The Food and Drug Administration (FDA) on September 24 published the final rule for its Unique Device Identification (UDI) system to provide a consistent way to identify medical devices throughout their distribution and use.

“A UDI system for medical devices is an important step towards increasing patient safety, modernizing postmarket surveillance, and facilitating medical device innovation,” says Jay Crowley, the FDA’s senior advisor for patient safety, center for devices and radiological health.

Once implemented, the UDI system is expected to have many benefits for the healthcare system and the device industry, says Crowley, including:

- improved visibility as devices move through the distribution chain up to the point of patient use
- enhanced ability to quickly and efficiently identify marketed devices during recalls and other safety actions
- enhanced ability to accurately identify devices and adverse event reports
- strengthened support for electronic health records through a standard way to document device use.

**UDI core elements**
The UDI system has 2 core elements:

- A unique number assigned by the device manufacturer, called a unique device identifier, which includes information such as lot or batch number, serial number, expiration date, and manufacturing date. A distinct identification code will be used for human cells, tissues, or cellular- and tissue-based products regulated as devices.
- A publicly searchable database administered by the FDA, called the Global Unique Device Identification Database (GUDID), that will catalogue device information for every device required to bear a UDI. No identifying patient information will be stored in this database.

Crowley says he expects the FDA, medical device industry, healthcare systems, clinicians, patients, and others will use the GUDID to obtain important descriptive and use information and to find similar devices in cases of recalls or shortages.

“The GUDID will be used as a foundation for improving the quality of device public health reporting and medical device recalls,” he says.

“The new UDI rule will—over time—impact all medical devices used in the hospital,” says James P. Keller, Jr, vice president, health technology evaluation and safety, ECRI Institute. “Some of the first to be affected are key parts of a surgery department’s operations (ie, implants). It’s important for OR managers to first become familiar with the gist of the rule and work with materials management and clinical engineering professionals to consider how medical devices with new UDI labeling will be recorded in their inventory management and purchasing systems.”

**Phased-in implementation**
Implementation of the UDI system will take place over 7 years, focusing first on high-risk devices and extending to most other devices. Some low-risk devices are completely exempt from the rule.
In general, the rule requires:

- 1 year after publication of the final rule—labels and packages of Class III devices and devices licensed under the Public Health Service Act must bear a UDI. A 1-year extension may be requested; submission must be no later than June 23, 2014.
- 2 years—labels and packages of implantable, life-supporting, and life-sustaining devices must bear a UDI, and the UDI must be permanently marked on the device if it is intended to be used more than once and reprocessed before each use. Data for these devices must be submitted to the GUDID database.
- 3 years—Class III devices with a UDI on the label and package must be permanently marked if intended to be used more than once and reprocessed before each use. Labels and packages of Class II devices must bear a UDI, and data for these devices must be submitted to the GUDID database.
- 5 years—Class II devices requiring a UDI on the label or package must be permanently marked if intended to be used more than once and reprocessed before each use. Labels and packages of Class I devices and devices that have not been classified must bear a UDI, and these devices must be submitted to the GUDID database.
- 7 years—Class I and unclassified devices with a UDI on the label and package must bear a permanent UDI marking if intended to be used more than once and reprocessed before each use.

The UDI system, which builds on current device industry standards and processes, reflects substantial input from the clinical community and the medical device industry, says Crowley. By building on systems already in place, the FDA strives to reduce the burden on the medical device industry.

—Judith M. Mathias, MA, RN

References
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/default.htm