Background and History

• 1999 – IOM publishes report “To Err is Human: Building a Safer Health System”

• 2004 - FDA issues final rule requiring bar codes of NDC numbers on drugs and biological products to help reduce medication errors

• Devices specifically excluded from bar code rule because devices lack a unique numbering scheme

• 2005 - FDA receives letters from Congress and a consortium of hospital groups asking that we revisit the issue of bar coding medical devices.
Three Stakeholder Meetings

• April 2005 - meeting with representatives of the medical device industry
• September 2005 - meeting with Federal Partners including DOD, CMS, AHRQ
• October 2005 - meeting representatives of health care related organizations
Stakeholder Meetings told us...

- The majority of stakeholders support the development of a uniform system of unique identifiers as a way to improve patient safety and recognized other ancillary benefits such as better management of the purchase, distribution, and use of medical devices.

- “Throughout the meeting, and in subsequent communications with participants, it became clear that many organizations clearly favored a mandatory approach to this issue”
FDA believes that UDI can...

- Reduce device related medical errors - identify compatibility and interoperability issues:
  - right device for right patient (latex allergy)
  - right accessory for right device
  - MRI compatibility
- Improve identification of specific device in adverse event reports and provide more “denominator” data
- 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 for a wide variety of stakeholders:
  • 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
Federal Register Notice

• 11 August 2006 – request comments to help FDA understand how the use of a unique device identification system may improve patient safety.
• Comments due 9 November 2006
• Notice focuses on 3 broad areas:
  • Developing a System of Unique Device Identifiers
  • Implementing Unique Device Identifiers
  • UDI Benefits and Costs
Combination of 3 Distinct Ideas

1. Developing a uniform, standard system of device attributes—which, when combined, would uniquely identify a particular device at the unit of use.

2. Place human readable UDI on device labeling. UDI could ALSO be encoded in any of a number of different automatic identification technologies.

3. UDI could also interface with a database that would access an additional data set with information related to safe use (a “minimum data set”).
1. UDI System

- At the “unit of use” – create a unique identifier by combining these device elements and attributes:
  - Manufacturer, make, and model;
  - Unique attributes (e.g., size, length, quantity, software version); and
  - Serial number, identifying lot number, manufacturing, or expiration date.
- Any change to the above criteria would necessitate a new UDI.
- “Unit of use” would vary for different device types.
2. Automatic ID Technologies???

• Any number of different automatic identification technologies – 1D, 2D barcode, RFID
• Do we specify one technology of different for different device types?
• Or be non-specific and allow different technologies depending on the stakeholders’ needs and uses?
• Should it be the same as the drug barcode rule?
• What about direct part marking?
3. Minimum Data Set

To promote safe device use – data would reside publicly and include:

- Manufacturer, make, and model
- Unique attributes (e.g., size, length, quantity)
- Serial number, lot number, or expiration date
- Product type
- Indications, contraindications, warning, precautions
- The accessories needed to operate the device
- If the device is an accessory to another device, the specific device with which it operates.
Public Meeting

• 25 October 2006 – Gaithersburg, Maryland, USA
• Meeting will focus on:
  • Benefits and costs of a UDI system
  • Design and implementation of UDI system
  • Data repository – design, maintenance, use
  • Automatic identification technologies
Realities of the Device World

• Diverse industry
  • 28,000+ firms (many are small < 20 employees)
  • Global marketplace – international harmonization

• Diverse population (of devices):
  • 100,000+ brands/models of devices
  • Vary in size, complexity, packaging and use
  • High volume, low volume
  • Kits; components; systems
  • Implants
  • Reprocessed devices
Next Steps

After Public Meeting and docket closes…

- Analyze Comments
- Determine FDA’s role
- Mandatory/voluntary? Guidance/regulation?
- Standards?
- On all or some devices – risk based?
- One format or flexible?
- Auto ID Technology?
- Issues of data ownership?
- What minimal information will be needed?
Unique Device Identification
www.fda.gov/cdrh/ocd/udi/
cdrhudi@cdrh.fda.gov