February 27, 2009

Frank M. Torti, M.D.
Acting Commissioner
Food and Drug Administration
Center for Devices and Radiological Health (HFZ-500)
1350 Piccard Drive
Rockville, MD 20852

Re: Food and Drug Administration; Unique Device Identification; Request for Comments [Docket No. FDA2008N0661]

Dear Dr. Torti:

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 January 15 *Federal Register*. The AHA represents nearly 5,000 member hospitals, health systems and other health care organizations, as well as 38,000 individual members who include AHRMM's 4,000 executives responsible for health care resource and materials and supply chain management.

The Food and Drug Administration Amendment Act of 2007 amended the *Federal Food, Drug, and Cosmetic Act* by requiring the establishment of a UDI system. Specifically, the 2007 law states that the Secretary of Health and Human Services shall issue regulations establishing a UDI system for medical devices which would require the label of devices to bear a unique identifier, unless the Secretary requires an alternative placement or provides an exception for a particular device or type of device. The unique identifier shall adequately identify the device through distribution and use, and may include information on the lot or serial number. In addition, a UDI system may aid in detecting the early warning signs of a defective device and facilitate device recalls, among other benefits.

We fully support the FDA's efforts to create a UDI system to rectify the lack of a standardized identification system for medical devices. Attached are our responses to the FDA's questions pertaining to a national UDI system. 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 and that is globally harmonized. Hospitals and other health care providers are challenged every day to increase the safety and quality of the care given to 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.

As mentioned in our November 2006 and July 2007 communications to the FDA, 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 patients receive 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 about medical devices that are available to both suppliers and purchasers.

We appreciate the opportunity to express our views on developing a UDI system and look forward to working with the FDA on this important initiative, which will certainly improve patient safety. If you have questions on these comments, please contact Rod Piechowski, AHA's senior associate director of policy, at (202) 626-2319 or rpiechowski@aha.org, or contact Deborah Sprindzunas, AHRMM's executive director, at (312) 422-3842 or dsprindzunas@aha.org.

Sincerely,

Rick Pollack
Executive Vice President
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Executive Director
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**AMERICAN HOSPITAL ASSOCIATION AND
ASSOCIATION FOR HEALTHCARE RESOURCE & MATERIALS MANAGEMENT
RESPONSES TO THE FDA'S UNIQUE DEVICE IDENTIFICATION QUESTIONS
DOCKET NO. FDA2008N0661**

1. Which types of devices or particular devices should be subject to the requirements of a UDI system? Which types of devices or particular devices should be excepted?

a. Should all devices be subject to the requirements of a UDI system? Please explain your reasoning.

b. Are there types of devices or particular devices that should receive an exception from the requirements of a UDI system? If so, what types of devices or particular devices should receive an exception and why?

The UDI system should include all medical supplies and devices. Even the simplest of medical supplies, such as latex gloves, could have safety consequences for a patient due to allergies. 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. Hospitals and other providers do not want to maintain multiple tracking systems.

2. What are the characteristics or aspects necessary to uniquely identify a device?

a. What characteristics are needed to uniquely identify a device?

b. What core attributes, elements, or characteristics of a device should constitute a minimum data set for a device identifier?

The scope of a UDI system must be broad, but the depth of information needed about a device can vary by type. 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. At a minimum, all medical supplies and devices should include standardized data on the:

- Manufacturer
- Organizational identification (e.g., global location number (GLN))
- UNSPSC*
- Unique item number for the product (e.g., global trade item number (GTIN))
- Lot number
- Expiration date
- Unit of measure
- Date manufactured

*In developing a single, mandatory system, the FDA should rely on an existing classification system rather than develop its own. Previously, the AHRMM 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.

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. Additional information should include 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).

The AHA and the AHRMM advocate the use of other clinical attributes based on environmental and occupational needs. In addition to the Web address (URL location) of the Materials Safety Data Sheet (MSDS) information, these attributes would indicate whether the product:

- Contains latex
- Contains polychlorinated biphenyl (PCB)
- Contains polyvinyl chloride (PVC)
- Contains mercury
- Is considered a biological hazard
- Is considered a chemical hazard
- Is considered a nuclear hazard
- Is considered a radioactive hazard
- Is flammable

These attributes represent dangers that can threaten the health of patients, employees and communities, and create extra costs to manage the product lifecycle from procurement to disposal. The UDI also should connect to a "product data utility" (PDU) – a synchronized, industry-wide system that contains the supporting information necessary for a device to move through the entire supply chain and clinical record processes. By making this information available to a hospital through a PDU, health care professionals will be able to easily identify products that need special consideration in their handling and care and ensure they are managed correctly.

3. What should be the UDI's components?

a. Could existing standards, such as the standards used by GS1, Health Industry Business Communications Council (HIBCC), or others be used as a model for the UDI system? What are the advantages and disadvantages of these existing organizations and standards?

The AHA and the AHRMM support the use of the GS1 supply chain standards because the standards provide a global solution; identify products in and out of the med/surg industry; have been in use by other industries for many years; and can drive down significant costs based on current inefficiencies in the supply chain. GS1 also is committed to modifying the standards as needed for health care med/surg products.

b. Some identification systems currently in use employ a combination of a device identifier (meaning information that identifies the manufacturer, make, and/or model of the device) and a production identifier (meaning information that relates to the lot or serial number). What should the device identifier

component of the UDI cover or contain?

The UDI should contain a unique product number (e. g. GTIN), the lot number and serial number (if the product is serialized). Each of these numbers is needed to identify and recall a specific product or a lot of like products.

c. With respect to the production identifier, we note that the statute says that the UDI may include information on the device's lot or serial number. When should lot or serial number information be required for a device? Are there particular devices for which serial numbers should be required? If yes, what particular devices should be labeled with a serial number? Please explain your reasoning.

The UDI should contain the lot number, and in instances where there is no lot number the UDI would default to the date of manufacture. The UDI also should contain the serial number, if one is assigned by the manufacturer.

d. How might we ensure that UDIs, regardless of the manufacturers or devices associated with those UDIs, are uniform or standardized in their structure or composition? For example, the NDC (National Drug Code) number is always 10 digits long and always presents the labeler code first, followed by the product code and then the package code. Should we limit the number of ways that the UDI can be created or the standards to be used?

There should be one numbering, taxonomy and nomenclature system. Identifying a specific system (i.e. numbering would be the GTIN, taxonomy would be the UNSPSC and the nomenclature would be the Global Medical Device Nomenclature (GMDN)) would standardize the UDI process. The data carrier is not as important as long as the label is human readable.

e. How should the UDI be created to ensure that UDIs are unique?

The UDI should contain the unique product number, the lot number (or production date) plus the serial number (if the product is serialized). GS1 has a system already developed for uniquely identifying products that has proven successful in other industries. In addition, hospitals already conduct business with industries that utilize the GS1 standards.

4. Where should the UDI be placed? What should be the criteria for alternative placement of the UDI?

a. Should we specify where on the label the UDI must appear? If so, where should the UDI appear on the label? Please explain your reasoning.

As long as the UDI is human readable, location is not critical. If the UDI cannot be placed on the product, the UDI should appear on the package at the lowest salable unit of measure.

i. Should we allow the components of the UDI to be placed separately on the same package or on different levels of packaging? For example, if the UDI consists of a device identifier component and a production identifier component, should we allow the device identifier component of the UDI to be placed in one location and allow the production identifier component to be placed elsewhere on the label or on the device? Please explain your reasoning.

As another example, some devices are packaged individually and then packaged again in a larger container (such as a shelf pack). We are aware that some manufacturers would prefer placing both the device identifier component of the UDI and the production identifier component of the UDI on the larger container and placing only the device identifier component of the UDI on the individual packages. Separating UDI components or allowing part (rather than all) of the UDI on package labels may provide for flexibility in product labeling, but also generate confusion as to which UDI to read or scan (if the UDI components are separated) or limit the usefulness of the UDI if a component of the UDI is not present.

An exterior container needs to indicate that it contains serialized products. Labeling of the UDI on the shelf pack may be sufficient in instances where it is cost prohibitive to place the UDI on a low-risk product.

ii. For barcodes (whether linear or two-dimensional (2D)), should we require the UDI to be expressed in a concatenated manner (whereby the components of the UDI are expressed on the same line adjacent to each other) or in a stacked manner (whereby one component of the UDI rests atop the other component)?

Either method should be acceptable.

b. Are there devices where we should require the UDI to appear on the device itself (direct part marking)? For example, it might be beneficial to put the UDI on the device itself if the device is re-processed because this might help firms identify or record how many times a particular device has been reprocessed.

Similarly, certain single use devices (SUDs) sometimes are reprocessed, so a UDI on the device itself could facilitate the mandatory and voluntary MedWatch reporting relating to such reprocessed devices or facilitate other activities (such as documenting sterilization reprocessing of SUDs and validation studies) associated with SUDs. Conversely, are there devices where the UDI cannot or should not go on the device itself? If so, please describe those devices and explain why the UDI cannot or should not go on the device.

The product should be identified to the most unique level on the item as well as on the

packaging; therefore, the UDI should appear on the product itself wherever technologically possible. Reprocessors should be required to add a new UDI in addition to the existing UDI in order to provide traceability to either the reprocessor or manufacturer.

c. If we allow for alternative placement of the UDI for some particular devices or types of devices, what should be the general criteria for requiring alternative placement of the UDI, e.g., such as on the device itself or other location that is not on the label?

Based on current technology, the placement of the UDI should be in the best interest of patient safety. The UDI size and placement should be in locations that ensure UDIs are human readable at every level of packaging.

d. What specific challenges or limitations exist regarding alternative placement? For example, placing a UDI in an automatic identification form on an implantable device may present issues as to whether the automatic identification technology affects the device's integrity or function. As another example, certain devices, such as software, may pose particular challenges for how to label with a UDI.

The technology available today may not allow for labeling the UDI on the product itself. In that case, the UDI label should be placed on the next best location used on the lowest saleable unit of measure. The UDI should not identify a product by a software version number because the software version number may change.

5. How should the UDI be presented?
We are aware of several automatic identification technologies in use, such as linear bar codes, 2D bar codes, and radio frequency identification. We also note that various FDA regulations and initiatives have required or recommended one or more automatic identification technologies (see 21 CFR 201.25 (bar code label requirement for human drug products); 21 CFR 610.67 (bar code label requirement for biological products); Ref. 2; and section 505D of the act (21 U.S.C. 355e) (regarding pharmaceutical security and specifying promising technologies such as RFID (radio-frequency identification), nanotechnology, encryption technologies, and other track-and-trace or authentication technologies)). Therefore:

a. Should we require human-readable UDIs or automatic identification of UDIs or both? Are there devices where it would be sufficient to have human-readable UDIs alone? Please explain your reasoning. For example, devices used in a home care setting might not need an automatic identification UDI because the home might not be equipped to read the automatic identifier. Are there situations where we should require both human-readable and automatic identification UDIs? Please explain your reasoning.

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. In circumstances where the product is high risk and remains in the body for a period of time, the UDI should be on the product itself for recall or deficiency reporting capability.

To realize the greatest safety gains, the UDI must be placed on a product at the level it comes into contact with the patient. Previously 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.

> **b. Should we specify a particular type of automatic identification technology or should we allow the automatic identification technology to vary depending on the type of device? Should we identify automatic identification standards (as opposed to specific technologies) that can be used? Please explain your reasoning. Specifying a particular type of automatic identification technology would enable hospitals and other parties who might read or use a UDI to make specific investments in scanning or reading equipment, but the technology chosen might not be easily applied to all devices (if we require the UDI to be placed somewhere other than the label.) For this question, we are particularly interested in hearing from parties who might use UDIs as well as entities that may have already adopted or installed device identification systems.**

Technical standards required for the UDI must be neutral and support auto-ID technologies, including barcodes and RFID. These technical standards must be uniform across the health care field.

> **c. Should we allow the use of different automatic identification technologies to express different parts of the UDI? For example, the device identifier component might be expressed in a linear barcode and the production identifier component might be expressed in a 2D barcode. Allowing the use of different technologies for different components of the UDI may enable manufacturers to make more efficient use of label space or space on the device itself, but it also could generate confusion as to which identifier to read or scan and could necessitate the purchase of several types of reading and scanning equipment.**

Different technologies may be more appropriate for different products. The number is the critical consideration, not the data carrier. The type of data carrier should not be exclusionary or unique.

> **d. Are there existing standards or systems we should consider in establishing the requirements for how the UDI must be presented? For example, we are**

aware of various standards organizations, such as GS1 and the HIBCC, that exist and have specific formats or specifications for automatic identifiers for products. Should we allow any or all of these standards to be used?

The AHA and the AHRMM support the GS1 supply chain standards because the standards: provide a global solution, identify products in and out of the med/surg industry, have been in use by other industries for many years, and can drive significant costs based on current inefficiencies in the supply chain. GS1 also is committed to modifying the standards as needed for health care med/surg products and supports industry sunset dates to ensure an orderly transition while moving to one standard.

6. How should the UDI Database be developed and maintained?
For parties to benefit from UDI information, it would seem necessary for those parties to know, at a minimum, the UDIs that exist, the specific device associated with each UDI, and the information associated with each UDI. It might be efficient for one entity to collect the UDIs, associate those UDIs with specific devices, and make the information associated with those UDIs publicly available. However, it is also conceivable (but perhaps less efficient or more costly) that the information could rest with individual manufacturers themselves (rather than FDA) or with a third party or third parties. Consequently:

a. How and when should we require UDIs and associated information to be entered into a database? How frequently should we require changes to a UDI or to the information associated with or linked to a UDI to be reported?

The product identification (e.g., GTIN) should be held in a PDU (e.g., the Global Data Synchronization Network (GDSN) which includes the GLN for trading partners) and maintained as with other industries. The lot and serial numbers also should be maintained by the manufacturer.

b. Aside from information that is necessary to uniquely identify a device, what other information (if any) should be part of a UDI system database or otherwise linked to the UDIs?

The production date or expiration date should be linked to the UDI.

c. If variable data (such as a lot or serial number) is necessary to uniquely identify a device, should such data be included in a UDI system database?

The lot or serial numbers must be maintained by the manufacturer.

3. Questions for hospitals, nursing homes, and clinics

a. Using a UDI. If UDIs were placed on at least some medical devices, what functions could a UDI serve in your institution?

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. 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.

General Benefits. Other more general benefits include:

- Precise identification of the med/surg product throughout the supply chain.
- Assurance that hospitals are paying the right price for the right product.
- Assurance that the vendor understands exactly what product (and unit of measure) the hospital is purchasing, reducing returns and misused items.
- Precise costing of inventory on hand. Hospitals would know the exact price paid for each product in their inventory.
- Precise case costing. Hospitals would know the exact cost of every item used in patient care. Car manufacturers can determine the exact cost of every item used in assembling a car by providing the VIN. Hospitals could, likewise, tell the exact cost of a patient encounter by looking up the patient's account.
- Ability to assign clinical/functional equivalence to products with accuracy.
- Precise identification if an asset is owned, consigned, bulk-purchased or carried in by the sales representative, since all of these scenarios may occur in operating rooms or cath labs and each may carry a different price per product.
- Ability to consistently document the lot number of devices.
- Ability to use data for value analysis to help hospitals keep costs down by utilizing a PDU to quickly and easily cross reference products.

b. Expenses. What expenses do you foresee in attempting to capture and use UDIs placed on medical devices? If you foresee using UDIs, how would you modify operations in your facility?

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 information systems (MMIS), Enterprise Resource Planning Systems, Operating Room Information System (ORIS)/clinical systems, the financial accounting system and the EHRs, redesigning work processes and training staff in how to use the new systems.

Assuming the UDI is human readable, 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.

c. Adverse event reporting and recalls. How would capturing the UDI change your recall management or adverse event reporting? For recalls or adverse events involving the most serious device malfunctions or failures, how have problems in device identification impaired your recall management or adverse event reporting? Please describe the magnitude of the problems you have encountered.

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. The search for the product takes significant staff time, looking for the product in possible storage locations or examining records to track an implanted patient. Because of the labor intensive nature of doing a recall manually, the recall may be delayed, resulting in the use or implantation of products identified in the recall. The FDA should specify the file structure for the recall used by the manufacturer and the FDA. Software manufacturers need to revise their software to accept and upload the recall information and utilize the data within the hospital's information system. This would allow providers to report back in a uniform automated manner to enhance recall data collection.

The UDI would allow the same concept that the pharmacy uses for monitoring drug recalls, which is by NDC number. Once notification is received of a recalled drug product, the pharmacy has the ability to pull the recalled drug product out of circulation immediately based on NDC number.

Identification of patients who have received recalled devices requires manual review of medical records and in some cases a hospital has little ability to identify the actual patient. 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 serves 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.

Hospitals realize the promise of health information technology (IT) to improve quality of care and having a UDI goes hand-in-hand with the priorities hospitals place on implementing auto-ID technologies and EHRs. One does not take precedence over the other. The results of a 2007 AHA survey of hospitals show that hospitals are already adopting barcoding for a number of uses, including lab specimens, patient ID, supply chain management, pharmaceutical tracking and pharmaceutical administration. More than 1,500 community hospitals – about 31 percent of all U.S. community hospitals – responded to the survey. This sample fairly represents all community hospitals by size, location, and teaching status. In addition, 12 percent of the hospitals surveyed had fully or partially implemented RFID. These data are from the fall of 2006; we expect further adoption has occurred in the past two years. For hospitals already using auto-ID, the UDI could be incorporated into existing efforts. For hospitals yet to adopt auto-ID technologies, having a global, standardized UDI would increase the value of implementing auto-ID.