LUC Clinical Recognition of UOU Talk Track

(Slide 1): Welcome to the AHRMM Learning UDI Community. This presentation is intended to explain the Unit of Use (also known as the "UOU") and the key considerations needed to use this identifier for clinical purposes. This novel concept is not commonly used in industries outside of healthcare.

(Slide 2): Let's begin with a review of the FDA definition of the Unit of Use. This virtual identifier should be assigned whenever the base package for any product contains multiple items. In those instances, the individual products themselves may not contain printed identifiers. The FDA intended for the unmarked virtual UOU to allow for the identification of the individual item.

(Slide 3): All stakeholders in the healthcare supply chain need to understand exactly which Device Identifiers (or DI) are associated with individual medical devices at various packaging levels. This slide lists the basic information that must be included to meet that requirement.

All data originates with the medical device manufacturer or labeler. They should provide a full product hierarchy. A product hierarchy is defined as the complete listing of all identifiers associated with any individual device. This hierarchy should include all packaging levels. It should also indicate clearly which packaging level represents the "base" level, or lowest packaging level. It is also important to list the net content for each level for any given item. Finally, the hierarchy should also include the unmarked virtual identifiers known as UOU.

(Slide 4): Let's review an example of this concept as applied to an actual product. The item shown here is an allergist tray. Each tray contains 25 identical syringes. There are 40 trays in a case of this product for a grand total of 1000 syringes per case. There are printed barcodes at both the full case level and the tray level, but there are no barcodes available on any of the individual syringes. In this case, the FDA requires the manufacturer to assign an additional device identifier (DI) to the individual syringe. This identifier is also known as the "Unit of Use" level. The UOU DI is not marked on the product.

(Slide 5): Because the UOU is not marked, it may require a modified approach to use this DI properly. To simplify our understanding of the concept, the task force recommends that users differentiate between the "supply chain" and "clinical use" of identifiers.

In the standard healthcare supply chain, products can be shipped at multiple levels, but never at any unit lower than the lowest packaged level of the product. This is especially true for sterile products, since removing the product from a package renders it non-sterile. This lowest package level (or base unit) generally allows device manufacturers to print the physical barcode to identify the product.

In instances where the lowest packaged product contains multiple items, there may be a need to extend product information down to the individual, unpackaged item. In this example, we may need to identify the individual syringe (as opposed to the full tray). This is why the "clinical use" of the UOU may extend to a larger range of DI than the supply chain.

LEARNING UDI COMMUNITY

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

Clinical recognition of the Unit of Use (UOU)

FDA Definition of "Unit of Use"

A virtual identifier assigned to an individual medical device when a Unique Device Identifier (UDI) is not labeled on the individual device at the level of its unit of use. Its purpose is to associate the use of a device to/on a patient when a base package contains more than one device.

Full product hierarchy

- Manufacturers must provide all levels
- Clearly define “Lowest packaging level”
- Net content is essential

UOU Package Example

Single Item
(Unmarked)

Tray of 25
(Full UDI Marked)

Case of 1000
(Full UDI Marked)

Unit of Measure (Package Level)	ANSI UOM	Device Identifier (DI)	Qty	Units at Next pkg level	Contains DI Package
Single Item	-	**UOU DI (Unmarked)**	1	-	-
Tray (Lowest Pkg Level with DI)	TY	**Lowest Pkg Level DI (Full UDI Marked)**	25	-	No
Case	CA	**Case Level DI (Full UDI Marked)**	1000	40	Tray

"Supply Chain" vs. "Clinical Use"

- **"Supply Chain"** uses lowest package level (transactional)
- **"Clinical Use"** may reference UOU

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