February 16, 2012

The Honorable Jeff Zients
Acting Director, Office of Management and Budget
243 Old Executive Office Building
Washington, DC 20503

Dear Acting Director Zients,

The undersigned organizations strongly support efforts to improve safety and efficiency in the American health care system. We are writing to urge that the Office of Management and Budget (OMB) expeditiously release the Food and Drug Administration's (FDA) proposed rule on Unique Device Identifiers (UDIs) – RIN: 0910-AG31. The proposed rule is currently under review by the Office of Management and Budget and we urge you to approve it so that public comment may commence as soon as possible.

UDIs are numerical codes that are intended to identify medical devices used in a variety of processes and applications throughout the health care industry. The development of a UDI protocol was mandated in Section 226 of the Food and Drug Amendments Act of 2007. Section 226 of that Act provides in part:

> The Secretary shall promulgate regulations establishing a unique device identification system for medical devices requiring the label of devices to bear a unique identifier, unless the Secretary requires an alternative placement or provides an exception for a particular device or type of device. The unique identifier shall adequately identify the device through distribution and use, and may include information on the lot or serial number.

This section expresses a clear Congressional intent to improve the accuracy and timeliness of recalls of defective devices and promote patient safety.

The undersigned organizations support the general use of UDIs in the health care supply chain. We have not had the opportunity to review the specifics of the proposed draft FDA rule that is under review at the OMB. Therefore, we are not in a position to state that we support its specific provisions. However, we believe the proposal warrants public debate and comment and we, therefore, urge the OMB to move the regulatory process forward and allow for public comment.

As you are aware, the FDA's mission is to promote and protect public health by ensuring the safety, efficacy, and security of medical devices. A national UDI system for medical devices is a key component needed to:

- Improve the FDA's pre-market and post-market surveillance capabilities.
- Reduce transaction costs in the health care supply chain by increasing the accuracy of information exchanges, and facilitating improved tracking, storage and retrieval of products. These benefits have been experienced in other industries that have already adopted universal identifiers. A recent healthcare case study demonstrated the benefits in the health care sector as well.[1]
- Reduce medical errors by enabling medical information systems to more accurately track the type and dosage of products used in treatment and diagnosis.
- Assist clinicians in making treatment decisions by providing more accurate data about patient supply and device histories, past product utilization, and past treatments.
- Facilitate comparative effectiveness research by enabling researchers and analysts to more easily identify and analyze product data.

As we stated above, we have not had the opportunity to review the text of the proposal and we (and our members) may object to certain specific provisions. An opportunity for public comment would allow interested members of the health care industry and the public to offer suggestions for improving the rule if appropriate.

The great potential for UDIs to increase safety and lower costs for the American healthcare system means that widespread adoption is sorely needed now. Prompt action is also important because hospitals and physicians are in the process of implementing electronic health records as part of the Medicare and Medicaid EHR Incentive Programs. Ideally, those significant new systems should incorporate the capacity to capture and use UDIs. The industry cannot do so, however, if the FDA ruling is delayed much longer.

In closing, we urge you to release the proposed rule for comment as soon as possible to allow a full and informed debate on the FDA proposal.

---

[1] See *Perfect Order and Beyond - BD and Mercy/ROi Achieve Far-Reaching GS1 Standards Integration* by Becton Dickinson, a major device manufacturer, and Mercy/ROi, a large integrated provider network. This study cites the adoption of unique device identifiers and location standards yielded a 30% reduction in days payable outstanding, a 73% reduction in discrepancies in purchase orders, improved sourcing of products, fewer calls to customer service, fewer stock outages, and better patient charge compliance.

Sincerely,

Association of Healthcare Resource and Materials Management (AHRMM)
Healthcare Supply Chain Association (HSCA)
Health Industry Distributors Association (HIDA)
Medical Device Supply Chain Council (MedSC)
Strategic Marketplace Initiative (SMI)

About AHRMM
The Association for Healthcare Resource & Materials Management (AHRMM) is the leading national association for executives in the healthcare resource and materials management profession. A professional membership group of the American Hospital Association, AHRMM serves more than 4,000 active members. Founded in 1962, AHRMM prepares its members to contribute to the field and advance the profession through networking, education, recognition, and advocacy. For more information, visit www.ahrmm.org

About HSCA
The Healthcare Supply Chain Association, formerly the Health Industry Group Purchasing Association, is a broad-based trade association that represents 16 group purchasing organizations, including for-profit and not-for-profit corporations, purchasing groups, associations, multi-hospital systems and healthcare provider alliances. HSCA's mission is to advocate on behalf of healthcare group purchasing associations, to provide educational opportunities designed to improve efficiencies in the purchase, sale and utilization of all goods and services within the health industry and to promote meaningful dialogue between GPOs. For more information, visit www.supplychainassociation.org

About HIDA
The Health Industry Distributors Association is the premier trade association representing medical products distribution. HIDA members serve the nation's hospitals, long-term care facilities, physician practices, and other healthcare sites. For more information, visit www.streamlininghealthcare.org or www.hida.org

About MedSC
The Medical Device Supply Chain Council (MedSC) is an informal network of senior industry executives who are focused on identifying opportunities to improve the industry supply chain through focusing on global supply chain issues facing medical device companies, taking an end-to-end view of the supply chain - from Manufacturers to Providers, influencing industry standards that directly impact operational efficiency and effectiveness for all members of the supply chain, and sharing of leading practices and case studies from both inside and outside the Medical Device industry. For more information, visit www.medsc.org

About SMI - The Strategic Marketplace Initiative (SMI) is a non-profit, member-driven organization dedicated to improving the supply chain through direct information exchange and collaboration between senior healthcare supply chain executives and senior IDN supply chain executives. SMI members include healthcare providers, medical manufacturers, medical distributors, and other healthcare supply chain businesses. SMI, created to influence, shape and advance the future of the healthcare marketplace, provides an open forum for innovative idea-exchange and the development of collaborative improvement initiatives. For more information, visit www.smisupplychain.com