APS Advancing Patient Safety Coalition

March 22, 2012

The Honorable Jeff Merkley
United States Senate
313 Hart Senate Office Building
Washington, D.C., 20510

Dear Senator Merkley:

The Advancing Patient Safety Coalition is committed to improving patient safety through the establishment of national unique device identification (UDI) system. As prominent hospital, physician, nursing, research, quality and patient advocacy organizations, we are writing to express our strong support for the Ensuring Safe Medical Devices for Patients bill. We commend you for introducing this legislation which will help protect the safety of patients, reduce medical errors and strengthen the ability of the Food and Drug Administration (FDA) and manufacturers to monitor adverse events.

The Food and Drug Administration Amendments Act of 2007 requires the FDA to issue a regulation implementing a mandatory national UDI system. While the FDA has developed a proposed rule on UDI, it has been held up in the Office of Management and Budget (OMB) clearance process for over six months. We applaud you for recognizing the immediate importance of establishing a UDI system by introducing legislation that would require the FDA to issue a final rule by December 31, 2012, and implement the rule no later than one year after the date the final rule is released.

As the nation struggles to find ways to achieve savings while improving quality in the healthcare system, the creation of a medical device tracking system is a critical missing piece. Unlike virtually every other product on the market in America, there is no uniform identification system for medical devices. The lack of such a system means that most hospitals are left to manually enter data about devices and review countless records and patient charts when recalls occur—a labor-intensive process that poses a high risk for overlooking affected patients. The rapidly rising number of medical device recalls, accelerated by the increasing complexity of the variety of medical devices, adds urgency 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.

The resulting *ad hoc* approach not only results in increased clinical risks to patients, but also creates an estimated $16 billion in costs annually due to inefficiencies in the medical products supply chain. The efficiencies gained through UDI will allow providers to reinvest in initiatives to improve the quality and safety of care.

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

We thank you again for introducing the Ensuring Safe Medical Devices for Patients bill and stand ready to assist you in any way to ensure passage of this important legislation.

Sincerely,

Alliance for Advancing Nonprofit Health Care
Alpha-1 Association
Alpha-1 Foundation
American Association of Neurological Surgeons (AANS)
American Association of Orthopaedic Surgeons
American Heart Association
American Nurses Association
Association for Healthcare Resource & Materials Management
Association for Professionals in Infection Control and Epidemiology (APIC)
Association of American Medical Colleges
Catholic Health Association of the United States
Congress of Neurological Surgeons (CNS).
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
Truth in Medicine Incorporated
University HealthSystem Consortium
Valley Health System
VHA Inc.
West Virginia United Health System