



HEALTH INDUSTRY BUSINESS COMMUNICATIONS COUNCIL

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FDA RELEASES FINAL UDI REGULATION HIBC IDENTIFIED AS A DATA STANDARD FOR UDI

PHOENIX, AZ (September 24, 2013) - The U.S. Food and Drug Administration (FDA) today released its final regulation on Unique Device Identification (UDI) for medical-surgical products. In the ruling, FDA identifies the Health Industry Bar Code (HIBC) as an acceptable data standard for UDI.

Commenting on the FDA's final ruling, HIBCC President and CEO, Robert A. Hankin, Ph.D. noted, "The FDA's UDI initiative is fundamental to enhancing patient safety and cost containment measures. HIBCC looks forward to becoming an acting Issuing Agency to assist in providing the tools to implement UDI."

In support of the UDI initiative, HIBCC has developed the *UDI Resource Center*, available at www.HIBCC.org. It includes numerous implementation documents, as well as an on-line 'UDI Generator'. This web-based tool, now in beta testing, will provide users an easy formatter to quickly enter the required data fields and create the resulting HIBC-UDI.

For additional information on FDA's UDI initiative and HIBCC's UDI Resource Center, or to register for a HIBC LIC, please contact the HIBCC office at: 602.381.1091 or visit www.HIBCC.org.

HIBCC is an industry-sponsored, Standards Development Organization (SDO) founded in 1983 to develop a healthcare-specific standard for the unique identification of medical products. HIBCC is accredited by the American National Standards Institute (ANSI), the European Committee for Standardization (CEN) and is recognized by the International Organization for Standardization (ISO). Our efforts are supported worldwide by affiliate offices in Europe and Asia Pacific. The HIBC SLS has been recognized by the European Union in their developing regulation on device identification, as well as by the International Medical Device Regulators Forum. Additional information regarding the HIBCC organization can be accessed from the HIBCC website at: www.hibcc.org.

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