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BON SECOURS HEALTH SYSTEM, INC.

November 7, 2006

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

Re: Docket No. 2006-0292  
Unique Device Identification; Request for Comments

Dear Acting Commissioner von Eschenbach,

On behalf of Bon Secours Health System, I am writing to request that the Food and Drug Administration (FDA) require a national unique device identification (UDI) system for medical devices. As there are multiple and varied product numbering and coding systems, Bon Secours Health System supports a regulated, mandatory UDI with a global nomenclature, similar to the FDA National Drug Code system.

Specifically, in response to the FDA's August 11, 2006 Request for Comments published in the *Federal Register*, we offer the following comments on how a national UDI system will improve patient safety, reduce medical errors, facilitate device recalls and improve device adverse event reporting.

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

A compelling patient safety interest lies in requiring an UDI system for medical devices, especially when a defective device is recalled. 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 often ineffective recall process. There were more than 600 device recalls issued annually and in the past four years more than 60 of those recalls were Class I recalls. As you know, a Class I recall is defined as dangerous or defective and could cause serious harm and/or death to a patient.

Manufacturers also issue many "device corrections" that can have serious consequences for patients if not handled correctly. They are not technically recalls because they can be corrected by the user, but they 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 involved battery failures that have could resulted in severe patient outcomes if all the equipment was not located and the corrections were not made by the users. Although hospitals that are JCAHO accredited are required to have a policy on how the facility addresses recalls, this is in most cases a manual process that increases the potential for human error.

#### **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

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increasing complexity and variety of devices, the potential for problems is escalating. Implementation of an UDI would be a valuable step in improving processes for monitoring adverse events related to medical devices. For Bon Secours this has proven time and time again to be a duplicative and laborious but necessary process.

#### **Reducing Medical Errors**

Being able to correctly identify devices, track them through the healthcare system and inform the proper practitioner about any potential dangers such as device compatibility problems will reduce errors and improve patient care. For example, some implantable materials have turned out to be incompatible with magnetic resonance imaging (MRI) devices resulting in injuries and deaths. UDI systems could also 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). An UDI would allow healthcare supply chain to adopt consistent processes for handling and managing both the products and corresponding information. It is very important to be proactive in this matter versus reactive.

#### **Improving Efficiency**

Bon Secours Health System struggles to track devices through our inventories as the information is not available from the manufacturer. While it is true that many manufacturers bar code their products, there is no national repository of the information contained in the proprietary bar codes, which makes it meaningless to health care providers. Therefore, Bon Secours Health System and many other health systems must create and manage our 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 our facilities 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. 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 an UDI for medical devices is a basic requirement that must be in place before automated identification systems are effective. Bon Secours Health System has recently made a corporate decision to purchase and install a clinical information system/EMR named EPIC in all of its facilities. However, installation is projected to be a five-year project for seventeen facilities in eight states.

In closing, I thank you for the opportunity to provide comments on an UDI and reiterate Bon Secours Health System's support for a regulated, mandatory UDI with a global nomenclature, similar to the FDA National Drug Code system. We look forward to working with you on this important issue that can improve patient safety, reduce medical errors, facilitate device recalls and improve device adverse event reporting.

Sincerely,



Ed Boyer  
Senior Vice President of Corporate Services

cc: Bon Secours Health System's US Congressional Members