UDI Roundtable Discussion

7 April 2011

GS1 Healthcare Speakers

Chair

- Mike Wallace, Director Global Standards and Serialization, Abbott Laboratories

Panelists

- Terrie Reed, Senior Policy Analyst, FDA Center for Devices and Radiological Health
- Joe Pleasant, Senior VP & CIO, Premier Inc.
- Mike Sarachman, Manager, International Data Standards Adoption, Johnson & Johnson Health Care Systems, Inc.

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UDI Database Roundtable

April 7, 2011

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A Promise for Life

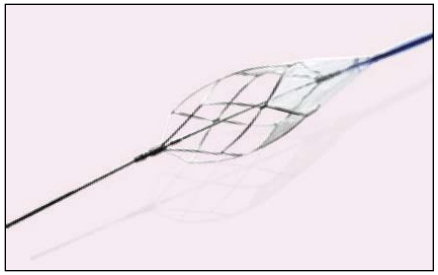
Agenda

- Abbott at a Glance
- What is Master Data?
- How does GS1 data fit with Master Data?
- What will the processes look like?
- The new paradigm
- The Panel

Medical Devices is one of Abbott's Three Areas of Business

Medical Devices

- Diabetes Care
- Laboratory Diagnostics
- Molecular
- Point of Care
- Medical Optics
- Vascular
- Animal Health



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What is Master Data?

Master Data is the *high value* information that an organization *uses repeatedly* across the enterprise and in many business processes.

– It describes the key business entities of a corporation, referred to as master records or data domains:

- Customer, Material, Vendor, Chart of Accounts and Employee

– It includes the data elements that help define the master records in support of transactional and reporting activity.

– Naming conventions and the adoption of industry standards are implemented where applicable.

Domain	Data Element Examples
Customer	Account Number, Customer Name, Address, GS1 standard for GLN
Material	Material Number, adoption of UNSPSC codes for material classification (Material Group), GS1 standard for GTIN, Units of Measure

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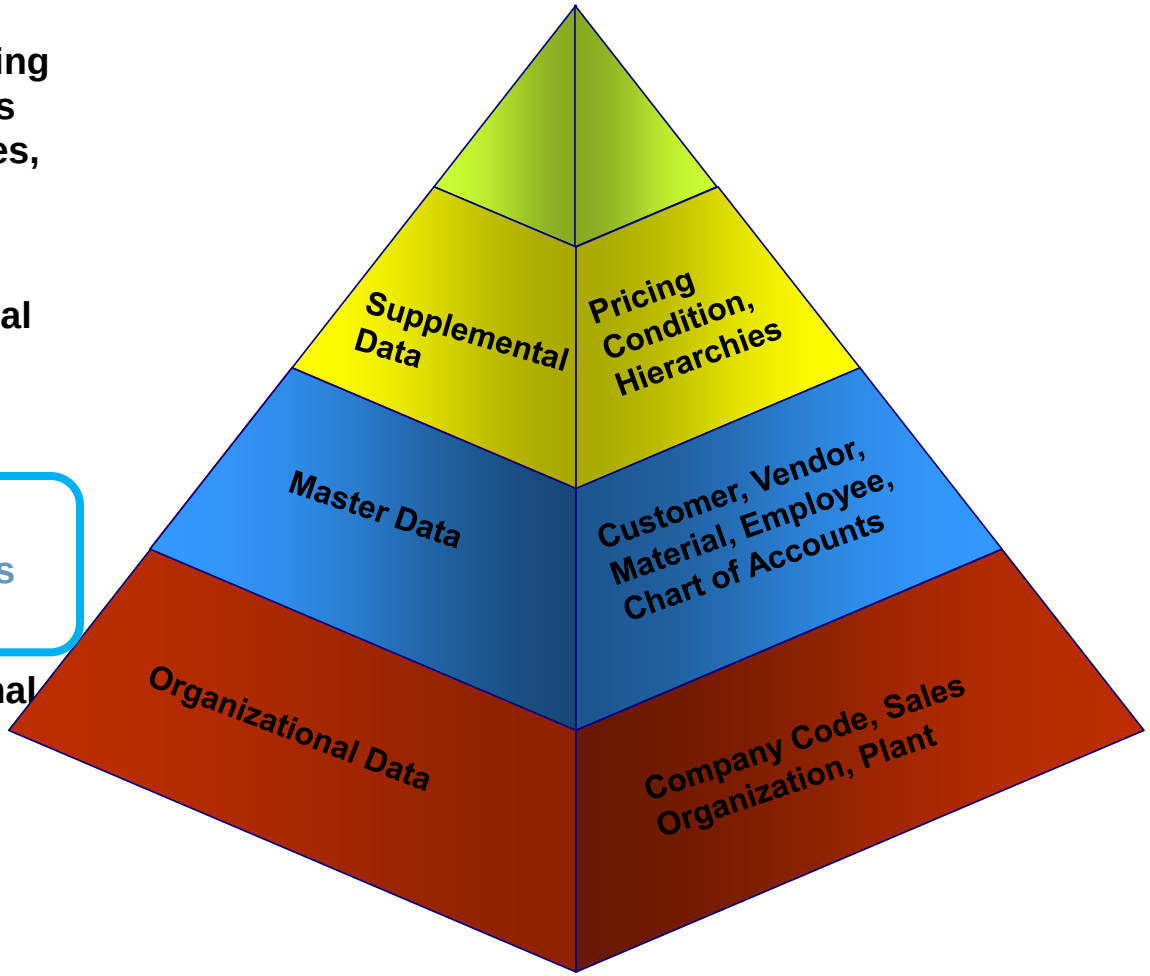
Where does Master Data fit?

- **Transactional Data – Data created during course of business operations such as sales orders, purchase orders, invoices, accounting postings are considered transactional data**
- **Supplemental Data – Non-transactional data such as pricing conditions and product hierarchies that is not considered master data**
- **Master Data – Corporate data assets such as customers, vendors, materials and chart of accounts**
- **Organizational Data (a.k.a. Foundational Data) – Essential elements such as company code, sale organization that should be in place for all other data to exist**



Enterprise Data Pyramid (SAP Proprietary Model)

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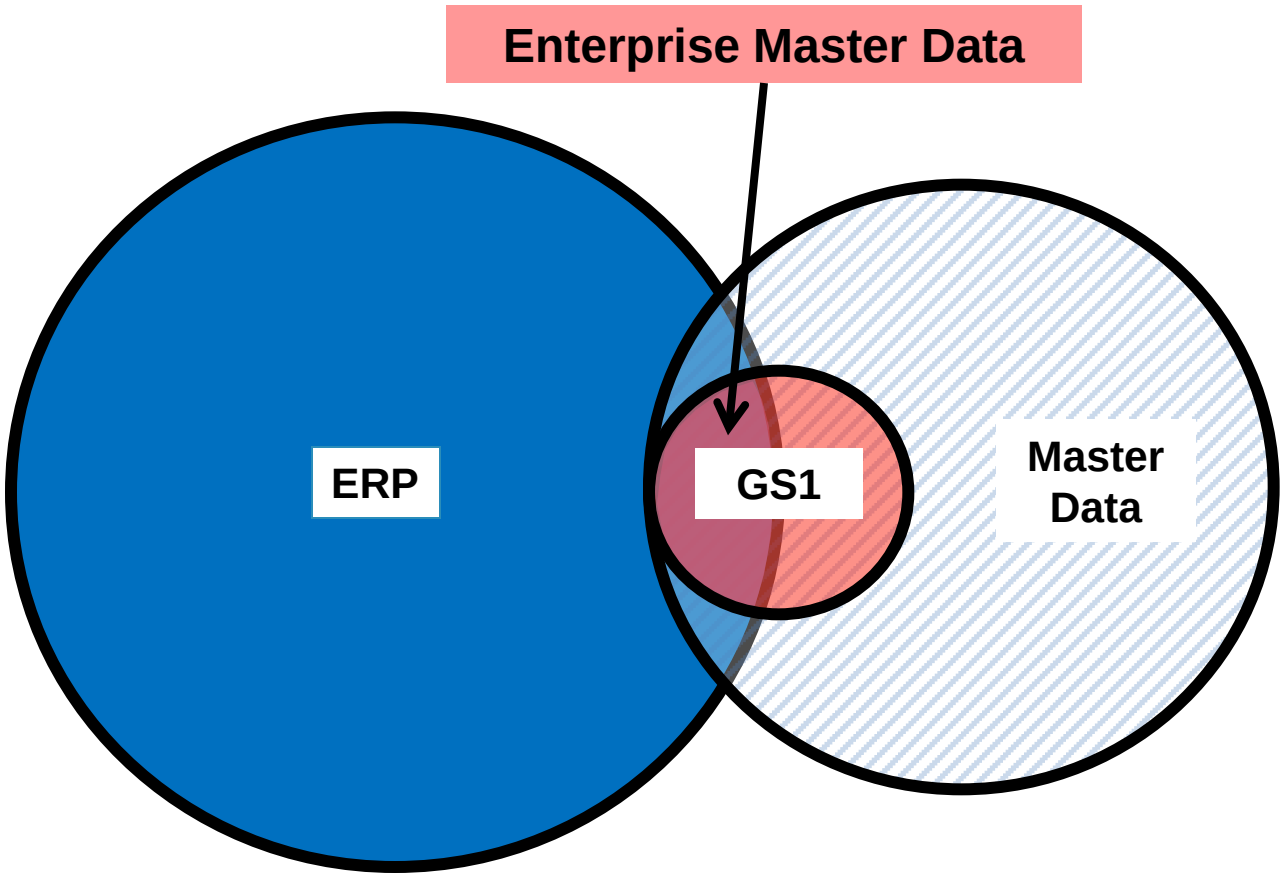
How Master Data Fits



All GS1 Data is Master Data, but not all GS1 data is necessarily Enterprise Master Data.

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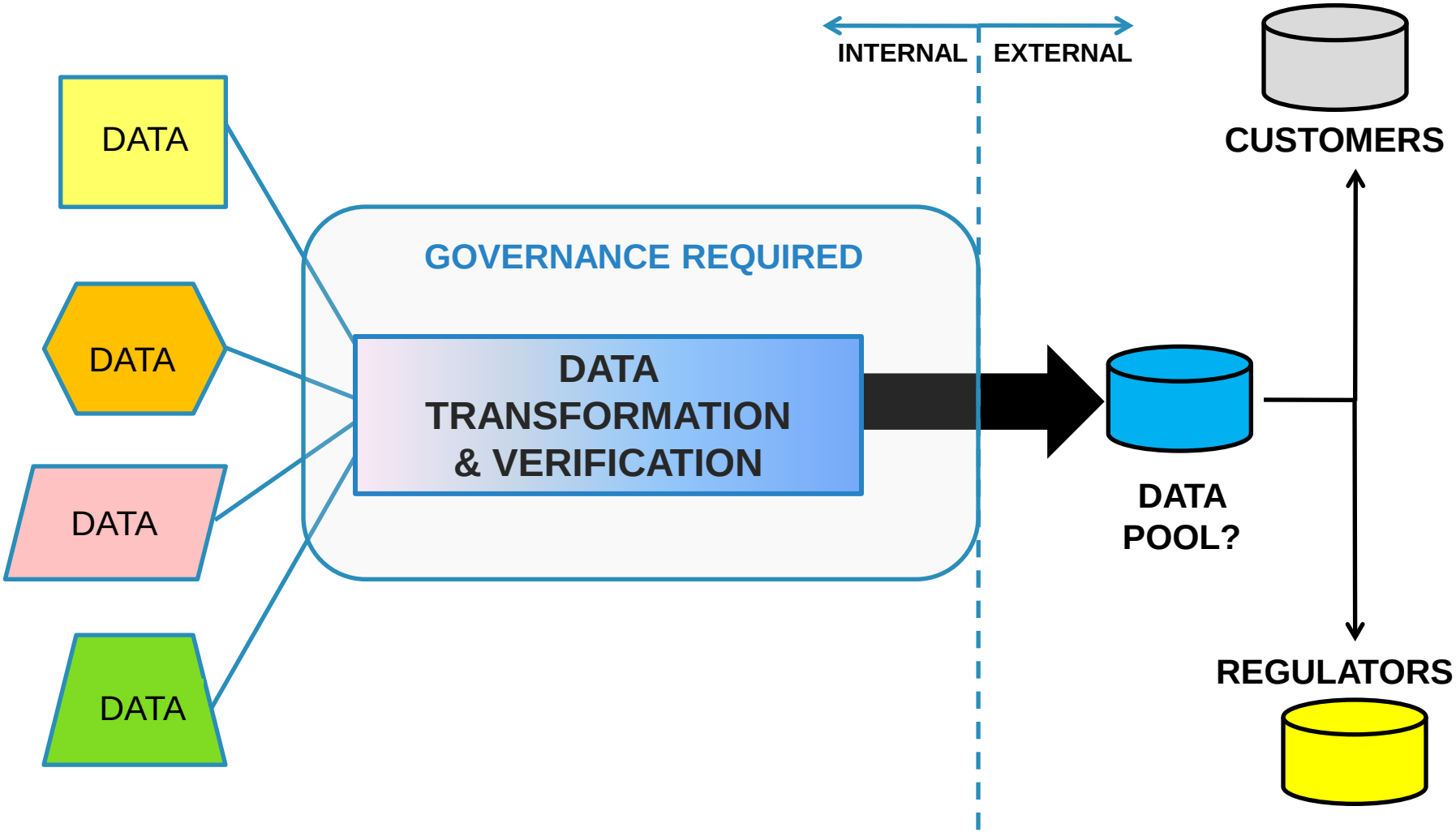
GDSN/UDID OVERLAP



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GDSN/UDI Database processes mimic MDM

- Assign product GTINs
- Locate GTIN attribute data
- Identify data owners
- Modify/establish data governance process
- Assess attribute data v. GDSN/UDI Standards
- Complete and/or Transform attribute data as required
- Verify attribute data in correct formats for publication
- Publish data as appropriate to GDSN Data Pool/UDID
- Update GDSN/UDID as required for changes in products, attributes, customers, regulators

Device Identification – A Paradigm Change

CURRENT	PROPOSED
Proprietary Identification – Manufacturers Catalogue Number	Open Identification – Manufacturers Standards-based UDI
Not Globally Unique	Globally Unique
Distributors may apply different proprietary identification number	Distributors use Manufacturers' UDI number
Distributors do not capture lot or serial numbers	Distributors may use AutoID to capture lot or serial numbers
Hospitals may apply different proprietary identification number	Hospitals use Manufacturers' UDI number
Hospitals do not capture lot or serial numbers	Hospitals use AutoID to capture lot or serial numbers
Non-standardized device information available on a limited, ad hoc basis	Standardized device information available in an FDA database

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UDI Panel Participants

- Mike Wallace – Abbott (Moderator)
- Terri Reed – FDA CDHR
- Michael Sarachman – JNJ Standards Adoption
- Joe Pleasant – Premier CIO

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C·D·R·H Center for Devices and Radiological Health

FDA Center for Devices and Radiological Health: UDI Database & CDRH Informatics Strategy

GS1 Conference
Bethesda, MD
4/6/11

Overview

- **Informatics Strategy at CDRH**
- **UDI as Master Data**
- **Ties to HL7 Standards**
- **Data Exchange as a Team Sport**

CDRH Informatics Goal: Improve Data Quality

- Current data meets requirements of a particular regulation or business need
- Standard Data exchange methods not used
- Some electronic data must be re-entered
- Data cleansed and linked after received and stored
- EXCEPTION: eMDR - standard vocabulary and data exchange format,

Focus on Fundamentals: Sharing and Reuse of Data

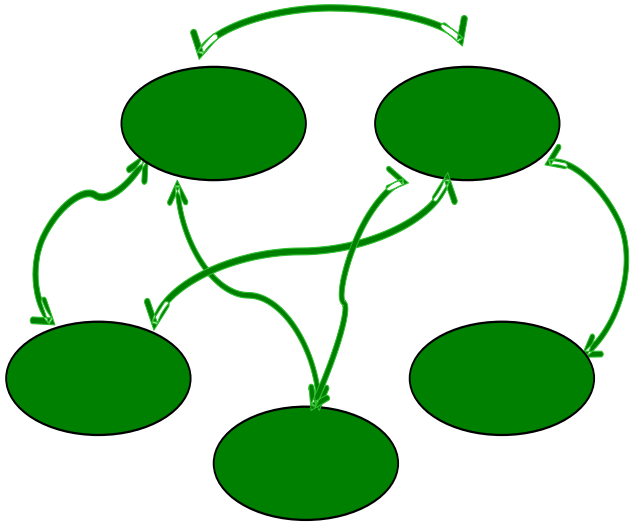
– Common Data Exchange **– Getting from A to B and back again (SYNTAX)**

- Standard Terminology **- Building Blocks - Allows Reuse of Data (SEMANTICS)**

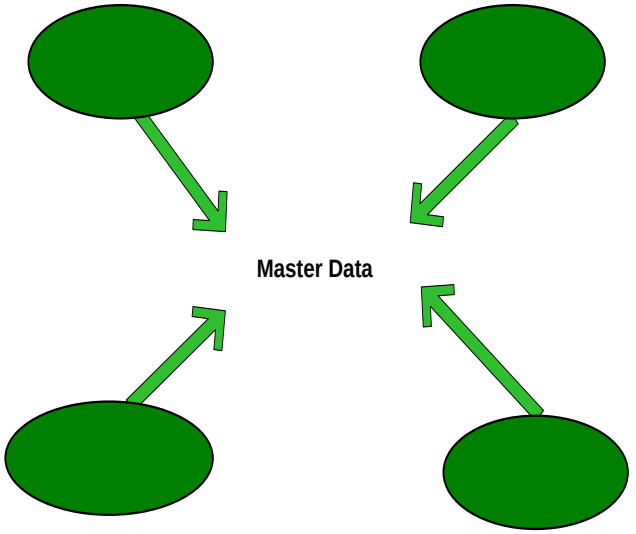
Master Data Management Plan

- Compliments development of standard data exchange and vocabularies
- Identifies the agreed to, standard critical business data (e.g., UDI info, device names, event codes, item codes, manufacturer names, GMDN codes) that can be shared across systems.
- Creates policies and procedures for creation, access, update, and overall management of this central resource.
- Emphasizes Data quality, Integration, Single version of the truth, Data stewardship.

Why Master Data Management



Multiple master – No
Authoritative data
Inconsistent Data
Semantic Differences
Data Duplicates



Data Hub- Single
Master
Harmonized
Consistent Data
Single Vocabulary
Governed by a single
group

UDI as Master Data

- **Core data for Regulatory product safety/effectiveness – DEVICE Information**
- **Means to increase quality & consistency of DEVICE Information**
  - **Applying UDI to label of device**
  - **Requiring standardized electronic submission of UDI data**

Establishing a UDI System

Combination of 4 distinct steps:

1. **Develop a standardized system to establish the unique device identifiers (UDI)**
2. **Place the UDI in human readable and/or AutoID on a device, its label, or both**
3. **Create and maintain the UDI Database**
4. **Promote Adoption and Implementation**

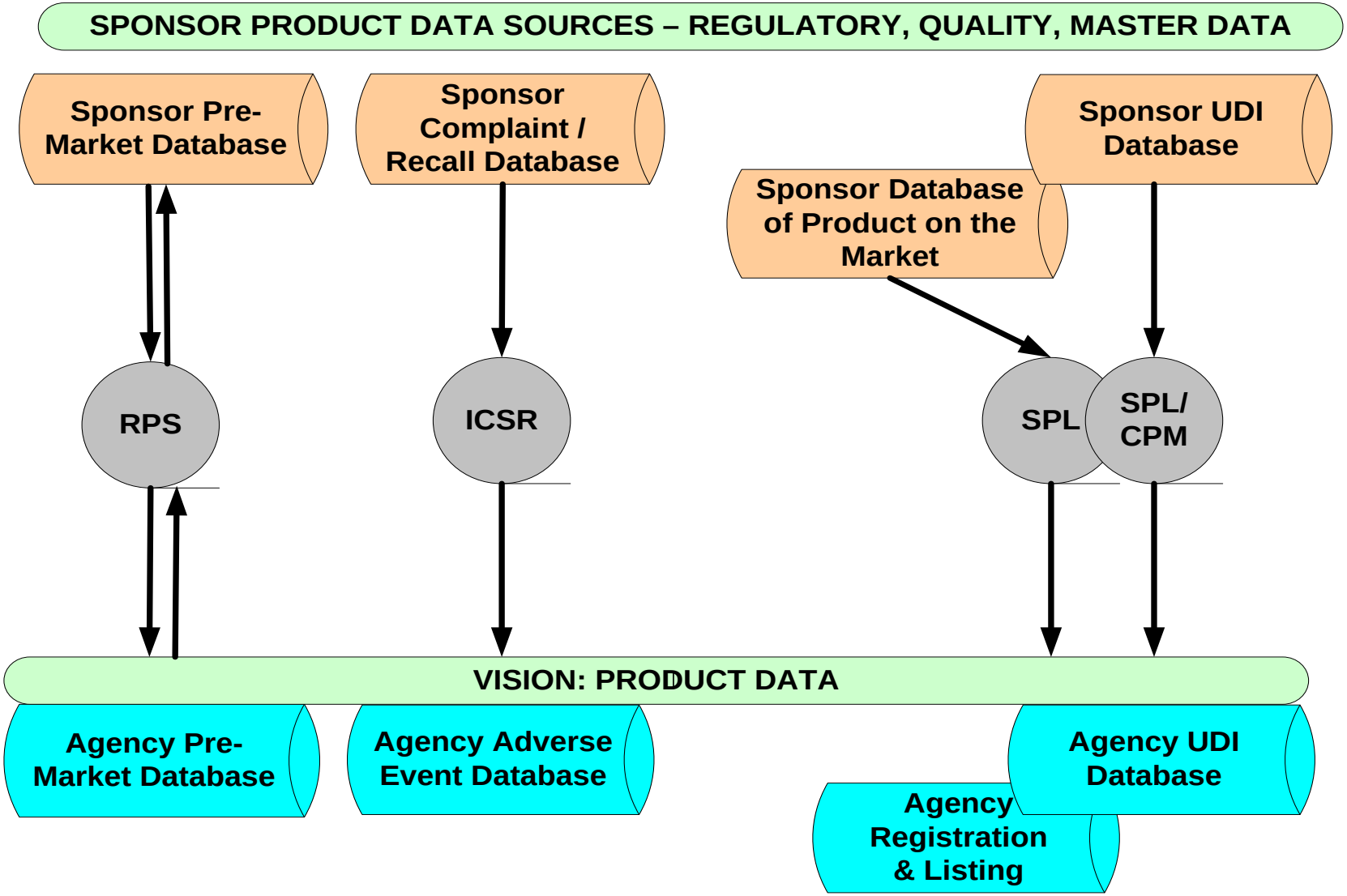
UDI: Ties to HL7 SPL r5

HL7 Data Exchange Standard

- **Global authority on standards for interoperability of health information technology with members in over 55 countries**
  - **Individual Case Safety Report (ICSR) Adverse Event Reporting**
  - **Structured Product Labeling (SPL) - UDI - Product Information**

http://wiki.hl7.org/index.php?title=Medical_Product_Information_(SPLr5)

Data Exchange Vision



UDI Database – Benefits of Adoption

FDA/Manufacturer adoption --

- **Improves ability to link internal databases around product information**
- **Provides improved device information in regulatory submissions**

Healthcare adoption -

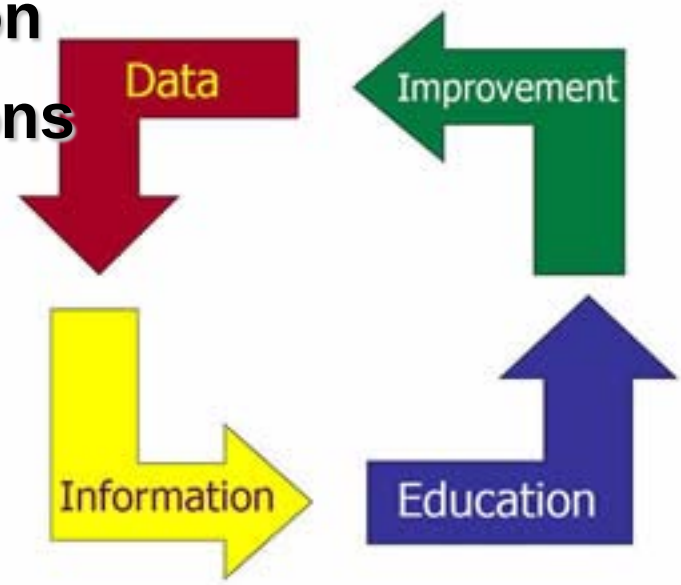
- **EHR as a rich data source for device-specific safety surveillance/observational studies**
- **Provides method to obtain 'real-world' data for pre-market decisions (registries)**
- **Improves ability to link Healthcare databases**

Data Exchange/Reuse Efforts lead to..

- **Improved Data Sharing with:**
  - **Regulated Industry**
  - **Professional Organization Registries**
  - **Healthcare IT Departments**
  - **Materials Management**
  - **Federal Health Partners**

Which leads to….

- Improved Patient Care – Device Info
- Improved Public Health
  - Improved Quality and Timeliness of Data
    - Improved Information from Clinical Research
    - Improved AE Reports (ASTER-D, PDRNet)
      - Improved Signal Detection
    - Improved Directed Inspections
    - Improved Recalls



Data Exchange is a Team Sport

Type	Group	UDI/Informatics Role
Regulated Industry	**AdvaMed, GHTF,**	**•Coordinate FDA data standards with industry** **•Educate and Facilitate Submissions**
Standards Development Organizations	**GS1, HL7, ISO, AAMI** **CDISC, GMDN** **IHTSDO, (SNOMED), NCPDC, X12**	**•CDRH advocate** **•Apply Stds at Agency and Center Level** **•Educate and Promote Adoption**
Supply Chain	**GS1, HIBCC** **Group Purchasing, Material Mgt, Hospitals, Distributors**	**•Promote UDI Adoption**

Questions?

terrie.reed@fda.hhs.gov

Johnson & Johnson SUPPLY CHAIN

Unique Device Identification Database: Managing UDI Data

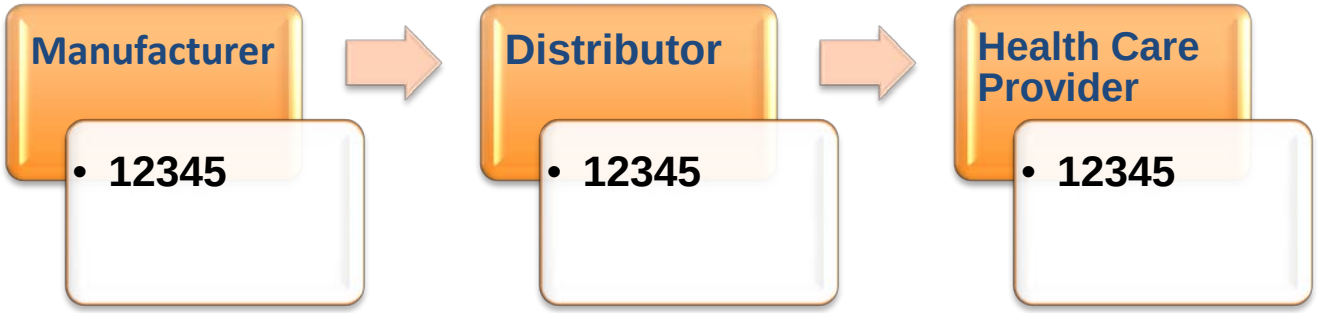
April 2011

Michael Sarachman
Manager, Industry Standards Adoption
Johnson & Johnson Health Care Systems Inc.

Impact of Unique Device Identification (UDI) Adoption

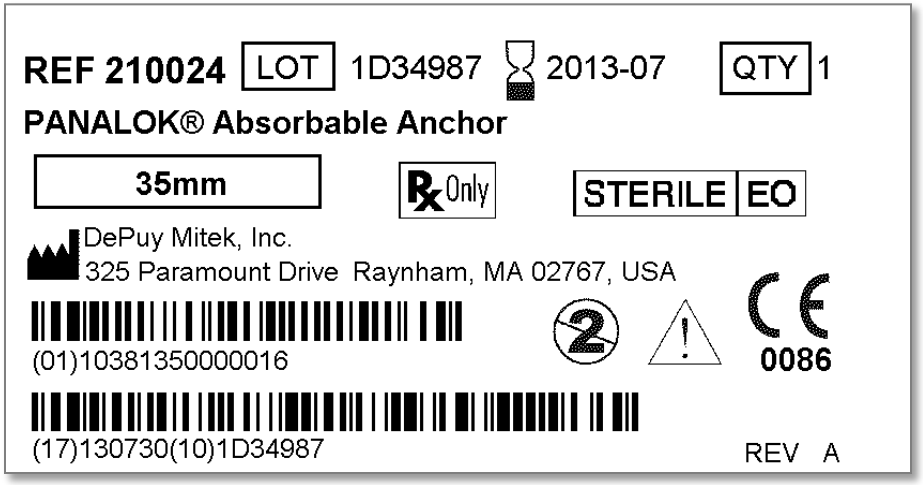
Current State

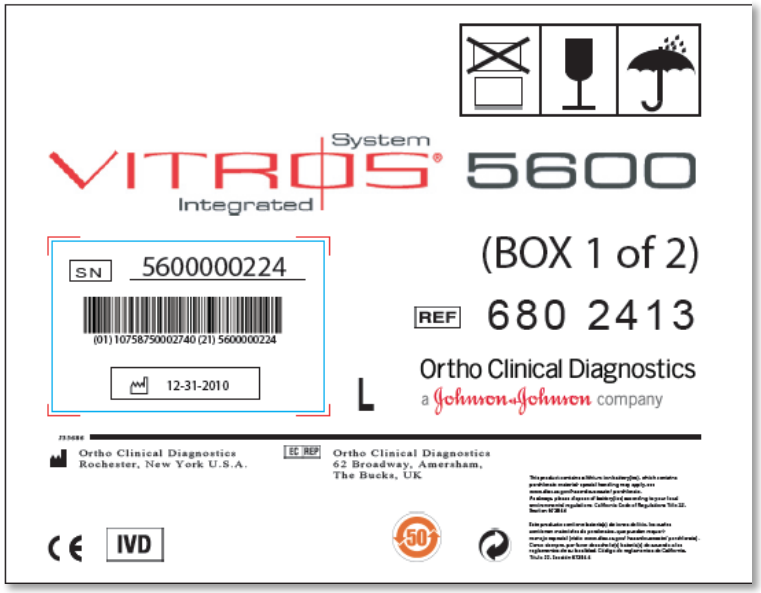
Future State



Perceived Benefits of UDI

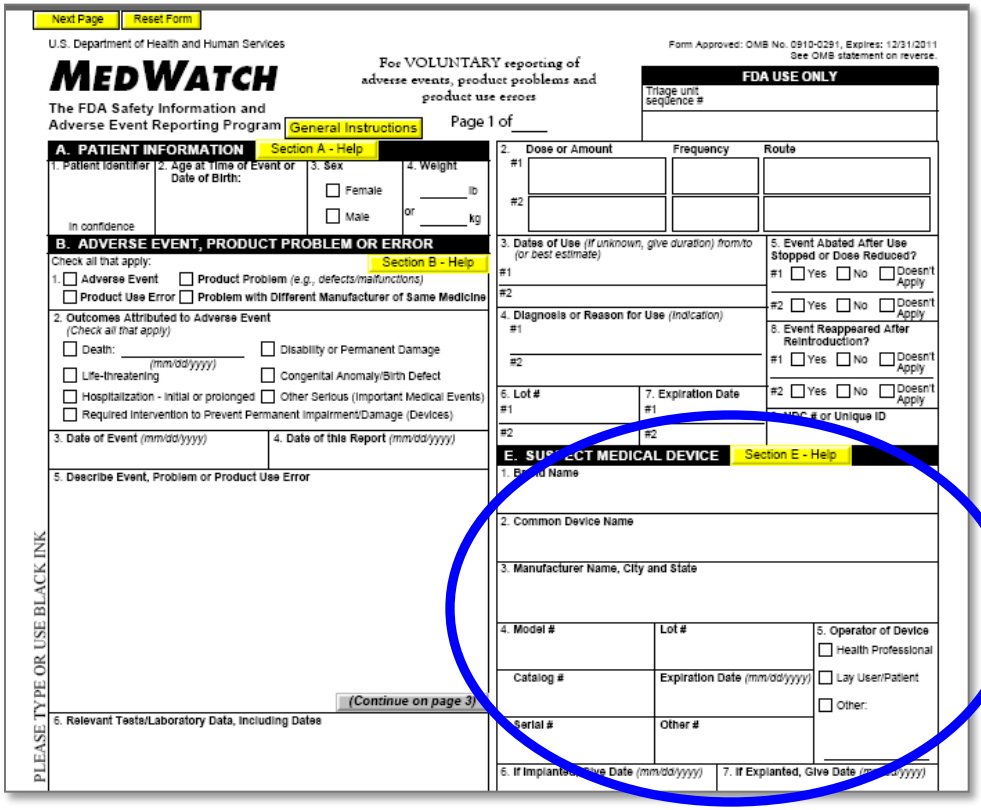
- Accurate sales orders
- Accurate and efficient recalls
- Accurate procurement
- Enable electronic health record usage
- Patient safety
- Efficient delivery of clinical care
- Foundational for track & trace





UDI Benefits

- Standardized & consistent safety data
  - Leverage common database
  - Ensure positive product identification
- Standardized production data collection
  - AutoID of Production Data
    - Lot Code
    - Serial Number
- Complements current data collection



Next Page | Reset Form

U.S. Department of Health and Human Services

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

General Instructions

For VOLUNTARY reporting of adverse events, product problems and product use errors

Form Approved: OMB No. 0910-0291, Expires: 12/31/2011
See OMB statement on reverse.

FDA USE ONLY

Triage unit seqdence #

Page 1 of ____

A. PATIENT INFORMATION Section A - Help

1. Patient Identifier / In confidence
2. Age at Time of Event or Date of Birth:
3. Sex: Female / Male
4. Weight: ____ lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR Section B - Help

Check all that apply:

1. Adverse Event / Product Problem (e.g., defects/malfunctions) / Product Use Error / Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event (Check all that apply)
Death: ____ (mm/dd/yyyy) / Disability or Permanent Damage / Life-threatening / Congenital Anomaly/Birth Defect / Hospitalization - Initial or prolonged / Other Serious (Important Medical Events) / Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (mm/dd/yyyy)
4. Date of this Report (mm/dd/yyyy)

5. Describe Event, Problem or Product Use Error

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

2. Dose or Amount / Frequency / Route
#1
#2

3. Dates of Use (If unknown, give duration) from/to (or best estimate)
#1
#2

4. Diagnosis or Reason for Use (Indication)
#1
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 Yes No Doesn't Apply
#2 Yes No Doesn't Apply

6. Event Reappeared After Reintroduction?
#1 Yes No Doesn't Apply
#2 Yes No Doesn't Apply

6. Lot #
#1
#2

7. Expiration Date
#1
#2

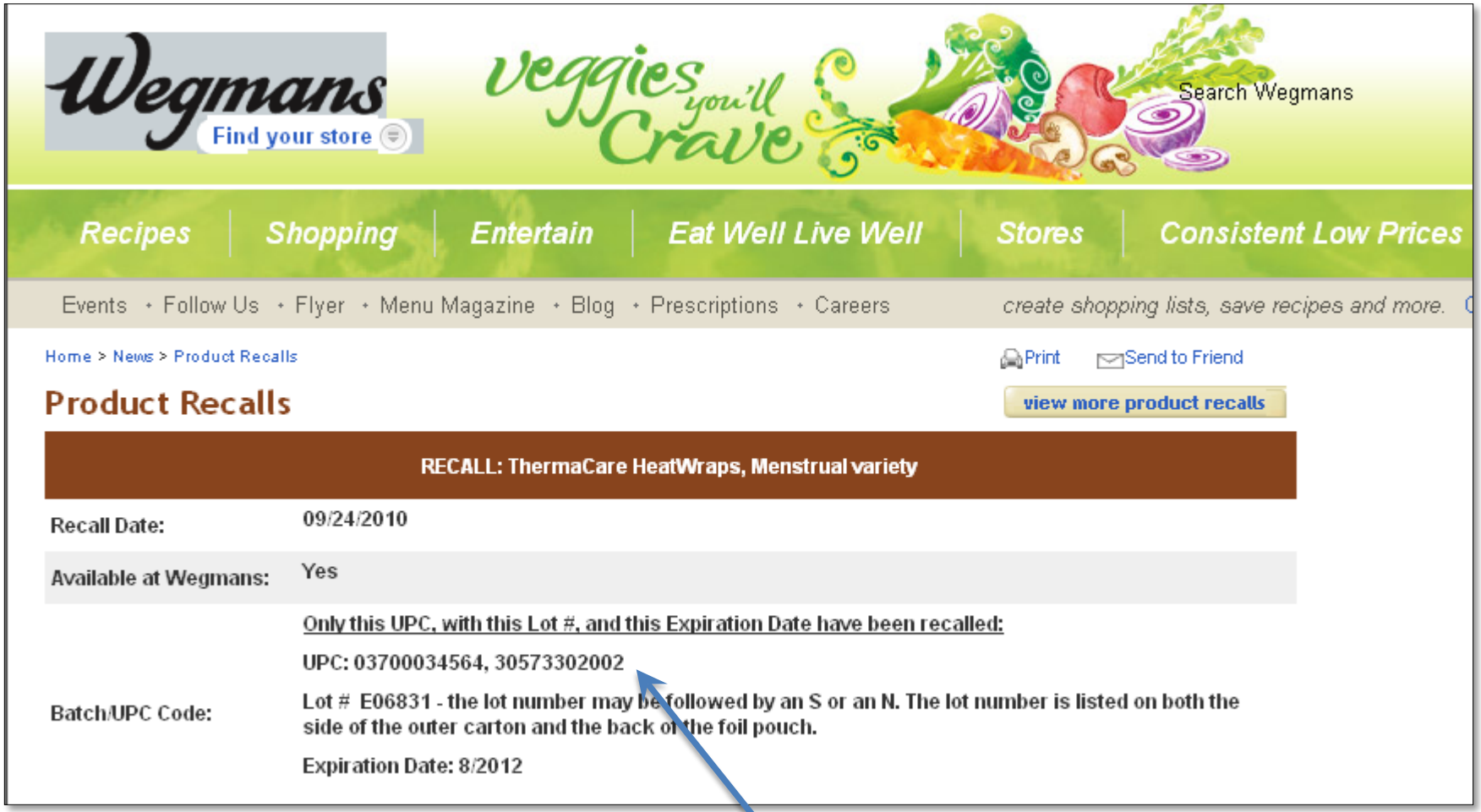
NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE Section E - Help

1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State
4. Model # / Lot # / 5. Operator of Device: Health Professional / Lay User/Patient / Other:
Catalog # / Expiration Date (mm/dd/yyyy)
Serial # / Other #
6. If Implanted, Give Date (mm/dd/yyyy)
7. If Explanted, Give Date (mm/dd/yyyy)

PLEASE TYPE OR USE BLACK INK

UDI Usage



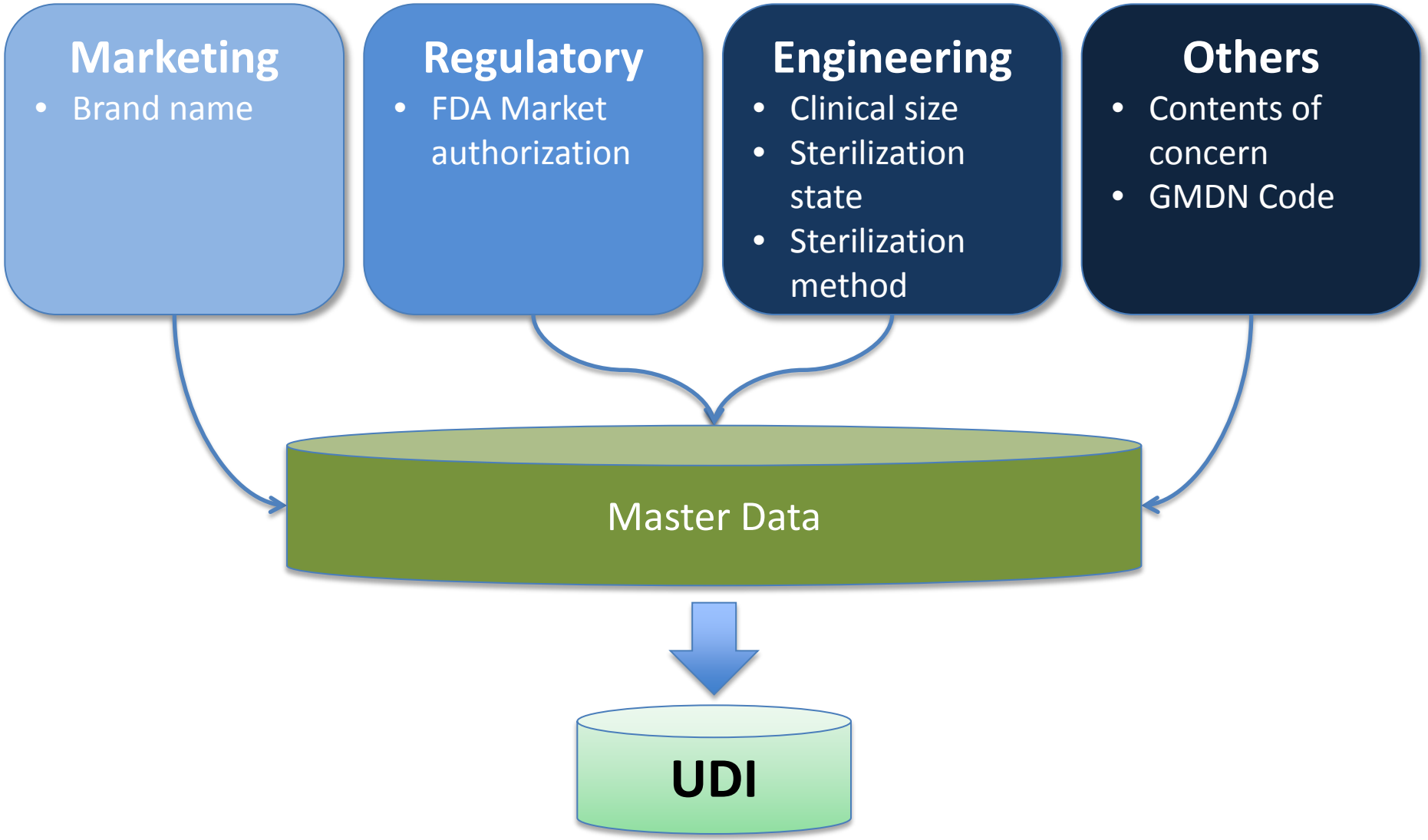
510K Notification No. K953442

UDI

UDI System Components

- The identifier
  - Global Trade Item Number + LOT
  - Global Trade Item Number + Serial Number
- The carrier
  - Bar code symbol
- The database
  - Global Trade Item Number
  - No LOT or Serial Number data
  - Additional attributes
    - Clinical size
    - Brand Name
    - Market authorization

Data Sources



Data Source Impacts

- Master Data
  - Transformed from commercial data to product labeling
- Initial data load
  - Collect data from disparate sources
    - Regulatory filings
    - Product labels & specifications
- Ongoing maintenance
  - Identification of new master data owners
    - Regulatory
    - Marketing and commercial
    - Engineering
  - Error handling
    - How will interface errors be flagged and resolved?

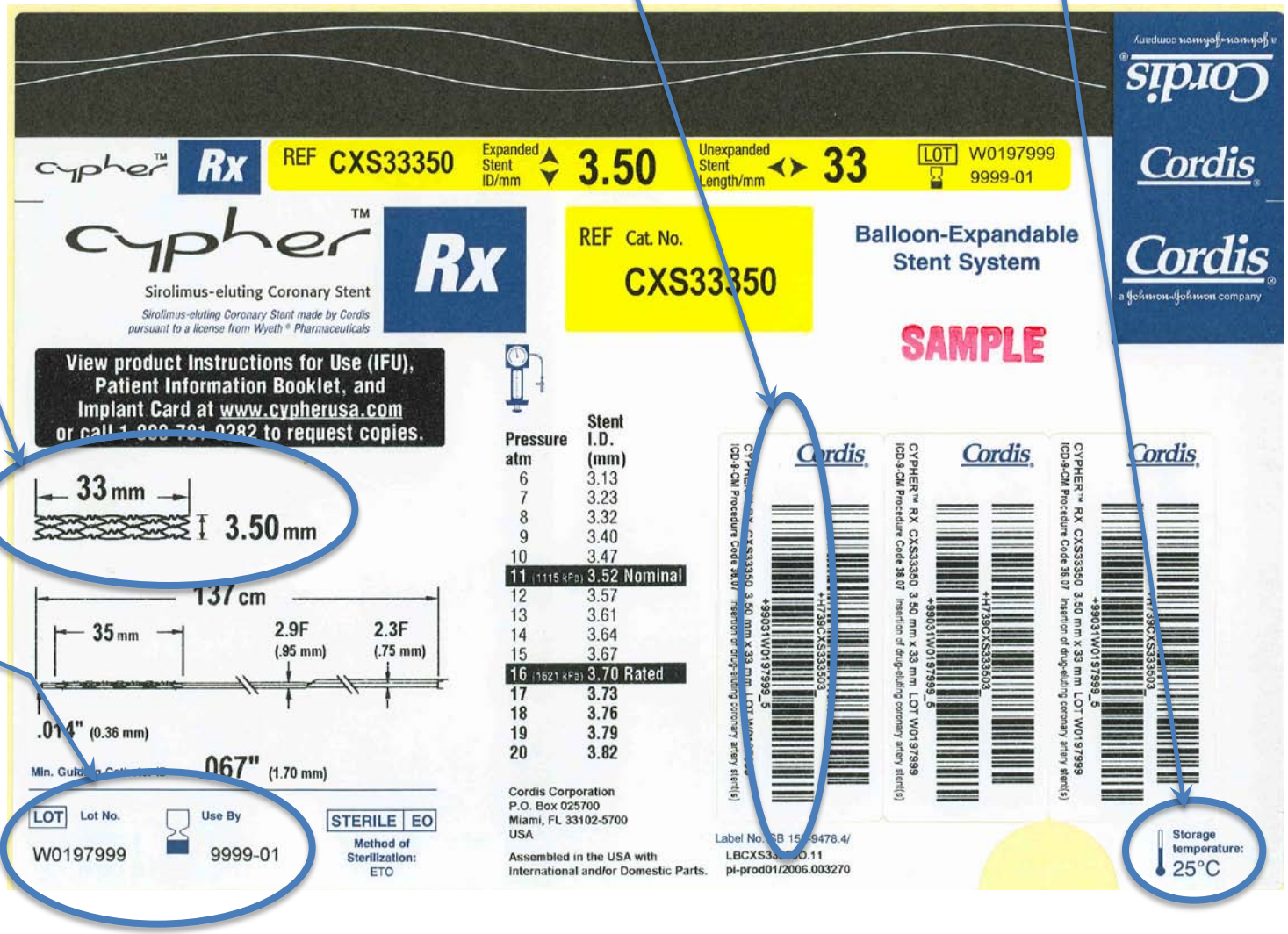
Label Example

Device Identifier

Storage Conditions

Clinical Size

Production Data



UDI Exemption Considerations

- The form factor of the product
- The clinical acuity of the product
- Complexity of the supply chain
  - The logistical/physical supply chain
  - The information supply chain

UDI Database Example

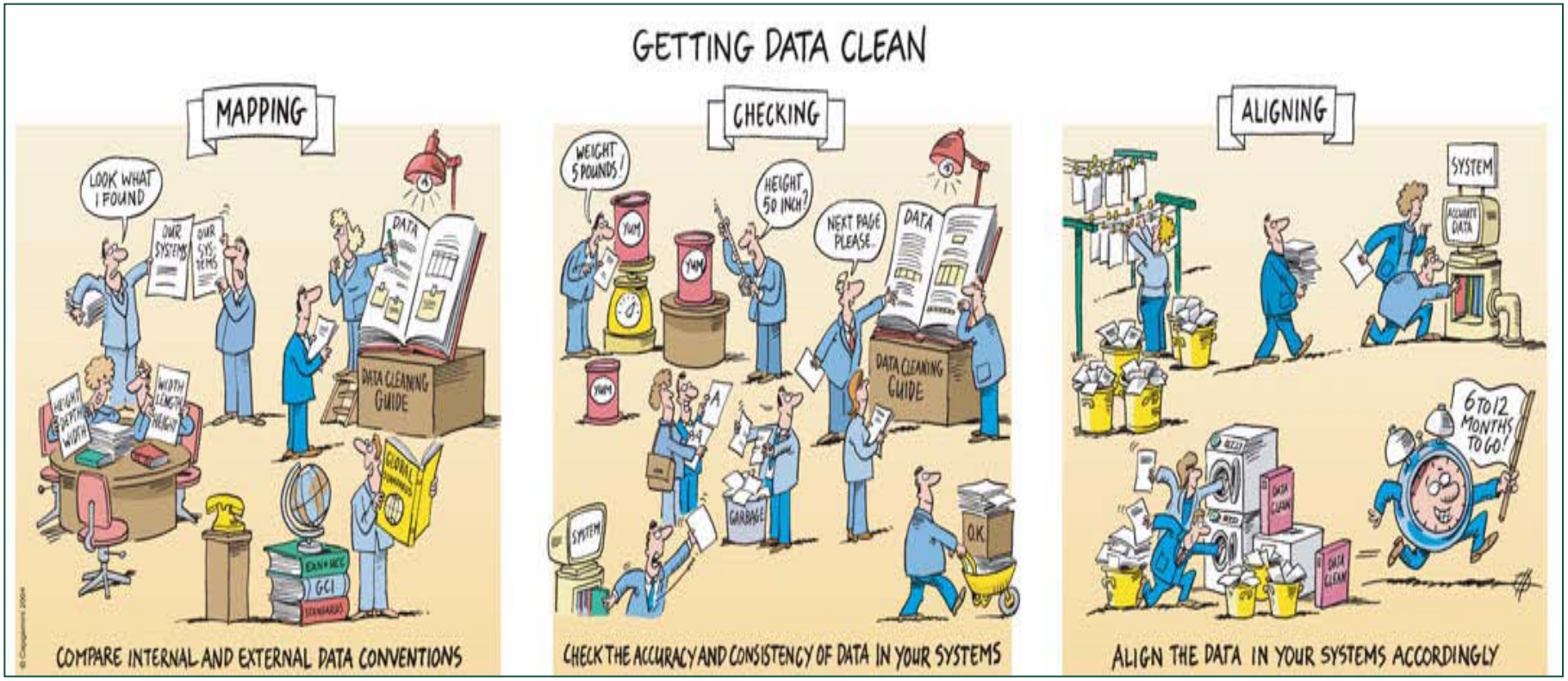
UDID Attribute	Value	Comment
Device Identifier Type	GS1	Some have both
Static UDI Code	20705032028421	HIBCC or GS1 GTIN
Manufacturer	Cordis Corporation	
Contact	Nancy Coulson 430 Route 22 East Bridgewater, NJ 08807 Phone: 908-5414908	
FDA Market Authorization	P020026	First or last?
FDA Listing Number	TBD	
BRAND/Trade Name	CYPHER®	
Model/REF number	CXS33350	
UOM/Package Level/Quantity	EA	

UDI Database Example

UDI Attribute	Value	Comment
Production Control	LOT	
GMDN Code	34179	
GMDN Term	Stent, cardiovascular	
Storage Conditions	25° C	
Single Use State	Single Use	
Sterility State	Sterile EO	
Contents of Concern	NA	(e.g., Latex)
Clinically Relevant Size	3.50 mm I.D. 33 mm L	

UDI and GDSN

Why are they Important? Provider and GPO Perspective



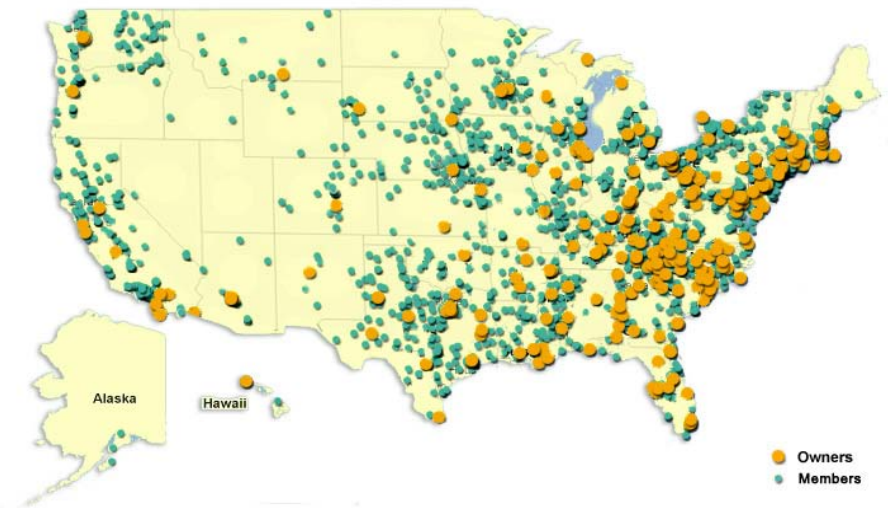
Joe M. Pleasant
Sr. VP and CIO
Premier Inc.

Malcolm Baldrige National Quality Award
2006 Award Recipient

Topics

1. **The Premier healthcare alliance.**
2. **Why is UDI and GDSN important to Premier and our members?**
3. **Information Technology and Data.** Critical components in Healthcare reform. Importance of medical device standard identification.
4. **What are Premier and our members doing to support UDI and GDSN?**

The Premier healthcare alliance



- Over 2,500 hospitals, more than 72,000 non-acute sites
- Using the power of collaboration to improve the health of communities
- Nation's largest clinical/operational/supply chain comparative databases
- 2010 member validated savings of $1.4 billion
- Safety, Diversity and Environmentally Preferred Purchasing programs
- $36 billion in annual group purchasing volume
- 2006 recipient of Malcolm Baldrige National Quality Award
- Three-time recipient of Ethisphere's Most Ethical Companies award.

Cost Reduction
Group Purchasing & Supply Chain Improvement, Labor Management

Quality Improvement
Quality Measurement & Benchmarking, Safety Surveillance

Risk Mitigation
Liability, Benefits & Risk Management

Advocacy
Shaping policy and advocating for members

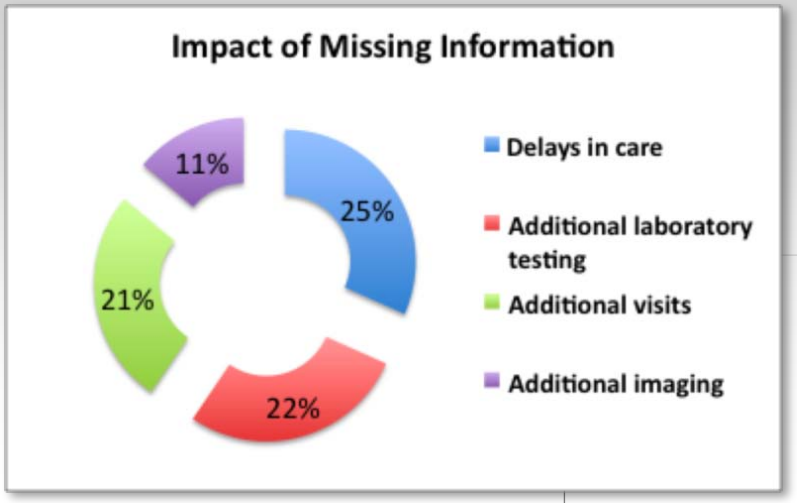
Execution Engine
Comprehensive, accelerated approach to improving financial, operational and clinical performance.

Why is UDI and GDSN important?

Healthcare spendi*n*g: Unsustainable

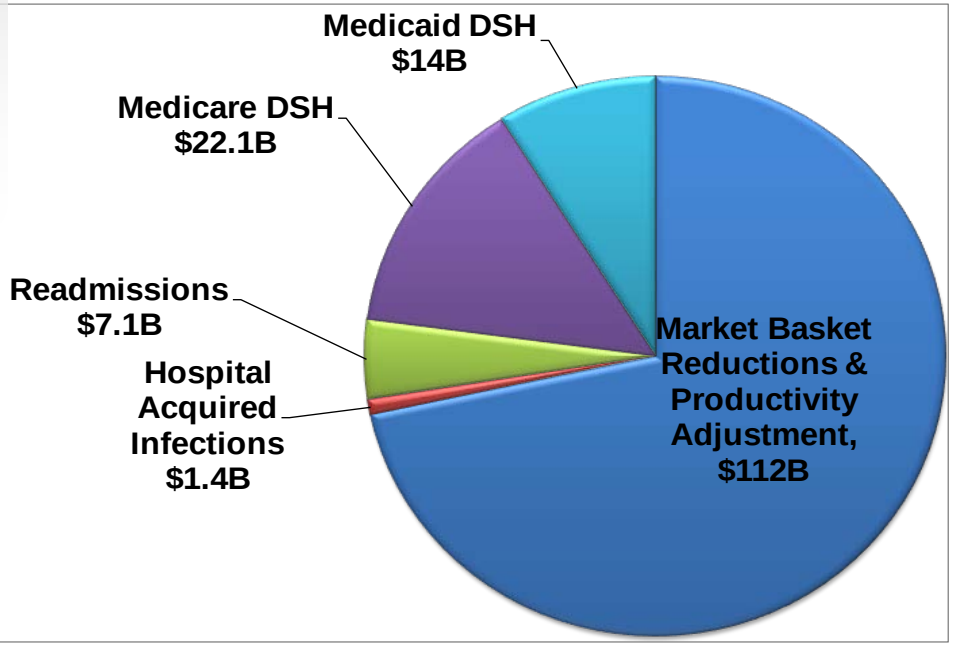
Why is UDI and GDSN important?
Provider Gaps and Cuts

Missing information affects care



Hospital Payment Cuts in Public Law No: 111-148 - Patient Protection and Affordable Care Act
CBO/JTC Estimate, CMS Actuary Estimate
2010 - 2019 (*in billions*)

Payment cuts to hospitals: $157B



Why is UDI and GDSN important?

Product Identification

Same Product, Different Numbers:

3M **8630**

DuraPrep™ Surgical

Skin Prepping Solution

DISTRIBUTORS

TM-8630	AmerisourceBergen
MMM-8630	Buffalo Hospital Supply
567008630	Burrows
1143890	Cardinal
01645.8630	Harris
MINN8630	Kreisers
4513-8630	Midwest Medical
4509008630	Owens & Minor
000104280	PHS

… plus different numbers in each Hospital Group's MMIS.

Premier's Product Item Master has **7 Million** products with 2.5M Manufacturer ID's and over 4.5M distributor ID's.

Why is UDI and GDSN important?

Poor Information throughout the Supply Chain

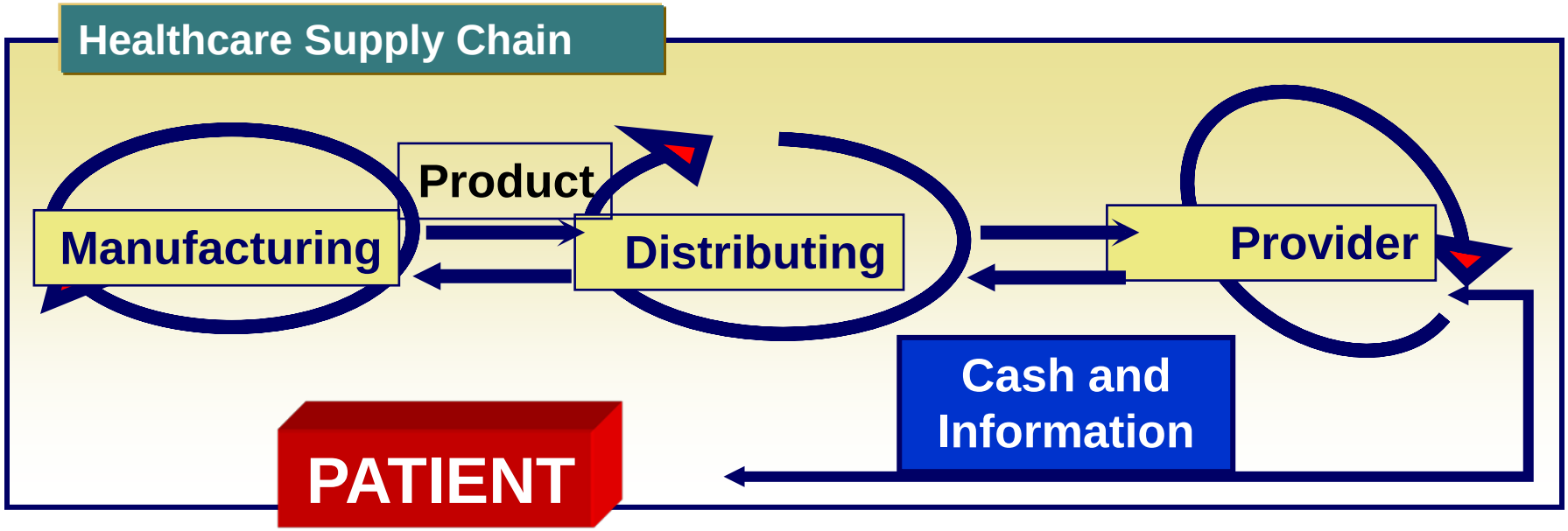
Percentage of Errors

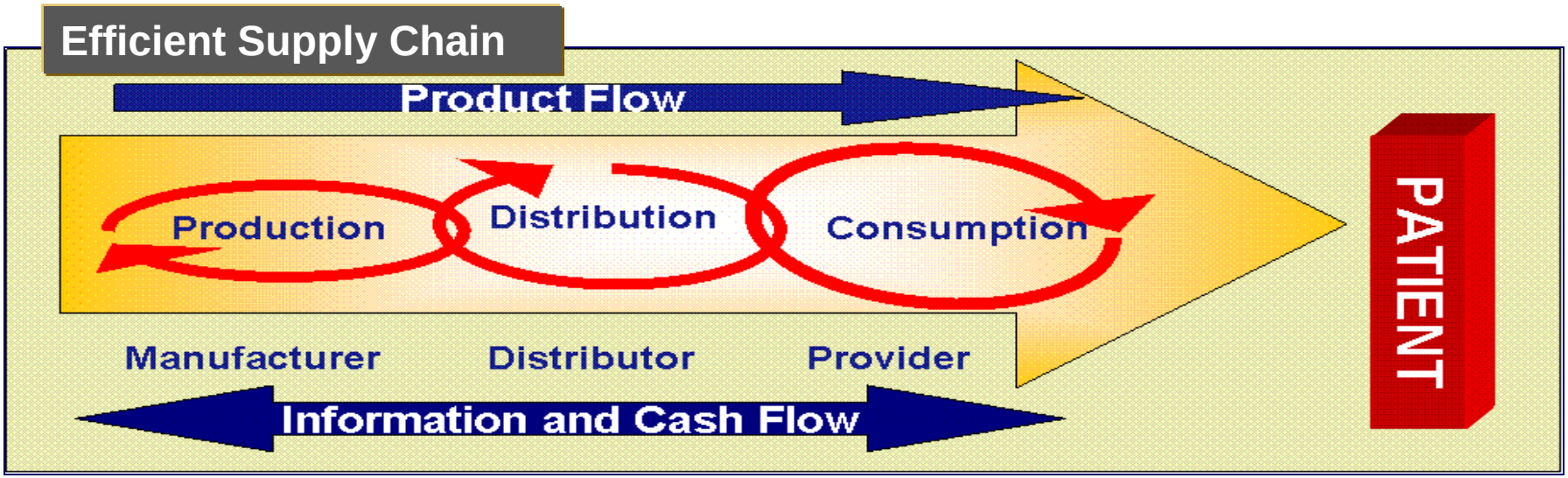
	Manufacturer	Distributor	GPO	Customer
Missing Middle Levels of Pkging	15-20%	1-4%	20-25%	15-25%
Hard "Packaging Quantity" Errors	1%	1%	2%	2-5%
Unit of Measure Confusion/Misuse	2-6%	1-3%	2-5%	Unknown
Missing Packaging—not Middle Level	3-8%	3-8%	3-7%	5%
Manufacturer Name Problems	NA	2-5%	1-4%	30%
Obsolete Products	1-4%	2-5%	1-8%	5-15%
Missing Product Brand Names	2-5%	5-10%	5-10%	20-25%
Incomplete Item Descriptions	5-15%	3-12%	5-15%	10-20%
Wrong Customer Unit Prices	Unknown	1-2%	NA	1-2%
Customer Paid More Than Lowest Contract Price	NA	Unknown	NA	3-6%

* Source: Department of Defense Data Synchronization Study

Why is UDI and GDSN important?

An Efficient Healthcare Supply Chain





Why is UDI and GDSN important?

Healthcare Reform: requires paradigm shift and delivery system changes

Value-based purchasing

Accountable Care Organizations

Bundled payments

Non-payment for preventable readmissions

Non-payment for infections and HACs

Transparency initiatives

Drive to tackle waste, fraud and abuse

Why is UDI and GDSN important?

The next horizon: Accountable Care Organizations (ACO's)

A group of providers willing and capable of accepting accountability for the total cost and quality of care for a defined population.

Payer Partners:

- Insurers
- CMS
- Employers
- States

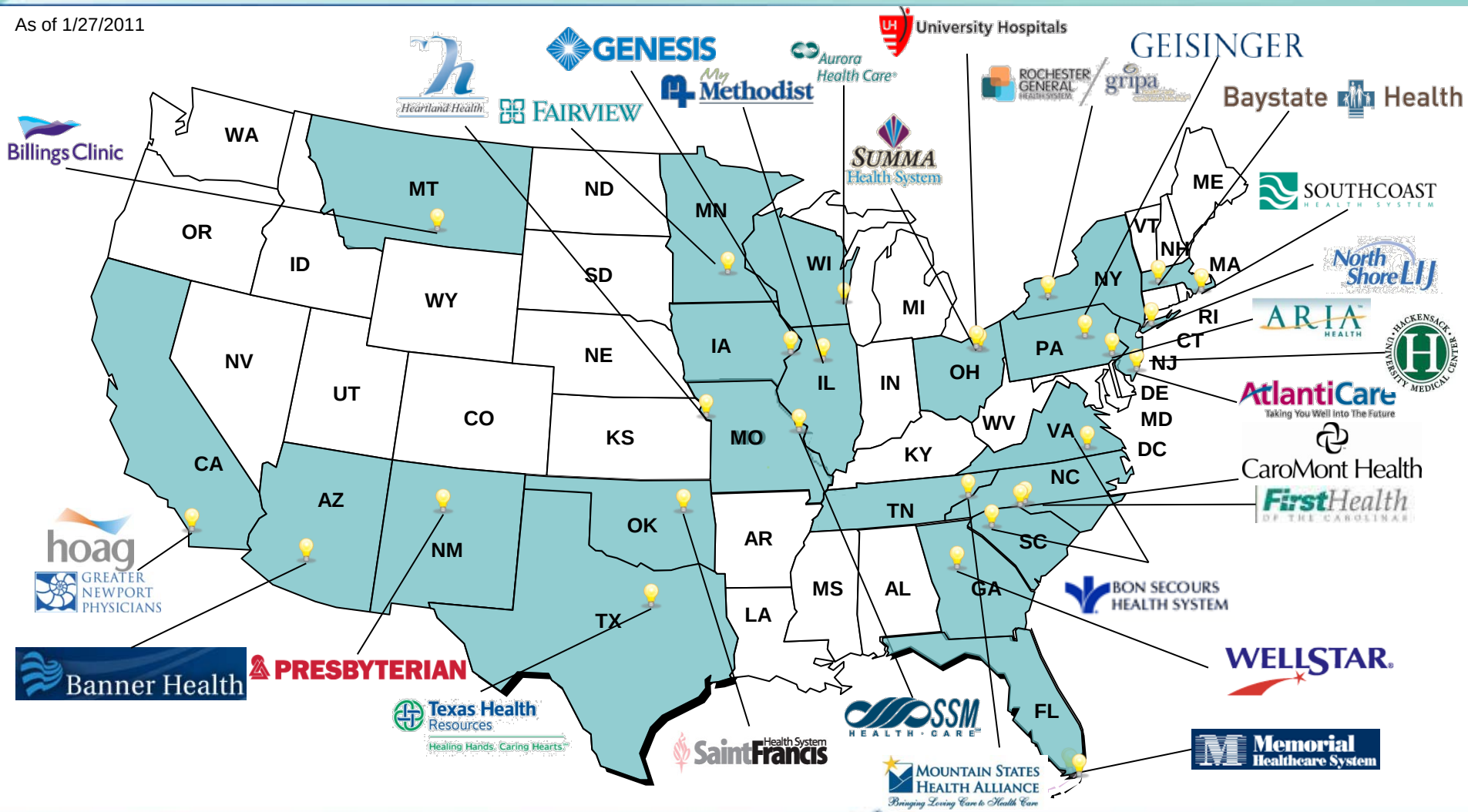
- **Builds patient centric systems of care**
- **Improves quality and cost for delivery system components**
- **Coordinates care across participating providers**
- **Uses IT, data and reimbursement to optimize results**
- **Builds payer partnerships & accepts accountability for the total cost of care**
- **Assesses and manages population health risk**
- **Reimbursed based on savings & quality – value**

Why is UDI and GDSN important?

ACO's are coming

Accountable Care
> IMPLEMENTATION COLLABORATIVE

As of 1/27/2011

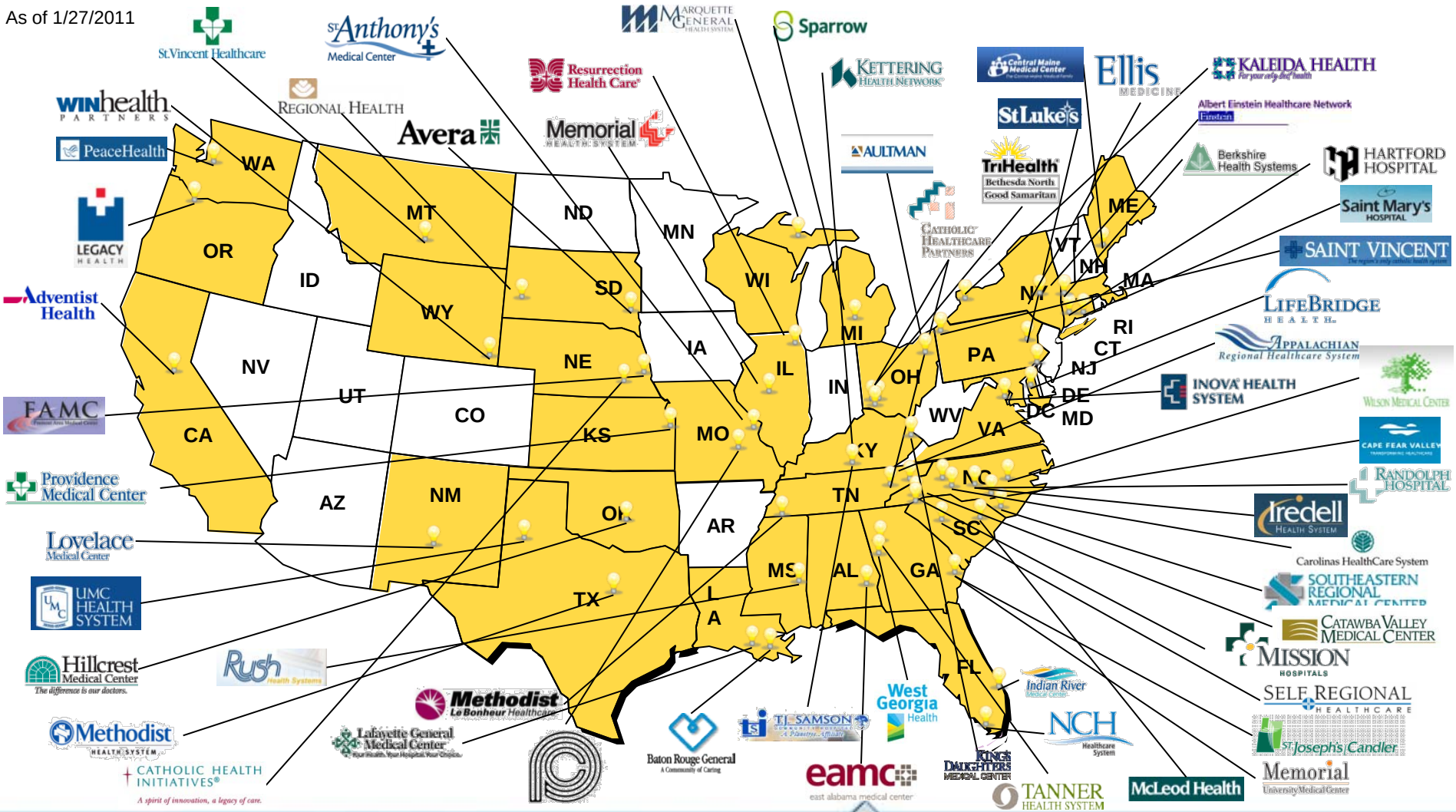


Why is UDI and GDSN important?

ACO's are coming

Accountable Care
> READINESS COLLABORATIVE

As of 1/27/2011



PREMIER

Transforming Healthcare Together

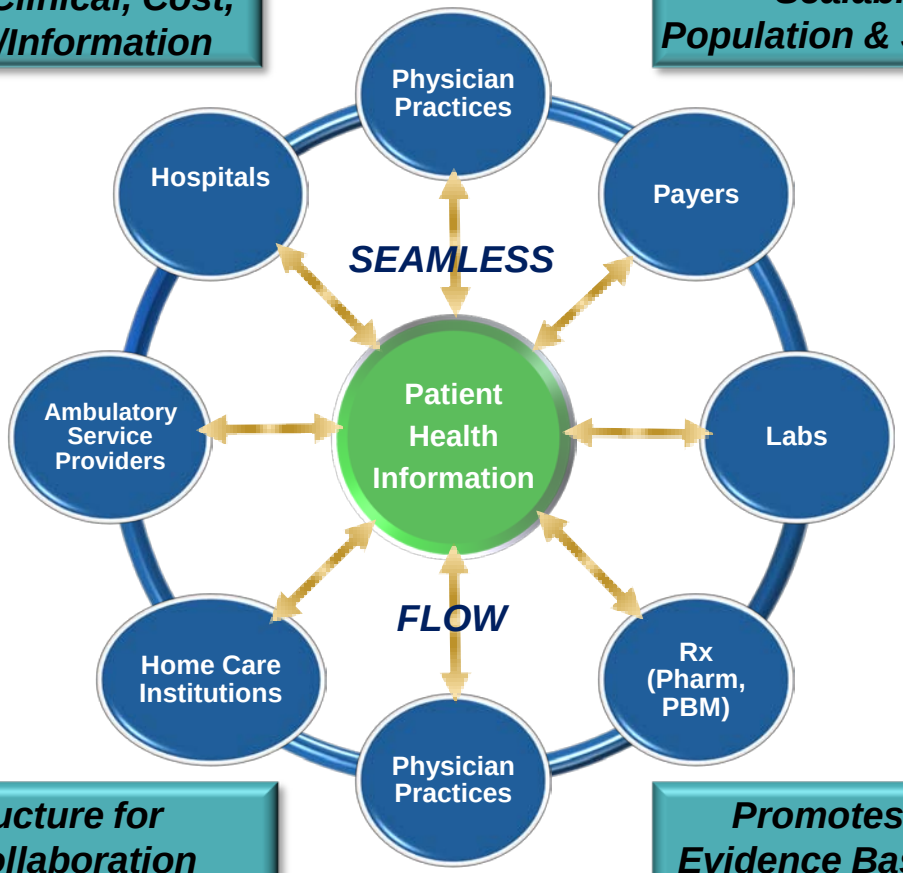
Information Technology and Data

At the heart of the ACO population health framework

Characteristics of the ACO Health Information Integration Platform (HIIP)

Enables Transparency of Clinical, Cost, and Patient Related Data/Information

Scalable to Accommodate Population & Stake Holder Fluctuations



Provides Connectivity to RHIO's, HIEs' and NHIN

ACO is "Easy to Do Business With" For All Stake Holders

Foundational Infrastructure for Care Coordination & Collaboration

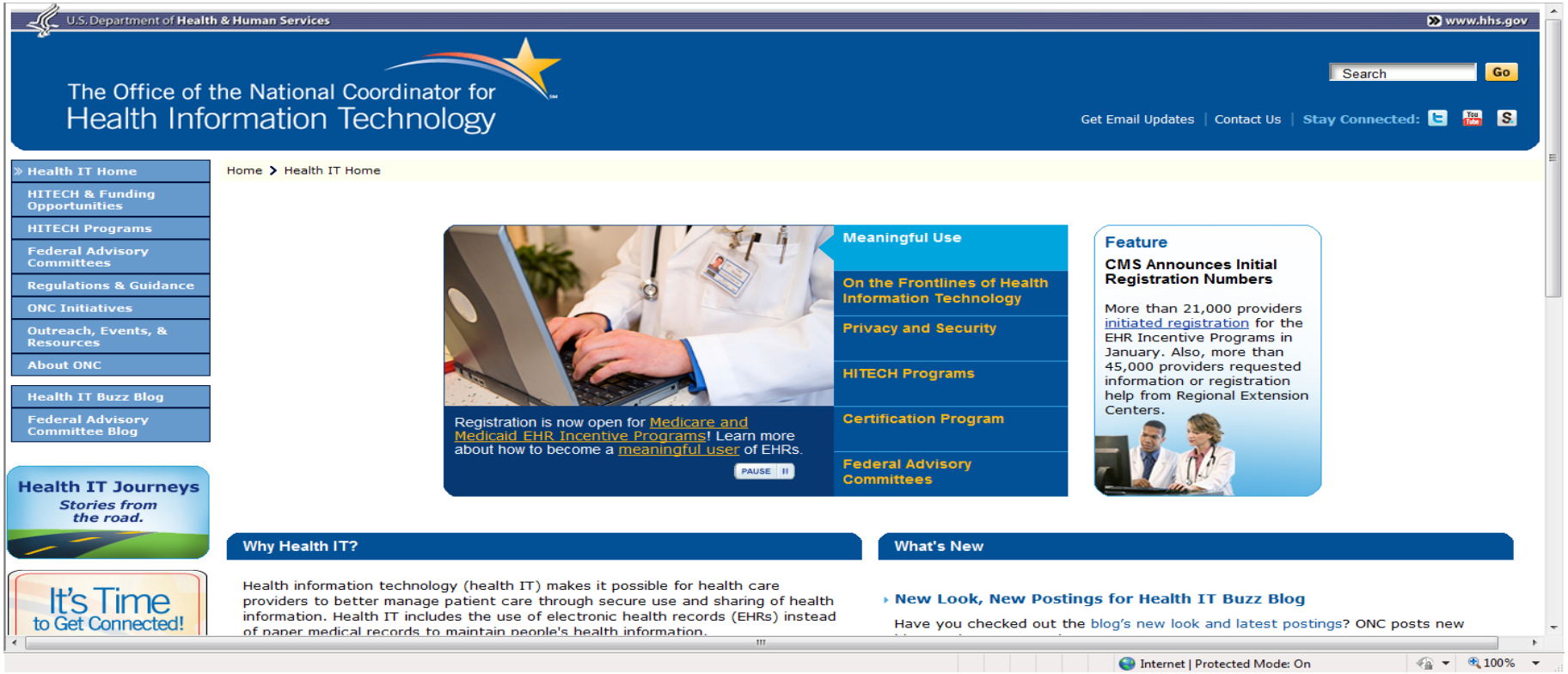
Promotes Clinical Integration & Evidence Based Care Delivery Models

Source: Premier health alliance, © 2010

Information Technology and Data

Health Information Technology for Economic and Clinical Health (HITECH) Act

The Office of the National Coordinator for Health Information Technology (ONC) is at the forefront of the administration's health IT efforts and is a resource to the entire health system to support the **adoption of health information technology and the promotion of nationwide health information exchange to improve health care**.

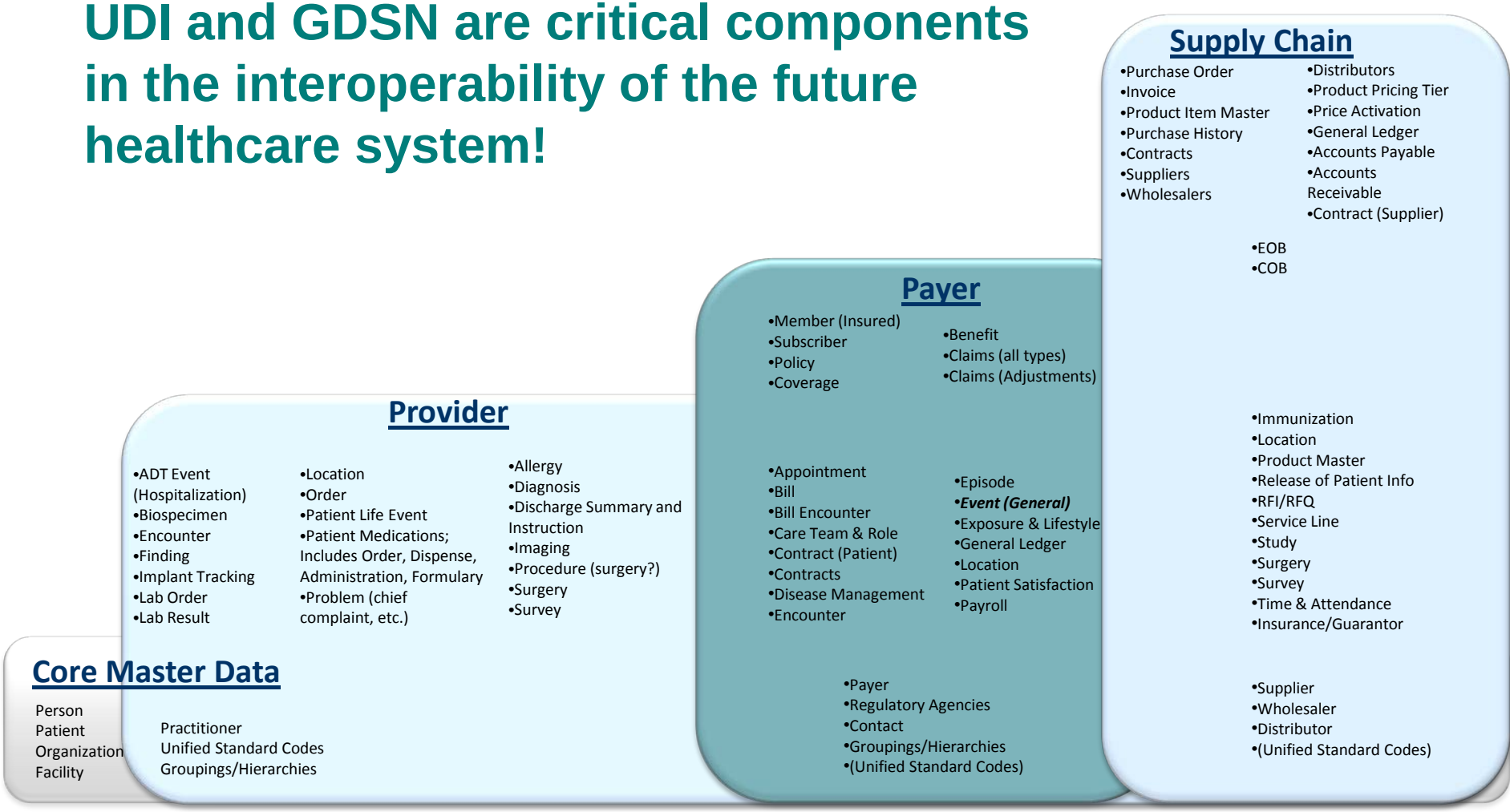


The **Health IT Standards Committee** is charged with making recommendations to the National Coordinator for Health IT on standards, implementation specifications, and certification criteria for the electronic exchange and use of health information.

What are we doing to support UDI and GDSN?

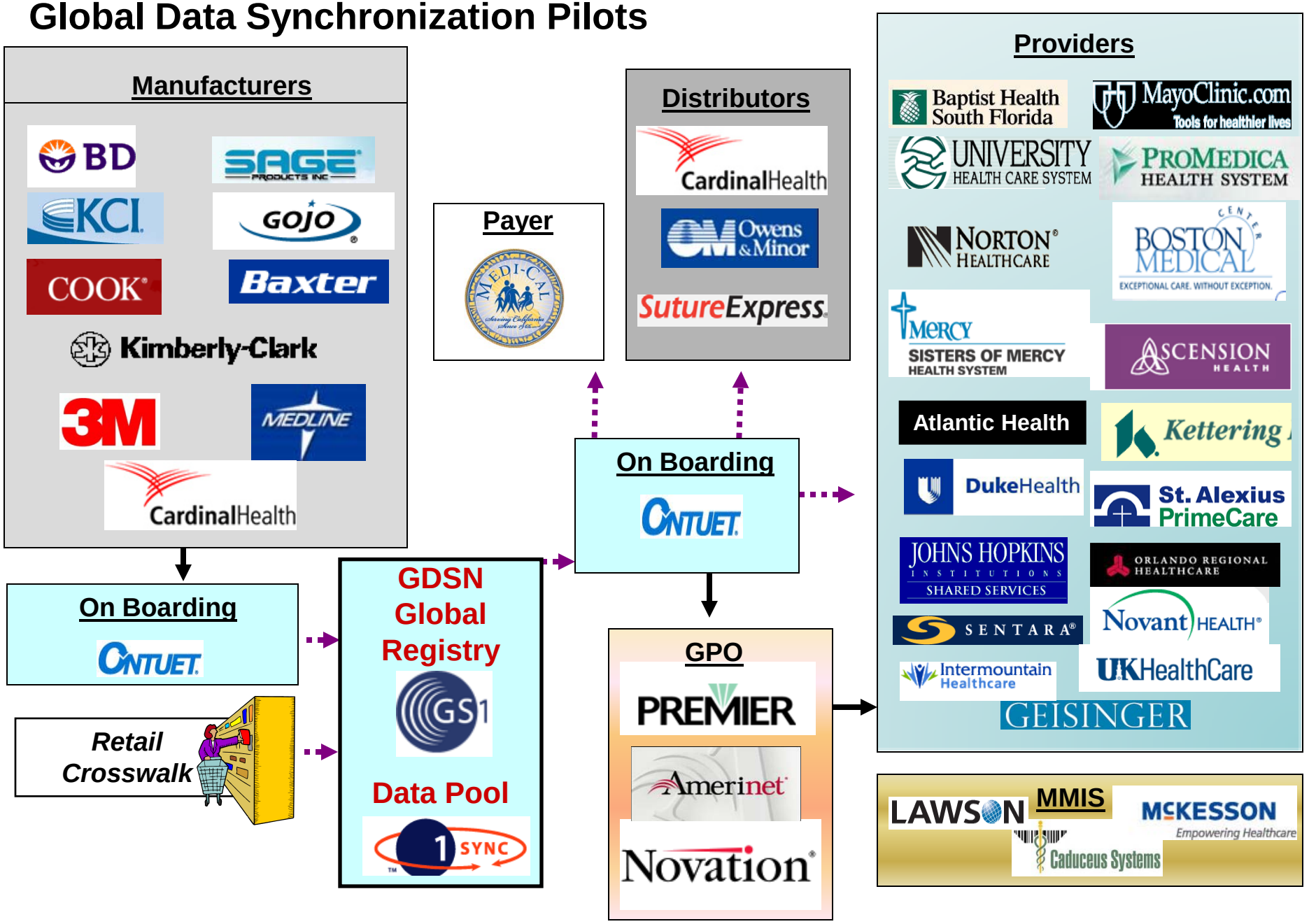
IBM Premier Integrated Healthcare Model supporting Accountable Care

UDI and GDSN are critical components in the interoperability of the future healthcare system!



What are we doing to support UDI and GDSN?

Global Data Synchronization Pilots



What are we doing to support UDI and GDSN?

Premier's Synchronization

Subscribed to the 1Sync Data Pool in 2010

- **Synchronized with 103 Suppliers.**
  - **Healthcare 39**
    (Includes 23 Healthcare Retailers)
  - **Retail 21**
  - **Food 43**

- **Products synchronized =14,510**
  - **Healthcare 6,575**
  - **Retail 854**
  - **Food 7,081**

What are we doing to support UDI and GDSN?

Premier and Member Hospital Pilots

Pilot provided GDSN data along with Premier enriched data.

Pilot included GDSN data along with Premier enriched data.

Participants - Allegiance Health, Boston Medical Center, Geisinger

Objectives - Combine data from GDSN with Premier contract data and member-specific tier pricing, and share data forward in a format that can be easily uploaded into the member MMIS.

Findings - Compiling data into MMIS-readable format was successful for MediClick and Lawson systems. Combining GDSN with Premier contract data required bridging different systems – should be easier once GDSN is integrated into PIM.

Thank you

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Questions?

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