UDI Ç What Hospitals Should Do to Prepare

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Legislation (FDAAA 07; FDASIA 12)

Not later than December 31, 2012, the Secretary shall issue proposed regulations establishing a unique device identification system for medical devices requiring the label of devices to bear a unique identifier, unless the Secretary requires an alternative placement or provides an exception for a particular device or type of device. The unique identifier shall adequately identify the device through distribution and use, and may include information on the lot or serial number. The Secretary shall finalize the proposed regulations not later than 6 months after the close of the comment period and shall implement the final regulations with respect to devices that are implantable, life-saving, and life sustaining not later than 2 years after the regulations are finalized, taking into account patient access to medical devices and therapies.
UDI General Rule

- The label* of EVERY medical device must have a UDI.
- EVERY device package (contains a fixed quantity of a version or model) must have a UDI.

Any other approach is an exception to or alternative from these requirements.

* Section 201(k) defines 'label' as a display of written, printed, or graphic matter upon the immediate container of any article...

WHAT ARE DEVICES IN THE US?

A very wide range of medical products such as:

- Traditional hospital based devices (beds, ventilator, monitors, infusion pumps)
- Implants
- Patient/home use devices (glucometers)
- Disposables, accessories (glucose test strips, catheters)
- In vitro diagnostic devices (IVDs) both clinical lab and Point of Care (POC).
- Health Information Technology (HIT)
- Convenience kits, Combination products
- Those used in alternative sites e.g., homecare, dental
## BENEFITS TO INDUSTRY

- Facilitate marketing clearance for new indications
- Help purchasers to identify, order, and receive the correct device
- Facilitate visibility of their products throughout the supply chain and improve logistics
- Allow stakeholders to use the manufacturer’s identifier
- Improve the efficiency/effectiveness of voluntary recall
- Help to identify counterfeit or diverted devices
- Facilitate importation activities
- Allow manufacturers to use a single UDI to meet global regulatory requirements

## BENEFITS TO FDA

- Better data on actual product performance when used as standard of care
- Improving FDA’s use and understanding of adverse event reports
- Helping FDA to better understand the risk profile of particular devices
- Allowing FDA to mine population-based data sets to better understand the risks and benefits of device use within certain patient populations and indications
- In turn, this will allow FDA to better and more quickly address new concerns raised in premarket submissions
PUBLIC HEALTH BENEFITS

GUDID provides global visibility and supports:
- Medical device recalls
- Adverse event reporting
- Tracking and tracing
- Supply chain security
- Anti-counterfeiting/diversion
- Disaster/terror preparation
- Shortages/substitutions
- Reduction of medical errors (e.g., bedside scanning)
- An easily accessible source of device information for patients and clinicians

UDI CAN ALSO SUPPORTÁ

- Device identification in registries
- Comparative effectiveness
- Documenting medical device use in patients' EHR/PHR, hospital information systems, and claims data
- Sentinel Initiative and other postmarket surveillance activities
Establishing a UDI System

Combination of 4 distinct steps:
1. Develop standardized unique device identifiers (UDIs)
2. Put the UDI in human readable and Automated Data Capture (AIDC) on the label
3. Submit data to the Global UDI Database (GUDID)
4. Implementation timelines

The Need for Standard IDs

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Only UDI compliant code on list
Why a Global Standard?

The package has:

- 6 machine readable codes (5 barcodes, 1 Data Matrix).
- 17 flags (UK, Ireland, Malta, Netherlands, Belgium, Germany, Austria, France, Spain, Portugal, Greece, Cyprus, Norway, Sweden, Denmark, Iceland, Finland) (not Italy)
- 12 different language texts (English, French and German are used in more than one country).

From Problem to Regulation

Preventable Medical Errors and Device Recalls
UDI: History and Purpose

- FDA Barcode Medication Rule Passed 2004
  - Based on existing NDC standard
- Lack of identifier for medical devices
- UDI included in the FDAAA of 2007

The Secretary shall promulgate regulations establishing a unique device identification system for medical devices requiring the label of devices to bear a unique identifier, unless the Secretary requires an alternative placement or provides an exception for a particular device or type of device. The unique identifier shall adequately identify the device through distribution and use, and may include information on the lot or serial number.

UDI: A Three-Part System

1. Assign a UDI compliant code to covered products
2. Label products with human and machine readable codes
3. Populate and maintain data in UDI database(s)

- UDI Code
  - Assign and label products:
    - Device ID (static data)
    - Production ID, e.g., lot, serial #, expiration date (dynamic data)

- UDI Database
  - Device ID the key
  - Specific static data
  - Multiple methods to populate
  - Publicly available data

- AIDC
  - Choice of auto id carrier
    - Linear barcode
    - 2-D barcode
    - RFID
    - Other
  - Direct Part Marking
FDA Listened

• Some Key Issues
  • Date Format
  • Existing Inventory
  • Kits and Combo Products
  • Shelf Packs
  • MRI Compatibility
  • Single Use Devices
  • Direct Part Marking for Implantable Devices
  • Global Medical Device Nomenclature (GMDN)

Standardized Date Format

Final rule if label includes a date (e.g., expiration):
- All numeric: YYYY-MM-DD (2013-06-19)
- Day must always be included
- Same Compliance Date as other UDI requirements
- Applies to all labels (even if exempt from UDI)
- If not subject to UDI applies at year 5
- A combination product with NDC number is exempt.
Packaged SUDs

Final rule extends this SUD exception to all classes.
- Modified exception only for devices that are intended to be stored in that device package until removed for use, and which are not intended for individual commercial distribution.
- Not applicable to implants.

Direct Part Marking

Direct part marking required for products intended to be used more than once and intended to be reprocessed before each use.

2 years after regular compliance date except for those products considered implantable, life-saving, and life sustaining. They must be in full compliance by September 24, 2015.
Direct Marking Exceptions

1. Direct marking would interfere with the safety or effectiveness of the device;
2. Direct marking is not technologically feasible;
3. The device is a reprocessed single-use device
4. The device has been previously marked

Exception to be noted in design history file Ç do not need to submit exception request.

UDI Database Synopsis

- There are currently no immediate plans to increase the UDI Database attributes*
  - *Attributes include latex, sterile, package size
- Attributes are expected to grow beyond the initial set in the future to support product description needs
- The FDA Listings Code was shown as a potential attribute UDI Database Pilot Report to be released on the FDA website within the next week
Global Medical Device Nomenclature (GMDN)

Final Rule:
- Labelers should obtain appropriate GMDN PT codes from GMDN Agency.
- Future GUDID tool will enable users to select a GMDN preferred term, to be used in their GUDID submission until a GMDN PT code can be obtained from the GMDN Agency.

The Clock is Ticking for Suppliers

Risk-based Compliance Deadlines
- September 24, 2014 - Class III devices (implants)
- September 24, 2015 - Devices that are implantable, life-saving, and life sustaining (DPM for required devices in this category)
- September 24, 2016 - Class II devices (DPM for Class III)
- September 24, 2018 - Non-exempt Class I devices, unclassified (DPM for Class II if required)
- September 24, 2020 - DPM for Class I and unclassified, if required
UDI = Unique Device Identifier

- Device Identifier (DI) + Production Identifier(s) (PI)

- DI = mandatory, fixed portion of a UDI that identifies the specific version or model of a device and the labeler of that device
  - Issued by FDA-accredited Issuing Agencies

- PI = a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of the device:
  - Lot or batch number
  - Serial number
  - Expiration date
  - Manufacturing date

Assigning UDIs - Different Packaging Levels

Each level of packaging requires a unique device identifier.
1. General Requirements
   - Package Labels
   - Plain-text (human readable) and Automatic Identification and Data Capture (machine readable)

2. The Device Identifier
   - Version or Model Number

3. The Production Identifier
   - Lot or batch Number
   - Serial Number
   - Expiration Date
   - Manufacture Date

Example of what a universal device identifier (UDI) would look like on a medical device label.

Device Identifier (DI) Record

Di,Record = Device Identifier (DI) + GUDID attributes
UDI Compliant Label: Linear Barcode

UDI Compliant Label: 2D/Data Matrix

Device Identifier or DI (GTIN)
Production Data (Application Identifier or AI)

Device Identifier: GTIN

Labels shown are drafts for illustrative purposes only.
UDI Compliant Label: 2D/Data Matrix

Production Data
Application Identifier
• Lot / Batch / Expiration Date

Labels shown are drafts for illustrative purposes only.

UDI Compliant Code: ISBT 128

Donated Human Tissue
Human Aortic Valve, Pathos 221211001

BRON: Denuoved Bone Strip
BRON: 6 x 6 x 6
EXP: JAN 27, 2013
Store at ambient temperature. Do not freeze.

Treated with gamma radiation. Tissue is recovered under sanitary conditions. Tissue is gamma-irradiated and passed USP 2211001 sterility tests. Trace amount of processing agents may remain. Fasten package over with tape. ISBT 128 code: 0101200BAD 1234567890 1234567890 1234567890

Generis Tissue Bank
Global Street
Any Town
Telephone: xxxxxxxxx
Fax: xxxxxxxxx
www.xxxxxxx.org

ISBT 128 Area of Label
Why is a GLN Needed?

Today, there are too many identifiers for the same healthcare location. This causes confusion, finger pointing & inefficiency.

ST JOHN’S QUEENS HOSPITAL
Hospital ID: 100084547

SAINT JOHNS QUEENS HOSPITAL
Hospital ID: JAOE

SAINT JOHN’S QUEEN HOSPITAL
Hospital ID: 50003000431

SAINT JOHN’S QUEEN’S HOSPITAL
Hospital ID: CA2053

ST. JOHN’S QUEENS HOSPITAL
Hospital ID: OM 12345

SAINT JOHN’S QUEENS HOSPITAL
GLN: 1100004570208
Imagine a every healthcare provider with a holster full of bar code scanners!!

we need technology to parse information
A Holistic Approach to UDI

This is not about just being able to identify devices. We (FDA) are talking about a holistic approach to integrating medical device identification throughout the entire healthcare system. UDI will be a fundamental piece of everything we do going forward.²

Jay Crowley, former Sr. Adviser for Patient Safety, U.S FDA Center for Devices and Radiological Health

FDA working on conforming amendments for:
- Premarket approvals
- Reports of Corrections and Removals
- Medical Device Recall Authority
- Quality System Regulation
- Medical Device Tracking Requirements
- Post Market Surveillance

UDI is Foundational

Strengthening Our National System for Medical Device Postmarket Surveillance

-U.S. FDA, April 2013
Visibility

- Medical device recalls
- Adverse event reporting
- Traceability
- Supply chain security
- Anti-counterfeiting/diversion
- Disaster/terror preparation
- Shortages/substitutions
- Point of Use Capture
- Supply Chain Efficiencies
- Comparative Effectiveness
- Value Analysis

UDI for Post Market Research

Unique Device Identifier Demonstration Project

- Utilize electronic health records and clinical registries to assess the safety and effectiveness of medical devices after they have reached the marketplace
  - Stents first, then ICDs

International Consortium of Orthopedic Registries

- Identify and capture clinical attributes that impact performance
- Address differences in orthopedic registries to better utilize available data
- Demonstration projects: bearing surface, femoral head size, fixed vs. mobile knees, pediatric joints
Promote Adoption with other Stakeholders

- Facilitate the incorporation of UDI into electronic health records as part of EHR Certification Criteria
- Create an initial think tank report to inform the development of a roadmap for successful UDI implementation
- Complete a pilot demonstrating the ability to incorporate UDI into a multi-hospital information system - Mercy Health Systems

UDI Implementation Project

- Retrieve UDI (Device Identifier) from GUDID for ERP
- Utilize ERP as master source of UDI (Device Identifier) + attributes for EHR
UDI Implementation Project

- Exchange UDI with Suppliers using UDI (Device Identifier)
- Automated replenishment from Inventory Management
- Point of Use integrated to EHR for UDI
- Automated charge capture
- UDI + Attributes in EHR
- Electronic management of Expiration Date
- Electronic management of Recalls
- Longitudinal data warehouse and CathPCI Registry utilize UDI (Device Identifier) + attributes from GUDID

• ERP/Supply Chain systems implementing UDI but working through bugs
  • Clinical systems in planning phase for UDI
UDI Implementation Project

- Manual efforts maintaining item master in multiple systems
- Workarounds required to incorporate UDI into EHR
- Clinical personnel not consistently scanning / proper barcode
- Double scan in Inventory Mgmt and Cath Lab
- GLN vs. DUNS use (data mapping required)
- Device descriptions not standardized (GMDN from FDA GUDID)

Source to Consumption Vision – Michael Inness/Curtis Dudley

The application of the GS1 standards will be used in all areas in the Source to Consumption model...

Master Data Synchronization

Enables end to end transactional efficiency
Source to Consumption Vision – Curtis Dudley

Master Data Synchronization

Supplier

Data Synch → Source → Order → Receive → Pay → Consume / Compare

Provider

Data Synch ← GLN Data Pool ← OTN

GLN Healthcare Registry

Price / Contract Update

Supply Chain System

Supply Chain System

Source to Consumption Vision – Brent Johnson

Source, Order, Receive, Pay & Consume

- Data Synch – Tying it together
- Source - Visibility drives accuracy
- Order – Speed & Accuracy
- Receive – Catching errors
- Pay – Eliminating the touch points
- Consume – Driving patient safety
UDI: Could Providers be Required?

- UDI in electronic medical records?
  - UDI on claims forms?
  - UDI as part of quality measures?

- Physician Value of UDI
  - Revision surgery, e.g., which hip implanted
  - Emergency cases, e.g., visibility into implants before patient arrives

Under healthcare reform, we need to know which products contribute to better outcomes at lower costs.
## EHR Adoption • Meaningful Use WG

<table>
<thead>
<tr>
<th>Stage 2 Final Rule</th>
<th>Stage 3 Recommendations</th>
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<td>NEW • NOT IN STAGE 2</td>
<td>MENU objective: Eligible Physicians and Eligible Hospitals should record the FDA Unique Device Identifier (UDI) when patients have devices implanted for each newly implanted device.</td>
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<td>MENU Measure: Eligible Physicians and Eligible Hospitals should record the UDI when patients have the device implanted for 80% of patients seen within the EHR reporting period.</td>
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### PROPOSED UDI REQUIREMENTS FOR 2017

- Record a minimum set of data elements for each UDI in a patient’s implantable device list, including:
  - Labeler Name (Manufacturer);
  - Brand Name;
  - Version or Model;
  - Global Medical Device Nomenclature Name;
  - Single Use indicator;
  - Labeled as containing natural rubber latex or dry natural rubber; and
  - MRI Safety Status.
ACCEPT ELECTRONIC UDI DATA VIA AUTOMATIC IDENTIFICATION & DATA CAPTURE

- Automatic identification and data capture (AIDC) means any technology that conveys the unique device identifier or the device identifier of a device in a form that can be entered into an electronic patient record or other computer system via an automated process.

INCORPORATE GUDID DEVICE IDENTIFICATION ATTRIBUTES

- Use the device identifier portion of the UDI to obtain and incorporate GUDID device identification attributes in the patient’s implantable device list.

- Specific challenges related to using the FDA GUDID as a data source:
  - Record the UDI in the EHR using the DI to provide the link to other authoritative data sources based on the system requirements and to support traceability.
  - Define the list of required UDI data elements, but do not specify the source for that information (to enable providers to use the best source for that information based on their requirements).
  - Record UDI data elements that cannot be edited without issuing a new UDI to minimize data quality issues.
MAKING UDI AND UDI DATA AVAILABLE TO OTHER SYSTEMS

- Use the device identifier or production identifier portion of the UDI to generate lists of patients with a particular implantable device.
- Make a UDI and its associated identification attributes accessible to the EHR technology for reporting purposes (e.g., adverse event reporting, registry population, recalls).
- Exchange a UDI and UDI data with procedure reporting systems (including adverse event incident reporting systems and medical specialty reporting systems) and other systems that associate a patient with a device.

COMMENTS REGARDING PROPOSED REQUIREMENTS FOR 2015

- CPOE: Computerized provider order entry
  - Medications
  - Lab
  - Radiology/Imaging
  - Drug allergy
- 2D Barcodes
- Access & View of Other Relevant UDI Data
- Recording & Presenting UDIs
Implantable device list. (i) Enable a user to electronically access and view a list of Unique Device Identifiers and other relevant information associated with a patient’s Implantable Device(s).
   ◦ (ii) Enable a user to electronically record in a patient’s Implantable Device list the following information at the time the Device is implanted or removed:
   • (A) The Unique Device Identifier associated with the Implantable Device; and
   • (B) Other relevant information about the Implantable Device or procedure.
   ◦ (iii) For each Unique Device Identifier in a patient’s Implantable Device list, allow a user to separately access and view electronically the Device Identifier and Production Identifier portions of the Unique Device Identifier

How can you achieve the most value?

Providers need to leverage UDI and product data for multiple purposes:
• Implant documentation
• Supply chain transactions
• Inventory management
• Charge capture
• Reimbursement
• Comparative Effectiveness
• Total cost of care
• What else?

Ask yourself:
• Where can you use UDI?
• What value can it deliver?
• Where will you be required to use UDI?
• How will you capture, share, store the required data?
• What data do you need to capture?
• What process changes are necessary?
• Who needs to be involved
Why are you waiting?

Focus on Implantables. The FDA is.

The Little Things Count

Overall costs for the devices related to the surgery has not declined as much as claimed because of peripheral products that remain under the radar.

Peripheral products like cutting guides for knees, antibiotic bone cement instead of regular cement, pin guides for surgical navigation systems, disposable instruments, and biologics.

These implant related costs have increased from about 3% of costs several years ago to 6% of implant costs in 2012.

Stan Mendenhall, Orthopedic Network News
September 27, 2013
Maximizing Value

To achieve return from Required investment, Manufacturers need to view as a strategy, not a project

Consider Objectives, Benefits, Impacts: Why are you doing this?
  - Regulatory compliance
  - Regulatory master data management
  - Competitive Advantage
  - Customer Service
  - Clinical Efficacy
  - Supply Chain efficiency
  - Other
Who needs to be involved?
Who, what is impacted?

Find the Best Path

Build a Global Master Data Management Strategy
Define ALL regulatory and commercial attributes (Super Spec)
Find a solution that works globally
UDI: A Global Issue
The Whole World is Watching

Other countries/regions looking at UDI:
European Union (draft regulations and common framework)
China, India, Japan, Korea, Netherlands, UK,
Turkey, Canada, Australia, Brazil, Argentina, and Turkey,
Canada, Australia, Argentina, India, UAE

Want to Learn More about UDI?

Check out blog posts and videos on UDI at The Healthcare Hub
http://www.thehealthcarehub.com

Check out AHRMM's UDI information site:
http://www.ahrmm.org/ahrmm/ext/standards/UDI_index.htm

Visit the FDA's UDI information page and sign up for regular updates on UDI at
http://www.fda.gov/udi
