Understanding the Drug Supply Chain Security Act

A presentation for HealthTrust Members

June 11, 2024

Samantha Randlett, PharmD

PGY1 Managed Care Pharmacy Resident
Clinical Services Group

Preceptor: Troy Watson, PharmD – Director of Pharmacy, HCA Physician Services

HCA Healthcare®

Disclosures

- Neither the speaker, nor her preceptor, or planners for this educational activity have relevant financial relationships to disclose with ineligible companies.
- Note: This program may contain the mention of suppliers, brand products, services, or drugs presented in a case study or comparative format using evidence-based research. Such examples are intended for educational and informational purposes only and should not be perceived as an endorsement of any particular supplier, brand, product, service or drugs.
- The content presented is for informational purposes only & is based upon the presenter(s) knowledge & opinion. It should not be relied upon without independent consultation with & verification by appropriate professional advisors. Individuals & organizations shall have sole responsibility for any actions taken in connection with the content herein. HealthTrust, the program presenter(s) & their employers expressly disclaim any & all warranties as to the content as well as any liability resulting from actions or omissions of any individual or organization in reliance upon the content

Learning Objectives

1. Recall rationale for the implementation of the Drug Supply Chain Security Act (DSCSA) for manufacturers and pharmacies

2. Recognize key supply chain security requirements under the DSCSA

3. Identify the expectations of trading partners during the stabilization period under the DSCSA

*For an in-depth definition of each term according to the DSCSA public law, please refer to the appendix.

Important Key Terms*

- Authorized Trading Partner
- Dispenser
- Distribute or Distribution
- Homogenous Case
- Illegitimate Product
- Manufacturer
- Product
- Product Identifier
- Quarantine
- Repackager
- Standardized Numerical Identifier
- Suspect Product
- Third-Party Logistics Provider
- Trading Partner
- Transaction
  - Transaction history (TH)
  - Transaction information (TI)
  - Transaction statement (TS)
- Wholesale Distributor

Important Key Term Definitions

- **Authorized**: “in the case of a manufacturer or repackager, having a valid registration in accordance with section 510; “in the case of a wholesale distributor, having a valid license under State law and complying with the licensure reporting requirements under section 503(e), as amended by the Drug Supply Chain Security Act; in the case of a third-party logistics provider, having a valid license under State law and complying with the licensure reporting requirements under section 584(b); and in the case of a dispenser, having a valid license under State law.”
- **Distribute or Distribution**: “the sale, purchase, trade, delivery, handling, storage, or receipt of a product, and does not include the dispensing of a product pursuant to a prescription executed in accordance with section 503(b)(1) or the dispensing of a product approved under section 512(b).”
- **Illegitimate Product**: “a product for which credible evidence shows that the product is counterfeit, diverted, or stolen; is intentionally adulterated such that the product would result in serious adverse health consequences or death to humans; is the subject of a fraudulent transaction; or appears otherwise unfit for distribution such that the product would be reasonably likely to result in serious adverse health consequences or death to humans.”
- **Product Identifier**: “a standardized graphic that includes, in both human readable form and on a machine-readable data carrier that conforms to the standards developed by a widely recognized international standards development organization, the standardized numerical identifier, lot number, and expiration date of the product.”
- **Quarantine**: “the storage or identification of a product, to prevent distribution or transfer of the product, in a physically separate area clearly identified for such use or through other procedures.”

Source: Drug Supply Chain Security Act of 2013, Pub. L. No. 113-54. 127 STAT. 599. (2013). https://www.govinfo.gov/content/pkg/PLAW-113publ54/pdf/PLAW-113publ54.pdf

Rationale for Implementation of DSCSA

HCA Healthcare®

Pharmaceutical Supply Chain

Process

Suppliers (APIs and raw materials) → FDA approved manufacturers → Wholesalers → Hospital/ Pharmacies → Patients

Questions

1. Who has touched the product?
2. Where has this product been?
3. Where are the vulnerabilities/weaknesses?
    A. Such as proper storage according to the package insert

Importance

- Many players to ensure the correct product is available for the correct patient.
- By maintaining integrity throughout the pharmaceutical supply chain, it guarantees the product is protected as well as the patient.

Source: Bilton L. Pharma Supply Chain: A comprehensive guide to the pharmaceutical supply chain. PharmaSource. Published February 29, 2020. https://pharmasource.global/content/pharma-supply-chain-a-comprehensive-guide-to-the-pharmaceutical-supply-chain/

Rea

AVOID COUNTERFEI

No Co From Coun

By Be Safe Team • Se

No country is imm country, from Aus Organization for E countries from wh Hong Kong, Singa known to have a h are also prevalent

Am J Trop Med Hyg. 2015 Jun 3; 92(Suppl 6): 59–67.
doi: 10.4269/aitmh.14-0389

PMCID: PMC4455087
PMID: 25897059

Counterfeit Version of Botox Found in Multiple States

Chains: A Global

Share | Post | Linkedin | Email | Print

Go to:

[redacted]

g the

ces. Of ountry erfeit

s were chain ıth needs to

en Español

[4-16-2024] FDA is alerting health care professionals and consumers that unsafe counterfeit versions of Botox (botulinum toxin) have been found in multiple states and administered to consumers for cosmetic purposes.

FDA is aware of adverse events, including hospitalizations, linked to the counterfeit Botox. Symptoms included blurred or double vision, difficulty swallowing, dry mouth, constipation, incontinence, shortness of breath, weakness and difficulty lifting one's head following injection of these products. These symptoms are similar to those seen when botulinum toxin spreads to other parts of the body.

Source(s): No Country is Immune From The Threat of Counterfeit Drugs. - (fakemedicinenomore.org); Counterfeit Version of Botox Found in Multiple States | FDA; Counterfeit Drug Penetration into Global Legitimate Medicine Supply Chains: A Global Assessment - PMC (nih.gov); Feds seize "staggering" amount of meth in fake Adderall pills laced with it - CBS News; FDA warns consumers not to use counterfeit Ozempic (semaglutide) found in U.S. drug supply chain | FDA

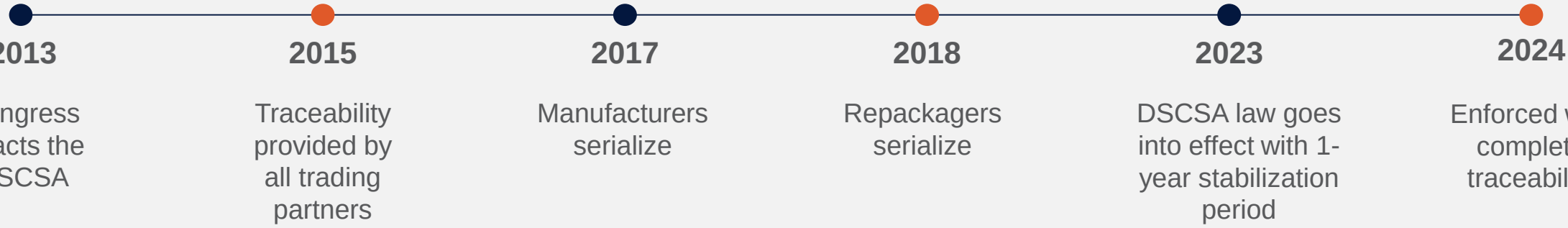
HCA Healthcare®

DSCSA Overview

PUBLIC LAW 113–54—NOV. 27, 2013

TITLE II—DRUG SUPPLY CHAIN SECURITY

- In 2013, the U.S. Food and Drug Administration (FDA) enacted the Drug Supply Chain Security Act (DSCSA), also referred to as Title II of the Drug Quality and Security Act (DRQA), with the intention of establishing an electronic, interoperable tracing system through the pharmaceutical distribution supply chain on prescription drug products.
- DSCSAs goal is to improve the oversight over those entities involved in the storage and distribution of prescription drugs and will ensure they are authorized to do so to protect consumers from exposure to drugs that could have been contaminated or otherwise harmful to humans.



Sources: Center for Drug Evaluation and Research. Drug Supply Chain Security Act (DSCSA). U.S. Food and Drug Administration. Published 2019. https://www.fda.gov/drugs/drug-supply-chain-integrity/drug-supply-chain-security-act-dscsa. Drug Supply Chain Security Act of 2013, Pub. L. No. 113-54. 127 STAT. 599. (2013). https://www.govinfo.gov/content/pkg/PLAW-113publ54/pdf/PLAW-113publ54.pdf

Scope of the Law

Product

- What's covered:
  - "Prescription drugs in finished dosage form for administration to a patient without further manufacturing (such as capsules, tablets, and lyophilized products before reconstitution)."
- What is NOT covered:*
  - Blood or blood components intended for transfusion
  - Radioactive drugs or radioactive biological products
  - Imaging drugs
  - Certain IV products
  - Any medical gas
  - Homeopathic drugs
  - Drug compounded in compliance with section 503A or 503B

Transaction

- "the transfer of product between persons in which a change of ownership occurs."
  - The term 'transaction' does not include:
    - Intracompany distribution
    - Distribution among hospitals under common control
    - Pubic health emergencies
    - Dispensed pursuant to a prescription
    - Product sample distribution
    - Distribution of blood and blood components for transfusion
    - Minimal quantities by a licensed retail pharmacy to a licensed practitioner for office use
    - Certain activities by charitable organizations
    - Distributions pursuant to a merger or sale
    - Certain combination products, medical kits, and IV products
    - Medical gas distribution
    - Approved animal drugs

*This is not a all inclusive list, please refer to section 582 of the food drug and cosmetic act for the specific exemption list.

Source: Drug Supply Chain Security Act of 2013, Pub. L. No. 113-54. 127 STAT. 599. (2013). https://www.govinfo.gov/content/pkg/PLAW-113publ54/pdf/PLAW-113publ54.pdf

HCA Healthcare®

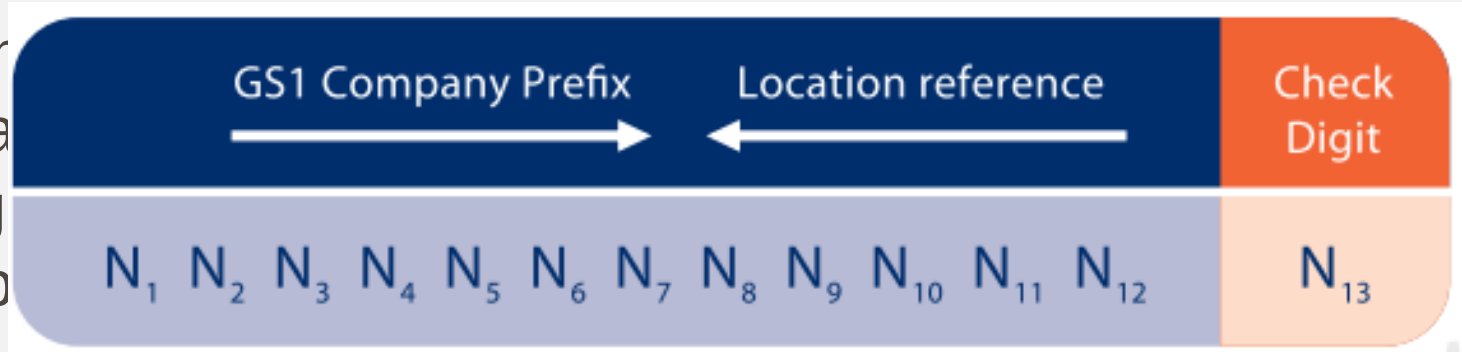
Importance Codes/Numbers To Keep In Mind

Electronic Product Code Information Services (EPCIS)

- Data-sharing interface that enables supply chain partners to capture and communicate data about the movement and status of objects in the supply chain.

Global Location Number (GLN)

- Globally unique 13-digit nur
  access master data about a
  communication with trading
  operational locations, and p



Source: GS1. “Global Location Number (GLN) | GS1.” *Www.gs1.org*, www.gs1.org/standards/id-keys/gln.

HCA Healthcare®

Importance Codes/Numbers To Keep In Mind

Global Trade Item Number (GTIN)

- Globally unique GS1 identification key used to identify “trade items”. GTINs are assigned by the brand owner of the product to uniquely identify a product at each packaging level (ex. A bottle of 100 aspirin tablets versus a case of 200 bottles of aspirin tablets)

Global Company Prefix (GCP)

- Unique string of 6-11 digits issued to your company by your local GS1 member organization. Allows enumeration of other GS1 identifiers like GTINs and GLNs.

Sources: GS1. GTIN Management | GS1 - The global language of business. www.gs1.org. Accessed May 17, 2024. https://www.gs1.org/1/gtinrules/en/decision-support. GS1. GS1 Company Prefix | GS1. www.gs1.org. Accessed May 17, 2024. https://www.gs1.org/standards/id-keys/company-prefix

Assessment Question #1

Why was Title II of the Drug Quality and Security Act (DQSA), DSCSA, enacted by the United States Congress?

A. To establish an electronic, interoperable tracing system through the pharmaceutical distribution supply chain on prescription drug products.

B. To improve the oversight over those entities involved in the storage and distribution of prescription drugs and will ensure they are authorized to do so.

C. To establish national standards for licensure for wholesale distributors and third-party logistics providers.

D. All of the above

Assessment Question #1: Correct Resp

Why was Title II of the Drug Quality and Security Act (DQSA), DSCSA, enacted by the United States Congress?

A. To establish an electronic, interoperable tracing system through the pharmaceutical distribution supply chain on prescription drug products.

B. To improve the oversight over those entities involved in the storage and distribution of prescription drugs and will ensure they are authorized to do so.

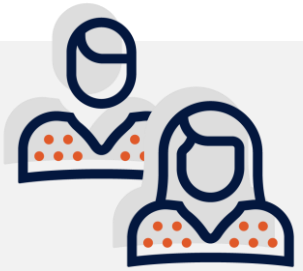
C. To establish national standards for licensure for wholesale distributors and third-party logistics providers.

D. All of the above

The Key Supply Chain Security Requirements

HCA Healthcare®

Overview

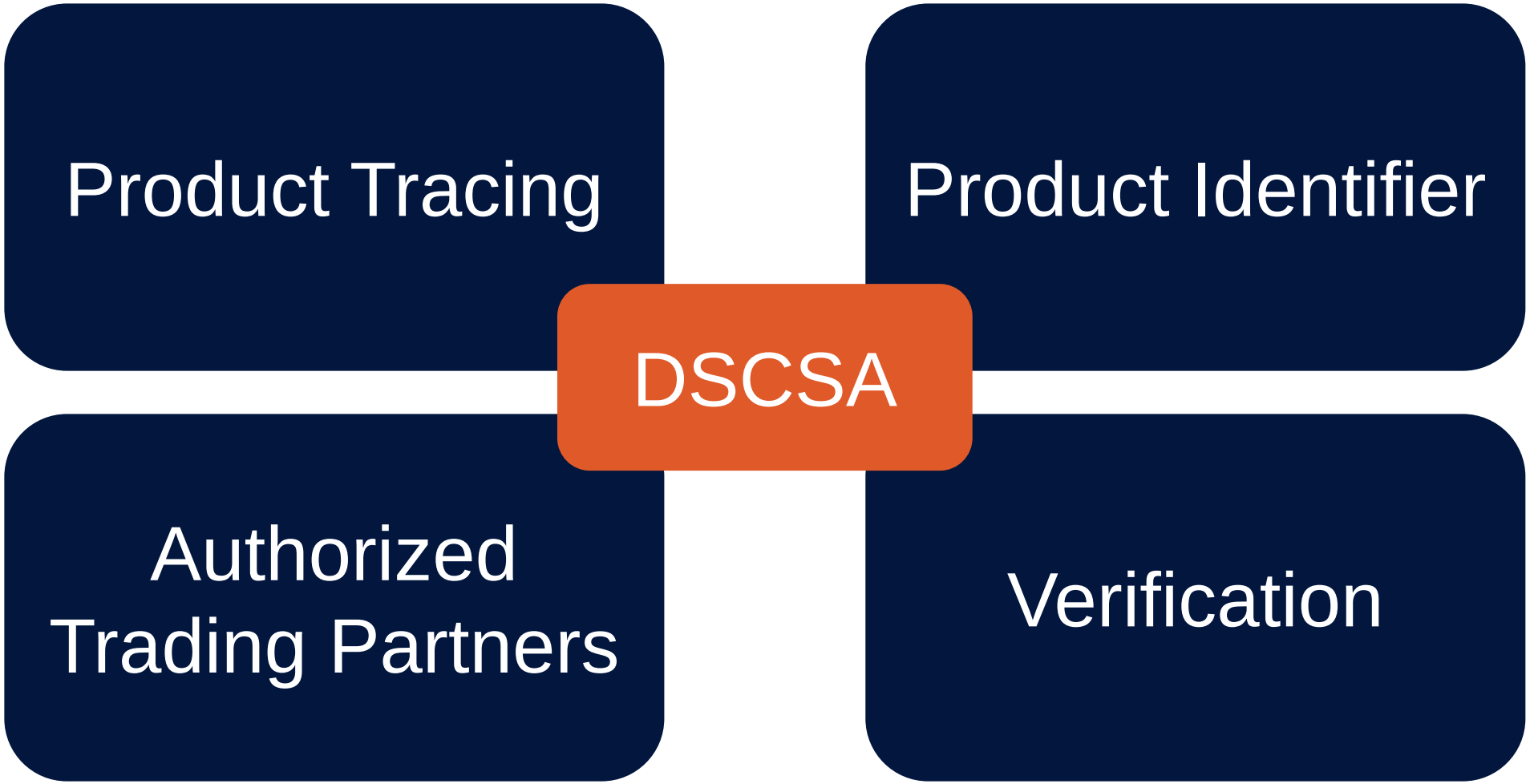


If we can protect the product… **…we can protect the patients!**

- With these new requirements, the drug supply chain will be:
  - More transparent and held accountable
  - Enable quick response to suspect and illegitimate products
  - Improve efficiency of recalls

Source: Drug Supply Chain Security Act of 2013, Pub. L. No. 113-54. 127 STAT. 599. (2013). https://www.govinfo.gov/content/pkg/PLAW-113publ54/pdf/PLAW-113publ54.pdf

Key Requirements of DSCSA



Source: Drug Supply Chain Security Act of 2013, Pub. L. No. 113-54. 127 STAT. 599. (2013). https://www.govinfo.gov/content/pkg/PLAW-113publ54/pdf/PLAW-113publ54.pdf

Product Tracing

Trading partners exchange transaction information, history and statement (3T)

FDA established standards for the exchange of transaction documentation:

Transaction Information (TI) = The Specifics

- Name of the product
- Dose & Strength
- NDC
- Lot number
- Date of transaction
- Date of shipment
- Container information
- Number of containers

Transaction History (TH) = The Outline

- Outlines all of the transactions a product has gone through starting from the manufacture

Transaction Statement (TS) = The Declaration

- Confirms the seller is authorized, received the product from a registered party, did not purposefully change anything or alter any part of the product, and has acknowledged the transaction statement from the previous seller

Source: Drug Supply Chain Security Act of 2013, Pub. L. No. 113-54. 127 STAT. 599. (2013). https://www.govinfo.gov/content/pkg/PLAW-113publ54/pdf/PLAW-113publ54.pdf

Product Identifier (serialization)

A unique product identifier must be placed on certain prescription drug packages (in human and machine readable format)

Example of 2D data matrix barcode

- NDC
- Serial number
- Lot number
- Expiration date

Standardized Numerical Identifier (SNI)

Human-readable Format

NDC: [insert]
SERIAL: [insert]
LOT: [insert]
EXP: [insert]

Machine-readable Format

- 2-dimensional (2D) data matrix barcode when affixed to or printed on a package
- Linear or 2D data matrix barcode when affixed to or printed on a homogenous case

Source: Drug Supply Chain Security Act of 2013, Pub. L. No. 113-54. 127 STAT. 599. (2013). https://www.govinfo.gov/content/pkg/PLAW-113publ54/pdf/PLAW-113publ54.pdf

“Authorized” Trading Partners

Manufacturers

- Valid registration with FDA

Wholesale Distributors

- Valid State or Federal license and compliance with reporting requirements

Dispensers

- Valid State license

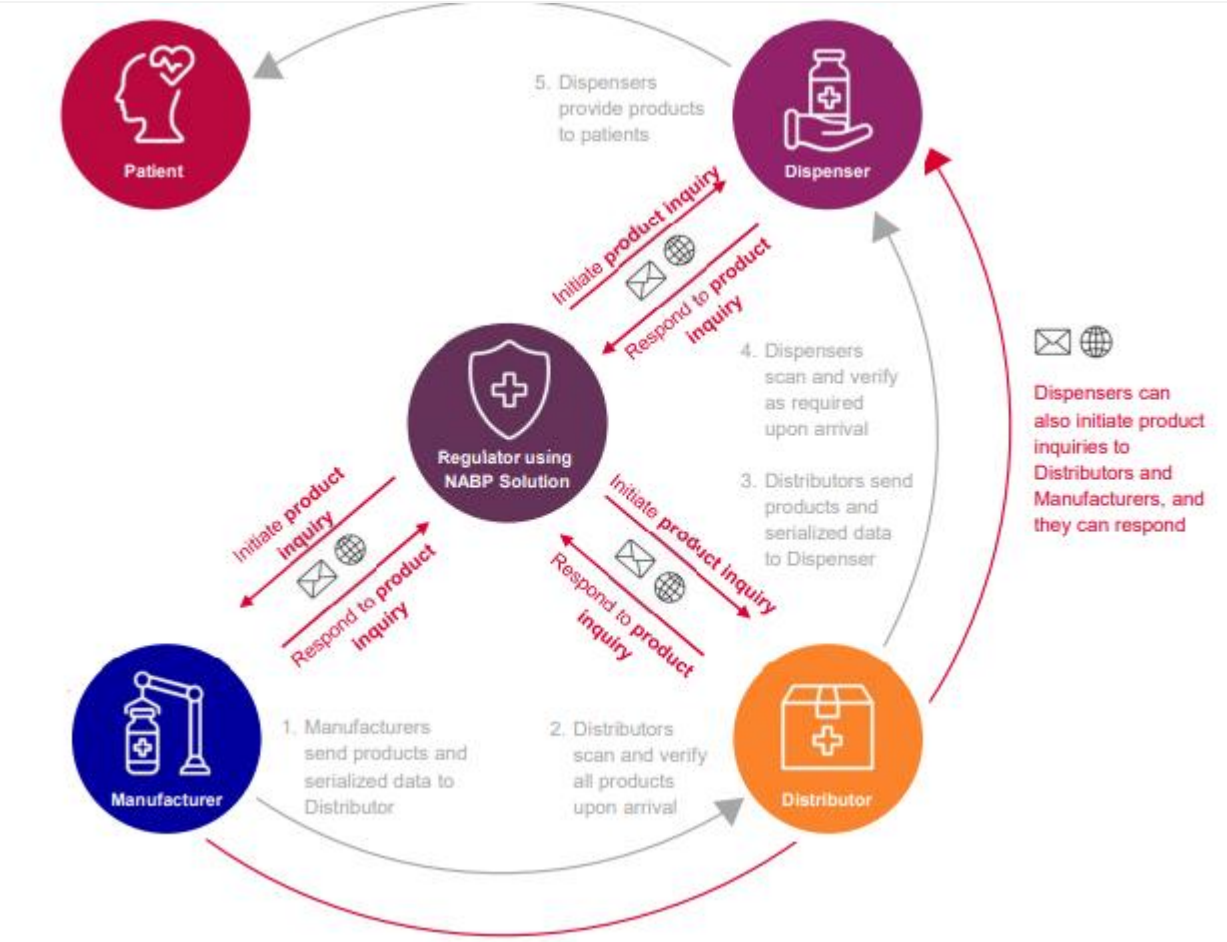
Repackagers

- Valid registration with FDA

Source: Drug Supply Chain Security Act of 2013, Pub. L. No. 113-54. 127 STAT. 599. (2013). https://www.govinfo.gov/content/pkg/PLAW-113publ54/pdf/PLAW-113publ54.pdf

“Authorized” Trading Partners

How to ensure your trading partners are authorized



- Sign up for updates at www.pulse.pharmacy
- Allows for easy communication
- Can easily check state licenses and Authorized Trading Partner status

Source: National Association of Boards of Pharmacy. Pulse by NABP | DSCSA Solutions | DSCSA Compliance Software. National Association of Boards of Pharmacy. Accessed May 17, 2024. https://nabp.pharmacy/pulse/solutions/

Verification

Determining whether the product identifier corresponds to the SNI or lot number AND expiration date assigned to the product by the manufacturer or repackager

WHO

- Manufacturers*
- Wholesale Distributors*
- Dispensers
- Repackagers*

WHY

- Due to the pharmaceutical supply chain vulnerabilities & weaknesses

WHAT

- To identify and determine whether a product is a suspect product
- To clear a product for distribution

*indicates additional requirements for these trading partners

Source: Drug Supply Chain Security Act of 2013, Pub. L. No. 113-54. 127 STAT. 599. (2013). https://www.govinfo.gov/content/pkg/PLAW-113publ54/pdf/PLAW-113publ54.pdf

Verification

"Why"

Weaknesses and/or threats to the pharmaceutical supply chain can occur in two main buckets: **Illegitimate Products** and **Fraudulent Players**

Illegitimate Product

"credible evidence shows that the product is counterfeit, diverted, or stolen; intentionally adulterated such that the product would result in serious adverse health consequences or death to humans; subject of a fraudulent transaction; or appears otherwise unfit for distribution such that it would be reasonably likely to result in serious adverse health consequences or death to humans

Fraudulent Players

- Does the package or container seem suspicious?
- Does it use foreign terms or is missing information?
- Is the product being distributed legitimate?
- Did the product maintain quality and security throughout supply chain?

Source: Drug Supply Chain Security Act of 2013, Pub. L. No. 113-54. 127 STAT. 599. (2013). https://www.govinfo.gov/content/pkg/PLAW-113publ54/pdf/PLAW-113publ54.pdf

Verification

What to do if a product is deemed suspect or illegitimate

Must maintain records related to suspect product investigations and illegitimate product for a minimum of 6 years

- When a product is deemed as illegitimate or suspected of adulteration, the trading partner shall **quarantine** such product until such product is cleared or dispositioned.
- The trading partner must promptly conduct an **investigation** in coordination with the manufacturer that the product came from to determine whether the product is an illegitimate product.
  - This includes validating any applicable transaction history and transaction information.
- Upon determining that a product is illegitimate, the **trading partner shall notify the FDA and all immediate trading partners not later than 24 hours after making such determination.**

Source: Drug Supply Chain Security Act of 2013, Pub. L. No. 113-54. 127 STAT. 599. (2013). https://www.govinfo.gov/content/pkg/PLAW-113publ54/pdf/PLAW-113publ54.pdf

Verification

How To Report an Illegitimate or Suspect Product

If a product is deemed to be illegitimate or suspected of adulteration, the dispenser must notify all trading partners and the FDA via **Form 3911 within 24 hours.**

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Drug Notification

Form Approved: OMB No. xxxx-xxxx
Expiration Date: Xxxxxxx xx, 201x
See PRA Statement on page 2.

Refer to instruction sheet (Form FDA 3911 Supplement) for more information.

1. Type of Report *(Select one)*: ☐ Initial Notification ☐ Follow-Up Notification ☐ Request for Termination

2. Incident Number *(Provide this number, assigned by FDA, if you selected Follow-up Notification or Request for Termination above; see instructions.)*

3. Date of Initial Notification *(mm/dd/yyyy)*	4. Date Company Determined Product Was Illegitimate *(mm/dd/yyyy)*	5. Classification of Notification *(Select from list)*

Description of Product

6. Name of Product as It Appears on Label

Source: Drug Supply Chain Security Act of 2013, Pub. L. No. 113-54. 127 STAT. 599. (2013). https://www.govinfo.gov/content/pkg/PLAW-113publ54/pdf/PLAW-113publ54.pdf

Assessment Question #2

In order to be compliant with DSCSA, if a product is deemed to be illegitimate or suspected of adulteration what must the dispenser do?

A. Notify all trading partners and the FDA via Form 3911 within 24 hours

B. Notify all trading partners and the FDA via Form 1139 within 48 hours

C. Notify all trading partners and the FDA via Form 3900 within 24 hours

D. Notify all trading partners and the FDA via Form 1193 within 48 hours

Assessment Question #2: Correct Resp

In order to be compliant with DSCSA, if a product is deemed to be illegitimate or suspected of adulteration what must the dispenser do?

A. Notify all trading partners and the FDA via Form 3911 within 24 hours

B. Notify all trading partners and the FDA via Form 1139 within 48 hours

C. Notify all trading partners and the FDA via Form 3900 within 24 hours

D. Notify all trading partners and the FDA via Form 1193 within 48 hours

The Expectations of Trading Partners during the Stabilization Period

HCA Healthcare®

Overview

The "Why" Behind the Stabilization Period

The stabilization period accommodates an **additional 1 year**, until November 27, 2024, to allow trading partners to implement, troubleshoot and mature their electronic interoperable systems in hopes to **avoid disruption** to the supply chain once fully implemented.

"*FDA is committed to successful implementation of interoperable systems required under the DSCSA*," said Leigh Verbois, director of CDER's Office of Drug Security, Integrity and Response.

Source: Research, Center for Drug Evaluation. DSCSA compliance policies establish 1-year stabilization period for implementing electronic systems. *FDA.* Published online 30, 2023. https://www.fda.gov/drugs/drug-safety-and-availability/dscsa-compliance-policies-establish-1-year-stabilization-period-implementing-electronic-systems

Responsibilities of Manufacturers Under DSCSA

A manufacturer is defined as "with respect to a product, a person that holds an application approved under section 505 or a license issued under section 351 of the Public Health Service Act for such product, or if such product is not the subject of an approved application or license, the person who manufactured the product; a co-licensed partner of the person that obtains the product directly from a person; an affiliate of a person that receives the product directly from a person."

Key Takeaways:

1. Ensure all suppliers are **authorized trading partners.**
2. Develop a system to affix or imprint a product identifier to each package or homogenous case.
3. Have systems in place to enable verification of suspect or illegitimate products.
4. Way to capture all transaction history.

Source: Drug Supply Chain Security Act of 2013, Pub. L. No. 113-54. 127 STAT. 599. (2013). https://www.govinfo.gov/content/pkg/PLAW-113publ54/pdf/PLAW-113publ54.pdf

Responsibilities of Wholesaler Under DSCSA

A wholesaler is “a person (other than a manufacturer, a manufacturer’s co-licensed partner, a third-party logistics provider, or repackager) engaged in wholesale distribution (as defined in section 503(e)(4), as amended by the Drug Supply Chain Security Act).”

Key Takeaways:

1. Ensure all suppliers are **authorized trading partners.**
2. Take in serialized data for products and distribute products with associated data to dispensers.
3. Have systems in place to enable verification of suspect or illegitimate products.
4. Way to capture all transaction history.

Source: Drug Supply Chain Security Act of 2013, Pub. L. No. 113-54. 127 STAT. 599. (2013). https://www.govinfo.gov/content/pkg/PLAW-113publ54/pdf/PLAW-113publ54.pdf

Responsibilities of Dispensers Under DSCSA

Pharmacists Role

A dispenser is “a retail pharmacy, hospital pharmacy, a group of chain pharmacies under common ownership and control that do not act as a wholesale distributor, or any other person authorized by law to dispense or administer prescription drugs, and the affiliated warehouses or distribution centers of such entities under common ownership and control that do not act as a wholesale distributor”.

Key Takeaways:

1. Ensure all suppliers are **authorized trading partners.**
2. Develop organizational **policies** and **procedures** for addressing DSCSA compliance to help employees understand their roles.
   A. Where are you storing product tracing information?
   B. What to do if a product is identified as suspect or illegitimate

Source: Drug Supply Chain Security Act of 2013, Pub. L. No. 113-54. 127 STAT. 599. (2013). https://www.govinfo.gov/content/pkg/PLAW-113publ54/pdf/PLAW-113publ54.pdf

340B Facilities & Contract Pharmacies

The 340B program is a US federal government program that requires drug manufacturers to provide outpatient drugs at discounted prices to eligible health care organizations and covered entities (those who care for vulnerable patients in some of the most underserved areas).

*MUST know contract pharmacy's Managed GLN

Source: How Will Serialization Affect 340B Pharmacies? TraceLink. Accessed May 17, 2024. https://www.tracelink.com/resources/resource-center/how-will-serialization-affect-340b-pharmacies

Transferring of Products

"transaction" where change in ownership occurs

Common Question: Does my pharmacy need a wholesaler license to transfer products?

A. If your pharmacy is transferring through owned facilities, then **no**.

B. Due to the 5% Transfer Rule not applying to DSCSA, if your pharmacy is engaging in any distribution activities that are not classified as exempt or exceptions, then **yes**.

Specific Patient Need

- Exempt but documentation is a good idea.
- Transfer of a product from one pharmacy to another to fill a prescription for an identified patient does not include the transfer of a product with the intent to replenish.

Source: Drug Supply Chain Security Act of 2013, Pub. L. No. 113-54. 127 STAT. 599. (2013). https://www.govinfo.gov/content/pkg/PLAW-113publ54/pdf/PLAW-113publ54.pdf

Responsibilities of Repackagers Under DSCSA

A repackager "means a person who owns or operates an establishment that repacks and relabels a product or package for further sale; or distribution without a further transaction."

*expected to know Ship To GLN

Key Takeaways:

1. Only accept ownership of a product that has transaction data.
2. Provide all transaction data to subsequent owner.
3. Maintain such information, history, and statement for not less than 6 years after the transaction.

Source: Drug Supply Chain Security Act of 2013, Pub. L. No. 113-54. 127 STAT. 599. (2013). https://www.govinfo.gov/content/pkg/PLAW-113publ54/pdf/PLAW-113publ54.pdf

Overview

What the Stabilization Period is Not

The FDA expects this **additional 1 year**, until November 27, 2024, to be utilized to build and validate and **should not** be viewed as providing justification for delaying efforts to comply with DSCSA.

"We have heard concerns about supply chain readiness, and we believe that some flexibility will support successful implementation and lead to a stronger and safer drug supply chain." said Leigh Verbois, director of CDER's Office of Drug Security, Integrity and Response.

Source: Research, Center for Drug Evaluation. DSCSA compliance policies establish 1-year stabilization period for implementing electronic systems. *FDA.* Published online 30, 2023. https://www.fda.gov/drugs/drug-safety-and-availability/dscsa-compliance-policies-establish-1-year-stabilization-period-implementing-electronic-systems.

Overview

Available Solutions

There are many solutions providers available for your company, however, a solutions provider is not required by law but can be helpful.

Educate yourself as well as your employees to ensure you chose the best solutions provider for your company.

Solutions Provider Insight

Real Life Experience Hurdles

- Setting up connections (length of time it takes to set up receiving data, lots of delay on data getting to facility after delivery truck arrives)
- Workflow changes
- Delays in creating education
- Pilot process – delays due to equipment, hardware, and data

Solutions Provider Insight

Real Life Experience Helpful Tips

- Take advantage of every and all webinars that your solutions provider is hosting
- Put together a timeline on implementation goals – including pilot locations, delivery of scanners (if applicable), education updates, etc
- Develop standard operating procedures (SOPs) to help all employees understand roles and responsibilities
- Schedule meetings with your solutions provider to understand where the industry is at (ex. Are certain companies files failing or having data issues?)

Assessment Question #3

What role can pharmacists play during the 1-year stabilization period under DSCSA?

A. Are relieved of obligations as a dispenser

B. Develop organizational policies and procedures for addressing DSCSA dispenser requirements

C. NOT educate staff regarding DSCSA requirements

D. Purchase prescription pharmaceutical products only from NON-verified primary wholesale distributors or manufacturers

Assessment Question #3: Correct Resp

What role can pharmacists play during the 1-year stabilization period under DSCSA?

A. Are relieved of obligations as a dispenser

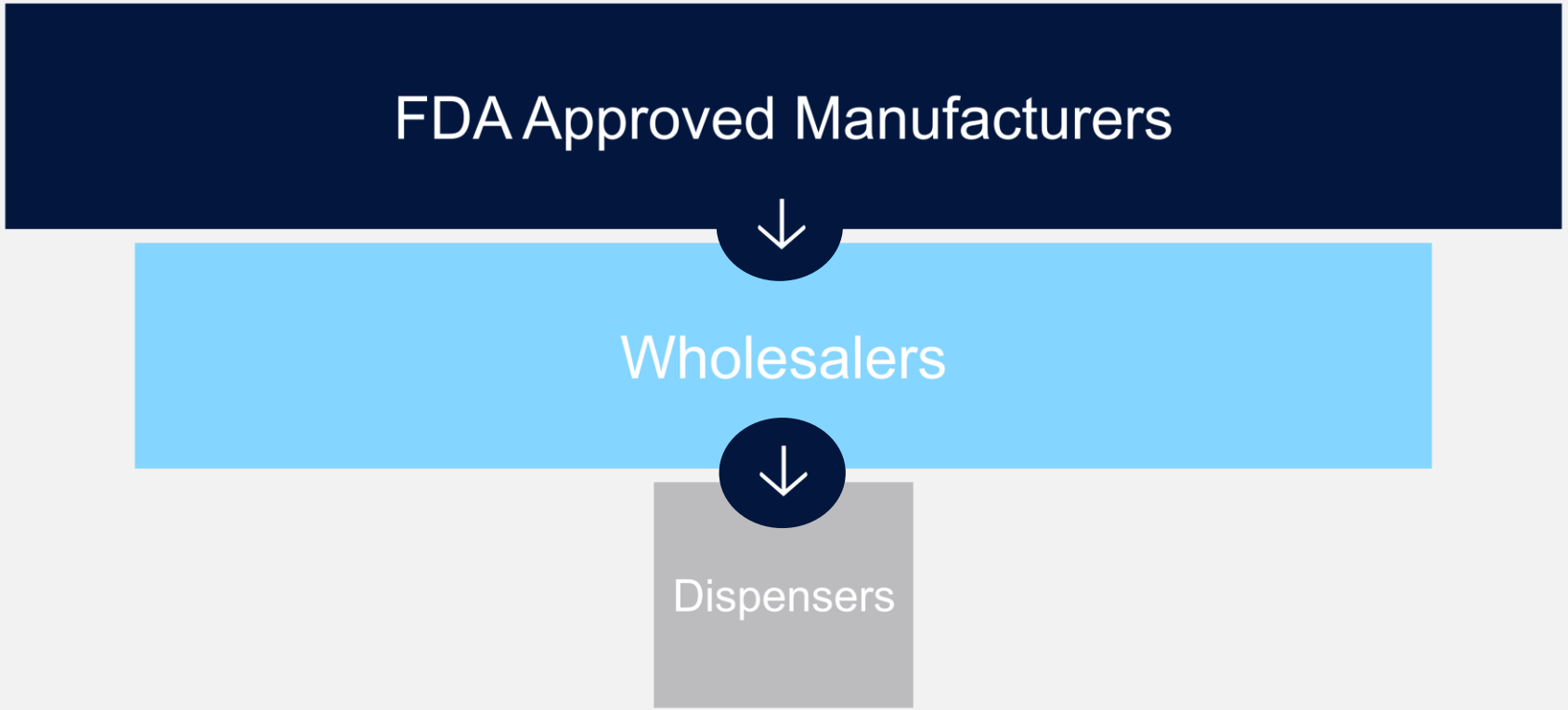
B. Develop organizational policies and procedures for addressing DSCSA dispenser requirements

C. NOT educate staff regarding DSCSA requirements

D. Purchase prescription pharmaceutical products only from NON-verified primary wholesale distributors or manufacturers

Where is the industry at right now?

Data Exchange & Readiness



Summary

DSCSA was initially enacted in 2013 with the intent to provide transparency and accountability within the pharmaceutical supply chain. Trading partners will now be required to trace and verify products to ensure integrity.

Not all products are considered under this law. Refer to section 582 of the food drug and cosmetic act for the specific exemption list.

The key requirements to the DSCSA are authorized trading partners, verification, product tracing, and product identification.

If at any point a product is deemed illegitimate or suspicious, the dispenser must contact all trading partners and the FDA (via a Form 3911) within 24 hours.

Appendix

- **Authorized**: “in the case of a manufacturer or repackager, having a valid registration in accordance with section 510; ‘‘in the case of a wholesale distributor, having a valid license under State law and complying with the licensure reporting requirements under section 503(e), as amended by the Drug Supply Chain Security Act; in the case of a third-party logistics provider, having a valid license under State law and complying with the licensure reporting requirements under section 584(b); and in the case of a dispenser, having a valid license under State law.”
- **Dispenser**: “a retail pharmacy, hospital pharmacy, a group of chain pharmacies under common ownership and control that do not act as a wholesale distributor, or any other person authorized by law to dispense or administer prescription drugs, and the affiliated warehouses or distribution centers of such entities under common ownership and control that do not act as a wholesale distributor”.
- **Distribute or Distribution**: “means the sale, purchase, trade, delivery, handling, storage, or receipt of a product, and does not include the dispensing of a product pursuant to a prescription executed in accordance with section 503(b)(1) or the dispensing of a product approved under section 512(b).”
- **Homogenous Case**: “a sealed case containing only product that has a single National Drug Code number belonging to a single lot.”
- **Illegitimate Product**: “means a product for which credible evidence shows that the product is counterfeit, diverted, or stolen; is intentionally adulterated such that the product would result in serious adverse health consequences or death to humans; is the subject of a fraudulent transaction; or appears otherwise unfit for distribution such that the product would be reasonably likely to result in serious adverse health consequences or death to humans.”

Source: Drug Supply Chain Security Act of 2013, Pub. L. No. 113-54. 127 STAT. 599. (2013). https://www.govinfo.gov/content/pkg/PLAW-113publ54/pdf/PLAW-113publ54.pdf

Appendix

- **Manufacturer**: “with respect to a product, a person that holds an application approved under section 505 or a license issued under section 351 of the Public Health Service Act for such product, or if such product is not the subject of an approved application or license, the person who manufactured the product; a co-licensed partner of the person that obtains the product directly from a person; an affiliate of a person that receives the product directly from a person.”
- **Product**: “means a prescription drug in a finished dosage form for administration to a patient without substantial further manufacturing (such as capsules, tablets, and lyophilized products before reconstitution), but for purposes of section 582, does not include blood or blood components intended for transfusion, radioactive drugs or radioactive biological products (as defined in section 600.3(ee) of title 21, Code of Federal Regulations) that are regulated by the Nuclear Regulatory Commission or by a State pursuant to an agreement with such Commission under section 274 of the Atomic Energy Act of 1954 (42 U.S.C. 2021), imaging drugs, an intravenous product described in clause (xiv), (xv), or (xvi) of paragraph (24)(B), any medical gas (as defined in section 575), homeopathic drugs marketed in accordance with applicable guidance under this Act, or a drug compounded in compliance with section 503A or 503B.”
- **Product Identifier**: “means a standardized graphic that includes, in both human readable form and on a machine-readable data carrier that conforms to the standards developed by a widely recognized international standards development organization, the standardized numerical identifier, lot number, and expiration date of the product.”
- **Quarantine**: “means the storage or identification of a product, to prevent distribution or transfer of the product, in a physically separate area clearly identified for such use or through other procedures.”
- **Repackager**: “means a person who owns or operates an establishment that repacks and relabels a product or package for further sale; or distribution without a further transaction.”

Source: Drug Supply Chain Security Act of 2013, Pub. L. No. 113-54. 127 STAT. 599. (2013). https://www.govinfo.gov/content/pkg/PLAW-113publ54/pdf/PLAW-113publ54.pdf

Appendix

- **Standardized Numerical Identifier**: “The term ‘standardized numerical identifier’ means a set of numbers or characters used to uniquely identify each package or homogenous case that is composed of the National Drug Code that corresponds to the specific product (including the particular package configuration) combined with a unique alphanumeric serial number of up to 20 characters.”
- **Suspect Product**: “a product for which there is reason to believe that such product is potentially counterfeit, diverted, or stolen; is potentially intentionally adulterated such that the product would result in serious adverse health consequences or death to humans; is potentially the subject of a fraudulent transaction; or appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans.”
- **Third-Party Logistics Provider**: “means an entity that provides or coordinates warehousing, or other logistics services of a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of a product, but does not take ownership of the product, nor have responsibility to direct the sale or disposition of the product.”
- **Trading Partner**: “a manufacturer, repackager, wholesale distributor, or dispenser from whom a manufacturer, repackager, wholesale distributor, or dispenser accepts direct ownership of a product or to whom a manufacturer, repackager, wholesale distributor, or dispenser transfers direct ownership of a product; or ‘‘a third-party logistics provider from whom a manufacturer, repackager, wholesale distributor, or dispenser accepts direct possession of a product or to whom a manufacturer, repackager, wholesale distributor, or dispenser transfers direct possession of a product.”

HCA Healthcare®

Drug Supply Chain Security Act of 2013, Pub. L. No. 113-54. 127 STAT. 599. (2013). https://www.govinfo.gov/content/pkg/PLAW-113publ54/pdf/PLAW-113publ54.pdf

Appendix

- **Transaction**: “means the transfer of product between persons in which a change of ownership occurs.” (of note, there are many exemptions to this that can be found on page 16 of the public law)
  - **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 information (TI):** “the proprietary or established name or names of the product; the strength and dosage form of the product; the National Drug Code number of the product; the container size; the number of containers; the lot number of the product; the date of the transaction; the date of the shipment, if more than 24 hours after the date of the transaction; the business name and address of the person from whom ownership is being transferred; and the business name and address of the person to whom ownership is being transferred.”
  - **Transaction statement (TS):** “a statement, in paper or electronic form, that the entity transferring ownership in a transaction is authorized as required under the Drug Supply Chain Security Act; received the product from a person that is authorized as required under the Drug Supply Chain Security Act; received transaction information and a transaction statement from the prior owner of the product, as required under section 582; did not knowingly ship a suspect or illegitimate product; had systems and processes in place to comply with verification requirements under section 582; did not knowingly provide false transaction information; and did not knowingly alter the transaction history.”
- **Wholesale Distributor**: “a person (other than a manufacturer, a manufacturer’s co-licensed partner, a third-party logistics provider, or repackager) engaged in wholesale distribution (as defined in section 503(e)(4), as amended by the Drug Supply Chain Security Act).”

Source: Drug Supply Chain Security Act of 2013, Pub. L. No. 113-54. 127 STAT. 599. (2013). https://www.govinfo.gov/content/pkg/PLAW-113publ54/pdf/PLAW-113publ54.pdf

References

1. Bilton L. Pharma Supply Chain: A comprehensive guide to the pharmaceutical supply chain. PharmaSource. Published February 29, 2020. https://pharmasource.global/content/pharma-supply-chain-a-comprehensive-guide-to-the-pharmaceutical-supply-chain/
2. Center for Drug Evaluation and Research. Drug Supply Chain Security Act (DSCSA). U.S. Food and Drug Administration. Published 2019. https://www.fda.gov/drugs/drug-supply-chain-integrity/drug-supply-chain-security-act-dscsa
3. Drug Supply Chain Security Act of 2013, Pub. L. No. 113-54. 127 STAT. 599. (2013). https://www.govinfo.gov/content/pkg/PLAW-113publ54/pdf/PLAW-113publ54.pdf
4. GS1. Global Location Number (GLN) | GS1. www.gs1.org. https://www.gs1.org/standards/id-keys/gln
5. GS1. GTIN Management | GS1 - The global language of business. www.gs1.org. Accessed May 17, 2024. https://www.gs1.org/1/gtinrules/en/decision-support
6. GS1. GS1 Company Prefix | GS1. www.gs1.org. Accessed May 17, 2024. https://www.gs1.org/standards/id-keys/company-prefix
7. Research, Center for Drug Evaluation. DSCSA compliance policies establish 1-year stabilization period for implementing electronic systems. *FDA.* Published online 30, 2023. https://www.fda.gov/drugs/drug-safety-and-availability/dscsa-compliance-policies-establish-1-year-stabilization-period-implementing-electronic-systems.
8. National Association of Boards of Pharmacy. Pulse by NABP | DSCSA Solutions | DSCSA Compliance Software. National Association of Boards of Pharmacy. Accessed May 17, 2024. https://nabp.pharmacy/pulse/solutions
9. How Will Serialization Affect 340B Pharmacies? TraceLink. Accessed May 17, 2024. https://www.tracelink.com/resources/resource-center/how-will-serialization-affect-340b-pharmacies

Thank you!!

Samantha Randlett, PharmD

Email: Samantha.Randlett@hcahealthcare.com

Phone: 248-884-3914

A presentation for HealthTrust Members, June11, 2024

HCA Healthcare®