



July 7, 2010

Ms. Margaret Hamburg, M.D., Commissioner
Food and Drug Administration
Parklawn Building, 5600 Fishers Lane
Rockville, MD 20857

Dear Commissioner Hamburg:

As members of the Advancing Patient Safety Coalition, we write to urge the Food and Drug Administration (FDA) to issue a proposed rule immediately that establishes a unique device identification (UDI) system that supports both national and global needs through the GS1 system. The Coalition membership, which includes prominent hospital, physician, nursing, research, quality and patient advocacy organizations, believes the proposed rule must be published now as UDI is critical to patient safety improvement initiatives as well as implementing electronic health records (EHRs) and the delivery system reforms included in the recently enacted health reform bill. Additionally, the efficiencies gained through UDI will save the healthcare system billions of dollars, which providers could reinvest in initiatives to improve the quality and safety of care.

While the Coalition recognizes and appreciates the work and interest of the FDA on UDI, it is taking the agency an unreasonable amount of time to publish a proposed rule. As you know, it has been **three years** since Congress passed the “The Food and Drug Administration Amendments Act of 2007,” which included language requiring the FDA to promulgate regulations establishing a national UDI system for medical devices. Moreover, the FDA has been working on this issue for years before the legislation was passed. With each day that elapses without a UDI system in place, patients’ lives are put at needless risk.

Improving patient safety:

Unlike medications, and virtually every other product in commerce, medical devices cannot be identified in a systematic and consistent manner. The resulting *ad hoc* approach results in increased clinical risks to patients. These clinical risks include implanting a defective, counterfeit, or recalled product; inability to track the recipient of a faulty product if it is recalled; and inability to appropriately track adverse events. UDI 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. 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.

Realizing the value of EHRs and goals of health reform:

Since the FDA Amendments Act of 2007 was passed, Congress has also enacted stimulus legislation that included over \$20 billion to incentivize providers to adopt EHRs. UDI is essential to maximizing the value of EHRs. The EHR will require that data standards, including those for medical devices, are in place and used by all institutions to transfer information. Having a UDI system for medical devices is a basic requirement that must be in place before automated identification systems are fully effective.

The Patient Protection and Affordable Care Act (PPACA) signed into law this spring included numerous quality improvement provisions and payment delivery system reforms that encourage collaboration among providers. These initiatives, such as accountable care organizations (ACOs), depend on providers working together to improve the overall health status of defined populations of patients. Technology will be an important part of this collaboration, but the data being shared on medical devices must be accurate and dependable.

Realizing efficiencies:

UDI will also greatly benefit the U.S. healthcare supply chain through increased efficiencies and improved order accuracy, which will result in substantial savings. Patients will be the ultimate beneficiaries of a more efficient supply chain system because providers will be able to track recalled products more accurately and improve the quality, safety and affordability of care they provide their patients.

In 1996, the Efficient Healthcare Consumer Response (EHCR) released a study entitled “*Improving the Efficiency of the Healthcare Supply Chain*” stating that \$11 billion of supply chain costs each year are avoidable process costs, which could be saved through improved efficiencies. These savings were tied to the adoption of a healthcare identifier, universal product number, identification standards and electronic data interchange and bar coding. This study was recently updated by Arizona State researchers and now estimates supply chain savings at a total of **\$16 billion annually**.

Additionally, a 2009 comprehensive survey entitled “*The State of Healthcare Logistics*” conducted by researchers at the University of Arkansas found that the average healthcare provider spends more than \$72 million a year on supply-chain functions, which is nearly one-third of their annual operating budget. UDI is key to the ability of providers to lower their supply costs.

In closing, we again thank you for the work of the FDA on this important issue and reiterate we cannot wait any longer. A regulated, mandatory UDI system that is globally harmonized will ultimately improve patient safety, reduce medical errors, facilitate device recalls, improve device adverse event reporting and recognize the full potential of EHRs and delivery system reforms.

Sincerely,

Alliance for Advancing Nonprofit Health Care
American Academy of Orthopaedic Surgeons
American Gastroenterological Association
American Hospital Association
American Medical Student Association
American Nurses Association
American Urological Association
Association for Healthcare Resources and Materials Management
Association for Professionals in Infection Control and Epidemiology
Catholic Health Association of the United States
National Association for Continence
Novation
PeaceHealth
Premier
Society for Cardiovascular Angiography and Interventions
Society for Healthcare Epidemiology of America
Texas Health Resources
The Hip Society
The National Association of Public Hospitals and Health Systems
The North American Spine Society
University HealthSystem Consortium
VHA Inc.
West Penn Allegheny Health System
West Virginia United Health System
White River Medical Center