How to comply with the U.S. Drug Supply Chain Security Act Rule using GS1® Standards

Christopher Reed | October 23, 2014
Agenda

• H.R. 3204: Drug Quality and Security Act of 2013
• TITLE II: The Drug Supply Chain Security Act (DSCSA)
  – January 1, 2015 Requirements
  – Serialization with Unique Product Identifier
  – Utilization of GS1® Standards to comply with DSCSA
• Next Steps
• Contact
A Short bit of history...

- Florida Pedigree/Licensure Law (S.B. 2312)
  - Paper Based
  - Lot Pedigree
  - Did not involve the Manufacturer

- California SB 1307
  - Item Level Serialization
  - Unique Identifier exchanged via electronic pedigree to trading partner
  - Responsibility was shared across supply chain

![Florida Flag](image1)

![California Flag](image2)
H.R. 3204 - Drug Quality and Security Act of 2013

Signed November 27, 2013 by President Barrack Obama

Title I, The Compounding Quality Act: contains important provisions relating to the oversight of compounding of human drugs.

Title II, The Drug Supply Chain Security Act: outlines critical steps to build an electronic, interoperable system to identify and trace prescription drugs as they are distributed in the United States.

DSCSA Milestones

http://www.healthcaredistribution.org/ir_issues/pedigree.asp
DSCSA Requirements: January 1, 2015

‘Setting the Groundwork’

All trading partners in the Supply Chain must:

• Engage in sales transactions with only appropriately licensed and registered trading partners.
  • Manufacturers/Repackagers – valid registration
  • Wholesalers/3PL – valid State or Federal license
  • Dispenser – valid State license
• Have systems in place to investigate, identify, and remove product suspected of being counterfeit, diverted, or otherwise unsafe.

Product verification

• No later than 1/1/15, manufacturers, wholesalers, drug distributors, repackagers, and many dispensers (primarily pharmacies) shall establish systems and processes to be able to comply with the verification requirements
  – Must be able to respond to verification requests from Secretary about suspect product
  – Quarantine and investigate suspect product to determine if illegitimate product
  – Notify trading partners and FDA of illegitimate product
  – Respond to notifications of illegitimate product
  – Recordkeeping

DSCSA Requirements: January 1, 2015

‘Setting the Groundwork’

Finally, all trading partners in the Supply Chain must:

• Pass and accept Transaction Information (TI), Transaction Statements (TS), and Transaction History (TH) with all sales. (Dispensers shall not accept transaction without TI, TS, TH after 1 July 2015)

**Transaction Information (TI):**
- Proprietary or established name or names of the product;
- strength and dosage form of the product;
- NDC number of the product;
- container size;
- number of containers;
- lot number of the product;
- date of the transaction;
- date of the shipment, if more than 24 hours after the date of the transaction;
- business name and address of the person from whom and to whom ownership is being transferred.

**Transaction History (TH):** A statement in paper or electronic form, including the transaction information for each prior transaction going back to the manufacturer of the product.

**Transaction Statement (TS):**
- A statement, in paper or electronic form, that the--
  - entity transferring ownership in a transaction is authorized as required under DSCSA;
  - received the product from a person that is authorized as required under DSCSA;
  - received transaction information and a transaction statement from the prior owner of the product, as required under the law;
  - did not knowingly ship a suspect or illegitimate product;
  - had systems and processes in place to comply with verification requirements under the law;
  - did not knowingly provide false transaction information; and
  - did not knowingly alter the transaction history.
### Ship Notice/Manifest

**General Information**
- **Beginning Segment for Ship Notice:**
  - Transaction Set Purpose Code: Original
  - Transaction Set Identification: 61001607
  - Date: 1/1/2015
  - Time: 2:02:00 PM
- **Hierarchical Structure Code:**
  - Shipper, Order, Packaging, Item
- **Transaction Type Code:** Shipment Advice

**Shipment Level Information**
- **Carrier Details (Quantity and Weight):**
  - Packaging Code: GTN
  - Lading Quantity: 2
  - Weight Qualifier: Gross Weight
  - Weight: 78.00
  - Unit of Basis for Measurement Code: Pound

- **Carrier Details (Routing Sequence/Transit Time):**
  - Routing Sequence Code: Origin/Delivery Carrier (Any Mode)
  - Identification Code Qualifier: Standard Carrier Alpha Code (SCAC)
  - Identification Code: POGI

- **Transportation Method Type Code:** Motor (Common Carrier)
- **Routing:** POGI

**Reference Identification:**
- Bill of Lading Number: 61001607
- Carrier's Reference Number (PRO/Invoice): 123-000106

**DateTime Reference:**
- **Shipped:** 1/8/2015 2:02:00 PM
- **Estimated Delivery:** 1/8/2015 4:00:00 PM CS

**Ship To: **

**Buying Party (Purchaser):**

**Contact Information:**
- **Certifier:**
  - **Telephone:** 972-446-4600

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[https://sv-db.hdma.net/EWEB/dynamicPage.aspx?webCode=productDetail&prc_prd_key=64b24e67-147d-4db0-9053-1e1fcca0f1d6](https://sv-db.hdma.net/EWEB/dynamicPage.aspx?webCode=productDetail&prc_prd_key=64b24e67-147d-4db0-9053-1e1fcca0f1d6)
DSCSA Milestones – November 27, 2017

http://www.healthcaredistribution.org/ir_issues/pedigree.asp
DSCSA: Serialization

Serialization with Unique Product Identifier; ‘2017-2020’

Supply Chain trading partners must only engage in transactions of products encoded with a unique product identifier and be able to verify the products legitimacy by:

- Manufacturers: November 27, 2017
- Repackagers: November 27, 2018
- Wholesale Distributors: November 27, 2019
- Dispensers (Clinics, Retail): November 27, 2020

DSCSA: Unique Identifiers

We need to uniquely identify our products...

Utilizing FDA NDC in Product Identifier (GTIN)

Unique Product Identifier (GTIN + S/N) to enable Serialization

DSCSA: Data Carriers

…at all packaging levels…

<table>
<thead>
<tr>
<th></th>
<th>GTIN</th>
<th>S/N</th>
<th>Lot</th>
<th>Expiry</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carton</td>
<td>(01)00361414123414</td>
<td>(21)123456789012</td>
<td>(10)ABC123</td>
<td>(17)141023</td>
</tr>
<tr>
<td>Vial</td>
<td>(01)10361414123417</td>
<td>(21)123456789013</td>
<td>(?)</td>
<td>(10)ABC123</td>
</tr>
<tr>
<td>Case</td>
<td>(01)20361414123412</td>
<td>(21)123456789014</td>
<td>(10)ABC123</td>
<td>(17)141023</td>
</tr>
</tbody>
</table>

…ensuring they can be universally interpreted…

GTIN S/N Lot Expiry
(01)00361414123414 (21)123456789012 (10)ABC123 (17)141023

GS1 Data Carriers
DSCSA: Standards in Practice

...to bring safe medicines to our doctors, nurses, and patients.

Serialized PREZISTA® 600 encoding the GTIN, Serial Number, Expiry, and Lot in a 2D Data Matrix.

Utilizing:
1) GS1 standards,
2) FDA SNI guidance, and
3) HDMA shipper bar code recommendations
Next Steps

- Long term traceability – EPCIS
  - EPCIS 1.1 for Lot Level requirements
  - Tracking serialized products
- Scaling serialization to more products
- Electronic exchange for more customers

GS1® Standards are vital to DSCSA compliance!

http://www.gs1.org/gsmp/kc/epcglobal/epcis/epcis_1_1-standard-20140520.pdf
Contact

Christopher Reed, Johnson & Johnson Healthcare Systems

Email: creed9@its.jnj.com
Thank you!