American Hospital Association

AHRMM
Association for Healthcare Resource & Materials Management of the American Hospital Association

November 7, 2006

The Honorable Andrew C. von Eschenbach, M.D.
Acting Commissioner
Food and Drug Administration
5600 Fishers Lane
Parklawn Bldg., Room 14-7
Rockville, Maryland 20857

Ref: Food and Drug Administration; Unique Device Identification; Request for Comments [Docket No. 2006N-0292]

Dear Acting Commissioner von Eschenbach:

On behalf of the members of the American Hospital Association (AHA) and the Association for Healthcare Resource & Materials Management (AHRMM), we appreciate the opportunity to respond to the Food and Drug Administration's (FDA) request for comments on a unique device identification (UDI) system published in the August 11 *Federal Register*. The AHA represents nearly 5,000 member hospitals, health systems and other health care organizations, and 37,000 individual members who include AHRMM's 3,900 executives responsible for health care resource and materials management.

BACKGROUND

Many health care providers, including those represented by the AHA and the AHRMM, requested that the FDA include medical devices in its February 26, 2004 final rule requiring the use of barcodes on certain human drug and biological products to help reduce medication errors. The FDA, however, did not include devices in its barcode rule. This was due, in large part, to the lack of a standardized, unique identification system for medical devices comparable to the National Drug Code that is used for pharmaceuticals.

We applaud the FDA for seeking comment on the ways to rectify this situation and urge you to mandate development and use of a UDI expeditiously. Hospitals and other health care providers are challenged every day to increase the safety and quality of the care they give patients while increasing efficiency. A UDI system will facilitate providers' efforts to meet that challenge. It also will add an element of transparency to the medical device industry by providing basic, standardized information on all medical devices.

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Further, the ability to uniquely identify devices will allow health care providers to use automatic identification technologies, such as barcoding and radio frequency identification (RFID), to realize improvements in patient safety and quality of care and increase efficiency in supply chain management. On the quality side, UDI and auto-ID will allow providers to ensure that patients are receiving the right devices, reduce medical errors such as infections and allergic reactions, better manage device recalls, and increase their ability to submit data on adverse events involving medical devices. In the supply chain, UDI will allow providers to better track medical devices at lower costs and allow the industry to develop real-time information sources about medical devices that are available to both suppliers and purchasers.

Following the FDA's request, our comments will focus on the development, implementation and benefits and costs of UDI.

DEVELOPING A SYSTEM OF UNIQUE DEVICE IDENTIFIERS (QUESTIONS 1-8)

The AHA and the AHRMM support the expeditious development of a mandatory UDI system overseen by the FDA that is based on existing classification systems.

Characteristics of the UDI System. Currently, most manufacturers use proprietary numbering systems for their own products that are not open to purchasers or shared across manufacturers. It is, in essence, a voluntary system where duplicate classification systems are operating in parallel. Consequently, there is little ability for hospitals and other purchasers to implement and use automated systems to track and report on medical devices. Without a mandate from the FDA, manufacturers are unlikely to coalesce around a single standard. Given the substantial safety benefits that could be realized, the FDA has grounds to act.

In developing a single, mandatory system, the FDA should rely on an existing classification system rather than develop its own. The AHRMM recently declared its support of the United Nations Standard Products and Services Codes (UNSPSC®) that classifies all products. This classification system is a mature, open standard. It also is used globally, which is an important consideration given that medical supplies are manufactured and sold around the world.

Scope of the UDI System. The scope of a UDI system must be broad, but the depth of information needed about a device can vary by type. All medical supplies and devices must be included in the UDI. Even the simplest of medical supplies, such as latex gloves, could have safety consequences for a patient due to allergies. In addition, the efficiency gains of a UDI system will be limited if it is not universal. Hospitals and other providers do not want to maintain multiple tracking systems. In addition, the benefits of implementing an auto-ID system are diminished if it cannot be used for all medical supplies and devices, or requires barcoding by the purchaser for some products.

The UDI system should include basic information on all medical supplies and devices, but allow for variations in the required elements according to certain attributes of the supply or device, such as degree of patient contact and risk.

To realize the greatest safety gains, the UDI must be placed on a product at the level it comes into contact with the patient. As previously mentioned, the FDA issued a barcode rule for drugs. It did not, however, require the barcode to be on the unit dose. Therefore, hospitals and other providers using auto-ID systems for medication administration have had to re-package and barcode products in-house. This additional step reduces the safety benefits of the barcode by allowing for human error in the re-packaging process and poses significant costs. Any UDI for medical devices should seek to avoid these problems by ensuring that the product identifier is available on the product at the level of issue to the patient.

Possible Barriers. The barriers to hospital use of UDI can be overcome, particularly if the UDI can be read by the human eye. Most hospitals already have information systems to manage and track inventory. The introduction of a UDI would require replacing the codes currently used to identify products, which are not standard, with standard codes. Software vendors supplying these systems would need to modify their products to accommodate the identifier, staff would need to be trained and work processes changed to use the UDI.

As hospitals move to implement auto-ID technologies, additional financial, work process redesign and training challenges will arise. However, hospitals have already begun using auto-ID technology for other purposes, and are gaining familiarity with it. Having a UDI would provide additional incentive to invest in this technology.

In addition, the barriers within the hospital field would be minimized by making the UDI mandatory and broad in scope. If the UDI were not mandatory or broad in scope, hospitals would be using a hybrid system, where some items had standard identifiers and others did not.

IMPLEMENTING UNIQUE DEVICE IDENTIFIERS (QUESTIONS 9-12)

All medical supplies and devices should include standardized data on the:

- manufacturer
- make
- model
- lot
- serial number
- unit of measure
- expiration date (if applicable)
- software version (if applicable)

Medical devices that pose a higher risk to patients, such as implantable items, infusion pumps, surgical instruments and cardiac or respiratory monitors, should include more detailed information, such as a serial number identifying the exact device, whether the product is sterile, or the UDIs for necessary related equipment (such as the leads that are

compatible with a given implantable cardioverter defibrillator). We address the safety benefits of having this minimum data set in the next section.

Existing standards organizations, such as GS1, already develop and maintain classification systems. By choosing an existing standard that is already supported, the FDA could require that manufacturers work with the standards organization to obtain a UDI for each product. It is important that only open standards are considered.

The UDI also should connect to a "product data utility" (PDU) – a system and organization that interconnects trading partners across the supply chain to synchronize core product data to standard specifications. The Coalition for Healthcare eStandards' PDU Organizing Committee recommends that PDU data sets include:

- basic catalog and purchasing transaction data
- basic usage cautions and restrictions data
- patient use and billing data
- product classification data
- logistics data
- expanded product attributes

The PDU would distribute standardized product data from manufacturers and distributors to data aggregators and end-users. It would enable participants to synchronize and maintain accurate product and packaging information in near real time. Specifically, the PDU functions would include:

- Loading and validation of standardized data from manufacturers and distributors;
- Comparison of product information from manufacturer and distributor files to identify and correct disparities and omissions;
- Access to a central repository of verified, standardized and certified product information for authorized users; and
- Ongoing updating and maintenance of the data.

Furthermore, the UDI should be both human-readable and encoded in an auto-ID format. The human-readable format will be needed as the field moves toward the use of auto-ID technologies, and may be the only version that can be used by very small providers without the means to invest in auto-ID. Ideally, the UDI would be on the product itself, although in some circumstances, such as tiny devices, it may be on the packaging. Technical standards required for the UDI must support auto-ID technologies, including barcodes and RFID. These technical standards must be uniform across the health care field.

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UNDERSTANDING THE BENEFITS AND COSTS OF UNIQUE DEVICE IDENTIFICATION (QUESTIONS 13-20)

In the absence of a UDI system, it is difficult to quantify its benefits. However, hospitals and their patients experience daily the consequences of not having one. The benefits of the UDI span the safety spectrum, including the management of recalls, support of the culture of safety and electronic health records and increased supply chain efficiency. Given these significant benefits, once a UDI system is implemented, hospitals will quickly adopt it.

Safety Benefits. The UDI could greatly facilitate the process of managing device recalls, which, according to ECRI (formerly the Emergency Care Research Institute), are issued more than 600 times per year. Currently, the numbers used to identify a product can change between the number assigned by the manufacturer, the number used by a distributor (who may add a prefix or suffix) and the number maintained in a hospital's inventory management system. Therefore, recalls generally require manual searches of inventory and cannot be done by searching inventory management systems. Identification of patients who have received recalled devices requires manual review of medical records. With a UDI, these processes could be conducted via electronic searches, resulting in more timely, complete and accurate management of the recall. Most importantly, hospitals could more quickly and accurately notify and, if necessary, treat patients who have received a recalled device. All recalls would be facilitated by having a UDI system, as long as all devices have a UDI.

In addition to recall notices, hospitals also must manage device "corrections," which require the hospital to modify equipment to avoid safety problems. According to ECRI, recent device correction notices have included problems, such as battery failures in IV pumps and ventilator alarm issues, which could seriously impact patient safety. The UDI would facilitate hospitals' ability to locate and service items subject to a correction notice.

The UDI also would facilitate the culture of safety within hospitals. For example, the UDI would allow hospital staff to quickly differentiate equipment that often looks the same, but serve different functions, such as telling the difference between a general purpose infusion pump and one of the same model that has been programmed for newborns. This level of information will prevent errors such as providing the wrong dose of medication.

If problems or device failures do occur despite all precautions, the UDI would make it easier to identify and report these adverse events. These reports also could facilitate the FDA's post-marketing surveillance of devices.

Finally, having a UDI and associated PDU would make it more difficult to counterfeit medical supplies and help track down counterfeit products. This aspect of a UDI benefits manufacturers economically and improves the integrity, and therefore the safety, of the supply chain.

Support of Electronic Health Records. As the hospital field moves toward implementing electronic health records (EHRs), the UDI and the related PDU could provide information that allows the use of clinical decision support mechanisms that further improve safety. For example, EHRs could be programmed to provide warnings against possible complications, such as allergic reactions to latex or the use of unsterilized equipment in the operating room.

The UDI also would address one of the difficulties of implementing EHRs – a lack of agreed-upon standards for clinical information. Having a UDI would facilitate accurate documentation of care, which could help to inform future care needs for a patient. For example, if the leads of a pacemaker must be changed, having the UDI in the medical record would be more reliable than having staff enter the make, model and other pertinent information in the medical record to ensure that compatible leads are used. Accuracy would improve further with the use of auto-ID. For example, rather than manually entering the length, gauge, manufacturer and product code for a peripherally-inserted central catheter into the medical record, the UDI could be captured and linked to the relevant information.

Efficiency Gains. In addition to safety benefits, a UDI would allow hospitals and others to realize efficiencies in the inventory, tracking and purchasing of devices. Hospitals struggle to track devices through their inventories because the information is not available from manufacturers. While many manufacturers barcode their products, there is no national repository of the information contained in the proprietary barcodes, which makes it meaningless to providers. Therefore, many hospital and health care systems create and manage their own barcoding systems and then contract with a third party to synchronize their data with the manufacturer, distributor or other entity. This costly undertaking has the potential to generate errors by adding another layer to the process of tracking medical devices. Finally, the UDI also could assist in ensuring the integrity of the supply chain by making it more difficult to counterfeit.

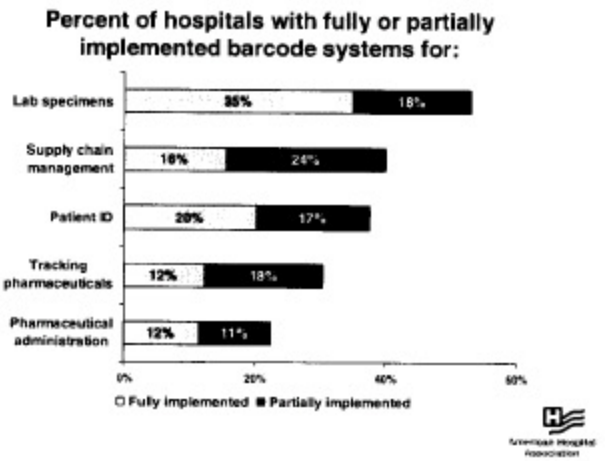
Implementation in Hospitals. Implementing a UDI would impose costs upon hospitals. However, the potential safety and efficiency benefits outweigh those costs. In considering costs, the implementation of a UDI should be considered separate from the implementation of auto-ID technology.

Setup costs for implementing the UDI include changing existing hospital materials management and related information systems, redesigning work processes and training staff in how to use the new systems. Assuming the UDI is readable by the human eye, all hospitals could make these changes and realize quality and efficiency gains. These gains are of a sufficient scope that hospitals would begin to use the UDI quickly.

Having a UDI goes hand-in-hand with the priorities hospitals place on implementing auto-ID technologies and electronic health records. One does not take precedence over the other. The results of a 2005 AHA survey of hospitals (see figure below) show that hospitals are already adopting barcoding for a number of uses, including lab specimens, supply chain management, patient ID and pharmaceutical tracking and administration. In

addition, 8 percent of the hospitals surveyed had fully or partially implemented RFID. These data are from the spring of 2005; we expect further adoption has occurred in the past year. For hospitals already using auto-ID, the UDI could be incorporated into existing efforts. For those yet to adopt auto-ID technologies, having a universal, standardized UDI would increase the value of implementing auto-ID.

Hospitals are adopting barcoding



In closing, both the AHA and the AHRMM appreciate this opportunity to express our views on the development and implementation of a UDI. If you have questions on our comments, please contact Chantal Worzala, AHA's senior associate director of policy, at (202) 626-2319 or cworzala@aha.org or Deborah Sprindzunas, AHRMM's executive director, at (312) 422-3842 or dsprindzunas@aha.org.

Sincerely,

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