



February 27, 2009

Food and Drug Administration
Center for Devices and Radiological Health (HFZ-500)
1350 Piccard Dr.
Rockville, MD 20852

Re: Unique Device Identification System; Request for Comments [Docket No. FDA-2008-N-0661]

To Whom It May Concern:

As members of the Advancing Patient Safety Coalition, we are committed to improving the quality of care for our nation's patients and fully support the Food and Drug Administration's (FDA) efforts to create a national unique device identification (UDI) system for medical devices that supports both national and global needs. Today there are multiple and varied product numbering and coding systems and medical devices are becoming increasingly complex. Therefore, we appreciate the opportunity to comment on the FDA's January 15, 2009 Request for Comments published in the *Federal Register*.

The FDA has been working on this issue for more than five years. In that time, the agency has held several public stakeholder meetings, solicited comments and commissioned several studies. While the Advancing Patient Safety Coalition appreciates the open and transparent process the agency has followed, the time to act is now. UDI is too important to patient safety to delay any longer. Therefore, we strongly urge the FDA to move the rulemaking process forward this year to implement a regulated, mandatory UDI system that is globally harmonized.

Unique device identification is the missing link to protect the safety of patients by improving processes for device recalls and corrections. The rapidly rising number of device recalls points to the need for UDI for effective management of recalls. More than 700 medical device recalls were issued in 2008, including more than 100 Class 1 recalls (defined as dangerous or defective products that predictably could cause serious health problems or death). Manufacturers also issue many "device corrections" that can have serious consequences for patients if not handled correctly. Because of the absence of UDI, providers often must use manual and imprecise systems to identify if they have any recalled products.

UDI will strengthen the ability of the FDA and manufacturers to monitor adverse events related to medical devices. A national UDI system would create a common vocabulary for reporting and enhance tracking abilities. Currently, analysis of adverse event reports

is limited by the fact that the specific devices involved in an incident are often not known with the required degree of specificity. Without a common vocabulary for medical devices, meaningful analysis based on data from existing voluntary systems is extremely problematic.

UDI is essential to maximizing the value of electronic health records (EHRs). EHRs will require that data standards, including those for medical devices, are in place and used by all institutions to transfer information. Having a UDI for medical devices is a basic requirement that must be in place before automated identification systems are fully effective. A common vocabulary for medical devices is necessary for healthcare providers to be able to effectively document devices in patient records. In addition, the recently enacted American Recovery & Reinvestment Act contains \$19 billion to encourage health information technology adoption through direct grants to providers as well as Medicare and Medicaid payment incentives. This substantial federal investment in HIT also speaks to the need for a UDI system as soon as possible.

Improving Patient Safety/Recalls:

Clearly, a compelling patient safety interest lies in requiring a UDI system for medical devices, especially when a defective device is recalled. Today, the majority of providers must conduct recalls manually—a labor intensive and time consuming endeavor that does not guarantee a 100 percent success rate, which makes it difficult to definitely associate the use of a device with a particular patient. This greatly delays timely notification of patients if a particular device is recalled and can put patient safety at great risk.

For example, one large teaching hospital only learned about a recall of potentially contaminated bronchoscopes after noticing and investigating reasons for their higher than expected patient infection rate. Hundreds of patients had to be contacted and evaluated for possible infections and two may have died as a result of the contamination. This can be a widespread problem. A study based on the FDA's records over the last 10 years found that 164,000 emergency defibrillators – about one out of every five sold – had been subject to an FDA recall or alert. Automatic, standardized identification would facilitate and improve upon the tracking of these devices in the event of a recall or other safety concern.

Additionally, the counterfeiting of medical devices is on the rise, threatening to compromise the safety of patients. An example was an October 2006 FDA warning about counterfeit blood glucose strips that were identified in the market. A consistent and unique method of identifying medical devices could have helped in the detection and prevention of these counterfeit items before they passed into the supply chain to the patient.

Reducing Medical Errors:

Being able to correctly identify devices, track them through the healthcare system and inform the proper practitioner in a timely fashion about any potential dangers will reduce errors and improve patient care. According to a March 2006 report by the Eastern Research Group (ERG), UDI has the potential to facilitate the identification of device compatibility problems. Some implantable materials have turned out to be incompatible with magnetic resonance imaging (MRI) devices resulting in injuries and deaths. ERG concluded that UDI systems might help reduce such episodes by facilitating communication of more information about implants and implant accessories and by helping to get the additional information into patients' medical records. Additionally, UDI systems could improve methods for ensuring patients with allergies are not treated with or touched by medical devices to which they are allergic (i.e., latex gloves).

Reporting of medical errors will be enhanced when devices – as well as drugs – are uniquely identified. Reporting efforts like the newly created Patient Safety Organizations under AHRQ's purview could capture and use this information to better understand and prevent errors and improve patient safety.

Improving Adverse Event Reporting/Post Market Surveillance:

Accurate and reliable device tracking would also enable data mining so that FDA and manufacturers could better identify potential problems or device defects. Because of the increasing complexity and variety of devices, the potential for problems is escalating. Implementation of a UDI would be a valuable step in improving processes for monitoring adverse events related to medical devices, something that is currently being done by the FDA related to drug safety because of clarity in identifying drugs.

Current systems such as MedSun – a collaborative pilot project launched by the FDA and a group of 350 healthcare facilities to share information about the use of medical devices – only focus on providing information on safety issues with devices and do not address the user issue of tracking the use of the device and locating it easily if there is a recall because of an identified safety problem. Also, the FDA's Sentinel Initiative will be significantly more accurate and efficient if UDI has been implemented first.

Specifically, in response to the questions posed by the FDA in its January 15, 2009 Request for Comments, the Advancing Patient Safety Coalition offers the following responses on how a national UDI system should be structured.

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 exempted?

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 Advancing Patient Safety Coalition believes the UDI should be considered for all devices to improve recall processes, adverse event reporting and patient safety. The information that is included for the products should vary based upon the class of device. Therefore, it is recommended that FDA require basic information for all devices and a more extensive database in the data repository for those devices that require additional information be available.

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

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

The attributes or elements needed to create a UDI will vary based upon the classification of the device. Therefore it is important that the UDI system include a classification system that places the device into a class that will in turn determine the appropriate attributes. The UDI, at a minimum, should include manufacturer, product name, make, model, lot number, unique description, expiration date, and unit of measure.

d. Should the UDI include a component that represents package size or packaging level?

UDIs should be implemented at the package level that is issued to the patient. This would ensure the identification of the device as it is provided to the patient (right product and right patient) and minimize the errors associated with the provider organization re-labeling the device for issue to the patient. The information included at the point of issue to the patient should be sufficient to identify the device and allow it to be linked to the provider database which would be synchronized to the product data repository.

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?

There is a clear advantage for using the GS1 system in that it has been in use by other industries for many years, it is recognized globally, and it is committed to modifying its standards as needed for healthcare products. It has over 105 global offices that allow it to have the global reach for healthcare products and it is currently used by other industries from which healthcare organizations buy products.

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

Identification systems for products are already prevalent in the grocery, food service, automotive and electrical industries. All of these industries have successfully adopted the GS1 system of identification and classification. We should not reinvent the wheel. Since

providers purchase products from each of these industries it makes sense to build upon what is already in place and utilize the GS1 system for medical devices.

5. How should the UDI be presented?

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 Coalition supports the UDI being both human readable and encoded in automatic technology. The human readable information on the device should be limited to what is minimally required to properly identify the product before applying to a patient. Likewise the information encoded on the device would only need to be the minimum necessary to identify the product for safe distribution to the patient. The encoded information would allow the automated system to access a richer database on the device that would contain more extensive information to assist in recalls and other patient specific safety checks.

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.

UDI should be technology neutral in order to accommodate all methods of labeling, marking, identifying products and software (one-dimensional linear barcode, two-dimensional barcode, RFID or other Automatic Identification and data capture media).

In closing, we thank you for the opportunity to provide comments on a UDI and reiterate our strong support for a regulated, mandatory UDI that is globally harmonized. We look forward to working with you on this important issue that will ultimately improve patient safety, reduce medical errors, facilitate device recalls and improve device adverse event reporting.

Sincerely,

AAMC

AARP

Alliance for Advancing Nonprofit Health Care

Alpha-1 Foundation

American Academy of Orthopaedic Surgeons

American Association of Neurological Surgeons

American Heart Association

American Hospital Association

Association for Healthcare Resource & Materials Management

Association for Professionals in Infection Control and Epidemiology (APIC)

California Hospital Association

Catholic Health Association

Congress of Neurological Surgeons

Federation of American Hospitals

The Joint Commission

National Association For Continence

National Rural Health Association

Novation

PeaceHealth

Premier Inc.

Scoliosis Research Society

Texas Health Resources

The Society of Healthcare Epidemiology of America

University HealthSystem Consortium

VHA Inc.

West Penn Allegheny Health System

West Virginia United Health System

White River Health System