**What is a UDI?**
A national standard code that is applied to a medical device.

**Why is the Food & Drug Administration (FDA) issuing regulations on UDI?**
The FDA proposed rule\(^1\) envisions a UDI system that can help manage medical device recalls, reduce medical errors, enhance data on postmarket surveillance, and improve adverse events reporting.

**Who must comply with the new FDA requirements?**
Manufacturers, reprocessors, specification developers, repackagers, relabelers, and companies who assemble kits.

**Are there new federal requirements for distributors?**
At this time, there are no direct responsibilities for most distributors under the FDA proposed rule unless they manufacture products.

**Are any devices exempt from UDI requirements?**
Yes; the FDA is proposing full exemptions from UDI labeling and data reporting for certain low-risk devices (such as most Class I devices). The FDA plans to exempt “devices that are sold at retail establishments.”

**What does a UDI look like?**
A UDI consists of two parts; 1) an identifier that shows the type of device and who applied the label (the “labeler”), and 2) a production identifier that identifies one or more of the following:
- Lot or batch within which a device was manufactured
- Serial number of a specific device
- Expiration date of a specific device
- Date a specific device was manufactured

**When do UDI requirements start?**
Class III medical devices must have a UDI within one year of a final rule being published, Class II devices must have a UDI within three years, and Class I devices must have a UDI within five years. The final rule is expected to be released by Spring 2013.

**What will the start-up costs be?**
Labelers of medical devices will have to 1) integrate a UDI system, 2) install, test and validate barcode printing software, 3) train employees, and 4) purchase equipment needed to print and verify the UDI on labels.

**Will the FDA distinguish between HIBCC and GS1 standards?**
No; the FDA’s UDI proposal permits both of these systems.

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**For more information, please see HIDA’s UDI summary document.**