FDA’s Unique Device Identification Program

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Device Information Lifecycle

- Manufacturer
  - Device X
    - Lot Y
    - Exp Date Z
  - Distributor
    - Direct
      - Hospital
        - Recall
        - Clinical Substitution
      - Sold
      - Rentals
    - Physician preference
    - Off-master purchase
    - Hoarding
    - Emergency Preparedness
    - Anticounterfeit
    - Import Safety
    - Traceability
    - Listing
- Reuse
- Reorder
- Clinical Use
  - Reduce Medical Error
- Reimbursement
- Registries
  - EHR
    - Clinical effectiveness
  - AE Reporting
  - Population Databases
    - Postmarket Surveillance
- Sales Rep
UDI Can Improve… Visibility

- Medical device recalls
- Adverse event reporting and postmarket surveillance
- Tracking and tracing, supply chain security; and anti-counterfeiting/diversion
- Clinical/cost effectiveness (registries)
- Disaster/terror preparation and shortages/substitutions
- Reduce medical errors

- Documenting medical device use in patient’s EHR/PHR, hospital information systems, claims data
- Sentinel Initiative - strengthening FDA’s ability to query data systems for relevant device information
Recalls

Device X
Lot Y
Exp Date Z

Manufacturer

Reuse

Direct

Distributor

Recall

GPOs

Clinical Substitution

Hospital

Rentals

Sold

Physician preference

Off-master purchase

Hoarding

Postmarket Surveillance

EHR

Registries

Reimbursement

Sales Rep

Clinical effectiveness

AE Reporting

Population Databases

Anticounterfeit

Emergency Preparedness

Cost Effectiveness

Supply Chain Efficiency

Shortage/Substitution

Reduce Medical Error

Availability

Unit

Reduces Medical Error

Reorder

Clinical Use

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September 27, 2007, the FDAAA signed into law:

- 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 Public Workshop

12 February 09 - 300 people attended; 4000 webcast

4 Panels addressed issues related to:

• Developing standardized UDIs
• Placing the UDI in human readable and/or AutoID on a device, its label, or both
• Creating and maintaining the UDI Database
• Promoting adoption and implementation

Received 60 written comments.
The label of Medical Device 123 Size 45:  
Device Identifier (Device XYZ123)  
Production Identifier (Lot #ABC)  
Expiration date (MMDDYYYY)  
Sterile; Latex free

FDA’s UDI Database

Manufacturer  
(Acme)

Minimum Data Set  
For each Device Identifier:  
• Manufacturer and model  
• GMDN Code  
• Other attributes

GSI GDSN  
or  
HIBCC UPN  
or  
FDA eList

Business Rules  
FDA’s UDI Database  
Public User Interface

Other options

FDA

FDA Managed
UDI Database Development

- Unique Device Identifier Type/Code [GTIN, HIBICC, NDC]
- Make/model; Brand Name; Long/Short Description
- Unit of Measure/Packaging level/quantity
- Parent/child relationships – e.g., combination product, kits
- Control mechanism – Lot and/or Serial Number; Exp. Date
- FDA Registration number; Contact name, phone, email
- Device status (prescription or over-the-counter)
- US Marketing Authorization Type/Code [e.g., 510K, PMA]
- GMDN Classification code/term
- Country of Origin Code/manufacture/Intended sale
- Storage conditions; Single Use/reusable; Sterility
- Contains known, labeled allergen (e.g., latex)
Establishing a UDI System

Combination of 4 distinct steps:

1. Develop a standardized system to develop the unique device identifiers (UDI)
2. Place the UDI in human readable and/or AutoID on a device, its label, or both
3. Create and maintain the UDI Database
4. Adoption and Implementation
Adoption and Implementation

- Technology issues/role of technology – barcodes, RFID, DPM
- Distributor uptake and use
- Hospital uptake and use
- Use of UDID
- Medical error reduction (e.g., latex)
- Integration issues – MMIS-Clinical
- EMR$
- Reimbursement
- Privacy
Unique Device Identification
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