database, the GUDID."[15]

All UDIs would need to include a device identifier segment. Whenever a device is labeled with a lot or batch number, a serial number, an expiration date, or a manufacturing date, the UDI would need to include a production identifier segment that conveys such information.[16] However, the UDI of a class I device is not required to include a production identifier.[17]

The UDI must be presented in both easily-readable plain text and automatic identification and data capture (AIDC) technology.[18] FDA did not specify a particular font or point size for the UDI; rather, the UDI is subject to existing requirements that govern medical device labels. FDA also did not specify any particular AIDC technology, which may be a bar code, RFID, near-field communications, or any other technology. FDA recognized that the most appropriate technology might depend on the device type and that the technology might evolve over time. However, FDA believes that most labelers would choose to meet the AIDC technology requirement by providing a bar code.[19]

If the AIDC technology is not evident upon visual examination of the label or device package, the label or package must bear a symbol that provides notice of the presence of AIDC technology. The symbol may be a symbol approved by the issuing agency, a symbol endorsed in a national or

[12] *Id.* at 40749-51, 40770 (proposed 21 C.F.R. § 801.30(a)).
[13] *Id.* at 40751, 40770 (proposed 21 C.F.R. § 801.40(a)).
[14] *Id.* at 40748, 40769 (proposed 21 C.F.R. § 801.3).
[15] *Id.* at 40748.
[16] *Id.* at 40748, 40770 (proposed 21 C.F.R. § 801.45(b)).
[17] *Id.* (proposed 21 C.F.R. § 801.30(c)).
[18] *Id.* at 40751, 40770 (proposed 21 C.F.R. § 801.45(a)).
[19] *Id.* at 40751.

international standard recognized by FDA, a symbol generally recognized by the persons who typically use the device, or the generic symbol provided in the rule.[20]

4. Where would the UDI be required to appear?

The UDI would have to appear on medical device labels and all distinct device packages, including the inner and outer packages, if applicable.[21]

Three categories of devices would be required to be directly marked with a UDI, including implantable devices, devices intended to be used more than once and intended to be sterilized before each use, and stand-alone software devices.[22] However, direct marking would not be required for any such device that meets any of the following criteria:

- direct marking would interfere with the safety or effectiveness of the device;
- direct marking is not technologically feasible for the device (e.g., bone cement, or small-sized stents);
- the device is intended to remain implanted continuously for a period of less than 30 days (unless FDA determines marking is needed to protect the public health);
- the device has been previously directly marked;
- the device is sold at retail and bears a UPC; or
- software is not stand-alone software, but is a component of a medical device.[23]

If a manufacturer decides not to mark a device under one of these exceptions, the exception must be documented in the design history file. If the manufacturer relies on the exceptions that direct marking would interfere with safe or effective use, or is not technologically feasible, the manufacturer must send notice to FDA no later than the date on which distribution begins.[24]

5. When would a new UDI be required?

The proposed rule would require a new UDI for each new version or model of a device. A new UDI would be required for any of the following changes to a device: a change in specifications, performance, size, or composition of the device to an extent greater than the specified limits; a change in the quantity in a device package or an addition of a new device package; a change that could significantly affect the safety or effectiveness of the device; a change from a nonsterile package to a sterile package or vice versa; and a relabeling of the device.[25]

6. When would the requirements be implemented?

The proposed rule specifies that UDI labeling requirements and the data reporting requirements would take effect as follows:

---

[20] *Id.* at 40751, 40771 (proposed 21 C.F.R. § 801.45(c)).
[21] *Id.* at 40748, 40769 (proposed 21 C.F.R. § 801.20).
[22] *Id.* at 40751-52, 40771 (proposed 21 C.F.R. § 801.50(a)
[23] *Id.* at 40752-53, 40771 (proposed 21 C.F.R. § 801.50(e)
[24] *Id.* at 40771 (proposed 21 C.F.R. § 801.50(f), (g)
[25] *Id.* at 40754-55, 40775 (proposed 21 C.F.R. § 830.50).

Class III devices	One year after the date of publication of the final rule
Devices licensed under the Public Health Services Act	One year after the date of publication of the final rule
Class II devices	Three years after the date of publication of the final rule
Class I devices	Five years after the date of publication of the final rule
Unclassified devices	Five years after the date of publication of the final rule

For devices required to be directly marked with a UDI, the rule would apply two years after the effective date for the device noted above.[26]

7. Who would be authorized to issue UDIs?

FDA has proposed that every UDI must be issued under a system operated by FDA, or an FDA-accredited "issuing agency."[27]

An issuing agency would be an FDA-accredited private nonprofit organization or State agency. Under the proposed rule, FDA would act as an issuing agency during any period where there is no accredited issuing agency, or if it determines that a significant number of small businesses would be substantially and adversely affected by the fees required by all accredited issuing agencies. FDA anticipates that issuing agencies will be sensitive to the needs of small businesses, so that FDA will not have to invoke this authority.[28] FDA would not assess a fee for its services as an issuing agency, and any labeler would be permitted to use FDA as its issuing agency.[29]

8. What information would be submitted to the GUDID database?

Whenever a device must be labeled with a UDI, the labeler would be required to submit data concerning that device to the GUDID no later than the date the label of the device must bear a UDI, or whenever the information changes, by the date a device is first labeled with the changed information.[30] For each version or model of a device, the labeler would be required to submit the following information:

- the name and contact information of the labeler;
- the issuing agency;
- the device identifier portion of the UDI;
- the proprietary, trade, or brand name of the device as it appears on the label;
- any version or model number or similar reference as it appears on the label;
- a statement if the device is labeled as sterile;
- a statement if the device is labeled as containing natural rubber latex;
- the size of the particular version or model with the unit of measure as it appears on the label, if applicable;

---

[26] *Id.* at 40751-52, 40771 (proposed 21 C.F.R. § 801.50(d)).
[27] *Id.* at 40754, 40775 (proposed 21 C.F.R. § 830.20).
[28] *Id.* at 40756, 40777 (proposed 21 C.F.R. § 830.200).
[29] *Id.* at 40756.
[30] *Id.* at 40777-78 (proposed 21 C.F.R. §§ 830.300, 830.330).

- the type of production identifiers that appear on the label of the device;
- the FDA premarket submission number of a cleared or approved device, or a statement that the device is exempt from premarket submission;
- the FDA listing number assigned to the device;
- the Global Medical Device Nomenclature code for the device; and
- the total number of individual devices contained in the package.[31]

All information in the GUDID (except for listing numbers) would be posted on FDA's website, so that it will be readily available to the public.[32]

9. What other requirements would the rule impose?

FDA proposed several conforming amendments to clarify how FDA plans to integrate the use of UDIs and the data from the GUDID into the existing regulatory systems and processes. For example, the Medical Device Reporting regulations would be amended to require UDIs to be included in individual adverse event reports.

The Quality System Regulation would also be amended to: (1) include examination of the accuracy of the UDI within the scope of the labeling inspection; (2) clarify that the device history record is to include any UDI that is used to identify the device; (3) clarify that complaint records must include any UDI used to identify the device; and (4) clarify that a service report is to include any UDI used to identify the device.[33]

UDI requirements would also be added to the regulations governing notices of correction and removal, device tracking, device recalls, PMA periodic reporting, and postmarket surveillance.

COMMENTING ON THE PROPOSED RULE

FDA listed 35 specific questions for which it was seeking comments. These questions covered most aspects of the rule on which it was seeking comment, including the following categories: implementation dates, UDI labeling requirements, combination products, convenience kits, direct marking, labeling requirements exceptions, form of a UDI, roles of the issuing agency, and data submission requirements.[34] Interested parties may submit comments to FDA until November 7, 2012 on these or any other issues raised by the proposed rule.

If you are interested in submitting comments or would like to discuss any aspect of FDA's proposed rule, please feel free to contact any of the following attorneys:

Ellen Flannery	202.662.5484	eflannery@cov.com
Scott Danzis	202.662.5209	sdanzis@cov.com
Christina Kuhn	202.662.5653	ckuhn@cov.com

---

[31] *Id.* (proposed 21 C.F.R. § 830.310).
[32] *Id.* at 40758.
[33] *Id.* at 40758-59.
[34] *Id.* at 40764-67.