U.S. Drug Supply Chain Security Act
“Work in Progress”

GS1 Healthcare Conference
21 October 2015
DSCSA Overview

- DSCSA Requirements
- Implementation Status
- Next Steps
- Questions
November 27, 2013
H.R 3204
Public Law No: 113-54

Drug Quality and Security Act
DSCSA Language

Title II – Drug Supply Chain Security Act (DSCSA)

PRODUCT TRACING – Manufacturer Requirements

(i) prior to, or at the time of, each transaction where a manufacturer transfers ownership of a product, manufacturer will provide the subsequent owner with transaction history, transaction information, and transaction statement, in a single document (paper or electronic format)

(ii) capture TI/TH/TS for each transaction and maintain such information . . . for not less than 6 years after the date of the transaction

*Exception for Drop Shipments
Drug Supply Chain Security Act
Key Manufacturer’s Mandates

Jan 1, 2015
• “Product” Tracing (Lot Info)
  Provide for each Change of Ownership:
  • Transaction Info (TI)
  • Transaction History (TH)
  • Transaction Stmt(TS)
  • Single Document
  • Paper or Electronic
• Verification & Sys Requirements
  • Suspect Product
  • Illegitimate Product
• Requests for Information
  • TI, TH, TS < .48 hrs
• Notifications – Illegitimate <24 hrs
• Authorized Trading Partners

Nov 2017
• Serialized Product Identifiers
  • Each Pkg. and Case
  • 2D DataMatrix on Pkg.
  • Linear or 2D on Case
  • NDC + Serial Number (SNI)
  • Lot and Exp Date
  • Human Readable and Machine Readable
  • Provide TI, TH, TS in electronic format
  • Verification Requirements
    • Product ID/SNI’s < 24 hrs
    • SNI for Saleable Returns
• Maintain Product Identifiers – 6 yrs

Nov 2023
• Pkg (Item-level) traceability
• Interoperable electronic “Tracing”
• Exchange TI, TS in a secure, interoperable electronic manner
• TI to include product identifier
• Systems and Processes for “Verification” of Product at Pkg. level, including the SNI
• Systems and Processes to promptly respond with TI and TS and gather Transaction History
• Saleable Returns – TI and TS
• Requests for Information < 24 hrs

SELF-EXECUTING
Transaction Information

- Proprietary or established name(s) of product
- Strength and dosage
- National Drug Code (NDC) number
- Container size
- Number of containers
- Lot number of product
- Date of transaction
- Date of shipment if occurs more than 24 hours after transaction
- Business name and address of the person to whom ownership is being transferred
- Business name and address of the person from whom ownership is being transferred

Transaction History

- “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

- 7 declarations by the entity transferring ownership confirming legal compliance and product integrity
Manufacturer will deliver transaction data for prescription trade items sold to downstream trading partners.

Successful delivery requires alignment between partners on key master data elements.

<table>
<thead>
<tr>
<th>Element</th>
<th>Description</th>
<th>Metric</th>
</tr>
</thead>
<tbody>
<tr>
<td>Products</td>
<td>Prescription trade items (no OTC)</td>
<td>SKUs: 1,450</td>
</tr>
<tr>
<td>Partners</td>
<td>Located in the United States and Puerto Rico</td>
<td>Direct Partners: 22,800</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Physicians: 18,000</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Other Partners: 4,800</td>
</tr>
<tr>
<td>Shipment Type</td>
<td>• Includes sales shipment</td>
<td>2014 Deliveries: 497,000</td>
</tr>
<tr>
<td></td>
<td>• Excludes intercompany shipments</td>
<td>2014 Delivery Line Items: 1,270,000</td>
</tr>
<tr>
<td></td>
<td>• Excludes samples</td>
<td>2014 Dropships: 257,000 shipments</td>
</tr>
</tbody>
</table>
Suspect and Illegitimate Product

Suspect = “Reason to believe” that such product is potentially…
Illegitimate = “Credible Evidence” shows that the product is…..

- Counterfeit
- Diverted
- Stolen
- Intentionally adulterated such that the product would result in serious adverse health consequences or death to humans
- Subject of a fraudulent transaction
- Appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans

Prescription products in, or intended for, the U.S. legitimate supply chain
### Key 2015 DSCSA Deadlines and Milestones

#### Other Anticipated Activities

- Release of Final Suspect and Illegitimate Product Guidance
- Release of Final Licensure Reporting Guidance
- Additional IIES Guidance
- Public Meetings/Workshops
Implementation Status

- Industry stakeholders have made significant progress to comply with the Phase 1 U.S. DSCSA product tracing and verification requirements – open questions remain

- Technical implementation issues are being addressed

- Product serialization efforts are underway for 2017

- Much work remains to define the 2023 item-level traceability and reporting requirements – Pilots are expected
Next Steps

• November 1 – Dispenser Enforcement Discretion Ends

• Resolve technical implementation issues with dispensers

• Address open questions with the FDA and provide input to the development of the FDA Guidance documents

• Prepare for serialization and serialized (item-level) data exchange

• Advance efforts around data architecture and choreography

• Conduct pilots
Thank you!

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