Hospitals Worry About New FDA Proposal For Medical Devices

Technical Complexities of Labels Could Compromise Utility

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The proposed rule also raises the possibility that hospitals could have trouble reading the UDIs that medical device manufacturers imprint on the devices and packaging. Although hospitals might not be obligated to comply, they do want to take advantage of UDIs in support of billing, patient safety, and product recall objectives. It is true that many hospitals use linear bar-code readers in some parts of their operations. Data from the American Hospital Association in 2011 showed that 96% of hospitals were using bar-code technology for at least one of the following: tracking of laboratory specimens, drug products and their administration, and patient identification.

However, considerably more information will probably be required for UDIs compared with the amount of information now necessary for linear bar codes on drugs. Thus, manufacturers would probably start labeling medical devices with two-dimensional (2-D) data-matrix bar codes, which are smaller than one-dimensional bar codes and can be printed on small devices. Hospitals that recently invested in linear readers are not suddenly going to dispose of them and their investment and buy 2-D readers.

Yet the need to include UDIs could complicate hospital operations beyond billing. Judith Lipscomb, Vice President of Materials Management at BayCare Health Systems, an area not-for-profit hospital system in Tampa, Florida, says there are implications for warehouse-management systems, which cost upward of $1 million. Current systems may have to be customized or replaced. Moreover, electronic health record (EHR) systems that are now in place in hospitals do not allow for the parsing of bar-code data. Therefore, if the FDA requires hospitals to input UDI data into patient EHRs, this could be problematic or expensive, or both.

Lisa Swirsky, a spokesperson for Consumers Union, says, “The FDA should do more than encourage inclusion of the UDI in medical records; the agency should actively work with the Centers for Medicare & Medicaid Services to require UDIs to be included in medical records and on electronic claims and billing records as soon as UDIs are available.”

The proposed rule requires each UDI to be provided in a plain-text version and in a form that uses automatic identification and data capture (AIDC) technology. AIDC technology could be a bar code, radiofrequency identification (RFID), near-field communication (NFC), or any other technology that serves the same objectives. A UDI would include two parts:

- a device identifier that identifies the specific version or model of a device and the labeler (i.e., the manufacturer) of that device
- a production identifier that identifies one or more of the following, when present on the label of the device:
  - the lot or batch within which a device was manufactured
  - the serial number of a specific device
  - the expiration date of a specific device
  - the date on which a specific device was manufactured

The device identifier is a reference number that allows a health care provider or the FDA to locate data about the device in a new FDA database, known as the Global Unique Device Identification Database (GUIDD).

Hospital concerns about the UDI proposal issued by the FDA last summer extend to the naming of the numbering system for the device-identifier portion of the UDI. The FDA has proposed Global Medical Device Nomenclature (GMDN) as the naming convention for this portion of the UDI. Most health care facilities in the U.S. and supply-chain providers track devices using either ECR Institute’s Universal Medical Device Nomenclature System (UMDNS) or the United Nations’
Standard Products and Services Code (UNSPSC). ECRI Institute has provided free non-commercial access to UMDNS for 41 years and is committed to continuing to do so. UNSPSC can also be licensed free of charge. GMDN is produced and administered by a European agency and charges for access to the nomenclature.

“Why make us pay for what we get for free and the additional labor of changing what we already use?” asks Stephen M. Mosher, Assistant Administrator of Engineering/Facility Services at South Georgia Medical Center in Valdosta, Georgia. He recommends that the FDA drop its approval of the GMDN only.