APS Advancing Patient Safety Coalition

January 14, 2010

The Honorable Nancy Pelosi
Speaker of the House
H-232 Capitol Building
Washington, DC 20515

The Honorable Harry Reid
Senate Majority Leader
S-221 Capitol Building
Washington, DC 20510

The Honorable Henry Waxman, Chairman
House Energy and Commerce Cmte.
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Tom Harkin, Chairman
Cmte. on Health, Education, Labor and Pensions
428 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Charles Rangel, Chairman
Committee on Ways and Means
1102 Longworth House Office Building
Washington, DC 20515

The Honorable Max Baucus, Chairman
Senate Finance Committee
219 Dirksen Senate Office Building
Washington, DC 20510

Dear Speaker Pelosi, Senate Majority Leader Reid, Chairman Waxman, Chairman Harkin, Chairman Rangel and Chairman Baucus:

As members of the Advancing Patient Safety Coalition, we are committed to improving the quality of patient care. To that end, we ask that you retain language in the final health reform bill that was included in the House-passed version requiring the Food and Drug Administration (FDA) to promulgate regulations to create a unique device identification (UDI) system for medical devices within six months of enactment of health reform. The FDA Amendment Act of 2007 required FDA to issue regulations, but no deadline was given. Therefore, the House-passed language is critical to moving forward on this important patient safety issue.

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 (recalls) and inability to track adverse events appropriately. We can simply and quickly identify each and every jar of peanut butter that might have salmonella and remove them from store shelves in hours but we cannot do that reliably today with potentially life threatening defective medical devices.

Unique device identification 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 of recalls. 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.

UDI 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 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.

As Congress works to finish health reform legislation that will improve the quality of healthcare we urge you to retain the House-passed language that gives FDA a six month deadline for issuing UDI regulations. UDI is a key part of improving patient safety, quality and efficiency and we look forward to working with you on this important issue.

Sincerely,

Members of the Advancing Patient Safety Coalition:

AAMC
AARP
Alliance for Advancing Nonprofit Health Care
Alpha-1 Association
Alpha-1 Foundation
American Autoimmune Related Diseases Association
American Association of Neurological Surgeons
American Association of Orthopaedic Surgeons
American College of Obstetricians and Gynecologists
American Heart Association
American Hospital Association
American Medical Student Association
American Nurses Association
Association for Healthcare Resource & Materials Management
Association for Professionals in Infection Control and Epidemiology (APIC)
Bon Secours Health System, Inc.
California Hospital Association
Catholic Health Association of the US
Colorado Hospital Association
Congress of Neurological Surgeons
Federation of American Hospitals
Florida Hospital Association
Georgia Hospital Association
Health Care Without Harm
Kentucky Hospital Association
National Association For Continence
National Association of Public Hospitals and Health Systems
National Rural Health Association
Novation

Partners Healthcare
PeaceHealth
Premier Inc.
Texas Health Resources
The Joint Commission
The Society of Healthcare Epidemiology of America
University HealthSystem Consortium
Utah Hospitals and Health Systems Association
Valley Health System
VHA Inc.
West Penn Allegheny Health System
West Virginia United Health System
White River Health System