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ALERTS

Food, Drug & Device Law Alert - FDA Finalizes Rule On Unique Device Identification

September 23, 2013 | Atlanta | Chicago | Columbus | Delaware | Elkhart | Fort Wayne | Grand Rapids | Indianapolis | Los Angeles | Minneapolis | South Bend

On Sept. 20, 2013, the FDA issued the final version of its rule to implement a unique device identification (UDI) system for medical devices. In the Food and Drug Administration Amendments Act of 2007, Congress directed the FDA to develop regulations establishing such a system for medical devices. The FDA touts several potential benefits for the system once it is fully implemented, including:

- To allow more accurate reporting, reviewing, and analyzing of adverse event reports.
- To reduce medical errors by enabling health care professionals to more rapidly and precisely identify a device and obtain important information concerning the characteristics of the device.
- To enhance FDA's analysis of devices on the market by providing a standard way to document device use in electronic health records, clinical information systems, claim data sources, and registries.
- To provide a standardized identifier that will allow manufacturers, distributors and healthcare facilities to more effectively manage medical device recalls.
- To secure the distribution chain, helping to address counterfeiting and diversion.

According to Jay Crowley, an FDA official, in response to industry comments the final rule includes at least seven major changes compared to the proposed rule that was issued in July 2012. Those changes include:

1. The FDA abandoned its proposed American date format in favor of a more international format of yyyy/mm/dd.
2. Except for devices that may be used more than once and are intended to be reprocessed after each use, the UDI does not have to be directly marked on the device; it can appear on the label.
3. Manufacturers have three years from the compliance date to sell off existing inventory.
4. For products sold in a kit or in combination with other products, each individual component need not be labeled, only the kit or combination.
5. Where multiple devices are sold in a single package, each device need not be labeled, only the package.
6. Manufacturers of Class III devices must comply within one year of the compliance date, but can apply for an extension of up to one year.

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7. MRI compatibility information need not be added to the device label, but must be included in FDA's Global UDI Database

A summary of other significant changes from the proposed rule to the final rule can be found on pages 15-19 of the final rules package. A copy of the final rule can be found here.

A copy of our Alerts on the proposed rule and on an amendment to the proposed rule can be found here and here, respectively.

For more information, please contact the Barnes & Thornburg LLP attorney with whom you work or one of the following attorneys in the firm's Food, Drug & Device group: Lynn Tyler at (317) 231-7392 or lynn.tyler@btlaw.com; and Hae Park-Suk at (202) 408-6919 or hae.park.suk@btlaw.com.

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