New FDA Medical Device Rule Imposes Minimal Burden on Hospitals
Facilities Able to Scan Unique Device Identifiers Will Benefit

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The FDA’s final rule requiring manufacturers to put identification marks, known as unique device identifiers (UDIs), on some of their moderate-risk (Class II) and high-risk (Class III) medical devices and packaging should pose little, if any, burden on hospitals. To the extent that hospitals have already voluntarily purchased acceptable scanning technology for supply-chain tasks, they will benefit if they are able to quickly and cost-effectively respond to recalls and to chart any adverse reactions caused by the devices.

With that benefit, however, comes a cost.

“Hospitals will need to upgrade their electronic health records, billing software, and supply-chain management programs to capture the new codes and train staff on how to properly work with unique device identifiers,” explains Lee H. Perlman, President, Greater New York Hospital Association (GNYHA) Ventures. He also worries that device manufacturers will pass along to hospitals their new manufacturing costs accruing from labeling their devices and packages, resulting in a double hit for hospitals.

The FDA left the door open for hospitals to decide which Automatic Identification and Data Capture (AIDC) technology to implement in order to read UDIs if they wanted to make that investment. There was some concern that by allowing a UDI to be read by several scanning technologies, the FDA would be forcing hospitals and medical practices to buy multiple scanning devices or more expensive scanners than necessary in order to accommodate numerous standards.

Lisa P. Goldstein, JD, Associate Director of Regulatory Affairs at the American College of Cardiology, said:

Given the lack of a requirement for manufacturers to adopt a particular AIDC technology, there remains the prospect that different manufacturers will select different technologies to use for labeling devices with the UDI. As such, hospitals and others who use and implant medical devices may be forced to purchase separate readers for each technology.

In 2008, the American Hospital Association estimated that 52% of surveyed hospitals already had implemented bar-code technology for supply-chain management or were planning to do so within a year. The survey has not yet been updated.

Those bar-code readers will be logging in UDIs that are placed on some devices and on almost all device packaging by manufacturers and repackagers. The FDA has stated that hospitals that repackage medical devices—for example, breaking down a multipack of some sort into individual devices, which are then packaged in some way—are not subject to the UDI rule.

UDIs will include two parts:

1. A device identifier identifies the specific version or model of a device and its manufacturer.
2. A production identifier identifies one or more of the following when present on the label of the device:
   a. the lot or batch within which a device was manufactured
   b. the serial number of a specific device
   c. the expiration date of a specific device
   d. the date on which a specific device was manufactured

The UDI is a reference number that enables health care professionals or the FDA to locate information about the device in the FDA’s Global Unique Device Identification Database (GUDID). After this database is up and running, hospitals will be able to check information about a device beyond what is known from the UDI. For example, does the device contain latex? Is the device compatible with magnetic resonance imaging (MRI) technology?

The hospitals may also be able to use the GUDID to learn whether a device in their inventory has any of the same problematic components as a device subject to an FDA recall. However, a hospital’s ability to query the GUDID might be limited by the product-numbering system it uses. The FDA specified Global Medical Device Nomenclature (GMDN) as the naming convention for the device portion of the UDI. Many hospitals today use a rival naming convention, the Universal Medical Device Nomenclature System (UMDNS), developed by ECRI Institute (formerly, Emergency Care Research Institute). Hospitals that use a no-fee UMDNS can stay with it. The GMDN, which hospitals must pay to use, will make some of its system available free to the GUDID, but that does not include the product codes. Therefore, public users, including hospitals, might be limited in the extent to which they can query the GUDID.

The time frames by which a medical device must comply to bear a UDI on the label range from 1 year for Class III devices (the riskiest implantables) and devices licensed under the Public Health Service Act to 5 years for the least risky devices, in Class I. The FDA had initially proposed schedules extending to 7 years and made some changes in the final schedules.

The concern for hospitals is not how fast the manufacturers put UDIs on their devices and packaging. The concern is how fast hospitals in the U.S. that don’t have scanners (probably most smaller facilities) buy those scanners—if they buy them at all.