Incorporating the Unique Device Identifier (UDI) into Health Care Delivery

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Unique Device Identifier (UDI)

- Unique Device Identifier (UDI) – an identifier that adequately identifies a device through its distribution and use.
- A UDI is composed of:
  - (1) A device identifier (DI) - a mandatory, fixed portion of a UDI that identifies the specific version or model of a device and the labeler of that device and
  - (2) A production identifier (PI) - a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of the device:
    - The lot or batch within which a device was manufactured;
    - The serial number of a specific device;
    - The expiration date of a specific device;
    - The date of a specific device was manufactured;
    - And for a human cell, tissue, or cellular or tissue-based product (HCT/P) regulated as a device, the distinct identification code required by 1271.290(c)

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UDI = DI + PI
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Unique Device Identifier (UDI)

- Obtained from an accredited issuing agency
  - GS1
  - HIBCC
  - ICCBBA
- Located on device labels, and directly on re-usable and reprocessed devices
- To obtain information regarding a device, the DI can be used to query the Global Unique Device Identification Database (GUDID).
  - Free, public access to the device information via search or web services
- General exemptions
DI Record Key Characteristics

- GUDID will only contain the DI
  - Each DI record will have a primary DI
    - Lowest level of a medical device package containing a full UDI
      - Also called a base package
  - GUDID will contain production identifier flags to indicate which PI attributes appear on the device label
    - Lot or batch number
    - Serial number
    - Expiration date
    - Manufacturing date
DI Record Key Characteristics

- All DIs checked for uniqueness
  - Once used, a DI can never be reused
- May also contain additional device identifiers
  - Secondary identifier
  - Unit of Use
  - Direct Marking
  - Package
- Business rules to ensure data quality
UDI Form

- Must be issued under a system operated by the FDA or an FDA-accredited issuing agency
- Conform to the following standards:
  - ISO/IEC 15459-2
  - ISO/IEC 15459-4
  - ISO/IEC 15459-6
  - Characters and numbers from the invariant character set of ISO/IEC 646
- Must be presented in 2 forms:
  - Easily readable plain-text
  - Automatic identification and data capture (AIDC) technology
    - Exception - when a device must bear a UDI as a direct marking: either or both
- The Universal Product Code (UPC) of a class I device will serve as the UDI
UDI Example

Base Package label

Oral/Enteral Syringe, 60ml
Device Count = 1

Package Configurations of the Base Package

Package DI = 30884838035683

Oral/Enteral Syringe, 60ml, Box of 100
Contains 100 units of
Base Package DI 00884838035683
Quantity per package = 100

Box of 100 label

Base Package is the lowest level of a medical device package containing a full UDI.

Package Configurations inherit the Base Package device attribute values, except for attributes specific to the particular package.
UDI Example

Base Package
Primary DI = 1001

Package Configurations of the Base Package

Package DI = 2001

Catheter, 12 Fr, Box of 30
Contains 30 units of
Base Package DI 1001
Quantity per package = 30

Package DI = 3001

Catheter, 12 Fr, Case of 540
Contains 12 units of
Package DI 2001
Quantity per package = 12

Package Configurations inherit
the Base Package device
attribute values, except for
attributes specific to the
particular package.
Discontinuation of Legacy IDs

- On the date the device must bear a UDI on its label, any National Health-Related Item Code (NHRIC) or National Drug Code (NDC) number assigned to the device is rescinded.

- Device is not required to bear a UDI on its label, any NHRIC or NDC number assigned to that device is rescinded as of September 24, 2018 and beginning on that date, no longer provide a NHRIC or NDC.
Sources of Electronic Health Information

Electronic Health Records
- New certification criteria
- New Meaningful Use objective

Claims Transactions
- Electronic claims
- Paper claims
Value Specific to Claims

Major Safety/Quality Advances
- Larger data sets
- Longitudinal outcomes, especially when different providers involved in care
- Provides denominator information unavailable elsewhere
- FDA cannot use Sentinel for devices without UDI

Significant Interest Already in Utilizing Claims Data
- FDA
- California previously sought claims transaction revisions
- Mentioned by multiple other stakeholders already
Significant Support Already

“I believe that CMS ought to establish a date certain in the future, let’s choose January 1, 2011, and say that as of that date every device that’s used on a patient for which you expect Medicare reimbursement has the device identifier placed on the claims form.”

Steve Phurrough, M.D., M.P.H., former director of the coverage and analysis group, CMS, in comments at an FDA public meeting on UDI, February 2009

“Health plans have long used administrative claims information to evaluate patterns of care, identify missed opportunities, assess effectiveness, and monitor product safety. Given health plans’ ability to aggregate administrative claims data and analyze trends using this data, much could be learned about the safety and effectiveness of particular devices with inclusion of UDI information.”

AHIP in comments to FDA on the UDI proposed rule, November 2012

“Ideally, the Healthcare Common Procedure Coding System (‘HCPCS’) codes should be replaced by UDI whenever information about payment for devices (coded as procedures) is conveyed through standard transactions.”

Kaiser Permanente in comments to FDA on the UDI proposed rule, November 2012
Next Steps

**ASC X12**
- Pew submitted a preliminary change request due to the deadline
- Pew will update that request with more information in March

**WEDI**
- Will hold stakeholder meetings and Technical Advisory Committees
- Will develop a white paper to supplement ASC X12 submission

**There are still many outstanding issues to address**
- What mechanism (claims or otherwise) is most appropriate for transmitting UDI data?
- Under which conditions should UDI be transmitted to payers?
- How can UDI provide information for FDA and payers to improve patient care?
- Can hospitals and health plans benefit from UDI transmission?
- Others
Thank you!

Questions and Discussion