



November 9, 2006

The Honorable Andrew C. von Eschenbach, M.D., Acting Commissioner  
Food and Drug Administration  
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Rockville, MD 20857

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PREMIERINC.COM

***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:

I am writing in my capacity as chairman of the Quality Improvement Committee for the Premier Inc. healthcare alliance to urgently call upon the Food and Drug Administration (FDA) to require a national unique device identification (UDI) system for medical devices.

First, the Quality Improvement Committee of Premier 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.

The Quality Improvement Committee of Premier includes CEOs from 17 health systems representing nearly 100 hospitals from across the nation. Our committee helps guide decisions about quality initiatives for Premier, which is the largest healthcare alliance owned by over 200 non-profit hospitals and health systems. Premier is dedicated to improving patient outcomes while safely reducing the cost of care.

One of the key ways in which Premier 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 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.

### **Improving Patient Safety/Recalls:**

Clearly, patient safety is a compelling reason to require a UDI system for medical devices, especially when a defective device is recalled. Today, the majority of hospitals must conduct recalls manually—a labor intensive and time consuming endeavor that does not guarantee a 100 percent success rate. Automatic, standardized identification would facilitate and improve the tracking of these devices in the event of a recall or other safety concern. Highly publicized device recall cases provide strong evidence of the inefficient and, in some cases, ineffective recall process.

- One 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. This institution’s experience was documented in the January 16, 2003 edition of the *New England Journal of Medicine*.
- Another large teaching hospital system that is part of the Premier alliance struggles with tracking human tissue. It has an automated system in its operating room (OR) computer software, but software problems prompted 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. That system has also failed at times. Information must be gathered from three sources (implant log book, OR software system, and OR notes with stickers) when there is a recall.
- 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.

Manufacturers also issue many “device corrections” that can have serious consequences for patients if not handled correctly. These can be facilitated, tracked and more quickly resolved by hospitals with the use of UDI. They are not considered recalls by the FDA because they can be corrected by the user, but can often be just as serious as a Class I recall. For example, the majority of problems over the last several years with IV pumps were device correction issues that could result in severe patient outcomes if all the equipment was not located and corrections were not made by the users.

According to ECRI, a not-for-profit health services agency in Pennsylvania, some

of the more serious device problems – such as ventilator alarm failures, tracheal tube surgical fires, and gas embolism deaths during use of argon beam coagulation – were never classified as FDA recalls.

### **Improving Adverse Event Reporting/Post Market Surveillance:**

Accurate and reliable device tracking would also enable data mining so that the 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 as a way to more clearly identify 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. The user issue of tracking use of the device and locating it easily if there is a recall is not a focus because devices cannot be accurately identified.

### **Reducing Medical Errors:**

The ability 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 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 (e.g., latex gloves).

### **Improving Efficiency:**

Hospitals struggle to track devices through their inventories as the information is not available from the manufacturer. Although many manufacturers bar code their products, there is no national repository of the information contained in the proprietary bar codes, making it meaningless to healthcare providers. Therefore, many health systems must create and manage their own bar coding systems and then contract with a third party to synchronize their data with the manufacturer, distributor, or other entity. This is a costly undertaking for hospitals and has the potential to generate errors by adding another layer to the process of tracking medical devices.

### **Enhancing Electronic Health Records/Clinical Data Flow:**

Electronic health records (EHRs) will require that data standards are in place and used by all institutions in order to transfer clinical information and be fully



interoperable. While much of the EHR discussion has centered on clinical procedures and orders, the ability for clinicians to have full information of the supplies and devices utilized during a patient's treatment will be required to improve patient care. Therefore, having a UDI for medical devices is a basic requirement that must be in place before automated identification systems are effective. Implementation of an EHR was shown to be the #1 priority for hospitals in a 2005 *Modern Healthcare* survey.

In closing, I thank you for the opportunity to provide comments on a UDI on behalf of Premier's CEO Quality Improvement Committee 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,

Stephen R. Mason, Chairman  
Premier Inc. CEO Quality Improvement Committee  
President & CEO  
BayCare Health System

Members of Premier Inc. CEO Quality Improvement Committee:

Edward Boyer, Senior VP, Corp Services, Bon Secours Health System  
Michael Bryant, President & CEO, Methodist Health Svcs.  
Robert L Colones, CEO, McLeod Regional Medical Center  
John Currin, CEO, Alamance Regional Medical Center  
Dr. Charles Hart, CEO, Rapid City Regional Hospital, Inc.  
Michael Halseth, President & CEO, Valley Health System  
Jim Hinton, CEO, Presbyterian Health Care Svcs.  
Michael Jhin, President & CEO, Emeritus, St. Luke's Episcopal Health System  
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Michael Sellards, President & CEO, Pallottine Health Systems, Inc.  
Wayne Sensor, CEO, Alegend Health System  
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Clark Taylor, CEO, Ephraim McDowell Health  
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