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U.S Drug Supply Chain Security Act (DSCSA)

Scott Mooney
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Wholesaler Vantage Point

- DSCSA is a 10 year evolution
 - Every two years or so requirements increase
 - Culminate with serialized traceability in 2023 down to the dispenser level
- Wholesalers required to receive AND send DSCSA data for transactions with trading partners
- Wholesalers distribute more than 96% of the US pharmaceutical volume to dispensers



Uniqueness for Wholesalers

- Wholesaler largely unaffected by November 2017 bar coding requirements of manufacturer to begin affixing 2D data matrix
- Wholesaler must use 2D data matrix to verify returned goods in November 2019
- Also in November 2019, unless the Secretary of the FDA completes guidance on grandfathering determining when and under what circumstances grandfathering is allowed, wholesaler cannot transact after that date (buy or sell) without a 2D data matrix affixed



Returns verification

- Begin November 2019 for saleable returns to be restocked by a wholesaler
- Requires distributor to perform two tests before accepting saleable return
 - Must be able to associate original DSCSA transaction data with the product being returned
 - Must verify that the information in the 2D data matrix corresponds to the data the manufacturer assigned to that product.
- Break outs this afternoon will focus deeper on the subject of returns and the November 2019 requirements.



Data included in 2D bar code

- Beginning by November 2017 Manufacturers must begin affixing 2D bar code with:
 - NDC included in a GTIN 14 format
 - Serial
 - Expiry
 - Lot/Batch
- McKesson, ABC and GS1 US will be performing warehouse scans May 2017, November 2017 and May 2018
 - Looking to confirm 2D bar codes reflects expected data formats and structure
 - Accumulate resulting data to be able to provide feedback to manufacturers as they move forward with 2D data matrix bar coding



Data included in 2D Bar Code Continued

- Experiencing a challenge with some product manufactured in India.
 - Several companies have failed to embed the required NDC number in the GTIN14
- Incompatibility between 2D data matrix date encoding and EPCIS date format
 - “00” for day works in 2D but fails in EPCIS transaction



Nov 2019 “Cannot Transact”

- Confusion/Lack of FDA Guidance on Grandfathering
 - Manufacturers begin affixing 2D in Nov 2017
 - Repackagers begin affixing 2D in Nov 2018
 - Distributors “cannot transact” in Nov 2019
 - Cannot transact is both buy and sell according to recent FDA presentations
 - Dispensers cannot purchase in Nov 2020
- Need to understand what, if any, grandfathering activities the FDA may allow



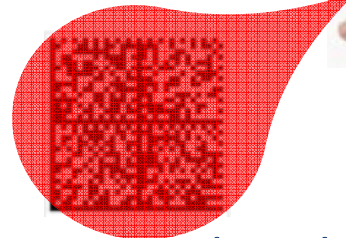
Contact Information

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- Reminder that we will be having a DSCSA breakout in greater detail during the Ask the Expert sessions this afternoon

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Jeff Denton

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AmerisourceBergen Corporation

**GS1 Global Event – Berlin
DSCSA & EPCIS**

**Jeff Denton, SR. Director
Global Secure Supply Chain**

05-Apr-17



US DSCSA Requirements – Short Recap



- **November 27, 2017:**
 - **Manufacturers are required to place a serialized barcode on the smallest salable unit, no mandate to incorporate the serialized barcode data into the required transactional data exchange.**
- **November 27, 2018:**
 - **Repackages are required to place a serialized barcode on the smallest salable unit, no mandate to incorporate the serialized barcode data into the required transactional data exchange.**
- ✓ **The serialized barcode contains the following data elements on both each and case packages: product identifier, serial number, batch and the expiration date.**



Global Trade Identification Number (GTIN)
Serial Number (SNI)
Lot (Batch) Number
Expiration Date

■ US DSCSA Requirements – Short Recap

✓ November 27, 2019:

- Wholesalers may only engage in transactions that have the serialized barcode placed on the package.
- Upon the receipt of a saleable return, verify the serialized barcode is accurate before being able to resell that return, and also associate the transactional information to the returned product.

✓ November 27, 2020:

- Dispensers may only engage in transactions that have the serialized barcode placed on the package.

✓ November 27, 2023

- Manufacturers, wholesalers and dispensers shall exchange the required serialized transactional information in a secure, interoperable, electronic system. Serialized data exchange is required between all trading partners upon a change of ownership.

Utilizing EPCIS for DSCSA

- EPCIS is explicitly recognised in FDA draft guidance (Nov 2014) as a means for interoperable exchange of Rx traceability data
 - ✓ Must contain necessary data attributes for TI, TH (lot Level only) and TS, including:
 - Seller (GS1 GLN)
 - Buyer (GS1 GLN)
 - Product Identifier (GS1 GTIN)
 - Unique serial number
 - Transaction Statement
 - *Transaction history (for lot level transactions)*

EPCIS Applying GS1 Standards for DSCSA & Traceability

- defines interfaces for **capturing & sharing** data
- defines a framework data model for event data
- helps create & **share visibility data** across enterprises
- enables services & solutions for supply chain visibility
- Approved as ISO/IEC 19987 in July 2015
- Sept 2016: EPCIS 1.2, including *Error Declaration* mechanism

■ Four Dimensions of an EPCIS Event

- **WHAT** objects are the subject of event?
Item-level (GTIN + serial) or Lot-level (GTIN + lot)
- **WHEN** did this event take place?
Date, time, time zone
- **WHERE** did this occur? / **WHERE** are the objects thereafter?
Read Point (GLN) & Business Location (GLN)
- **WHY** did this event take place?
*Business step (e.g., “Shipping”), Disposition (e.g., “in transit”),
Source/Destination info (for CoC / CoO)*

EPCIS for Serialized Item Level Traceability

- Events are captured at instance-level (GTIN+Serial, SSCC)
- DSCSA CoO transaction info integrated in *Shipping* event
- *Packing & Unpacking* events record packaging hierarchy
 - **Aggregation** of item -> case -> pallet (outer containers)
- Commissioning events enable validation of serial numbers
- Receiving, Void Shipping, Dispensing, Decommissioning, Destroying record product lifecycle beyond DSCSA compliance
 - The events comprise TI & TH for DSCSA; TS included in header
 - Single XML document containing all DSCSA-required information

■ EPCIS Events are captured and shared by trading partners

Party at Beginning of the Supply Chain (e.g., manufacturer)

- Commissioning
- Packing
- Shipping

Intermediate Parties (e.g., distributor)

- Receiving
- Unpacking
- Commissioning
- Packing
- Shipping

• Party at End of the Supply Chain (e.g., Hospital, Pharmacy)

- Receiving
- Unpacking
- Packing
- Dispensing
- Destroying
- Decommissioning

Updates to Guideline Version 1.2

Applying GS1 Standards for DSCSA & Traceability

- Rules for expressing Expiration Date
 - ✓ as printed on label, encoded in barcode and in EPCIS Events
- Additional clarification regarding EPCIS event times
- Best practice for Exception handling & resolution
- Incorporates new features of EPCIS 1.2 & CBV 1.2
 - ✓ including **Error Declaration** mechanism & additional vocabulary
- EPCIS specifications for lot-level and serialized item traceability updated to provide for all data requirements of DSCSA

■ Updates to Guideline Version 1.2

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Reference Materials

- GS1 EPCIS Specifications v 1.2
- GS1 US EPCIS Implementation Guidelines v 1.2
- GS1 Core Business Vocabulary v1.2

Coming Soon

- GS1 Quick Reference Guide

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