APS Advancing Patient Safety Coalition

July 12, 2013

Sylvia Mathews Burwell
Director
Office of Management and Budget
725 17th Street, NW
Washington, D.C. 20503

Dear Director Burwell:

The Advancing Patient Safety Coalition is committed to improving patient safety through the establishment of the national unique device identification (UDI) system. As prominent hospital, physician, nursing, research, quality and patient advocacy organizations, we are writing to reiterate the critical importance of expedited implementation of the UDI rule, currently under review by the Office of Management and Budget.

The Food and Drug Administration Amendments Act of 2007 requires the Food and Drug Administration (FDA) to release a regulation implementing a UDI system. The UDI rule is critical to achieving patient safety improvement initiatives and medical error reduction.

Unlike virtually all other products on the market in America, there is no uniform identification system for medical devices, many of which are implanted in patients. Considering the number of medical device recalls each year, the risk and costs to patients continues to grow until we have a national UDI. In fact, in 2012 alone, the FDA recalled a total of 50 medical devices that were either defective or a risk to health. 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.

It is critical now more than ever to expeditiously implement UDI. As we recommended in our previous comment letter, the implementation timetable in the proposed rule would mean that UDI labeling and related Global Unique Device Identification Database (GUDID) information submission requirements for class III, II and I devices would apply beginning one, three, and five years, respectively, following publication of the final rule. Further, for devices subject to direct marking requirements, compliance with these requirements would be required two years after the date specified for compliance with UDI label requirements for a device category. This would make for a seven-year implementation timeframe.

We believe that the proposed seven-year timeframe is simply too long and that patient safety would not be well served by such a leisurely implementation schedule.

We, therefore, urge the OMB to make clear the importance of an expeditious implementation of UDI and require a shortened timetable, where implementation of the UDI requirements relating to device labels and packaging would be completed within two years of the effective date of the final rule, and under which implementation of the UDI requirements related to direct marking of devices would be completed within three years of such effective date. And we strongly support the proposed one-year implementation timeframe for class III devices.

We also wish to emphasize that under our recommended timetable, labelers should be required to submit all relevant information to the GUDID at the same time that UDI requirements relating to labels and packaging take effect. The information to be incorporated into the GUDID is important to public safety, and public access to such information at the earliest opportunity will be of enormous benefit to all stakeholders.

We are anxious to see the UDI system up and running and contributing to patient safety efforts as soon as possible, and we appreciate your serious consideration of our recommendation regarding the critical importance of an expedited UDI implementation timeline.

Sincerely,

AARP
Association of American Medical Colleges (AAMC)
Alpha-1 Association
Alpha-1 Foundation
America's Essential Hospitals (formerly NAPH)
American Medical Association (AMA)
American Nurses Association (ANA)
Association for Professionals in Infection Control and Epidemiology (APIC)
Catholic Health Association of the United States (CHAUS)
COPD Foundation
Federation of American Hospitals (FAH)
National Association for Continence (NAFC)
Novation
PeaceHealth
Premier healthcare alliance
National Rural Health Association (NRHA)
The Society for Cardiovascular Angiography and Interventions (SCAI)
Truth in Medicine Inc.
University Health Systems Consortium (UHC)
VHA Inc.
West Virginia United Health System (WVUHS)