AHRMM
Association for Healthcare Resource & Materials Management
Advancing the Healthcare Supply Chain
A personal membership group of the American Hospital Association

February 9, 2016

AHRMM Issues & Legislative Committee Awareness Brief

Draft Guidance for UDI: Convenience Kits

This Awareness Brief provides a quick reference to the Draft Guidance for UDI Convenience Kits, released by the FDA in January 2016. The draft guidance defines the term "convenience kit" for purposes of compliance with UDI labeling and data submission requirements only.

- "Convenience kit" as defined by 21 CFR 801.30 (a)(11), applies solely to two or more different medical devices packaged together for the convenience of the user, where they are intended to remain packaged together (wrapped or sealed, in a single container that is not intended to be unwrapped or unsealed before it is used by an end user) and not replaced, substituted, repackaged, sterilized, or otherwise processed or modified before the devices are used by an end-user.
- Devices packaged within the immediate container of a "convenience kit" are exempted from UDI labeling requirements, provided that the label of the kit bears a UDI.
- Previously, medical procedure kits, including orthopedic procedure kits, were considered "convenience kits". Some medical procedure sets consist of hundreds of implants and reusable instruments on numerous trays configured specifically to the requirements of the surgeon and individual surgical procedure. Only a few of the individual implants are used, kits are replenished and sterilized. An individual implant may undergo this process repeatedly for months or years before implantation. With the publication of this draft guidance, the FDA proposes that applying the term "convenience kits" to these procedure kits would be inconsistent with the purpose of the exceptions at 21 CFR 801.30 and UDI Rule generally.
    - UDI should be in conformity with 21 CFR 801.40, be available to identify a device in both easily readable plain-text and in a form that can be entered into an electronic patient record or other computer system via an automated process
    - Where the kit is not intended to be altered prior to use, the UDI label of the container of the "convenience kit" serves to adequately identify the device from distribution through use.
    - The UDI on the label of procedure kits may not follow the group of devices until end use, and devices originally contained in the kit may be intended to be replaced.
    - FDA expects that this interpretation may also provide additional benefits such as inventory management and the detection of counterfeit devices.

Examples that are considered "convenience kits":

- First aid kit
- ACL disposable kit
- CVL dressing change kit

Examples that are not considered "convenience kits":

- Non-sterile orthopedic device or tray set
- Reusable medical devices packaged together

Additional questions and answers are found on pages 6 – 8 of the full draft guidance document. Review the full document on the FDA's website and provide any comments here.