Unique Device Identifiers in Health Care Administrative Transactions

California UDI Pilot Overview, Lessons Learned and Recommendations

Engelberg Center for Health Care Reform at Brookings
UDI Implementation Expert Workshop
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Presentation Objectives

- Background
- UDIPilot Overview
- Main Findings and Experiences
- Lessons Learned
- UDI as a HIPAA Coding Standard
- Recommendations

Background

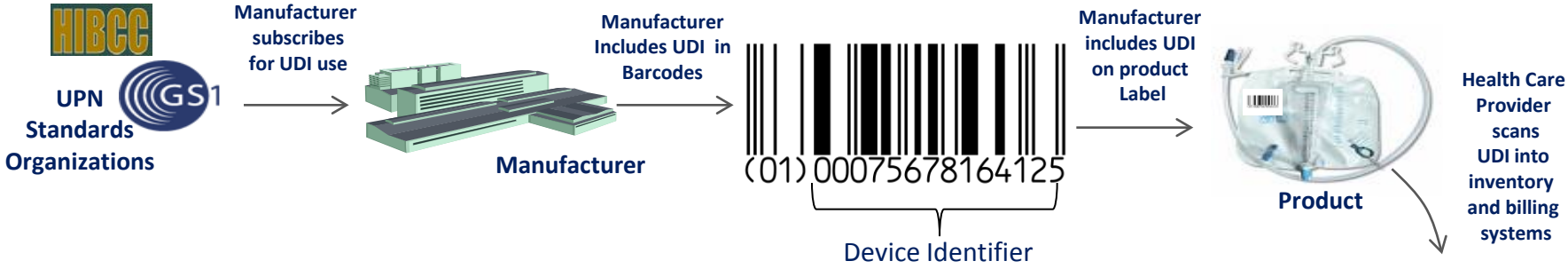
- The Health Insurance Portability and Accountability Act (HIPAA) of 1996, Transactions and Code Sets (TCS) final rule named the Healthcare Common Procedure Coding System (HCPCS) as the standard for reporting medical equipment, supplies and devices on covered electronic transactions [45 CFR Section 162.1002].
- HCPCS is a 5-digit alphanumeric classification system designed to aggregate products based on use and common physical characteristics into a single code. HCPCS are not designed to uniquely identify medical devices.
- Essential information necessary for product validation, reporting, rate setting and establishing quality and utilization controls is lost with the use of HCPCS codes.
- To overcome this reporting gap, health plans, including Medicare and Medicare programs, typically require providers to submit additional product information on claim attachments, which increases the time and costs to process claims and promotes administrative inefficiencies.

Background, cont.

- California passed a state law requiring Medi-Cal (California's Medicaid Program) to contract with medical supply manufacturers for the purpose of establishing rebates or other cost saving mechanisms.
- California determined that the HCPCS did not provide the level of specificity needed to pay for contracted items.
- California determined that the Unique Device Identifier (UDI), formerly referred to as the Universal Product Number (UPN), would provide a simple and cost-effective method to uniquely identify medical supplies on claim transactions.
- California pursued the use of the UDI by requesting an exception to the HIPAA standards pursuant to 45 CFR Section §162.940, "*Exceptions from standards to permit testing of proposed modifications*".

Background, cont.

What is the Unique Device Identifier (UDI)



- Often referred to as a “Bar Code”
- Uniquely identifies medical devices and supplies
- Designed for electronic product tracking throughout the supply chain
- HIBCC and GS1 are the two leading coding councils for UDI, and are internationally recognized
- Current use of HIBCC and GS1 standards is voluntary

Provider

Product is dispensed to the patient. UDI can be Used to track Final destination.

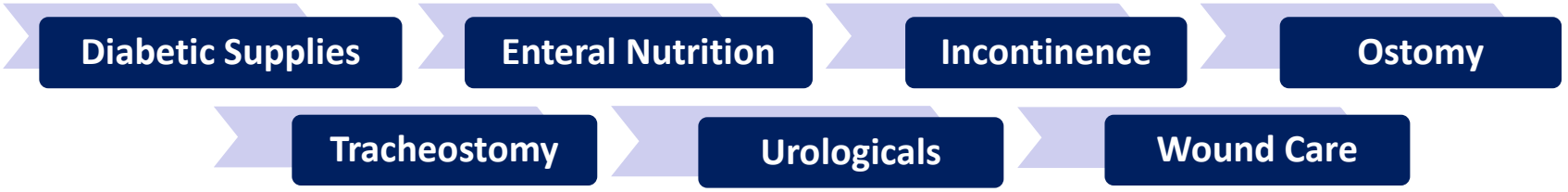
Patient

California UDI Pilot Overview

- Authorized by the HHS Secretary to test the "cost-effectiveness and feasibility" of the UDI as a HIPAA coding standard
- Pilot Objectives:
  - ✓ *Lower Program Costs*
  - ✓ *Enhance the Quality of Reporting Data*
  - ✓ *Reduce Fraud and Abuse*
  - ✓ *Improve Patient Safety*

California UDI Pilot Overview, cont.

- Test period from July 1, 2009 through June 30, 2011
- Participating providers included retail and hospital based pharmacies, durable and medical equipment suppliers (approximately 5,000 providers)
- Over 90 participating manufacturers and distributors. 95% of used GS1 or HIBCC standards.
- Included over 6,700 distinct products in the following service categories:

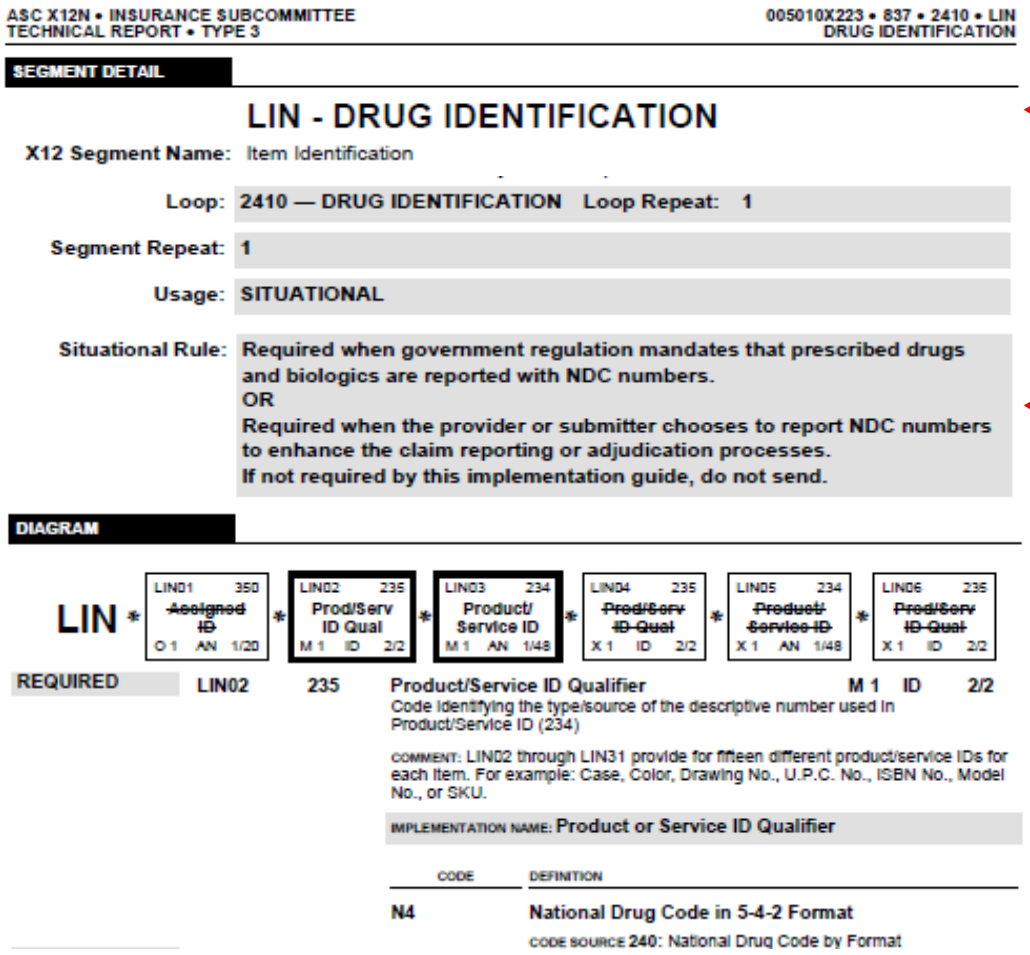


California UDI Pilot Overview, cont.

Claims Processing

- UDIs for Incontinence, Urologicals, Ostomy, Tracheostomy and Wound Care Products allowed on the ASC X12 837 professional claim transactions (reported in the 2400 Product Identification Loop).
- UDIs for Diabetic Supplies and Enteral Nutrition Products allowed on NCPDP Pharmacy claim transactions (reported in the Product Identification Segment).
- Processed over 7 million claims with UDIs that resulted in over $600 million in provider reimbursements.

Placement of the UDI on the X12 837 Institutional and Professional Claim Transaction



ASC X12N • INSURANCE SUBCOMMITTEE
TECHNICAL REPORT • TYPE 3

005010X223 • 837 • 2410 • LIN
DRUG IDENTIFICATION

SEGMENT DETAIL

LIN - DRUG IDENTIFICATION

X12 Segment Name: Item Identification

Loop: 2410 — DRUG IDENTIFICATION **Loop Repeat:** 1

Segment Repeat: 1

Usage: SITUATIONAL

Situational Rule: Required when government regulation mandates that prescribed drugs and biologics are reported with NDC numbers.
OR
Required when the provider or submitter chooses to report NDC numbers to enhance the claim reporting or adjudication processes.
If not required by this implementation guide, do not send.

DIAGRAM

LIN * LIN01 350 ~~Assigned ID~~ O 1 AN 1/20 * LIN02 235 Prod/Serv ID Qual M 1 ID 2/2 * LIN03 234 Product/ Service ID M 1 AN 1/48 * LIN04 235 ~~Prod/Serv ID Qual~~ X 1 ID 2/2 * LIN05 234 ~~Product/ Service ID~~ X 1 AN 1/48 * LIN06 235 ~~Prod/Serv ID Qual~~ X 1 ID 2/2

REQUIRED LIN02 235 **Product/Service ID Qualifier** M 1 ID 2/2
Code identifying the type/source of the descriptive number used in Product/Service ID (234)

COMMENT: LIN02 through LIN31 provide for fifteen different product/service IDs for each item. For example: Case, Color, Drawing No., U.P.C. No., ISBN No., Model No., or SKU.

IMPLEMENTATION NAME: **Product or Service ID Qualifier**

CODE	DEFINITION
N4	National Drug Code in 5-4-2 Format CODE SOURCE 240: National Drug Code by Format

← Change Segment Description from Drug Identification to Product Identification

← Change Situational Rule to include UDI reporting requirements:

- Required when government regulations mandate that medical devices or supplies are reported with UDI codes.

OR

- Required when the payor or provider chooses to report the UDI to enhance claim reporting or adjudication processes.

← Add new qualifier code for UDI

*Similar changes will be required for the NCPDP HIPAA Implementation Guides. NCPDP and X12 standards include qualifiers for GTIN and HIBCC codes.

HIPAA Covered Transactions Impacted by the UDI

45 CFR Part 162 , Subparts K, M, N, P, R, S:

Transactions

- Claims or Equivalent Encounter
- Claim Status Response/Request
- Eligibility Benefit Inquiry and Response
- Claim Payment and Remittance Advice
- Service Authorizations
- Coordination of Benefits
- Medicaid Pharmacy Subrogation

Standards

- ASC X12 Version 5010 Technical Reports Type 3
- NCPDP Version D.0 and Equivalent Batch Standards

Main Findings and Experiences

The UDI helped lower program costs

- ✓ The UDI is an essential component of the Medi-Cal medical supply contracting program which has reported annual savings of $30 million
- ✓ Each contracted item must be uniquely identified in order to collect rebates from manufacturers and to reimburse claims according to contract terms. Manufacturer rebate invoices include the UDI.
- ✓ The UDI eliminated the need for Medi-Cal to request additional product information on claim attachments; resulting in lower operational costs and claims adjudicating faster and more accurately.

Main Findings and Experiences, cont.

- The UDI helped improved the quality of data
  - ✓ The UDI identifies the specific product paid for and delivered to Medi-Cal beneficiaries.
  - ✓ This product specificity allows California to have better control over key business processes such as rate setting, determining medical necessity, establishing utilization controls, preparing fiscal reports, and monitoring health care outcomes.
  - ✓ The UDI allows for enhanced reporting and trending of claim data by specific product attributes such as manufacturer name and product functionality. This is not possible with the HCPCS alone on the claim.

Main Findings and Experiences, cont.

HCPC vs. UDI – An Example

HCPCS A7520
Tracheostomy/Laryngectomy tube

Represents →

- ✓ Over 200 distinct products in pilot
- ✓ Neonatal, pediatric and adult tubes
- ✓ Various standards, sizes and materials
- ✓ Cost Variance: $21.62 - $280.32
- ✓ Medicare Rate: $49.80

Extract of Corresponding UDIs to HCPCS A7520

UDI Code	Manufacturer	Product Description	Maximum Acquisition Cost*
35019315047675	Sims Portex	Blue Line trach tube uncuffed, 6.0mm Id	$21.62
10351688003782	Sims Portex	DIC trach tube uncuffed fenestrated, 7.0mm Id, 9.9mm Od	$33.60
10351688009586	Sims Portex	Uncuffed DIC tracheostomy tube, size 10	$39.00
05021312005557	Bivona	Adult trach tube, cuffless, all silicone, 6.0mm Id	$50.40
20840029007840	Shiley	Neonatal 3.5 tracheostomy tube	$57.60
20840029008229	Shiley	Disposable cannula, cuffless, size 4	$63.41
20840029008106	Shiley	Disposable cannula low pressure, cuffed trach tube, size 6	$70.48
20840029007741	Shiley	Trach tube, fenes, cuffless, size 4 FR	$82.52
20840029007802	Shiley	Laryingectomy tube, size 8	$96.89
04026704011957	Rusch	Tracheoflex trach set, Pediatric, no cuff, adj flange, size 6.0mm	$155.19
05021312014733	Bivona	Flextend Plus neonatal trach tube, size 3.5	$200.55
35021312012570	Bivona	Neonatal Tracheostomy Tube 3.5 mm	$280.32

*The maximum acquisition cost guaranteed by manufacturers and distributors participating in the Medi-Cal medical supply contracting program (based on 2011 data).

Main Findings and Experiences, cont.

- The UDI has the potential to help reduce fraud and abuse
  - ✓ Fraud and abuse investigators report that the UDI on claim transactions improves their ability to analyze claim billing trends, conduct investigations, and recoup funds.
  - ✓ The UDI allows manufacturers to validate that the products paid by Medi-Cal were actually purchased by the billing provider as indicated on the claim transaction. A number of fraud cases have been opened based on manufacturer review of claim expenditures reported on rebate invoices.
  - ✓ The UDI adds an additional level of accountability which makes it more difficult for providers to claim for products that were not actually delivered to beneficiaries.

Main Findings and Experiences, cont.

- The UDI helps improve patient safety
  - ✓ Staff conduct quality reviews of products covered under the Medi-Cal contracting program in order to ensure products meet industry quality standards.
  - ✓ Providers use the UDI to ensure they are purchasing and dispensing only those products that meet Medi-Cal's quality standards.
  - ✓ The UDI has also been useful for identifying and removing defective products from Medi-Cal's list of covered benefits.

Main Findings and Experiences, cont.

- Challenges with using the UDI
  - The lack of a single authority to maintain UDIs and a central repository to validate UDI codes
  - Complex package labeling formats can make it difficult to visually identify and decipher the UDI, without enhanced training
  - Lack of a mandate for all manufacturers to use a specific coding standard such as the GS1 or HIBCC for unique product identification
  - Multiple lengths and formats

Evaluating the UDI as HIPAA Standard

45 CF4 162.940 – Exceptions from standards to permit testing of proposed modifications (1) *Comparison to a current standard:*

HHS Criteria for Considering a Proposed Standard	CA Scoring of the UPN/UDI
1. Improve the efficiency and effectiveness of the health care system	Met
2. Meet the needs of the health data standards user community	Met
3. Be uniform and consistent with other HIPAA standards	**Partially Met**
4. Have low development costs relative to benefits	Met
5. Be supported by an ANSI-accredited or other private/public organization	Met
6. Have timely updating procedures	Met
7. Be technologically independent	Met
8. Be precise, unambiguous, and as simple as possible.	**Partially Met**
9. Result in minimum data collection and paperwork burdens on users	Met
10. Incorporate flexibility to adapt to changes in health care	Met

California scored 8 or the 10 HIPAA Standard Evaluation Criteria as Met.

Evaluating the UDI as HIPAA Standard, cont.

HIPAA Standard Evaluation Criteria Scored as "Partially" Met:

(3) Be Uniform and Consistent with Other HIPAA Standards

(8) Be Precise, Unambiguous and Simple as Possible

- ✓ Lack of a single authority to maintain and publish UDIs
- ✓ Lack of a mandate for manufacturers and distributors to assign UDIs to products
- ✓ Lack of a publicly available repository that lists all product UPNs and associated descriptions
- ✓ Multiple UPN formats and lengths
- ✓ UDIs can be difficult to identify on packaging labels. Some labels will have multiple barcodes and UDI formats

Lessons Learned

- ✓ UDI can play an important role in improving the efficiency and effectiveness of electronic data exchange between health care providers, clearinghouses and health plans.
- ✓ The benefits and advantages of including the UDI on claim transactions significantly outweighs the implementation costs – based on California's experience.
- ✓ The FDA UDI regulations will play a critical role in moving the UDI standards from a voluntary reporting system to a robust coding system, similar to the National Drug Code (NDC).
- ✓ The FDA UDI regulations, when implemented, will help overcome challenges identified in the California UDI Pilot.

Recommendation to the Secretary

- Modify the HIPAA medical code set standards specified under 45 CFR Section 162.1002 to allow for the reporting of the UDI, as defined and designated by the FDA, for medical equipment, supplies and devices.
- Modify the applicable HIPAA transaction standards to allow for UDI reporting as a situational data element, using the same location currently used for reporting the NDC.
- Allow HIPAA covered entities to report the UDI on HIPAA covered transactions to support business needs; including California's continued use of the UDI.

Recommendation to the Secretary, Cont.

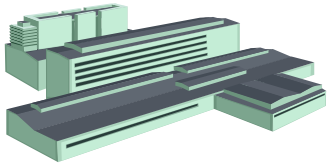
- Industry Collaboration with the FDA to:
  - Ensure manufacturers use the designated UDI standards on product labels.
  - Implement a publicly available UDI database and include a process to map UDIs to HCPCS for transition purposes.
  - Ensure UDIs are clearly identifiable on packaging labels and develop a national training program to educate users on formats and application rules.

  - Establish a committee composed of industry experts* to develop a plan to transition from HCPCS to UDIs as a HIPAA coding. Anticipate a multi-year process, but the planning process should start now.

*Industry experts should include representatives from the FDA, X12, NCPDP, GS1, HIBCC, public and commercial health plans (including Medicare and Mei, hospitals, pharmacies and physician groups.

UDI Potential for the Broader Health Care Community

Improve Patient Safety | **Reduce Fraud and Abuse** | **Enhance Data Quality** | **Efficient Data Exchange** | **Cost-Savings**



Manufacturers/ Distributors

Contract Product/ Discounts/Rebates

Discounts/Rebates

Health Plans

Medicare **Commercial** **Medicaid**

UDI

Purchase Product

Deliver Product

Submit Claim

Pay Claim

Hospitals
Clinics
Physicians
Pharmacies

Providers

Dispense Product

Patients

Questions?