UDI in the US

Ms. Terrie Reed, Senior Advisor for UDI Adoption
U.S. Food and Drug Administration

19 October 2017
UDI: Regulatory Update

Terrie L. Reed, MS. Ind. Engineering
Center for Devices and Radiological Health
Senior Advisor for UDI Adoption

www.fda.gov
Core Strategy: Leverage Real-World Evidence

National Evaluation System for health Technology (NEST)
- Real World Evidence Final Guidance
- Medical Device Innovation Consortium
  NEST Coordinating Center

Data sources:
- Registries
- Medical Claims
- Electronic Health Records (EHR)
- Others

Work collaboratively with:
- Patients/consumers
- Professional societies and Registries
- Academia
- Payers/Health care industry
- Device industry
The Value Proposition for NEST

Patients/Clinicians
- More timely access to safer, more effective devices
- Better information about the use of a given device in practice

Hospitals, Health Systems
- Improved quality
- Reliable assurances of safety
- Possibly, reduced reporting requirements
- Access to high-quality evidence on device performance in clinical practice

Payers
- High-quality evidence at lower cost, in less time, to support premarket approval/clearance, payer coverage
- Meet or reduce the need for postmarket study and adverse event reporting requirements
- Potential for premarket-postmarket shift owing to strong assurances that postmarket RWE would be generated

Medical Device Industry
- May obviate the need for FDA premarket review of some device modifications because more timely and informative routine data collection

UDI
- Standard reference source for FDA regulated devices
- Manufacturer submits DI data once for multiple purposes
- Replaces text, non-standard data with meta-data in AccessGUDID
GUDID Records and Submission Compliance Deadlines
Data Current as of September 5, 2017

Class I
Class II
Class III
I/LS/LS
Class I & Unclassified

0
200,000
400,000
600,000
800,000
1,000,000
1,200,000
1,400,000
1,600,000


200,000
400,000
600,000
800,000
1,000,000
1,200,000
1,400,000
1,600,000

0
200,000
400,000
600,000
800,000
1,000,000
1,200,000
1,400,000
1,600,000

Most Primary DIs Have Been Issued by GS1
Data Current as of September 6, 2017

HIBCC: 200,000 Records

ICCBBA: 40 Records

GS1: 1.2 Million Records
219 Companies Have Submitted 80% of GUDID Records
Data Current as of September 1, 2017
# UDI Regulatory Dates

<table>
<thead>
<tr>
<th>Compliance Date</th>
<th>Must bear a UDI &amp; submit data to GUDID</th>
<th>Direct Marking (for certain intended uses)</th>
</tr>
</thead>
<tbody>
<tr>
<td>September 24, 2014</td>
<td>• Class III devices</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Devices licensed under the PHS Act</td>
<td></td>
</tr>
<tr>
<td>September 24, 2015</td>
<td>• Implantable, life-supporting and life-sustaining (I/LS/LS) devices</td>
<td>• LS/LS devices</td>
</tr>
<tr>
<td>September 24, 2016</td>
<td>• Class II devices</td>
<td>• Class III devices and devices</td>
</tr>
<tr>
<td></td>
<td></td>
<td>licensed under the PHS Act</td>
</tr>
<tr>
<td>September 24, 2018</td>
<td>• Class I devices and unclassified devices</td>
<td>• Class II devices</td>
</tr>
<tr>
<td>September 24, 2020</td>
<td></td>
<td>• Class I devices and unclassified</td>
</tr>
<tr>
<td></td>
<td></td>
<td>devices</td>
</tr>
</tbody>
</table>

Intend to extend
UDI Adoption: Linking and Learning

Manufacturer (Labeler) → FDA GUDID via NLM AccessGUDID

LEARN

FDA GUDID → Point of Implant → Item Master → Electronic Health Records → FDA Device Recalls

FDA Device Recalls → Incident Report

FDA Adverse Event Reporting → Registry

USE
## Regulations: Adoption in EHRs

<table>
<thead>
<tr>
<th>Vendor</th>
<th>Software</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allscripts</td>
<td>Allscripts Professional EHR</td>
</tr>
<tr>
<td>Allscripts</td>
<td>Allscripts TouchWorks EHR</td>
</tr>
<tr>
<td>CureMD.com, Inc.</td>
<td>CureMD SMART Cloud</td>
</tr>
<tr>
<td>Epic Systems Corporation</td>
<td>EpicCare Ambulatory EHR Suite</td>
</tr>
<tr>
<td>Epic Systems Corporation</td>
<td>EpicCare Ambulatory EHR Suite</td>
</tr>
<tr>
<td>Epic Systems Corporation</td>
<td>EpicCare Inpatient EHR Suite</td>
</tr>
<tr>
<td>Epic Systems Corporation</td>
<td>EpicCare Inpatient EHR Suite</td>
</tr>
<tr>
<td>Cerner Corporation</td>
<td>FirstNet (Clinical)</td>
</tr>
<tr>
<td>MEDHOST</td>
<td>MEDHOST Enterprise</td>
</tr>
<tr>
<td>Henry Schein Medical Systems</td>
<td>MicroMD</td>
</tr>
<tr>
<td>Netsmart Technologies</td>
<td>myAvatar Certified Edition</td>
</tr>
<tr>
<td>McKesson</td>
<td>Paragon® for Hospitals 2015 Certified EHR</td>
</tr>
<tr>
<td>Cerner Corporation</td>
<td>PowerChart (Clinical)</td>
</tr>
<tr>
<td>SRS-Health</td>
<td>SRS EHR</td>
</tr>
<tr>
<td>Greenway Health, LLC</td>
<td>SuccessEHS</td>
</tr>
<tr>
<td>Allscripts</td>
<td>Sunrise Acute Care</td>
</tr>
<tr>
<td>Allscripts</td>
<td>Sunrise Ambulatory Care</td>
</tr>
<tr>
<td>Medical Transcription Billing Corporation (MTBC)</td>
<td>TalkEHR</td>
</tr>
<tr>
<td>Evident</td>
<td>Thrive EHR</td>
</tr>
<tr>
<td>Evident</td>
<td>Thrive Provider EHR</td>
</tr>
</tbody>
</table>
## Early Adopters

<table>
<thead>
<tr>
<th>Vendor</th>
<th>Software</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allscripts</td>
<td>Allscripts Professional EHR</td>
</tr>
<tr>
<td>Allscripts</td>
<td>Allscripts TouchWorks EHR</td>
</tr>
<tr>
<td>CureMD.com, Inc.</td>
<td>SMART Cloud EHR</td>
</tr>
<tr>
<td>Epic Systems Corporation</td>
<td>EpicCare Ambulatory EHR Suite</td>
</tr>
<tr>
<td>Epic Systems Corporation</td>
<td>EpicCare Inpatient EHR Suite</td>
</tr>
<tr>
<td>MEDHOST</td>
<td>MEDHOST Enterprise</td>
</tr>
<tr>
<td>Henry Schein Medical Systems</td>
<td>MicroMD</td>
</tr>
</tbody>
</table>

- **Materials Management:** Improved Recall Management
- **Nursing:** Operating Room Efficiency
- **Clinical Engineers:** Improved Tracking
- **Information Systems:** Meaningful Use
- **Quality:** Workflow Improvements
- **Risk Management:** Patient Safety Projects
- **Researchers:** Medical Device Registries
Demonstration Projects

Tracking Implantable, Life-Supporting, or Life-Sustaining Devices

1. FDA GUDID
2. Order
3. Provider
4. Procedure
5. UDI
6. Manufacturer
7. EHR system

Slides by Ioana Singureanu for VHA
Demonstration Projects

Medical Device Epidemiology Network (MDEpiNET)
Registry Assessment of Peripheral Interventional Devices (RAPID)

- Develop UDI registry team that includes Manufacturers, Registry Owners, Vendors, FDA, Clinicians
- Educate on known UDI gaps and issues
- Identify medical devices covered by registry using:
  - Product code x Company x Brand x GMDN/SNOMED terms
- Run AccessGUDID reports to pull DI device records
- Identify gaps, improve GUDID
- Use UDI and GUDID data in Registry

MDEPINET.ORG
<table>
<thead>
<tr>
<th>Primary Device Identifier</th>
<th>GMDN term</th>
<th>Clinically Relevant Size Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Secondary Device Identifier</td>
<td>SNOMED CD/Term</td>
<td>Mapped from GMDN</td>
</tr>
<tr>
<td>Company Name</td>
<td>Device Description</td>
<td></td>
</tr>
<tr>
<td>Brand</td>
<td>Version or Model</td>
<td></td>
</tr>
</tbody>
</table>
RAPID: Integration of UDI
Enter data ONCE to support data capture and device evaluation
UDI as a Global Standard

- ISO/IEC - HL7 - GMDN – SNOMED – Issuing Agencies
- Scan4Safety - UK National Heath System
- EU Final Regulation April 2017
  - UDI assignment and submission of UDI core data elements to EUDAMED
  - Linking of DI information across jurisdictions

Funded: Government of Canada, Networks of Centers of Excellence
Hosted: University of Windsor Odette School of Business
Participation: Representations from Canada, Australia, Netherlands, UK, US

Adopt and scale best practices in healthcare supply chain

New Work Item:
UDI Harmonized Unique Device Identification (UDI) Application Guide
UDI as a Global Standard

Consistent, universal approach to UDI will facilitate:

• Traceability of medical devices through distribution and use
• Identification of specific medical devices and device attributes associated with adverse events
• Reduction of medical errors
• Documentation of specific device data in the course of patient care
Summary

- **UDI** – standard that opens up ability to scan and identify devices more accurately in electronic supply chain, device maintenance and clinical sources. Foundational to National Evaluation System for health Technology

- **AccessGUDID** - reference data source that associates DI of UDI with standard meta-data that can be shared across care continuum

- **Value of Demonstration projects** – cross-stakeholder demonstration projects show value and will lead to improved patient and device safety and innovation

- **Global Harmonization** – a founding principle of the IMDRF UDI Working group was establishment of a global standard. This requires commitment.
UDI Resources

- Association for Healthcare Resources and Materials Management (AHRMM) Learning UDI Community
  - UDI Resources
  - Workgroups to address adoption challenges
- Medical Device Epidemiology Network (MDEPINET)
  - UDI and National Education System education, case studies, bibliographies
- Medical Device Innovation Consortium (MDIC) National Evaluation System for health Technology (NEST) Coordinating Center
  - Status of Center
  - Demonstration projects

[www.fda.gov](http://www.fda.gov)
UDI Resources

- FDA UDI Website
  - [AccessGUDID, UDI Help Desk](https://www.accessgudid.gov), Regulations and Guidance, Benefits of UDI
- Office of National Coordinator for Health IT (ONC)
  - [Implantable Device List](https://www.fda.gov/medical-devices/implantable-device-list)
  - [Common Clinical Data Set](https://www.fda.gov/medical-devices/common-clinical-data-set)
  - Meaningful Use
- Office of the Assistant Secretary for Planning and Education (ASPE)
  - [Strategically Coordinated Registry for Women’s Health Technologies and other projects](https://www.fda.gov/medical-devices/strategically-coordinated-registry-for-womens-health-technologies-and-other-projects)