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:

As organizations committed to improving the quality of care for our nation's hospitals and the patients they serve, we urgently call upon the Food and Drug Administration (FDA) to require a national unique device identification (UDI) system for medical devices. Today there are multiple and varied product numbering and coding systems. Therefore, we support a regulated, mandatory UDI with a global nomenclature that complements the FDA National Drug Code system.

Specifically, in response to the FDA's August 11, 2006 Request for Comments published in the *Federal Register,* the undersigned organizations offer comments 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.

As you know, one of the barriers to implementing automatic identification for medical devices cited in the comments submitted to 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. FDA and other federal agencies, such as the Agency for Healthcare Research and Quality (AHRQ) have asserted that an urgent need exists for a unique identifier for medical devices. 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. We believe that the unique device identification (UDI) system is a crucial missing link in improving patient safety, conducting efficient recalls, improving adverse event reporting, preventing errors, and harnessing the power of health information technology.

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 hospitals must conduct recalls manually—a labor intensive and time consuming endeavor that does not guarantee a 100 percent success rate. Moreover, it is not possible to 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 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 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.

Manufacturers also issue many "device corrections" that can have serious consequences for patients if not handled correctly, which can be facilitated, tracked and undertaken more expeditiously with the use of UDI. They are not technically recalls 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. These involved battery failures that could result in severe patient outcomes if all the equipment was not located and the 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.

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).

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.

Improving Efficiency:

Providers struggle to track devices through their 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 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 providers 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 a UDI for medical devices is a basic requirement that must be in place before automated identification systems are effective

In closing, we 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 that complements the FDA National Drug Code system. 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,

AARP
American Hospital Association
American Nurses Association
Association for Professionals in Infection Control and Epidemiology
Association of American Medical Colleges
Bon Secours Health System, Inc.
Catholic Health Association
Federation of American Hospitals
Joint Commission on Accreditation of Healthcare Organizations
National Association of Public Hospitals and Health Systems
Novation
Partners Healthcare
Premier Inc.
The ERISA Industry Committee
The Society of Healthcare Epidemiology of America
University Health System Consortium
VHA Inc.