Unique Device Identification Update on FDA Activities

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FDA believes that UDI can…

- Reduce device related medical errors - identify compatibility and interoperability issues, e.g.:
  - right device for right patient (latex allergy)
  - right accessory for right device
  - MRI compatibility
- Improve identification of specific device in adverse event reports
- Facilitate more effective device recalls – identify and locate recalled devices in a timely fashion

UDI can also…

- Facilitate the population of device use information in Electronic Medical Record Systems (HIT)
- Provide ancillary benefits:
  - Improve materials management and associated healthcare cost savings
  - Help track devices and identify counterfeit devices
  - Identify similar or substantially equivalent devices to avoid shortage
  - Emergency preparedness – national, military

FDA Amendments Act of 2007

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.

FDA Amendments Act of 2007

Establish a unique device identification system:

- Requires that the label of devices bear a unique identifier ["Label" is defined as "…a display of written, printed, or graphic matter upon the immediate container of any article."];
- Allows FDA to describe an alternative placement (e.g., on the device itself or its packaging) for a particular device or device type;

FDAAA of 2007 (continued)

Establish a unique device identification system:

- Allows FDA to exempt a particular device or type of device from the UDI requirements;
- The UDI must adequately identify the device through distribution and use; and
- The UDI includes information on the lot or serial number.

Developing the UDI

The UDI would be constructed by:

- Concatenating the Device Identifier and the Production Identifier

  UDI = Device Identifier + Production Identifier
- Device Identifier: Manufacturer, make, model and critical attributes [e.g., GS1 GTIN]
- Production Identifier: if currently serialized – serial number; if currently identified at the lot level, the lot number, expiration date – or some combination.

UDI Application

The UDI would be:

- applied at the “patient use level” (“unit of use”);
- created and maintained by the manufacturer;
- constructed following GS1 or HIBCC standard for device identification; and
- be human readable AND encoded in a form of automatic identification technology; however
- no specific technology would be identified (technology neutral).

UDI Database (1/2)

Minimum Data Set for each **Device Identifier**:

- Device identifying information (e.g., manufacturer, make, model, size);
- Global Medical Device Nomenclature (GMDN);
- Accessory Information (accessories needed to operate the device, or, the specific device it operates with); and
- Other FDA identifying information (premarket authority, listing).

UDI Database (2/2)

Certain additional attributes to facilitate safe use:

- Allergens (e.g., whether it contains latex);
- Compatibility issues (is it MRI compatible);
- Single use/reusable; and
- If reusable, how to reprocess.
- and … ???

Other UDI Issues

- NDC/NHRIC issues
- AutoID or human readable only?
- Combination products
- Reprocessed Single Use Devices (SUDs)
- Legacy devices
- Capital equipment; components; configurable devices
- Tracking/maintaining dynamic information (e.g., recalls, software version
- Hospital and other healthcare facility uptake

Unique Device Identification

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