FOR IMMEDIATE RELEASE
November 13, 2012

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HSCA SUBMITS FINAL COMMENTS TO FDA IN SUPPORT OF UNIQUE DEVICE IDENTIFICATION (UDI) SYSTEM FOR MEDICAL DEVICES

Unique Device Identifiers Critical to Protecting Patient Health and Reducing Healthcare Costs

Washington, DC (November 13, 2012) – The Healthcare Supply Chain Association (HSCA) recently submitted final comments to the U.S. Food and Drug Administration (FDA) regarding the proposed rule to establish a Unique Device Identification System (UDI) for medical devices. In its November 7th final comments, HSCA applauded FDA for releasing guidelines to implement a UDI system, called on FDA to adopt GS1 global standards for the UDI system, and urged FDA to shorten the proposed phase-in period for the UDI system from seven years to three.

"A UDI system properly aligned with widely recognized GS1 global standards will not only enhance patient safety and achieve numerous health benefits, but will also yield significant savings to the healthcare system that will far outweigh any costs incurred by manufacturers, suppliers or providers," said HSCA President Curtis Rooney. "HSCA is committed to increasing efficiency in the healthcare supply chain through the adoption of global standards. We look forward to continuing to work with FDA to successfully implement the unique device identification system, which will help protect patients and remove healthcare costs from the system."

HSCA focused its comments primarily on the following recommendations:

- The FDA should establish a single standard based on GS1 – HSCA firmly believes that FDA should adopt GS1 standards for the UDI system. The GS1 system is one of the most widely used supply chain standards in the world.

- The FDA should shorten the proposed seven-year phase-in to three years, because patient safety outcomes far outweigh any rationale, economic or otherwise, for such a prolonged phase-in. Furthermore, the proposed phase-in period does not lessen the burden imposed on labelers by the rule, but may in fact increase the burden.

- The FDA should adopt a policy requiring that if a device can be labeled, that it must be labeled – The FDA should exempt applicable devices from direct marking requirements only if it is infeasible or impossible for labelers to direct mark such devices.

- The FDA should adopt the ISO standard for the date format on device labels, YYYYMM-DD.

In its recent report, *Strength in Unity: The Promise of Global Standards in Healthcare*, McKinsey & Company found that "the healthcare industry can create significant value from the adoption of a single global standard – both in terms of business value and in terms of meaningful improvements in patient safety and quality of care." McKinsey concludes in the report: "The healthcare industry is at a crossroads, and our research suggests that the case for alignment on a single global standard is compelling at both the total industry level, and for representative players in the industry. More importantly, the case for alignment on a single global standard is compelling in terms of the number of lives saved and medication/device errors averted. The industry has an opportunity to create a true win-win opportunity: a 'win' for industry, and a 'win' for the patient."

For more information about the HSCA comments to the FDA on the proposed UDI system, please visit www.supplychainassociation.org

For the full text of the McKinsey global standards study, please visit the GS1 website, at www.gs1.org

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About the Healthcare Supply Chain Association (HSCA)
The Healthcare Supply Chain Association, formerly the Health Industry Group Purchasing Association, is a broad-based trade association that represents 15 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.