



HIBCC Guideline: Understanding FDA's Proposed UDI Requirement



What is a UDI and the GUDID?

The *Unique Device Identifier* (UDI) is a system used to mark and identify medical devices within the healthcare supply chain. The proposed rule by the Food and Drug Administration (FDA) will establish a UDI system that will require manufacturers to include both a plain-text version of the identifying data, and a version encoded using Automatic Identification Data Capture (AIDC) technology such as linear or two-dimensional bar codes, RFID tags, etc.

A new Global Unique Device Identification Database (GUDID), accessible to the public, will contain specified information about UDI-labeled medical devices. Additional information about the GUDID follows in this report.

What comprises a UDI?

The FDA has stated that a UDI will be comprised of two parts:

- An identifier of the specific model and labeler (usually the manufacturer) of the device;
- As required based upon the class of device, a production identifier that may potentially include lot/batch of manufacture, serial number, and/or expiration date or date of manufacture.

For some devices, specifically those that remain in use for an extended period of time (such as implantables), are sterilized routinely, or that may become separated from their original label, the rule would require the UDI information to be directly marked/etched on the device.

Additionally, certain combination products and their constituent parts, as well as convenience kits will also require a UDI.

The FDA has specified that a new UDI will be required in the event of a quantity change in packaging or when the model or version of a device changes.

Why has the FDA proposed a UDI requirement?

For many years the FDA and industry partners have been studying the benefits associated with automatic-identification technologies that have been deployed in both healthcare and non-healthcare industries. With this proposed requirement, the FDA is reinforcing the importance of these technologies developed by organizations like HIBCC in support of enhanced safety and cost containment strategies.

What are the benefits?

The FDA and its industry partners believe that the implementation of UDIs and AIDC systems can help reduce the incidence of medical error, thereby enhancing patient safety efforts, and can also assist with streamlining supply chain processes, reducing costs to all parties.

In the proposed rule, the FDA outlines several public health objectives they believe will be served by this rule. They include, but are not limited to:

Reduction of Medical Errors. The FDA believes that the presence of a UDI, in combination with the GUDID database, will facilitate rapid and more accurate identification of the device. This will remove potential confusion that can lead to the misuse of a device, such as when there are products of a similar nature and design, or when a product has been flagged for regulatory action.

Integration of Device Usage Data. Using the UDI/GUDID system with the AIDC technologies, the FDA envisions faster and more accurate data acquisition, recording and retrieval. This will enable all parties across the supply chain access to timely and consistent data. The FDA also believes that this will facilitate the development of more effective computerized physician order entry systems, as well as more useful electronic medical records applications.

Faster Device Identification in Event of Adverse Event or Recall. Essential to effectively resolving adverse events associated with a device failure, is its timely and precise identification. FDA believes the inclusion of a UDI will lead to greater accuracy in reporting, allowing care providers access to potentially vital information. Additionally, manufacturers and the FDA would be able to more rapidly collect and analyze reports about a device, thereby allowing for faster identification of a problem and the isolation of the device.

Are there exemptions to the proposed rule?

Yes. Non-prescription devices that are sold in a retail setting, as well as production identifiers for Class I devices, are exempt. Additional information about proposed exemptions can be found in the Federal Register Vol. 77/ No. 132, parts 801.30, 801.35 and 801.128, which can be accessed at www.hibcc.org. The FDA is currently seeking public comment on the possible need for additional exemptions.

Are there reporting requirements? What is the GUDID?

Yes. The FDA is proposing that all UDI data be submitted to a new Global Unique Device Identification Database (GUDID) where it will be housed and made accessible to the public. The UDI will act as a “key” to other identifying information about the device, including, but not limited to: the proprietary, brand or trade name of the product, the Global Medical Device Nomenclature (GMDN) generic descriptor, unit of measure and contact information for the manufacturer.

The FDA believes that “open access to the GUDID would encourage the integration of UDI data into healthcare delivery support systems, electronic medical records, procurement, inventory management, and accounting systems,” thus allowing them to work more cohesively and effectively throughout the healthcare environment.

The FDA has also stated that no trade secret, confidential commercial or personal privacy information will be collected.

Additional information on the data elements required in the GUDID will be forthcoming from the FDA.

How do HIBC Labelers comply with the requirement?

The thousands of current and future HIBC Labelers are already a long-way to complying with the proposed regulation, as the HIBCC Supplier Labeling Standard (HIBC SLS) has been identified by FDA as an acceptable UDI format. As a consequence, HIBCC will apply to the FDA to become an issuing agency for data standards as described in the FDA rule. HIBCC already provides several tools to assist with the creation of UDIs, including the HIBCC resource desk, the on-line bar code formatter, and participation with the AIDC Technical Committee. New labelers will find registration with HIBCC to be both straightforward and inexpensive.

How do manufacturers become HIBC Labelers?

The process is simple. First, organizations must apply for a Labeler Identification Code (LIC) assignment from HIBCC by submitting an application on-line, by mail or by fax. The application is available at www.hibcc.org.

The assigned LIC identifies the registered company, not an individual product or device, and thus can be used across multiple product lines. The cost of an LIC assignment is based upon a company’s gross annual sales and is a one-time fee. There are no reoccurring costs to maintain the global LIC registration with HIBCC.

Then, utilizing the HIBC Supplier Labeling Standard (SLS), companies can begin to create identifiers at multiple packaging levels, depending upon the required granularity of identification necessary.

What are the main advantages of using the HIBC Standard for UDI?

Safety. The HIBC SLS was designed by the healthcare industry for the unique needs of its products, its supply chain and the patient care environment. Existing retail standards were deemed by some to be inadequate, as they were based on

all-numeric, point-of-sale based transactions. Because medical devices often contain both alphabetic and numeric characters, HIBCC developed the HIBC SLS based upon an alphanumeric format that allows for direct and literal encoding of identifiers. Many industries for which safety is essential, such as aviation, automotive and blood banking also rely on alphanumeric-based standards.

Cost. Registration for an LIC assignment is based upon an organization’s gross annual sales, and is a one-time fee. There are no reoccurring costs to maintain the registration. Additionally, the LIC is a global identifier so can be used throughout the world with no addition application costs.

Flexibility. The data structure of the HIBC SLS was designed to accommodate identification of multiple levels of packaging from pallets down to individual units of measure, using a standardized code and consistent format. This allows for easier identification within various packaging configurations, as well as consistency throughout the global marketplace.

Are there requirements for the type of AIDC technology to be utilized?

No. The FDA did not specify, nor prohibit, a specific type of AIDC to be used, believing that the selection decision is best left to the issuing agency or labeler. Bar codes, RFID and near-field communications were noted as potential options. Through the many years of development of these regulations, the FDA has maintained that they did not wish to hinder the development of new and improved technologies, nor the broader adoption of them, with overly prescriptive rules.

What is the timeframe for implementation?

As it currently stands, implementation would occur in stages over a period of seven years after the issuance of the final ruling. This will provide the industry ample time to understand the required processes and manage the associated costs.

Where can we get additional information or provide feedback on the proposed UDI requirement?

HIBCC is your resource for information on the FDA’s current proposed rule and how to begin planning for implementation of UDI. If you have comments or questions for HIBCC, or for the FDA, please contact us via email at info@hibcc.org or via telephone at 602.381.1091. The FDA will be accepting public comments on this volume of the proposal for 120 days from its initial release on July 10, 2012.

For additional information or to begin labeling contact us at:

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