



November 9, 2006

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

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

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Dear Acting Commissioner von Eschenbach:

On behalf of the Premier Inc. healthcare alliance, I write to urgently call upon the Food and Drug Administration (FDA) to require a national unique device identification (UDI) system for medical devices. Specifically, I am submitting detailed responses to the FDA's August 11, 2006 Request for Comments published in the *Federal Register* on how a national UDI system should be structured to improve patient safety, reduce medical errors, facilitate device recalls and improve device adverse event reporting.

First, Premier Inc. would like to thank the FDA for its work on UDI. We appreciate the FDA's open and collaborative efforts in holding several public stakeholder meetings to solicit candid input on how a national UDI system for medical devices should be crafted. Premier Inc. is fully supportive of the FDA's efforts on this issue and looks forward to continuing to work with the FDA as the regulatory process moves forward.

One of the key ways in which Premier Inc. supports the efforts of more than 1,500 local hospital members is by aggregating and analyzing clinical and financial data. Hospitals use this data to identify opportunities to improve patient care and to track the progress of their efforts. A UDI system would provide a vital flow of information that hospitals need to accelerate their improvement efforts.

Today there are multiple and varied product numbering and coding systems. Therefore, we support a regulated, mandatory UDI with a global nomenclature, similar to the FDA National Drug Code system.

As you know, one of the barriers to implementing automatic identification for

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medical devices cited in the comments submitted to the FDA in response to the 2004 bar code rule for drugs and biologics was the lack of a standard, unique device identifier accepted by all stakeholders. The FDA and other federal agencies, such as the Agency for Healthcare Research and Quality (AHRQ), have asserted that a unique identifier for medical devices is urgently needed. A unique identifier has benefits on its own for patient safety and supply chain efficiency. It would also encourage industry use of automatic identification technologies such as bar codes or radio frequency identification (RFID), and facilitate the implementation of these technologies. Use of unique device identification is a crucial missing link in helping hospitals conduct efficient recalls, improve adverse event reporting, prevent errors, and harness the power of health information technology.

The need for a unique device identification system is well understood by people who work every day in hospitals. A recent survey of 950 hospital-based clinicians and administrators that lead patient safety programs found overwhelming recognition that a UDI system would greatly or somewhat increase patient safety. The full study findings are attached to this letter.

Premier's detailed responses to the FDA's Request for Comments are as follows:

Developing a System of Unique Device Identifiers

1. How should a unique device identification system be developed? What attributes or elements of a device should be used to create the UDI?

Medical devices lack a standard and unique identifying system that is comparable to the National Drug Code (NDC) system for pharmaceuticals. 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. (*GS1 is a global organization dedicated to the design and implementation of global standards and solutions to improve efficiency and visibility in supply and demand chains.*) We should not reinvent the wheel. Since the healthcare supply chain includes 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. GS1 has a nomenclature system in place that is used globally and should be utilized for a national unique device identification system. This should include the use of the Global Trade Item Number (GTIN) and development of a Product Data Utility (PDU) that is compatible with the



Global Data Synchronization Network (GDSN). (*GTIN is the globally unique identification number managed by GS1 for trade items, which encompasses both products and services. PDU is a system that interconnects trading partners across the supply chain to synchronize core product data to standard specifications and distribute standardized product data from manufacturers and distributors to data aggregators and end-users.*)

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. For example, the attributes for an adhesive bandage will be different than those for an implantable device. The UDI, at a minimum, should include manufacturer, product name, make, model, lot number, unique description, expiration date, and unit of measure. The use of a PDU will allow users to extract additional information on the product that might not be included on the label that is attached to the product. This would result in a richer database and the ability to add additional data elements as needed and agreed upon by the industry. The PDU has been successfully used in other industries and allows all supply chain participants to synchronize their master product files resulting in a more effective and efficient process for product identification, distribution, and recalls. Premier has participated with other supply chain parties in the Department of Defense (DoD) pilot PDU which should be reviewed as the FDA considers moving forward with the establishment of a UDI for medical devices.

2. What should be the role, if any, of FDA in the development and implementation of a system for the use of UDIs for medical devices? Should a system be voluntary or mandatory?

The industry has been trying to voluntarily adopt the Universal Product Number (UPN) for medical devices for over ten years and has made little progress. It is difficult to imagine that a voluntary system for a unique identification system would be advantageous since it would result in multiple systems that would add to the complexity. What we have today is a voluntary system where each manufacturer, distributor and provider has their own system. These dual systems increase the risk for patients and create operational and safety problems in hospitals.

FDA action is necessary because healthcare is structured differently than other sectors of our economy. American retailers have been able to require that manufacturers use bar codes because of their buying clout, but our



community-based healthcare system is unable to replicate that in the marketplace. Therefore, FDA action is needed to address this serious impediment to patient safety and enable increased efficiency in the healthcare system.

3. What are the incentives for establishing a uniform, standardized system of unique device identifiers?

The primary incentives are improving patient safety and reducing costs. Specifically, these include the reduction of medical errors, facilitation of recalls, identification of patient incompatibility with devices or allergic reactions, improving inventory control, reducing product counterfeiting and cost reductions for all supply chain participants associated with a more efficient supply chain. Another incentive would be more efficient sourcing and distribution of products because of the ability to consistently identify products across the supply chain through standardization of descriptions, packaging and labeling. The UDI would also aid in efficient reimbursement since most reimbursement programs are based upon broad billing codes that might not differentiate between expensive and inexpensive medical devices. Finally, UDI would also allow the product information to be more readily identified and therefore passed from provider to provider as a part of the electronic health record (EHR).

4. What are the barriers for establishing unique device identifiers? What suggestions would you have for overcoming these barriers?

Barriers for establishing a UDI include: 1) The current lack of a common taxonomy or classification system, 2) The absence of a common repository that serves as an industry wide utility and allows synchronization for all supply chain parties, 3) How to handle drug/device combination products and kits, 4) Cost of infrastructure and IT systems, 5) Funding for the data repository that will ensure longevity and quality, 6) Product labeling in which the information is both human and machine readable, 7) Small size of many device companies and their ability to conform, 8) Resistance from some manufacturers due to concerns over product commodization, 9) Need for global adoption and current efforts of other countries to implement standards, 10) Speed and cost of implementation for providers.

Premier believes these barriers can be addressed through FDA mandating the development and use of a UDI for medical devices as outlined in Question 1.

5. Have you implemented some form of UDI in your product line? Please



describe the extent of implementation, type of technology used, and the data currently provided.

Premier requests the use of a UPN on all products for which it contracts. However, Premier does not have the authority to force manufacturers to comply and is not in a position to mandate the data be regularly updated. The current repositories for UPNs are not managed for the quality of information and the timeliness of updating the information and lack standards for completeness. Thus, the current voluntary system of providing a UPN is not sufficient and needs to move to a PDU that requires certain attributes for different classifications of medical devices and has quality control processes that ensures the information is correct and timely.

Premier has implemented the United Nations Standard Product Service Code (UNSPSC) classification system for all products under contract and provides this classification for all products in our database. Premier does synchronization with the GHX healthcare exchange as well as with hospitals in their system. Synchronization with all of Premier's hospitals and business partners is a significant cost and burden to hospitals. A unique device identifier and the existence of a product data repository would simplify the process and reduce the cost for all supply chain partners.

6. Should unique device identifiers be considered for all devices? If yes, why? If not, what devices should be considered for labeling with a UDI and why?

The UDI should be considered for all devices to improve recall processes, adverse event reporting and patient safety and allow the healthcare supply chain to adopt consistent processes for handling and managing both the products and corresponding information. The information that is included for the products should vary based upon the class of device. For example, the information needed for an adhesive bandage would be different than that for an implantable 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 are classified as directly used on, in or with patients and those with foreseeable interactions concerns.

7. At what level of packaging (that is, unit of use) should UDIs be considered? Should UDIs be considered for different levels of packaging? If yes, should the level of packaging be based on the type of device? Why or why not?



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 containing a more extensive database on the device. This process would allow different classes of devices to have more information but at the same time limit the required fields on the device itself.

8. What solutions have you developed or could be developed for addressing the technological, equipment, and other problems that might arise in developing and implementing a UDI system (e.g., solutions for packaging issues)?

Premier, in conjunction with the Coalition for Healthcare Electronic Standards (CHeS), has selected standards for identification of supply chain participants, product identification, and product classification and is in the process of participating with the DoD on a pilot for a Product Data Repository. Each of these elements is needed in order to implement an effective UDI and associated information system. This system is modeled after similar systems that are operational in the grocery, food service, automotive and electrical industries. Premier believes it is important that the healthcare industry, which uses many products from these and other industries adopt similar standards and processes for medical device UDI. The standards used by these industries and recommended by Premier and CHeS are the GS1 standards that include GLN (location), GTIN (product), UNSPSC (classification) and GDSN (synchronization).

Implementing Unique Device Identifiers

9. What is the minimum data set that should be associated with a unique device identifier? Would this minimum data set differ for different devices? If so, how? How would the data in the minimum data set improve patient safety? What other data would improve patient safety?

The minimum data set for all devices should include: UPN, manufacturer, make, model number, serial number, expiration date, and the unit of measure. The minimum data set should be consistent but the database at the provider location and resident in the PDU would vary based upon the classification of the medical device. The data stored in the PDU could for example include



safety information about the product as well information for recall.

The data in the minimum data set would improve patient safety through allowing the patient provider and electronic ordering system to check at the point of issue to the patient the device type with the clinical order and ensure appropriate patient and device. In addition, flagging recalls before patient exposure will be possible and the ability to track the devices administered to the patient electronically will improve the ability to determine adverse reactions and to pass a more complete medical record to other providers.

10. How should the UDI and its associated minimum data set be obtained and maintained? How and by whom should the UDI with its associated minimum data set be made publicly available?

Other industries have utilized organizations that are in the business of developing and maintaining standards. The standard most logical for medical devices would be the GTIN that is maintained through the standards organization GS1. The manufacturer of the product would utilize the GS1 process for obtaining and maintaining a GTIN and that would become the UDI for their product. This would ensure a consistent description and identification of the product. As mentioned before, the information retained would vary based upon the classification of the product. The information would be available to the public for very little expense since GS1 is an open standards organization.

Not only would this information be available through GS1 but the healthcare industry should establish a PDU that would contain the product UDIs and the required information for that product. This would allow all parties to synchronize their files and effectively communicate across the supply chain information needed for ordering, distributing, maintaining, tracking and recalling products.

11. Should the UDI be both human readable and encoded in an automatic technology? Should the UDI be on the device itself (e.g., laser-etched) for certain devices?

Premier 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.

12. Should a UDI be based on the use of a specific technology (e.g., linear bar code) or be nonspecific? Please explain your response. If a bar code is recommended, is a specific type of symbology preferred, and if so, what type and why? Should the bar code be “compatible” with those used for the drug bar code rule? If yes, why? If not, why not?

Premier would support following the same guidelines as used for the drug bar code rule. This would allow the care giver to utilize similar technologies at the patient distribution location. We are not opposed to using multiple symbologies since most current technologies can read and capture most all of these. Establishing and using a UDI is the first step in effectively using auto identification such as bar codes and RFID.

UDI Benefits and Costs

13. From your perspective, what public health and patient safety benefits could be gained from having a standardized unique device identifier system? How would such a system contribute to meeting device recall and adverse event reporting requirements, and to reducing medical error? Please submit detailed data to support benefits you identify.

Recall Improvement:

Unlike virtually every other product sold in America, medical devices cannot be electronically tracked or inventoried, so finding recalled products is unreliable. As one Premier hospital executive stated, “We receive several recall notices per month which require a manual chart review of every patient who might have received the device for the given time period. This creates a significant work load impact, but more importantly, there is a significant risk of missing a patient who may have received a defective device. This is of tremendous concern to the caregivers.”

Research has begun regarding the difficulties with the current device recall system. A 2005 Institute of Medicine report cited the lack of communication between providers, manufacturers and the FDA as well as the mixed signals on urgency. Premier has undertaken efforts to determine the current efficiency of the recall process. Preliminary results indicate that in the case of



one Class I recall, over 50 patients in over 40 hospitals received the product several months after the device was recalled. However, many devices are difficult to identify with certainty to determine what product was used on the patient due to the lack of a UDI. Some highly publicized recall events have lent strong evidence on the inefficient and often ineffective recall process.

- 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. At least seven patients died during episodes where a defibrillator short-circuited.
- A large teaching hospital system struggles with tracking human tissue. It has an automated system in their operating room (OR), but software problems resulted in the need to conduct a manual chart review to get the lot numbers of the tissue. This hospital currently uses a paper system where stickers are placed in the chart after donated tissue is used, which has also failed at times.
- Another large teaching hospital learned about a recall of potentially contaminated bronchoscopes after noticing a 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. The experience of this institution was documented in the January 16, 2003 edition of the *New England Journal of Medicine*.

Premier hospital executives have shared their stories:

UDI is an opportunity to improve recall efficiency . . .

1. One large health system was adversely affected by three of the very public Class I recalls, with Boston Scientific on the Taxus DES; Guidant on Pacemakers and Baxter on Large Volume IV Pumps. They said, "Had there been bar coding on the Boston Scientific and Guidant products it would have expedited the tracking of these devices and the patients. In many cases, Cardiac logs are manual. Adding bar coding to medical devices would be beneficial to vendors, buyers and patients. This effort would align well with JCAHO's "Patient Safety Goals"; information could help to protect patients from preventable errors thereby improving quality of care for our customers."

2. Another Premier owner established a multi-disciplinary team to cope with



the urgent recall of Baxter IV pumps and worked through an entire weekend to manually locate and assess the condition of the pumps.

3. One Premier hospital executive believes that bar coding will improve their ability to process recalls as currently several departments (risk management, safety and clinical engineering) work as a team to log entries in a central Excel spread sheet – a very labor intensive process.

UDI is an opportunity to improve patient safety . . .

4. One Premier hospital executive said, “Another significant risk to patient care and safety is the possibility of implanting an outdated device or using an outdated device because we cannot track outdated information with bar code technology because the information is not available from the manufacturer. This is another area to which we extend significant manual processes and time to make sure that the device inventory is tightly managed to prevent an expired device being used.”

UDI is an opportunity to improve patient safety and increase supply chain efficiency . . .

5. A Premier hospital executive stated, “I believe that using technology to track equipment, implantable devices, etc. will surely have a positive impact on patient safety, supply chain efficiencies, and improved quality. I also believe that this will be accomplished through a combination of technologies including bar coding, as well as passive and active RFID systems. Regardless of the label, chip or tag, these devices should all tie to the appropriate tracking system platform and software. Bar code applications to tie the patient to the medication and administering nurse will certainly improve safety and patient care. RFID technology on patient care equipment can help maximize the use of the equipment, ensure proper maintenance, and reduce cost of rentals, etc. RFID or barcode technology on medical supplies in general can expedite the inventory control process from the vendor's perspective in the picking process, the customer's perspective in the receipt and replenishment processes.”

Adverse Event Reporting Improvement:

Accurate and reliable device tracking would enable data mining so that FDA and manufacturers could better identify potential problems or device defects.



Premier currently conducts drug monitoring for the Center for Drug Evaluation and Research because of the ability to electronically track drug usage and associate its usage with patient outcomes and potential complications. The same activity cannot be conducted for medical devices and because of the increasing complexity and variety of devices, the potential for problems is escalating. Product identification is particularly difficult for devices in the same therapeutic category.

Current systems are voluntary (i.e., MedSun and MAUDE) and were primarily created to monitor adverse events with a focus on providing information on safety issues with devices. Also, to extract data from the current systems requires all searches be done as free-text searches. However, there is no standard phrasing on how a user should type in a topic or device. As a result, each search result must be read in its entirety to ensure its validity with the search criteria.

Reducing Medical Errors:

Being able to correctly identify devices, track them through the healthcare system and inform the proper practitioner 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).

14. From your perspective, what are the setup costs measured in time and other resources associated with the development, implementation, and use of a UDI system? Please submit detailed data to support these cost estimates.

Hospitals are moving forward on the adoption of technology and with the current lack of a national standard have had to invest millions of dollars to create internal tracking systems for devices. It is clear this investment improves quality and supply chain efficiency for the hospital, but a national unique identifier system would accelerate these efforts that ultimately benefit



patients. A 2005 survey of hospital use of information technology done by the American Hospital Association concluded:

1. Hospitals are committed to adopting information technology;
2. More than half of all hospitals have adopted bar coding technologies for at least one purpose. Bar coding technologies have created significant safety benefits by matching patients and their drugs before they are administered. About 25 percent of hospitals surveyed have fully or partially implemented bar coding for pharmaceutical administration;
3. Approximately 10 percent of hospitals are beginning to use radio frequency identification to identify and track items; and
4. Those hospitals that are leading the way on bar coding also, in many cases, do their own bar coding of medical devices, but there is still no national, consistent number such as the UPN.

15. If you have already implemented a form of unique identification on your medical device labeling, what investments in equipment, training, and other human and physical resources were necessary to implement the use of UDIs? What factors influenced your decision to implement such a system? What changes in patient safety or economic benefits and costs have you observed since the institution of UDIs?

Many Premier hospitals have invested time and resources into implementing a UDI. Premier would welcome the opportunity to put the FDA in touch with these hospitals for further discussion.

16. From your perspective, what is the expected rate of technology acceptance in implementing or using a UDI system?

Given the successful implementation of bar coding pharmaceuticals, biologics and blood products, the unique identification of medical devices would be well accepted. Also, hospitals are continuously striving to improve patient safety and streamline their recall processes – a national unique identifier for medical devices would give hospitals a key tool to meet their patient safety improvement goals.

17. From your perspective, what are the obstacles to implementing or using a UDI system in your location?

Many Premier hospitals had to overcome obstacles to implement a UDI. Premier would welcome the opportunity to put the FDA in touch with these hospitals for further discussion.



18. For hospitals and other device user facilities considering technology investments, what would be the relative priority of developing UDI capabilities compared to other possible advancements, such as Electronic Health Records, bedside barcoding for pharmaceuticals dispensing, data sharing capabilities across hospitals and other device user facilities, and other possible advances?

Premier would welcome the opportunity to facilitate discussion between the FDA and Premier hospitals that have undergone this process.

19. What infrastructure or technological advancements are needed for hospitals and other device user facilities to be able to capture and use UDI for basic inventory control and recall completion purposes? How costly are these advancements?

Premier would welcome the opportunity to facilitate discussion between the FDA and Premier hospitals that have undergone this process.

20. Referring specifically to completing medical device recalls in your hospital or other device user facility, for what share of the most serious (Class I) or next most serious (Class II) recalls would having access to and an ability to capture UDI information help you to respond?

UDI information would be extremely helpful, especially for the devices having the most serious impact on patient safety. For example, devices used on or implanted in a patient (i.e., central lines, pacemakers, implantable drug pumps, ortho implants, etc.). Also, another important issue is the recall of items like pumps, which pose a challenge because of the different times of purchase and repair. A national unique device identifier would greatly assist in the tracking and recalling of these devices once fully implemented.

In closing, I thank you for the opportunity to provide comments on a UDI and reiterate our strong support for a regulated, mandatory UDI with a global nomenclature, similar to the FDA National Drug Code system. If you have any questions regarding our comments please call Premier's Chief Information Officer Joe Pleasant at 704.733.5415.

Sincerely,

Comments from Premier Inc. to FDA on UDI

November 9, 2006

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A handwritten signature in black ink, appearing to read "Blair Childs", is written over a light gray rectangular background.

Blair Childs

Senior Vice President, Public Affairs

Attachment