



September 19, 2011

The Honorable Jacob J. Lew, Director
Office of Management and Budget
725 17th Street, NW
Washington, DC 20503

Dear Director Lew:

The Advancing Patient Safety Coalition is committed to improving patient safety through the establishment of a national unique device identification system. As prominent hospital, physician, nursing, research, quality and patient advocacy organizations, we are writing to express our strong interest in seeing the Office of Management and Budget (OMB) release the proposed rule on the unique device identification (UDI) system for medical devices. The Food and Drug Administration Amendments Act of 2007 requires the Food and Drug Administration (FDA) to release a regulation implementing a UDI system.

It is imperative that OMB work expeditiously to release the proposed UDI rule, as the rule is critical to patient safety improvement initiatives and medical error reduction. Unlike other products on the market in America, there is no uniform identification system for medical devices. The resulting *ad hoc* approach results in increased clinical risks to patients and an estimated \$16 billion in costs annually due to inefficiencies in the medical products supply chain.

The rapidly rising number of medical device recalls, accelerated by the increasing complexity of the variety of medical devices, strongly points to the need for an effective UDI system which will promote a better managed system of recalls and corrections, and effectively match each patient to the device prescribed. Due to the absence of a UDI system, providers must often use manual and imprecise systems to identify products that are recalled as well as provided to the patient adding unnecessary costs and delays to the healthcare system.

Finally, an effective UDI system is essential to maximizing the value of electronic health records (EHRs). EHRs will require that data standards, including those for medical devices, are in place and used by providers to transfer information. 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.

We look forward to hearing about OMB's plan for releasing the proposed rule on a UDI system for medical devices, and we ask that you provide us with an update on where OMB is in the process.

Sincerely,

Alliance for Advancing Nonprofit Health Care
Alpha-1 Association
Alpha-1 Foundation
American Association of Orthopaedic Surgeons
American College of Obstetricians and Gynecologists
American Heart Association
American Hospital Association
American Nurses Association
Association for Healthcare Resources & Materials Management
Association for Professionals in Infection Control and Epidemiology (APIC)
Association of American Medical Colleges
Catholic Health Association of the US
COPD Foundation
Federation of American Hospitals
Georgia Hospital Association
MedicAlert Foundation
National Association For Continence
National Association of Public Hospitals and Health Systems
Novation
Peacehealth
Premier healthcare alliance
Society for Cardiovascular Angiography and Interventions
Texas Health Resources
University HealthSystem Consortium
Valley Health System
VHA Inc.
West Virginia United Health System