

Unique Medical Device Identifiers: The FDA Has Your Number

The FDA's Unique Device Identifier (UDI) proposal for medical devices presents many advantages and challenges. We examine the potential impact to providers and the industry.

Event

On July 3, 2012, the Food and Drug Administration (FDA) released a 46-page notice of proposed rulemaking (NPRM) that requires that most medical devices distributed in the US carry a unique medical device identifier, or UDI. This is in response to a few major events—one of which was Congress passing the FDA Amendments Act of 2007 (FDAAA) that supported the FDA's need for such a system and mandated the FDA create an identification system. The primary benefits of a UDI system are to aid in medical device adverse event reports and improve the recall process, and therefore, enhance patient safety. Accurately identifying devices would also assist health care organizations (HCOs) in their proper use, management, and tracking compliance (e.g., Joint Commission Medical Equipment Standards). Although Congress did not initially specify a time for the FDA to act, the FDA moved forward never-the-less by conducting a proof-of-concept test in 2009 and then sending a proposal to the Office of Management and Budget (OMB) in 2011. However, for various reasons, including too many competing priorities, the proposed rule languished without OMB approval. But the need remained.

Through pressure from groups such as the Advancing Patient Safety Coalition (represented by the American Medical Association, AARP, and the Federation of American Hospitals), language was recently added to the FDA user fee renewal bill (S 2187), just passed by Congress and signed into law by the President, that required the FDA to issue the proposed rule by the end of 2012. Although the FDA already met the deadline before the renewal bill was signed into law, most would agree that the FDA NPRM was still long overdue. The industry has 120 days (until November 7, 2012) to respond to the NPRM. According to the FDA Safety and Innovation Act (the user fee renewal bill was underneath it), Health and Human Services (HHS) has six months after the comment period ends (May 2013) for the UDI NRPM to issue the final UDI rule.

Implementing UDI

The UDI is a unique numeric or alphanumeric code placed on the device by the manufacturer or labeler in plain text and with an automatic identification and data capture (AIDC) technology (such as bar coding, radio frequency identification [RFID], or near-field approaches). The UDI includes two parts: (1) a device identifier specific to the device model or version and the manufacturer/labeler; as well as (2) a production identifier which may include information such as lot or batch number, serial number, and/or expiration date. The NPRM proposes the use of GS1 (and its GTIN - Global Trade Access Number format) and/or Health Industry Business Communication Council (HIBCC) standards. These standards could also help on more of a worldwide basis—for example, if devices could be tracked outside of the US, they could aid in device safety worldwide. This is being considered by the International Medical Device Regulators' Forum (IMDRF). It is estimated that 35% to 50% of medical devices are already labeled using GS1 or HIBCC identifiers.

Through a phased-in approach (generally one, three, or five years depending on whether the device is FDA class 3, 2, or 1), devices associated with more patient risk

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Analysis



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will be addressed first with UDI. Lower-risk devices would be exempt from some or all of the requirements. Over-the-counter devices would be exempt as they already carry a universal product code or UPC (operated by GS1). Some special and long-life devices such as implantables will eventually need the UDI directly marked on them (not a label). Costs to manufacturers and labelers to implement UDI was estimated to be approximately half a billion dollars over ten years.

A crucial part of the UDI initiative includes the FDA building a database of information, referred to as the Global Unique Device Identification Database (GUDID). This database will be accessible to regulators, physicians, companies, and the public via look-up. The database will contain useful data and attributes about the devices and their distribution and use, including information submitted by manufacturers, but will not contain private information about specific users.

The need for UDI labeling and tracking for medical devices has prompted considerable debate over the years. Proponents of UDI claim that manufacturer serial numbers are not adequate when it comes to the reporting of problems/glitches/failures, issuing recalls, reducing counterfeit devices, surveillance, and evaluating post-market performance. Those familiar with manufacturing, labeling, and distribution know the complexities of tracking which components were included from which suppliers in which devices provided by which part of the distribution channel network. Although the FDA’s UDI does not specifically address component tracking (The FDA’s Quality System, which is similar to ISO 9001 standards, can help here), a tracking system that can be used across manufacturers, distribution channels, and users to at least identify the device itself is necessary to help identify problems and ensure safety.

Detractors of the proposal cite unnecessary costs and limited value since there is inadequate ability of the government to monitor and deal with the information they currently receive. That would seem to support the need for a more information-enhanced approach to tracking and investigating issues, resolving inconsistencies, and identifying duplicates. From 2005 to 2009, the FDA received close to half a million adverse event reports involving devices per year. Of these, more than 17,700 reports involved a death and more than 283,000 involved an injury.

The need to track medical devices more closely is also tied to security and privacy. The Department of Homeland Security issued a report earlier this year citing the growing threat of medical devices being vulnerable to malware, viruses, etc., and the damage such devices can cause if connected to other data systems. In July, researchers from Harvard Medical School’s Beth Israel Deaconess Medical Center and the University of Massachusetts Amherst published a report showing that few FDA databases contain information about recalls related to medical device security and privacy issues when such devices have been compromised.

From the HCO perspective, that the FDA did not specify the particular AIDC technology in the NRPM could present some compatibility issues with the ability to read the UDI. Unless the FDA finalizes a rule that requires specific technology, some manufacturers might, for example, choose to use bar code labels and some might choose to use RFID tags. The situation is somewhat reminiscent of how the FDA in 2004 issued their regulation requiring bar codes on unit-dose medications in hopes that the hospitals would scan them to get the real value (e.g., right medication, patient, route, dose, and time of administration). There was debate leading up that regulation as to which ADIC technologies to require, and it was decided that bar

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codes were far more ubiquitous and cost effective to deploy vs. RFID. To date, even with the low cost of bar-code technology, less than half the hospitals in the country scan those bar codes (this is also partially a factor of the cost of bar-coded unit-dose packaging). Although the primary users of the UDI labels will be the FDA and the manufacturers, there are many possible uses for the provider as well (see below). RFID has had few deployments in HCOs, and if RFID tags were allowed to contain the machine-readable portion of the UDI, few HCOs would be able to read them.

The overall discussion of integration of medical devices and EMRs is coming to a head with the issue of who will provide oversight and certification in this increasingly overlapping area. The recent finalized FDA rule on medical device data systems (MDDS) and the NRPM for mobile medical applications are examples of steps the FDA is taking to address issues from their “side.” How far the Office of the National Coordinator (ONC) attempts to go to meet the FDA with connected medical devices and related applications is still to be decided. While medical devices are not discussed in Meaningful Use (MU) Stage 2, recently there has been industry discussion about the possibility of requiring EMRs to handle UDI codes in MU Stage 3 in terms of tracking which devices are associated with which patients. This could be used to help examine the effects of one or more devices on a patient or population of patients. In the case of implantable devices, it could be used by physicians to know more precisely what device was inside the patient. It could also be used for more accurate charge capture and for better supply chain and inventory management.

Time Lines

Not everyone is waiting for the FDA and government to make UDI a reality. The Healthcare Transformation Group, consisting of Geisinger Health (PA), Kaiser Permanente (CA), Intermountain Healthcare (UT), Mayo Clinic (MN, AZ, FL), and Mercy (MO) have gone to their top suppliers and asked them to start using GS1 standards as soon as possible. Whatever the future of regulation of medical devices and EMRs, being able to keep track of specific medical devices is long overdue.

Action Items

- HCOs should expect a UDI system will be put in place over the next two-plus years—and should become familiar with how to use it to investigate the performance of medical devices, report device problems/failures, manage security issues, and respond to recalls.
- HCOs should plan to incorporate UDI in asset management applications and workflow to keep better track of devices.
- HCOs should apply pressure to government and vendors to ensure the use of 2D bar-coding technology at a minimum for the machine-readable portion of the UDI (e.g., although linear bar coding was the minimum NDC requirement for unit-dose medications from the 2004 FDA regulation, the industry has now progressed such that 2D bar coding has become the more affordable and capable norm to accommodate the extra information proposed for UDI; RFID could be used in addition but should not be allowed by itself).
- HCOs should look to leverage UDI, perhaps in conjunction with Real-Time Locationing Systems (RTLS), to ensure better patient care and charge capture (e.g., right patient and device in the same room at the same time).
- Consider the timing of purchasing, leasing, renting, or retiring equipment with UDI including a plan as to how to deal with pre-UDI devices (the most value will occur if all devices are UDI labeled and tracked).

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