

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...



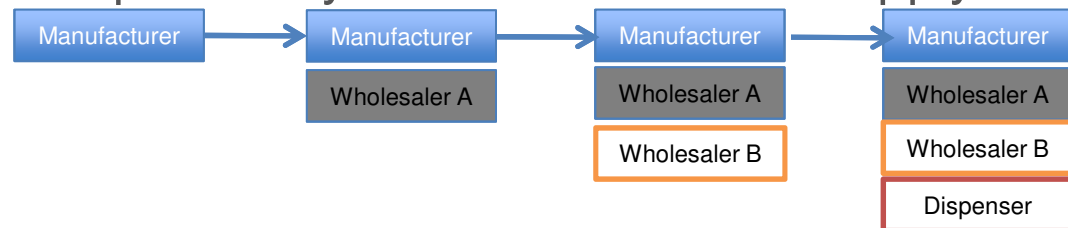
- Florida Pedigree/Licensure Law (S.B. 2312)

- Paper Based
- Lot Pedigree
- Did not involve the Manufacturer

Preempted!

- California SB 357

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



H.R. 3204 - Drug Quality and Security Act of 2013

Signed November 27, 2013 by President Barack 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.

ONE HUNDRED THIRTEENTH CONGRESS OF THE UNITED STATES OF AMERICA
AT THE FIRST SESSION
Begun and held at the City of Washington on Thursday, the third day of January, two thousand and thirteen

H. R. 3204

AN ACT

To amend the Federal Food, Drug, and Cosmetic Act with respect to human drug compounding and drug supply chain security, and for other purposes.

Section 1. Short title

This Act may be cited as the “Drug Quality and Security Act”.

Sec. 2. References in Act; table of contents

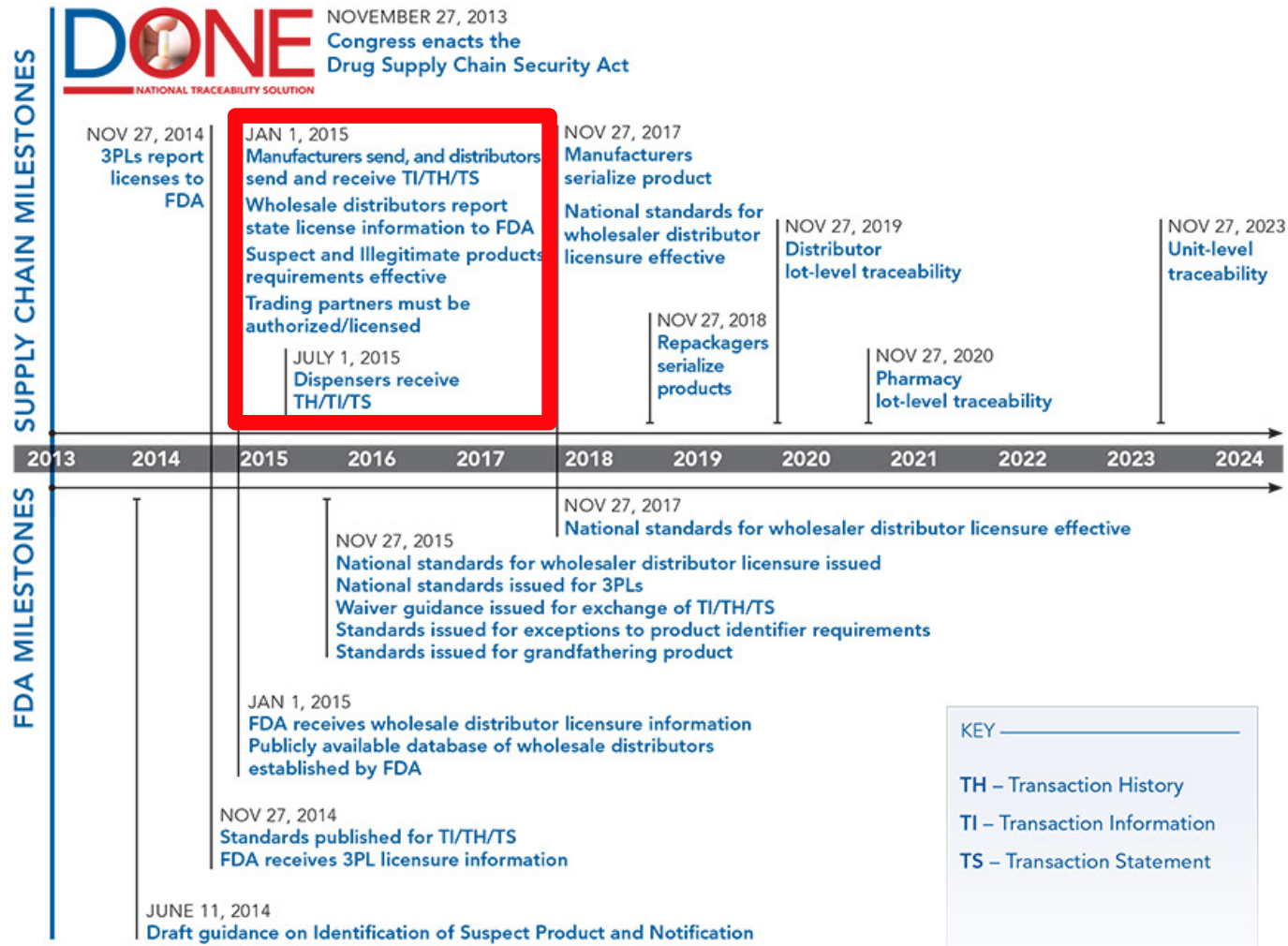
(a) References in Act.—

Except as otherwise specified, amendments made by this Act to a section or other provision of law are amendments to such section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

(b) Table of contents.—

<http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm376829.htm>

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 register** 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, wholesaler 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

<http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/UCM388945.pdf>

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.

DSCSA Requirements: January 1, 2015



HDMA Spec ASN for DSCSA Compliance

Ship Notice/Manifest

General Information

Beginning Segment for Ship Notice:
Transaction Set Purpose Code : Original
Shipment Identification : 51001807
Date : 10/1/2014
Time : 2:02:00 PM
Hierarchical Structure Code : Shipment, Order, Packaging, Item
Transaction Type Code : Shipment Advice

Shipment Level Information

Carrier Details (Quantity and Weight):

Packaging Code : CTN
Lading Quantity : 2
Weight Qualifier : Gross Weight
Weight : 78.89
Unit or 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 : PGSI
Transportation Method/Type Code : Motor (Common Carrier)
Routing : PGSI

Reference Identification:

Bill of Lading Number : 51001807
Carrier's Reference Number (PRO/Invoice) : 123-0036164

Date/Time Reference

Shipped : 10/1/2014 2:02:00 PM
Estimated Delivery : 10/02/2014 4:00:00 PM CS

Ship To:

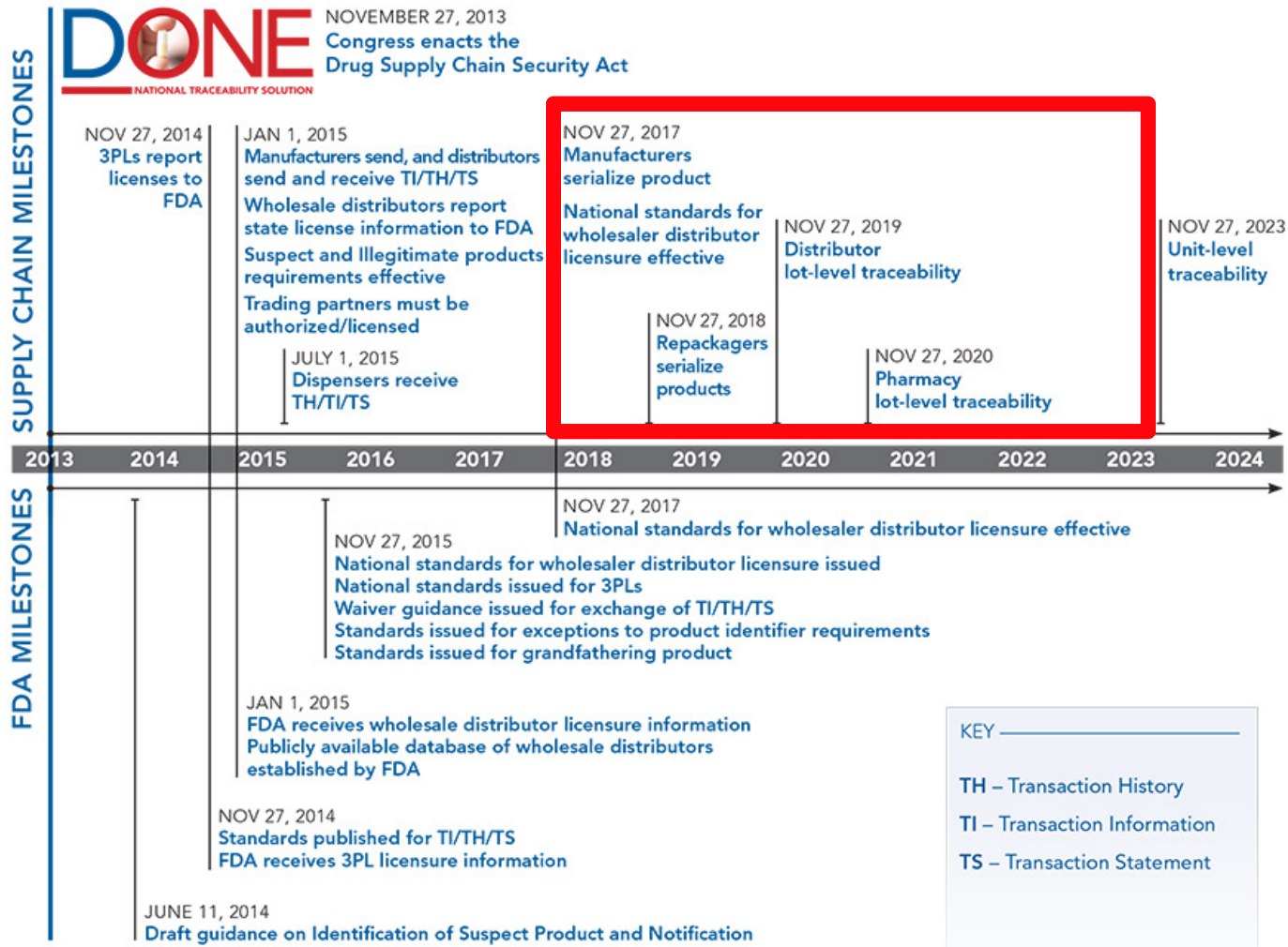
Buying Party (Purchaser):

Contact Information:

Certifier :
Telephone : 972-446-4800

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

Title II of the Drug Quality and Security Act

DRUG SUPPLY CHAIN SECURITY

SEC. 201. SHORT TITLE.

This title may be cited as the "Drug Supply Chain Security Act".

SEC. 202. PHARMACEUTICAL DISTRIBUTION SUPPLY CHAIN.

Chapter V (21 U.S.C. 351 et seq.) is amended by adding at the end the following:

"Subchapter H--Pharmaceutical Distribution Supply Chain

"SEC. 581. DEFINITIONS.

"In this subchapter:

"(1) Affiliate.--The term 'affiliate' means a business entity that has a relationship with a second business entity if, directly or indirectly--

"(A) one business entity controls, or has the power to control, the other business entity; or

"(B) a third party controls, or has the power to control, both of the business entities.

"(2) Authorized.--The term 'authorized' means--

"(A) in the case of a manufacturer or repackager, having a valid registration in accordance with section 510;

"(B) in the case of a wholesale distributor, having a valid license under State law or section 583, in accordance with section 582(a)(6), and complying with the licensure reporting requirements under section 503(e), as amended by the Drug Supply Chain Security Act;

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

<http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm376829.htm>

DSCSA: Unique Identifiers

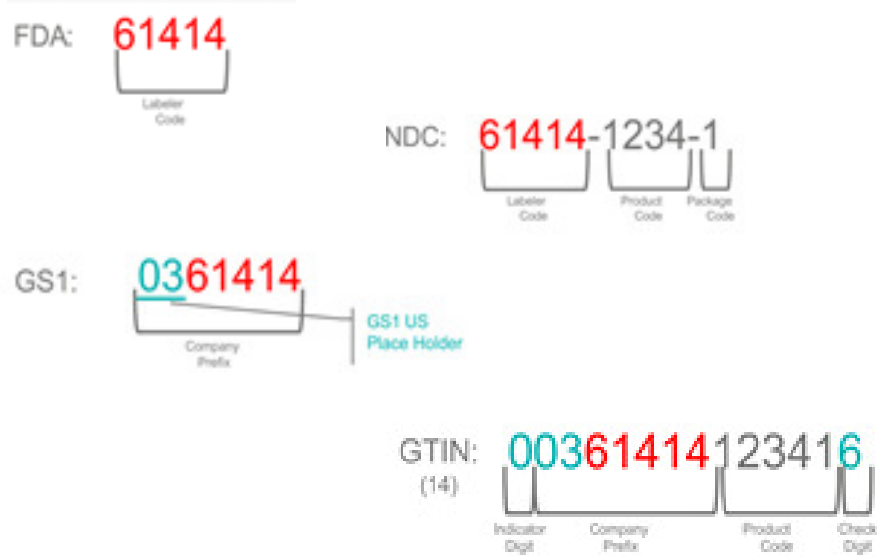
We need to uniquely identify our products...

Guidance for Industry
Standards for Securing the Drug
Supply Chain - Standardized
Numerical Identification for
Prescription Drug Packages

FINAL GUIDANCE

U.S. Department of Health and Human Services
Food and Drug Administration
Office of the Commissioner (OC)
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Office of Regulatory Affairs (ORA)
March 2010

Utilizing FDA NDC in Product Identifier (GTIN)






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




DSCSA: Data Carriers

...at all packaging levels...

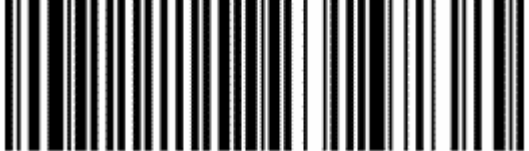
Utilizing GS1 Application Identifiers					
	GTIN	S/N	Lot	Expiry	
<i>Carton</i>	(01)00361414123414	(21)123456789012	(10)ABC123	(17)141023	
<i>Vial</i>	(01)10361414123417	(21)123456789013 (?)	(10)ABC123	(17)141023	
<i>Case</i>	(01)20361414123412	(21)123456789014	(10)ABC123	(17)141023	

...ensuring they can be universally interpreted...

GS1 Data Carriers



(01)00361414123414
(21)123456789012
(10)ABC123
(17)141023



(01)20361414123414(21)123456789012(10)ABC123(17)141023

DSCSA: Standards in Practice

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



N 3  6
59676-562-01

 GTIN:00359676562016
 S/N: 123456789012
 EXP: 01-2015
 LOT: 12G123456 X

 **Used for Component Control**

Standard Product License Plate GS1 Compliant with 2D Data Matrix

60 Tablets
 NDC 59676-562-01
PREZISTA®
 (darunavir) tablets
600 mg

Each tablet contains darunavir ethanolate equivalent to 600 mg of darunavir.

Store at 26°C (77°F); with excursions permitted to 15°-30°C (59°-86°F).
 USUAL DOSAGE: See package insert for full Prescribing Information.
 Keep out of reach of children.

ALERT
 Find out about medicines that should NOT be taken with PREZISTA.

Manufactured by:
 Janssen Ortho LLC
 Gurabo, PR 00778
 Manufactured for:
 Janssen Therapeutics
 Division of Janssen Products, LP
 Titusville, NJ 08850
 © Janssen 2008

Prezista 600mg 24 Bottles Store at controlled room temperature 15° - 25°C (59° - 77°F) Protect from light and moisture EXP: MON YYYY LOT: 123456 QTY: 06  (17) YYMMDD (10) LLLLLL (30) 0006  N (01) 103 50458 591 50 4 (21) Serial #	 NDC: 50458 591 50 PROD. CODE: 59150 CASE #: 12345
Prezista 600mg 24 Bottles Store at controlled room temperature 15° - 25°C (59° - 77°F) Protect from light and moisture EXP: MON YYYY LOT: 123456 QTY: 06  (17) YYMMDD (10) LLLLLL (30) 0006  N (01) 103 50458 591 50 4 (21) Serial #	 NDC: 50458 591 50 PROD. CODE: 59150 CASE #: 12345

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

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/gsm/kc/epcglobal/epcis/epcis_1_1-standard-20140520.pdf



Contact

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Thank you!