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1

## Drug Supply Chain Quality & Security Act (DSCSA) Information & Updates

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2

## Speaker Introduction – Teri Levitt

- Joined Vizient in October 2019 as a Product Advisor
- Holds Bachelors in Health Administration, Masters in Healthcare Informatics
- Prior experience includes various senior analytical roles in 340B audit & compliance and 340B operations as well as an inpatient pharmacy technician, gaining valuable insights into the dynamics of hospital operations
- 340B Apexus Certified Expert

3

## Agenda

- Pharmaceutical Supply Chain
- DSCSA Goals
- DSCSA Key Requirements
- Implementation Timeline
- Recent Policy Updates Late '21 & '22
- Summary & Recommendations
- Q&A

4

## Learning Objectives

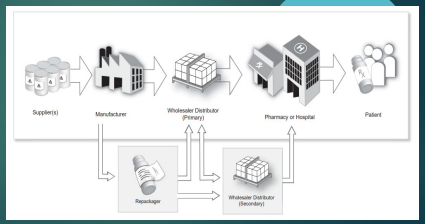
1) Summarize the key goals and requirements of the DSCSA
2) Explain how enhanced drug distribution security will help protect patients from exposure to drugs that may be counterfeit, contaminated, or otherwise harmful
3) Discuss the key complexities facing trading partners, in order to implement DSCSA requirements
4) Summarize the key takeaways from any proposed guidances & policies released in 2022

5

## Pharmaceutical Supply Chain

Maintaining integrity from manufacturer to patient(s)

- Who touches the product?
- Where are the vulnerabilities?
- What are the threats?




6

## Pharmaceutical Supply Chain Vulnerabilities

### Suspect & Illegitimate Product

- Counterfeit, diverted, stolen
- Subject of fraudulent transaction
- Intentionally adulterated or appears otherwise unfit for distribution such that would result in serious adverse health consequences or death

7

## Pharmaceutical Supply Chain Vulnerabilities *(continued)*

### Questionable Players

- Distribute illegitimate product
- Don't maintain quality of the product
- Don't maintain security or integrity of the supply chain

8

## DSCSA

Drug Quality & Security Act (DQSA)

- Title I: The Compounding Quality Act
- Title II: Drug Supply Chain Security Act (DSCSA)

- Enacted November 27, 2013
- Title II: DSCSA adds new sections in the Federal Food, Drug & Cosmetic (FD&C) Act
  - Definitions
  - Requirements
  - Standards for licensure for wholesale distributors & third-party logistics providers (3PLs)
  - Uniform national policy

9

## Goals Of The DSCSA

1) Implement interoperable, electronic tracing of products at the package level by 2023 that will:

- Enable secure tracing of product at the package level
- Use product identifiers to verify product at the package level
- Enable prompt response to suspect & illegitimate products when found
- Improve efficiency of recalls

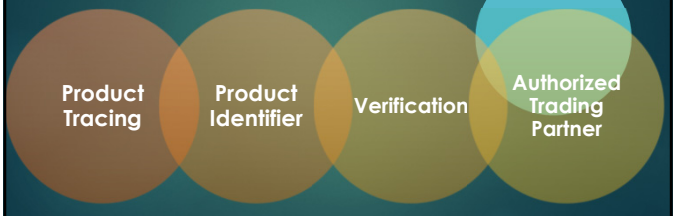
10

## Goals Of The DSCSA *(continued)*

2) Establish national standards for licensure for wholesale distributors and 3PLs

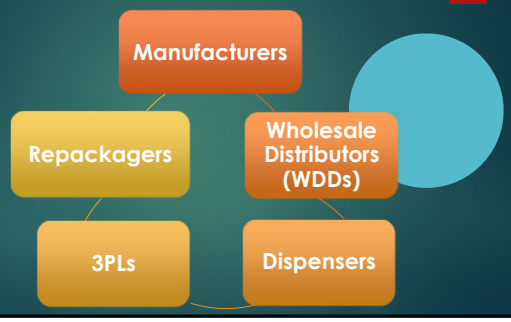
11

## DSCSA: Key Requirements




12

## DSCSA: Trading Partners




13

## Challenge Question #1

- Which of the following entities is **NOT** classified as a Trading Partner under the DSCSA?
  - a) Repackagers
  - b) Dispensers
  - c) Manufacturers
  - d) Wholesaler Distributors
  - e) None of the above

14

## Products - What's Covered?

- Prescription drug in finished dosage form for administration to a patient without further manufacturing, such as:
  - a) Capsules
  - b) Tablets
  - c) Lyophilized products (before reconstitution)

15

## Products - What's Exempt?

- Over-the-counter (OTC) Products
- Medical devices
- Blood products
- Imaging drugs
- Sterile water & products intended for irrigation
- Medical gas
- Certain IV products
- Drugs compounded in compliance with 503A or 503B

16

## Transactions - What's Covered?

- Prescription drug in finished dosage form
- Provide & receive product tracing information (T3):
  - Transaction Information (TI)
  - Transaction History (TH)
  - Transaction Statement (TS)

17

## Transactions - What's Exempt?

- Intracompany distributions
- Distribution among hospitals under common control
- Public health emergencies
- Dispenses pursuant to a prescription
- Product sample distribution

18

## What Is The T3?

### Transaction *Information* (TI)

- Product Name
- Strength & dosage form
- NDC Number
- Container size
- Number of containers
- Lot Number

19

## What Is The T3?

### Transaction *Information-TI (continued)*

- Transaction date
- Shipment date
- Business name & address of the entity from whom and to whom ownership is being transferred

20

## What Is The T3? *(continued)*

### Transaction *History* (TH)

- Paper or electronic statement
- Includes TI for each prior transaction back to the manufacturer

21

## What Is The T3? *(continued)*

### Transaction *Statement* (TS)

A paper or electronic attestation by the entity transferring ownership of the product that it:

- Is authorized as required under the DSCSA
- Received product from an authorized party
- Received TI & TS from a previous seller
- Did not knowingly ship suspect or illegitimate product
- Has systems & processes in place to perform verification
- Did not knowingly provide fraudulent TI & did not alter TH

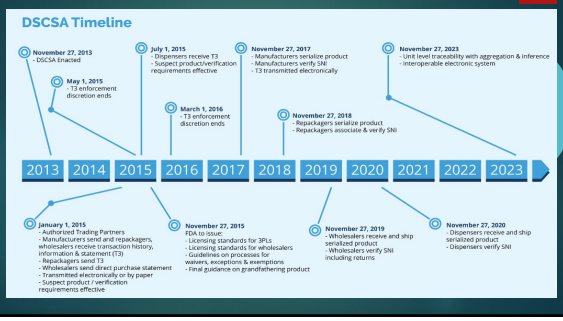
22

## Challenge Question #2

- Which of the following components comprise the required product tracing information (also known as T3), in order to maintain compliance under the DSCSA?
  - a) Transaction History (TH)
  - b) Transaction Statement (TS)
  - c) Transaction Information (TI)
  - d) All the above

23

## Implementation Timeline




24

## Implementation Milestones 2015

**Authorized Trading Partners**

- Manufacturers & Repackagers: registration with FDA
- WDDs & 3PLs: State or Federal license & compliance with reporting requirements
- Dispensers: State license

25

## Implementation Milestones 2015 *(continued)*

**Product Tracing**

- Lot-level
- Send & receive transaction documentation with each sale
- Store records
- Paper & electronic format

26

## Implementation Milestones 2015 *(continued)*

**Verification**

- Quarantine and investigate suspect and illegitimate product
- Notify FDA & trading partners of illegitimate product
- Response to verification requests
- Store records

27

## Implementation Milestones 2018 & Beyond

**Product Identification**

- Place product identifiers on prescription drug packages on the smallest individual saleable unit
- Product Identifier (Serialization):
  - National Drug Code (NDC)
  - Machine readable barcode
  - Expiration date
  - Serial number
  - Lot number

28

## Implementation Milestones 2018 & Beyond *(continued)*

**Verification**

- Serialized product can be verified down to the package level with product identifier
- Saleable returns
- Compliance policies issued that provide additional time

29

## Implementation Milestones 2023 & Beyond *(continued)*

Enhanced Drug Distribution Security Requirements

- All electronic
- Package level product tracing
- Enhanced verification

Enhanced System

- Enhanced drug distribution security
- Improved inspections & investigations
- Improved data analytics
- Continued compliance & enforcement

30

## Enhanced System Attributes

- Transaction Information (TI) & Transaction Statement (TS) will be exchanged in a secure, interoperable, electronic manner
- TI will include the product identifier at the **package level** for each package included in the transaction

31

## Enhanced System Attributes *(continued)*

- Systems & processes for:
  - Verification of product at the package level, including the standardized numerical identifier…which may include the use of aggregation & inference as necessary
  - Promptly responding with the TI & TS for a product upon a request by FDA (or other appropriate Federal or State official) in the event of a recall or for investigating a suspect product or an illegitimate product

32

## Enhanced System Attributes *(continued)*

- Systems & processes for:
  - Promptly facilitating gathering the information necessary to produce the TI for each transaction going back to the manufacturer, as applicable (upon a request by FDA or an authorized trading partner)
  - Allowing acceptance of saleable returns & only if such person can associate the saleable return product with the TI & TS associated with that product

33

## Challenge Question #3

- Which of the following statements is true about DSCSA requirements?
  - a) Verification includes quarantine & investigation of suspect product & quarantine & disposition of illegitimate product
  - b) When a trading partner identifies illegitimate product, it must notify the FDA & other immediate trading partners within 24 hours of making the determination
  - c) Product tracing changes in 2023 & the transaction information will need to include the data elements of the product identifier at the package level for each package
  - d) All the above

34

## Recent Policy Updates

- 6/3/21 Draft Guidance: Definitions of Suspect Product & Illegitimate Product for Verification Obligations
- 6/3/21 Final Guidance: Identification of Suspect Product & Notification
- 6/3/21 Final Guidance: Product Identifiers; Questions & Answers

35

## Recent Policy Updates *(continued)*

- 2/4/2022 Final Guidance: Drug Product Tracing: The Effect of Section 585 of the FD&C Act; Questions & Answers
- 3/10/2022 Draft Guidance: Verification Systems for Certain Prescription Drugs

36

## Challenge Question #4

- Which of the following topics has **NOT** been addressed in a Guidance published by the FDA in the last year?
  - a) Verification obligations for suspect and illegitimate products
  - b) Product identifiers
  - c) Prescription drug marketing
  - d) Verification systems for certain prescription drugs

37

## How DSCSA Protects Patients

**Prevent** harmful drugs from entering the supply chain

**Detect** harmful drugs if they enter the supply chain

**Respond** quickly when harmful drugs are found

38

## Recommendations To Prepare For The DSCSA

- Become familiar with the law
- Work with your trading partners to ensure they are familiar with the law
- Provide product tracing information
- Know how to handle suspect & illegitimate products
- Confirm authorized trading partners
- Report licensure to the FDA

39

## References


1) A Drug Supply Chain Example. (2011). Retrieved from U.S. Food and Drug Administration: https://www.fda.gov/media/81739/download
2) FDA (2022, May 25). Drug Supply Chain Security Act (DSCSA). Retrieved from U.S. Food & Drug Administration: https://www.fda.gov/drugs/drug-supply-chain-integrity/drug-supply-chain-security-act-dscsa
3) FDA (2022, May 25). Drug Supply Chain Security Act Law and Policies. Retrieved from U.S. Food & Drug Administration: https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/drug-supply-chain-security-act-law-and-policies
4) FDA (2022, April 22). Drug Supply Chain Security Act Webinars and Presentations . Retrieved from U.S Food & Drug Administration: https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/drug-supply-chain-security-act-webinars-and-presentations
5) Kundi, A., & Jung, C. (2021, October 5). Enhanced Drug Distribution Security In 2023. Retrieved from U.S. Food & Drug Administration: https://sbiaevents.com/files2/DSCSA-Webinar-October-2021.pdf
6) Solutions, B. P. (2018). The Race To The DSCSA Deadline. Retrieved from Bellwyck: https://bellwyck.com/the-race-to-the-dscsa-deadline


40

## Questions?

41