No Idea about UDI: FDA Issues Draft Guidance on UDI Form and Content

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In advance of the September compliance date for Class II medical devices, the Food and Drug Administration has issued draft guidance on the form and content of Unique Device Identifiers (UDIs).[1] Though the UDI Rule was finalized in September 2013, FDA intends this guidance to help clarify the Rule's requirements and "ensure the UDIs developed under systems for the issuance of UDIs are in compliance with the Rule."

Background

The UDI system's main goal is to adequately identify devices through distribution and use by creating a standardized identification system for medical devices. In the UDI Rule summary, FDA states that the system will reduce medical errors, lead to more accurate reporting of adverse events, and allow industry to more easily extract useful information from adverse event reports to take corrective action. Unless an exemption or alternative applies, every medical device distributed in the United States must be labeled with a UDI. The UDI must be present in two forms: "easily readable plain-text and automatic identification and data capture (AIDC) technology."

UDI Content

The UDI should consist of: (1) a device identifier (DI), (2) at least one production identifier (PI), and (3) the data delimiters[2] for the DI and PIs. The DI identifies the specific version or model of the device, as well as the labeler. The PI identifies more specific information about the device, including the lot or batch, the serial number, the expiration date, and the manufacturing date.

UDI Forms

The UDI must be presented in both easily readable plain-text and AIDC technology forms. The plain-text format is the legible interpretation of the data characters encoded in the AIDC form, and it should be presented near or below the AIDC form. This format allows users of the UDI system to read and enter the UDI into patient records without needing technological assistance.

The AIDC allows the UDI to be read and entered into patient records/other computer systems through an automated process, such as a bar code scanner. This form may be split into multiple segments, but the DI should still precede the PI. If the labeler uses a bar code form, FDA suggests that the bar code should be tested for print quality. If the UDI presented in this format is not visible to the human eye upon visual inspection, the label or device package must disclose the use of AIDC technology.

This guidance also provides the order for presenting the UDI and non-UDI elements in the UDI carrier. The UDI should precede non-UDI elements, such as the quantity of devices in a package. The easily readable plain-text form should begin with the DI, followed by the PI. Non-UDI elements may follow the PI.

1 http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM512648.pdf.

2 The guidance defines "data delimiter" as "a defined character or set of characters that identifies specific data elements" within an encoded data string. Notably, the final rule did not mention this term.

The UDI compliance date for Class II devices is September 24, 2016. Data for these devices must be submitted to FDA's Global Unique Device Identification Database. This guidance places responsibility on the FDA-accredited issuing agencies (currently, the three agencies accredited to assign UDIs) to develop and operate compliant systems for the UDI assignment process. However, labelers are still responsible for ensuring that their devices follow the UDI requirements, and failure to provide the proper labeling information renders a device misbranded.

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