FDA UNIQUE DEVICE IDENTIFICATION PROPOSED RULE AND GS1 STANDARDS SYSTEM

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What is UDI?
Explanation, definition, scope

Why is it important?
Global overview

How can I get support?
Planning and implementation

Questions and Answers
Where do I go from here?
U.S. Healthcare Community Initiatives

7/30/2012

- FDA Unique Device Identification (UDI) Public Workshop 2/1/09
- FDA Amendments Act (FDAAA) UDI Req 9/27/07
- FDA UDI Public Comments Due 2/27/09
- Phase 4 of the UDI Database Pilot (test UDI regs) 9/30/10
- UDI Database RFP 1/31/11
- 2/1/12 FDA Pharma Barcode Regulation Comments Closed
- 10/1/11 FDA Pharma Barcode Regulation Comments Open
- Proposed FDA UDI Reg Pub 7/10/12
- Pilot Version of UDI Database Complete 9/15/12
- FDA UDI Comment Closed 11/7/12
- 12/31/12 FDA Pharma Barcode Regulation Comments Revised
- Final FDA UDI Reg Pub* 5/30/13
- 5/28/09 GHX Certified Data Pool
- 4/16/09 Pharma Standardized Numerical Identification (SNI) Public Comments Due
- 3/26/10 FDA SNI Pharma Guidelines Pub
- 6/30/10 GS1 Global Traceability Stds for Healthcare (GTSH) Pub
- 12/7/10 HTG (Healthcare Transformation Group) Formed
- 12/31/10 2010 GLN Sunrise
- 12/31/12 2012 GTIN Sunrise
- 1/1/15 EHR Non-Compliance Penalties Begin (1-3% Deduction)
- 1/1/15 CA Pedigree (100% Mfg Prod)
- 1/1/16 CA Pedigree (50% Mfg Prod)
- 1/1/16 CA Pedigree (Wholesalers)
- 7/1/16 NY Pedigree (Mfg)
- 7/1/17 CA Pedigree (Retail/Hos. Pharmacies)
- 7/1/16 NY Pedigree (Retail/Hos. & Pharmacies)
- 7/1/17 NY Pedigree (Wholesalers)

* Estimated dates based on FDA presentations
DEFINITIONS

• FDA
  – Unique Device Identification (UDI)
  – Global Unique Device Identification Data Base
    – GUDID / UDID
  – National Health Related Item Code (NHRIC)
  – National Drug Code (NDC)

• GS1 US (formerly the Uniform Code Council)
  – Global Trade Item Number (GTIN) (e.g., U.P.C.)
  – Global Data Sync Network (GDSN)
  – Global Location Number (GLN)
CAVEAT: GTIN AND UDI

➢ GTIN is a UDI.
➢ U.P.C. encodes a GTIN.
➢ U.P.C. is a UDI.
FDA UDI is *not* an isolated move to standards.

Echoed in:
- Other Governments
- US Healthcare Providers

Manufacturer approach / response:
- Coached / budgeted / directed / planned
PERFECT STORM: GLOBAL

• May 2012 USP workgroup presentations:
  – Turkey
    • GTIN, serial number, GLN
  – Argentina
    • GTIN, serial number, GLN
  – France
    • GTIN, serial, lot, expiry, GLN
  – GHTF UDI - UDID Guideline
    • GTIN and Lot, GLN
GHTF Draft Proposal for

a draft guidance on

Unique Device Identification (UDI) System
for Medical Devices

Authoring Group: GHTF SC UDI AHWG

Proposed by the Global Harmonization Task Force

Date: November 4, 2010

Larry Kelly, GHTF Chair

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• GHTF: is now the IMDRF

• International Medical Device Regulators Forum (IMDRF).

http://www.imdrf.org/
PERFECT STORM: FDA REGULATIONS

- FDA Pharmaceutical Bar code Rule 2004
  - FDA proposed rewrite 2011 / 2012
    - Data Matrix
    - 20 of 22 comments supported
  - Serialized Numeric Identifiers
  - SNI Guidance 2010
PERFECT STORM: U.S. GLN ADOPTION AND 2012 GTIN SUNRISE

• Healthcare grassroots initiatives
• Continuing GLN adoption
  • Scorecards / Best Practices
• 2012 GTIN Sunrise
  – Scorecards
  – Road Map
  – Education
PERFECT STORM CUSTOMER

- Group Purchasing Organizations (GPOs)
  Amerinet, MedAssets, Novation, Premier
- Integrated Delivery Networks (IDNs)
  • Healthcare Transformation Group:
    Geisinger, Intermountain, Kaiser, Mayo, Sisters of Mercy
    (healthcaretransformationgroup.com)
HOW COMPANIES AND INDUSTRIES BENEFIT

STANDARDS ADOPTION & USAGE

BUSINESS ADOPTION & USAGE

PRODUCT DATA MANAGEMENT

INDUSTRY COLLABORATION & INNOVATION
ABOUT GS1

GS1 brings together stakeholders across an industry to develop, adopt, and use information standards that revolutionize the way they do business.

• GS1 Standards make it possible for companies to leverage the power of information by identifying, capturing, and sharing data about products, locations, and more.

• GS1 is a global, not-for-profit organization with more than 110 member organizations (MOs) serving business around the world.

• GS1 is neutral, user-driven, and user-governed.
ABOUT GS1 US

GS1 US serves more than 250,000 businesses across 25 industries in the United States.

• Leading industry initiatives in Apparel / General Merchandise, Consumer Packaged Goods / Grocery, Foodservice, Fresh Foods, and Healthcare

• Administrating the GS1 System of standards

• Providing support services, tools, education, and training

• Connecting communities through events and online forums

GS1 US is the pioneer of the Universal Product Code (U.P.C.) and the Electronic Product Code™ (EPC®).
GS1 BY THE NUMBERS

• 2 million companies around the world use GS1 Standards

• more than 5 billion GS1 barcodes are scanned every day

• 5 million products are assigned U.P.C.s in the GS1 Data Driver® item management tool

• 5 million products are registered by brand owners in the 1SYNC Data Pool
HOW WE ARE STRUCTURED

THE GLOBAL LANGUAGE OF BUSINESS

LEADING INDUSTRY TO ADOPT AND USE GS1 STANDARDS AND SOLUTIONS

STANDARDS, ADOPTION & USAGE

Engaging communities and companies to solve supply-chain problems by adopting and using GS1 Standards

PRODUCT DATA MANAGEMENT

Enhancing the GS1 Standards-driven supply chain (e.g., GDSN) by providing services and technologies to help manage product data
MOVING FORWARD IN HEALTHCARE
HEALTHCARE

• **We make it possible** for healthcare companies to follow drugs and medical devices from the factory to the patient, improving efficiency, safety, and patient care.

• **For Healthcare, GS1 Standards:**
  - Improve patient safety
  - Lower costs through increased efficiency
  - Reduce medication errors
  - Enable supply chain visibility
  - Facilitate faster product recalls
  - Enable efficient tracking of pharmaceutical products/medical devices
  - Reduce the introduction of counterfeit products
  - Enhance inventory management
  - Link critical product data to the patient record
  - Support regulatory compliance
  - Streamline business processes
GS1 STANDARDS

GS1 Standards for identifying, capturing, and sharing information - about products, business locations, and more - make it possible for companies to speak the same language, connect with each other, and move their business forward.

IDENTIFY  CAPTURE  SHARE
GS1 STANDARDS IN HEALTHCARE

**ITEM**
- **Barcodes**
  - EAN/UPC
  - GS1-128
  - GSI DataMatrix
  - GS1 DataBar™

**CASE**
- **ITF-14**
  - Carries a GTIN

**PALLET**
- **ITF-14**
  - Carries a GTIN

**OR**
- **GS1-128**
  - Carries a GTIN with extended data or a Serial Shipping Container Code (SSCC)

**AND**
- **EPC-ENABLED RFID**
  - Carries a Serialized GTIN (SGTN)

**OR**
- **GS1-128**
  - Carries a GTIN or an SSCC

**AND**
- **EPC-ENABLED RFID**
  - Carries an SGTIN or SSCC
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 UDI PROPOSED RULE

• Published Federal Register: July 10, 2012
  ▪ Comments due
  ▪ Information collection issues September 10, 2012
    ✓ (section V)
    ✓ (paperwork reduction act OMB)

• General comments on rule: published November 7, 2012
  • [www.regulations.gov](http://www.regulations.gov)
  • FDA-2011-N-0090
  • Three comments received
    • 2 were on HRI date
FDA UDI RULE SUMMARY

• Authority

• FDAAA 2007

1. All Medical device Label / label package to include UDI
   a) Exception OTC or “Low Risk” items
   b) UDI plain text and in AIDC
   c) UDI direct marked on certain item categories

2. Submission of device information to GUDID (formerly UDID)
   Global Unique Device Identification Database
   a) FDA intends to make database public to ensure that UDI can adequately describe device through its distribution and use
HEALTH CARE BENEFITS

• Reduce medical errors
• Simplify the integration of device use information into data systems
• Provide for more rapid:
  – identification of medical devices with adverse events
  – development of solutions to reported problems
  – more efficient resolution of device recalls
• Better-focused and more effective FDA safety communication
• Provide an “easily-accessible” source of definitive device identification information
• Additional benefits:
  – strategic stockpile; inventory management development (EPR)
• Standard format for dates provided on a device label or package:
  – month, day, year (e.g. Jan 1, 2012)
MAJOR PROVISIONS

• Labels of medical devices and device packages to include a UDI
  – There are exceptions
  – UDI in plain text and in form that uses AIDC
  – UDI direct marked certain categories
  – UDI data submitted to GUDID
    • Must adequately identify the device
    • No patient information
    • Require dates to be in standard format
  – UDI identify product
    • Lot identification, expiry date, and serial number
  – Exemptions
    • OTC at retail and when delivered directly to healthcare facility
    • FDA class one items by regulation
    • No production data for class 1 items
  – Rule effective in stages
FDA UDI RESPONSE COMMITTEE

• GS1 and GS1 US Joint Committee

• Current Members:
  – Manufacturers
  – Distributor
  – Providers
  – GPOs
  – Consultants / solution providers
  – Associations
  – GS1 & GS1 US staff

• Sharing information with other groups
  – AHRMM, AdvaMED, AIM, HDMA
QUESTIONS: 35

- Objectives uses of UDI system
  1, 2, 3
- UDI labeling requirements
  4, 5
- Combination products
  6, 7
- Combination Products not labeled with NDC
  8
- Convenience Kits
  9, 10, 11
- Direct marking
  12, 13, 14, 15
- UDI labeling exceptions and alternatives
  16, 17, 18, 19, 20
- Form of a UDI
  21, 22
- Role of an issuing agency
  23, 24, 25, 26
- Data submission (GUDID)
  27, 28, 29, 30, 31
- Format of date
  32, 33, 34, 35
SUMMARY

• Long awaited proposed rule

• Document has raised many issues across U.S. healthcare

• Needs to be read closely

• Need to respond

• Reply should not be U.S. centric, but a global view

• Look for GS1 / GS1 US comments in September
Reference Material
Standardized Data for Safer Healthcare

GS1 US is connecting the dots across the healthcare supply chain for improved patient safety and supply chain efficiency.

We’re working together with healthcare leaders to adopt and use standards that will help organizations share data, promote accuracy, and work more efficiently—to improve patient safety and lower healthcare costs. Learn more about our standards and the industry-wide initiatives to adopt them.

**Standardization... Stat! Our Industry's Responsibility**

See why healthcare leaders are calling for the industry to step up and address the standards challenge. [Click here](http://www.gs1us.org/healthcare) to view the video.
REFERENCE LINKS

• Healthcare Industry Sunrise Dates
  – www.gs1us.org/hcsunrise

• GLN and GTIN Industry Readiness Scorecards
  – www.gs1us.org/hcscorecard

• Industry Use Cases
  – www.gs1us.org/hcstudies

• Healthcare Tools & Resources
  – www.gs1us.org/hctools

• Education
  – www.gs1us.org/hcedu

• GS1 Healthcare US Initiative
  – www.gs1us.org/healthcare

• GLN Registry for Healthcare
  – www.gs1us.org/glnregistry
SUPPLIER AND PROVIDER TOOL KITS:
GTIN, GLN, GDSN, UNSPSC

• Introduction to the Standards
• Implementation Steps
• Lessons Learned
• Benefits to Healthcare
• ROI Hot Spots
• FAQs

http://www.gs1us.org/industries/healthcare/tools-and-resources/healthcare-tool-kits
What should happen if a barcode will not scan at the Hospital?

**Provider:**
1. Internal simple fixes
2. More complex verifier process
3. **Report to manufacturer**
4. If necessary, report to FDA
5. Document procedure

**Supplier:**
1. Take in call
2. Institute correct action if necessary
3. **Inform customer (provider)**
4. Inform FDA, if necessary
5. Document procedure
5.1.6 Declared change in net content

Any modification which leads to a declared change in net content of a healthcare item requires a new GTIN to be assigned…

Requires New GTIN
WHAT IS A GTIN?

• “GTIN” is a Global Trade Item Number®
  • A globally unique 8, 12, 13, or 14-digit number that uniquely identifies products and services.
  • An identification number of the GS1 System.
  • Unique and unambiguous.
  • Uniquely identifies a product at every level of packaging
    – A non-intelligent number
    – GTIN Allocation Rules
  • It is about the data not the carrier.

Examples:

GS1 -128 (14-digit GTIN)  GS1 DataMatrix (14-digit GTIN)  GS1 Databar (14-digit GTIN)
SUPPORT FOR UDI IMPLEMENTATION:
Simply log on and register to learn

Live monthly
Ask the Experts
GTIN Sunrise
3 Gs: presented by Jean Sargent (USC Health Sciences)

On demand
GS1 System Explained
  GS1 Company Prefix
  GTIN: Product Identification Number
  GDSN: Global Data Synchronization Network®
  GIAI: Global Individual Asset Identifier
  GLN 101: Location Identification Number
    GLN Registry for Healthcare®
  GDTI Global document Type identifier
SSCC: Serial Shipping Container Code

Technical
Barcoding is an Art & a Science
Scanner Versus Verifier
GS1 Data Matrix

Development
GS1 and UDI
Navigating the GS1 Specification

Education
Registration:
http://www.gs1us.org/hcedu
Perfect Order and Beyond
BD and Mercy/ROi Achieve Far-Reaching GS1 Standards Integration

Learn how BD and Mercy/ROi implemented GS1 global standards – from manufacturing plant to patient bedside – illustrating ways the supply chain can impact patient safety and optimize healthcare operations with fully automated order processes and transactions.

Benefits Achieved
- 30% reduction in days payable outstanding
- 73% reduction in discrepancies (part number and UOM)
- Improved sourcing of products (right product/right order number)
- Less calls to customer service
- Fewer stock outs
- Better charge compliance (scanning @ POU)

Download at www.gs1us.org/BDMercystudy
UDI APPLICATION EXAMPLE
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