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HEALTHCARE MANUFACTURERS MANAGEMENT COUNCIL

HMMC Webinar , August 9, 2016

Learn How To Get Started with UDI and Why All Channel Players Have A Market Stake

Presenters

Karen Wolfe, Mayo Clinic

Ellenmary Martin, Dukal

Amy Kohl, HIDA

Dennis Black, BD

Mark Thill, MDSI Editor

Repertoire, The Journal of Healthcare Contracting, First Impressions

Moderated by Kevin Neuman

Vice President of Marketing and Operations

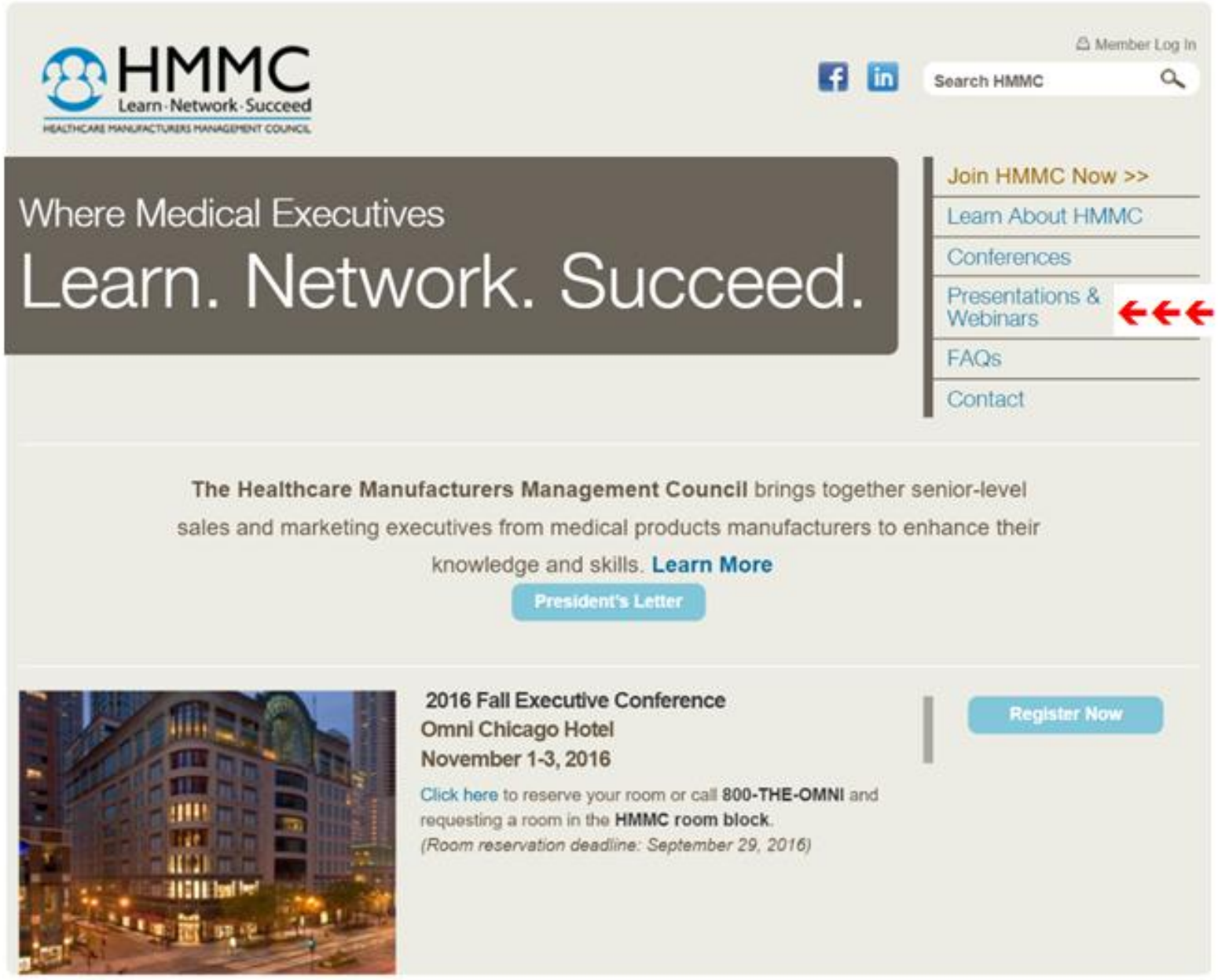
Innovative Healthcare Corporation

Office: 918-245-8400 Phone

Cell: 913-486-5545

kneuman@ihcsolutions.com

www.hmmc.com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UDI Requirements For The Brand Owner Of Class I Products & Global UDI Database (GUDID)
Ellenmary Martin, Dukal
HMMC Webinar August 9, 2016
Introduction To GUDID And GDSN
Presented March 12, 2015:
Click here for slides only
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Strategic Implications Of UDI And Contract Administration
Presented at the 2014 Fall Conference: December 9 – 11, 2014 at Omni Chicago Hotel
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UDI: Why is it importance for Providers

Karen Wolfe

Systems Analyst – Supply Chain Management

Mayo Clinic

Wolfe.karen@mayo.edu

Office: 507-266-9734

CLASS I – UDI Clinical Use

"THE NEEDS OF THE PATIENT COME FIRST"

- Customized care
  - Each and every patient is unique
- Attributes to name a few
  - Latex safe
  - MRI information
  - Sterile or not, sterilization needed prior to use
- Product Scanning
  - EHR Class I, what would be needed
  - Claims form requirement

CLASS I - UDI Product Labeling

- One standard UDI per product
  - Scanning confusion
  - Time wasted
  - Frustration to the point of not scanning at all

CLASS I – UDI Supply Chain Use

Provider uom for product - M-A-555	Supplier uom for product - MA-0555	Standard DI applied to product MA-0555
EACH (1)	--- There is not level	STD1234
PAIR (2)	EACH (1)	STD1235
BOX (20)	CONTAINER (10)	STD1236
CASE (50)	CARTON (5) sellable	STD1237

- Unit of Measure communication issues can be eliminated
- Invoice matching can occur at the standard DI level not uom and product ID
- Price Catalog will match easily
- Contract updates easily matched and loaded

UDI and responsibility of the Labeler

Ellenmary Martin

Chief Strategy Office/VP of Marketing

DUKAL Corporation

Emartin@dukal.com

Office: 631-656-3800 x 121

Cell: 203-494-6237

UDI and responsibility of the Labeler

FDA published a ruling requiring device labelers to include a unique device identifier (UDI) on device labels and packages.

A "labeler" is any person who causes a label to be applied to a device, or who causes the label of a device to be modified, with the intent that the device will be commercially distributed without any subsequent replacement or modification of the label.

UDI and responsibility of the Labeler

A UDI is a unique numeric or alphanumeric code that may consists of one or two parts:

- Device identifier (DI), a mandatory, fixed portion of a UDI that identifies the labeler and the specific version or model of a device
- Production identifier (PI), a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of a device: lot #, serial #, expiration date, date of manufacture

UDI and responsibility of the Labeler

All UDIs are to be issued under a system operated by an FDA-accredited issuing agency: Unique number assigned to labeler.

GS1 - GTIN: Global Trade Item Number

HIBCC – LIC: Labeler Identification Code

Example of a GS1-128 barcode with both the GTIN and the Lot/Batch # encoded:

(01) 10072534123451 (10) 12340223ABC

+A123BJC5D6E71G

UDI and responsibility of the Labeler

The device labelers are required to submit information to the FDA-administered Global Unique Device Identification Database (GUDID).

The GUDID contains ONLY the device identifier (DI), which serves as the primary key to obtain device information in the database. Production Identifiers (PI) are not submitted to or stored in the GUDID, but the GUDID will contain production identifier flags to indicate which PI attribute(s) are on the device label.

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/GlobalUDIDatabaseGUDID/ucm20038750.htm

UDI and Distribution Implications

Amy Kohl

Senior Manager, Government Affairs

Health Industry Distributors Association

kohl@hida.org

Office: 631-656-3800 x 121

UDI and Healthcare System

Objectives of the UDI Program:

Establish a system to adequately identify devices through **distribution** and use

Facilitate the rapid and accurate identification of a device

Enable access to important information concerning the device

Provide a standard and clear way to document device use in HER, clinical information systems, and registries

UDI and Healthcare Distribution

A supplier must be able to:

Transact using GTIN/LIC referenced on Purchase Order and Invoice doc. Suppliers will send price file using GLNs and GTINs.

A supplier's operations (e.g. Customer Service, etc...) must be able to recognize a GTIN when referenced.

Suppliers should have the ability to transact and maintain customer accounts through the GLN.

(Healthcare Transformation Group)

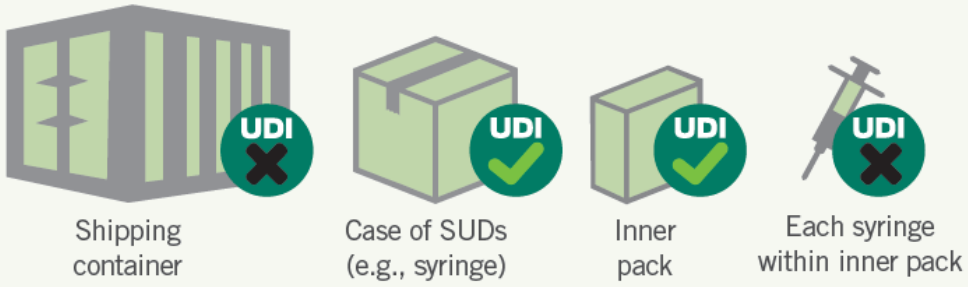
What is HIDA doing?

Device Packaging Levels

The FDA requires a UDI at every level of packaging except shipping containers; however devices that meet the SUD exception are mostly exempt from the rule because they are assumed to be distributed together in a package to the healthcare provider.

Examples of SUDs

Syringes	Drain bags	PPE barriers
Bandages	Needles	Otoscope tips
Blades	Scalpels	Hot/cold disposable packs



- HIDA is advocating that the FDA use enforcement discretion through September 2021 to allow distributors and manufacturers to determine how the labeling of the "each" will be handled and become compliant beyond the Class I grandfathered inventory deadline.

Recent Federal Guidance – July 2016

- Draft guidance issued July 26, 2016; Comments due Sept. 26, 2016
- Describes two forms of a UDI label
  - *Easily readable plain-text (single line or multiple lines of text displayed below or near the AIDC technology form of the UDI)*
  - *Automatic Identification and Data Capture (AIDC)*
- Clarifies the content of UDI
- Discusses the order of the data in a UDI and UDI carrier
- Impact on Distributors: TBD

UDI and Healthcare Provider use of Data Standards and Unit of Use

Dennis Black

Director, e-Business

BD

Dennis_Black@bd.com

UDI and Healthcare Provider use of Data Standards and Unit of Use

Healthcare Provider use of Data Standards

- - GLN for location identification
- - GDSN or GUDID for Item Master Maintenance
- - GLNs and GTINs in EDI transactions to eliminate errors
- - Barcode scanning at the point of care for device tracking
- - Use of UDI in recalls
- - UDI in data analytics and comparative effectiveness research

Healthcare Provider requests and FDA requirements may differ!

UDI and Healthcare Provider use of Data Standards and Unit of Use

Identifying the Unit of Use

- There is some confusion in the industry on how manufacturers are identifying the "each" level
- Questions have been raised concerning products such as
  - Sutures
  - Implants (unmatched GTIN on product/package)
  - Syringe Convenience Trays
  - Other Products
- An AHRMM Learning Community is focused on this topic
- Review Issuing Agency resources (GS1 Healthcare GTIN Guide)

UDI numbering assignments should follow Issuing Agency guidelines and use logic that is apparent for the industry.

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