

September 16, 2025

Navigating DSCSA Compliance: Protecting Patient Access While Meeting Federal Requirements

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National Association of Boards of Pharmacy**

Learning Objectives

- 1. Describe a pharmacy's compliance obligations under the DSCSA for conducting business with an authorized trading partner.**
- 2. Identify the tools that DSCSA provides to detect unsafe medications.**
- 3. Explain the impact of DSCSA on compounded products.**

Pre-Test Questions

- 1. True or False - dispensers are required to purchase software or hardware to comply with DSCSA**
- 2. True or False - dispensers must respond to a regulator request for information during a suspect product investigation within 2 business days**
- 3. True or False – dispensers are obligated to store transaction information for 6 years**

Drug Supply Chain Security Act (DSCSA) Summary

Components of Law



Part 2 of the Drug Quality and Security Act (DQSA)

[Link to FDA Copy of DSCSA](#)

Enacted Nov 27, 2013

Intended to supersede a growing number of differing state laws

Phases rolling out until Nov 2023 from manufacturer to dispenser

Facilitates the gathering of transaction data in the event of suspect and illegitimate product

Roles in DSCSA:



Manufacturers



Repackagers



Distributors



Dispensers



Third-Party Logistic Providers

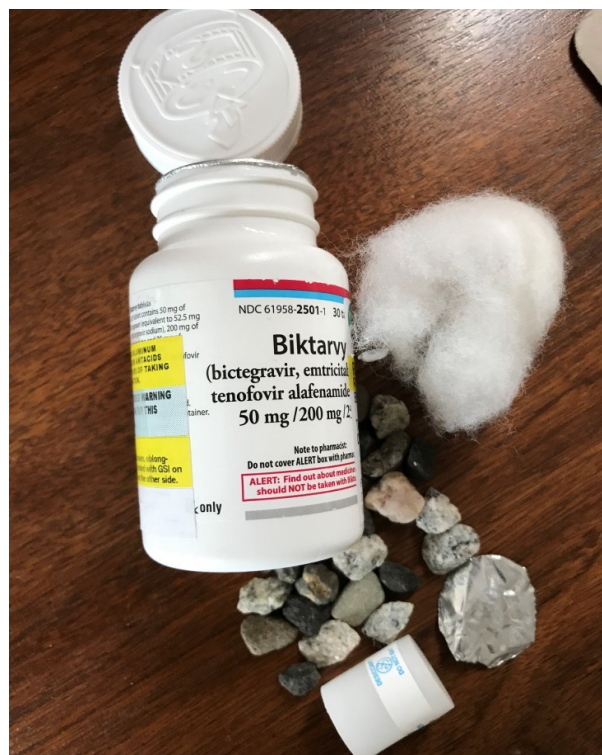
DSCSA Summary

Major Milestones



| Year | 2015 | 2018 | 2019 | 2020 | 2023 |
|--------------------|--|--|--|---|---|
| | Foundational | | Trading Partners | | Interoperability |
| Major Requirements | <ul style="list-style-type: none"> • T3 at the lot level (paper allowable) • Authorized TP • Suspect product handling & reporting | <ul style="list-style-type: none"> • Affix serial number • Provide T3 lot level (electronic) • Serial number retention and verification | <ul style="list-style-type: none"> • Transact only in serialized products • Accept return only with associated TI & TS • Initiate TH on saleable returns • Verify serial number for saleable returns (Enforcement delayed to 11-27-23) | <ul style="list-style-type: none"> • Accept only serialized product • Suspect product reporting • Verification of serial numbers for suspect (Enforcement delayed to 11-27-23) | <ul style="list-style-type: none"> • Implementation of an interoperable, electronic tracing of product at the S/N level (TI & TS) • Facilitate gathering of history for suspect, illegitimate, & recalls • Enhanced Verification • “Authorized” direct or indirect partners |
| Primary Impacted | All Trading Partners | Manufacturers/ Repackagers | Wholesalers | Dispensers/ Wholesalers | All Trading Partners |

Product Complaints Linked to Licensed Secondary Distributors



Patient reported consuming one tablet of an antipsychotic in bottle of BIKTARVY® and reported being unable to walk or talk.





PHARMA

Gilead says counterfeiters sold \$250M worth of fake HIV drugs, sues distributors

By Kevin Dunleavy • Jan 20, 2022 08:22am

counterfeit

counterfeit drugs

HIV

Biktarvy

Share

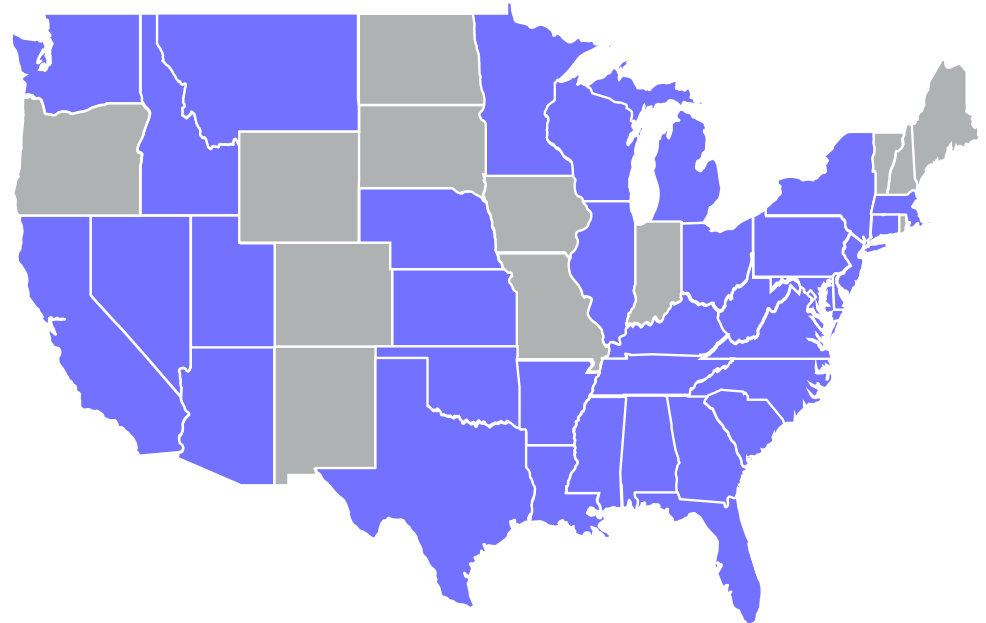


Gilead says it found counterfeit versions of its HIV drugs—mostly Biktarvy and Descovy—that were sold to pharmacies and distributed to patients. (Gilead Sciences)

Gilead [sued](#) a network of small drug distributors, claiming they endangered patients by selling more than \$250 million in counterfeit versions of the company's HIV drugs—mostly Biktarvy and Descovy—in the United States over the last two years.

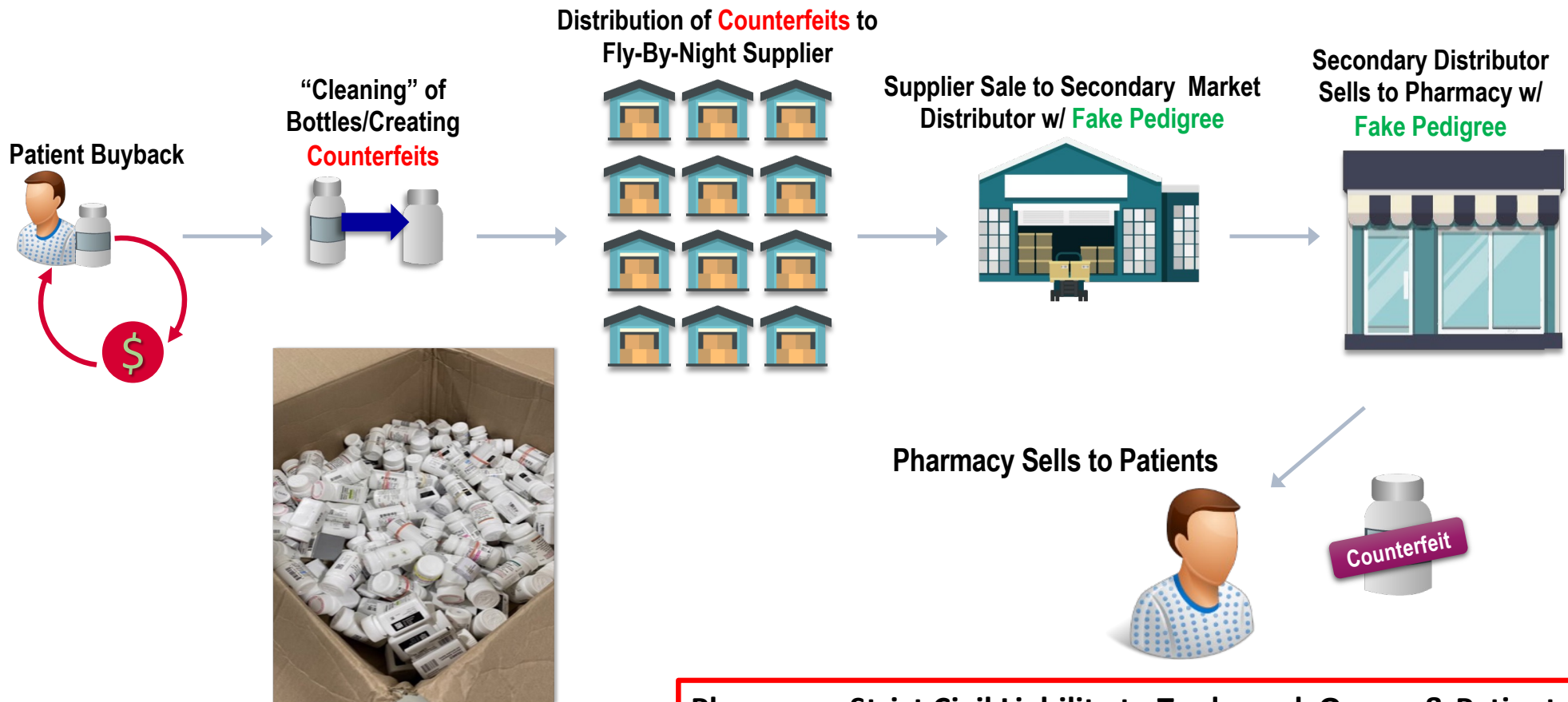
Distributors of the counterfeits sold to independent pharmacies throughout the country

Over 600 unique pharmacies in 36 states



NABP®

The Illicit Scheme



Transaction History: Useful Tool to Confirm Legitimacy

SAFE CHAIN SOLUTIONS, LLC

Drug Supply Chain Security Act Document

(TI) Transaction Information

Drug Name, Strength, Dosage Form, Container Size:
BIKTARVY 30 CT 50/20025 MG

NDC: 61958-2501-01

Reference Number: IN00002950
Document Type: INVOICE
Reference Date: 04/19/2021

| Lot Number | Quantity | Unique Serial # |
|------------|----------|-----------------|
| 021349 | 1 | |
| | | |
| | | |

(TH) Transaction History

Manufacturer's Name: GILEAD SCIENCES
Manufacturer's Information: 333 LAKESIDE DRIVE, FOSTER CITY, CA 94404

| | |
|---|--|
| SOLD TO: Name: CESAR CASTILLO INC Address: CARR. #1 SECTOR LA MUDA GUAYNABO, PR 00971 Date Purchased & Ref: 03/09/2021 3181920 | SHIPPED TO: Name: CESAR CASTILLO INC Address: CARR. #1 SECTOR LA MUDA GUAYNABO, PR 00971 Date Received & Ref: |
| SOLD TO: Name: SYNERGY WHOLESAL GROUP Address: 491 AMWELL RD HILLSBOROUGH, NJ 08844 Date Purchased & Ref: 03/30/2021 0099110 | SHIPPED TO: Name: SYNERGY WHOLESAL GROUP Address: 491 AMWELL RD HILLSBOROUGH, NJ 08844 Date Received & Ref: |
| SOLD TO: Name: SAFE CHAIN SOLUTIONS Address: 822 CHESAPEAKE DR CAMBRIDGE, MD 21613 Date Purchased & Ref: 4/9/2021 000094 | SHIPPED TO: Name: SAFE CHAIN SOLUTIONS Address: 822 CHESAPEAKE DR CAMBRIDGE, MD 21613 Date Received & Ref: 04/12/2021 |

| | |
|---|--|
| SOLD TO: Name: CESAR CASTILLO INC Address: CARR. #1 SECTOR LA MUDA GUAYNABO, PR 00971 Date Purchased & Ref: 03/09/2021 3181920 | SHIPPED TO: Name: CESAR CASTILLO INC Address: CARR. #1 SECTOR LA MUDA GUAYNABO, PR 00971 Date Received & Ref: |
|---|--|

- Gilead never sold the lot numbers listed to Cesar Castillo
- Cesar Castillo never sold any products to Synergy or Safe Chain
- Cesar Castillo sells only within Puerto Rico

The sunset of the Transaction History in November 2023 will require more vigilance on pharmacies to prevent them from purchasing counterfeits.

United States Prescription Drug Supply Chain

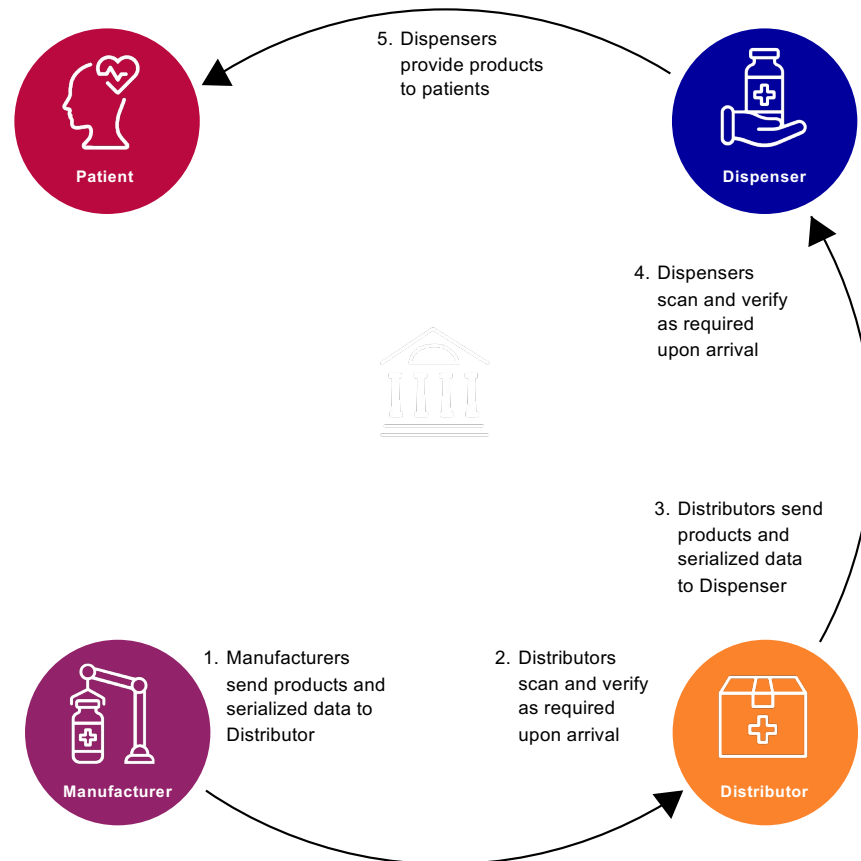
This ecosystem visualizes one way the product and product data moves throughout the supply chain from **Manufacturer** to **Patient** after November 27, 2023.*

Under DSCSA, the prescription drug supply chain is **DECENTRALIZED** – meaning there is no single source of data or truth.

Each trading partner is required to:

- 1) **store** their own serialized data;
- 2) **send and/or receive** serialized data via electronic and interoperable means; and
- 3) **respond** to requests from Federal and State Regulators and trading partners as part of investigations into suspect and illegitimate products.

DSCSA, in effect, allows and requires each trading partner to maintain sovereignty and control over their serialized data.



Today

Several hundred thousand lots
tracked by TI and TH

November 27, 2024

~4.5 Billion Units
Traced by TI



~2 Transactions per
Unit



~8-10 Billion
Transactions



~16-20 Billion
Instances of TI



6 Years of Record Retention



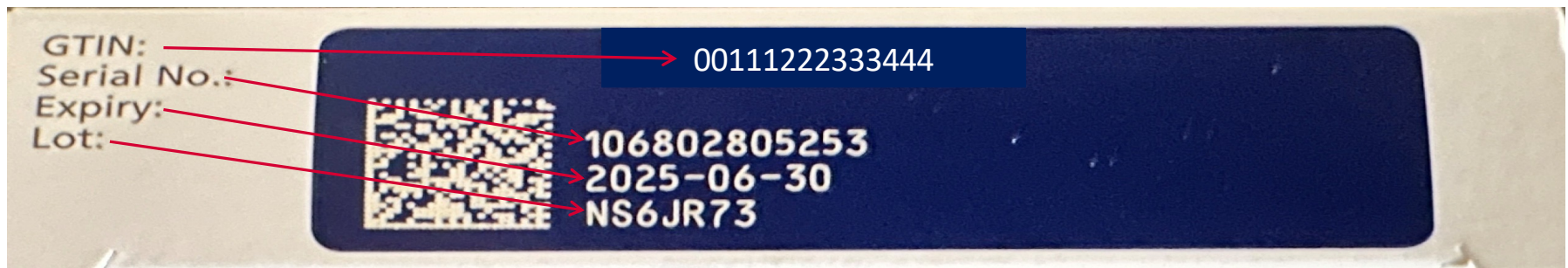
**~100 Billion
Instances of TI**

Today

Post-November

*10,000 – 20,000
times as many
DSCSA instances
recorded*

What tools does DSCSA provide to detect counterfeit medications?



Product Verification – A trading partner can verify the authenticity of the product identifiers (GTIN; S/N; Lot Number; Expiration Date) with the manufacturer.

“Manufacturer, did you affix these product identifiers to this package?”

Product Tracing – In the event of suspect, or illegitimate products, Product Tracing requests the prior ownership of the product by collecting transaction information from trading partners.

“Manufacturer, who did you sell this product to?” “Pharmacy, who did you purchase this product from?”

What is wrong
with this
picture?

pulse™
by NABP





Good morning, Josh Bolin




Product Verification

Verify product authenticity and status

Quickly verify products using serialized identifiers and ensure compliance with DSCSA requirements.

[Open Verification →](#)



 regvrs.pulse.pharmacy



What is Pulse?

Digital Directory

Pulse establishes trusted and verified relationships throughout the prescription drug supply chain.

- **Enables** secure data exchange
- **Unlocks** engagement and communication
- **Maintains** sovereignty and control

Integration Platform

With trusted and verified relationships established, Pulse securely facilitates DSCSA-related communications across a decentralized supply chain:

- Product Verification
- Product Tracing
- Authorized Trading Partner Status
- Contact Information



Network Reach – 2023 Tracing Pilot Participants



| State Regulators | Manufacturer or Repackagers | Distributors | Dispensers | Solution Providers | Trade, Standards, Other Orgs | Service Providers |
|---|--|--|--|---|--|--|
| Tracing Pilot Participants | | | | | | |
| 1. Alaska 2. Idaho 3. Iowa 4. Kansas 5. Kentucky 6. Maryland 7. Massachusetts 8. North Dakota 9. Ohio 10. Virginia | 1. Bristol Myers Squibb 2. EMD Serono 3. Eli Lilly 4. Genentech 5. Ingenus Pharma 6. J&J 7. Novo Nordisk 8. Pfizer 9. Sanofi | 1. Amerisource Bergen 2. Capital Wholesale Drug 3. Cardinal Health 4. Hercules Pharmaceuticals 5. McKesson 6. Mutual Drug | 1. Condo Pharmacy 2. Intermountain Health 3. Rite Aid 4. Sam's Healthmart 5. Veterans Affairs (VA) 6. Walgreens 7. Thrifty White 8. Indiana University Health | 1. Trust.MED 2. Advasur 3. Axway 4. Birch OS 5. ConsortiEX 6. Gateway Checker 7. LedgerDomain 8. LSPedia 9. Movilitas.Cloud 10. Optel 11. RfXcel/ Antares 12. RxScan 13. SAP 14. Systech 15. Tracelink 16. TrackTrace Rx | | |
| Observers & Stay Informed | | | | | | |
| 1. State BOP Executive Officers 2. NABP District 3 3. NABP District 5 4. California 5. CA BOP 6. MO BOP | 1. Amgen 2. Apotex 3. Gilead 4. Hikma 5. Novartis 6. Precision Dose 7. Sagent Pharma | 1. ANDA, Inc 2. Medline Industries 3. Morris & Dickson Co 4. Smith Drug Company 5. Premier Rx Wholesale 6. Value Drug Company | 1. Ro 2. CVS 3. Health Mart Pharmacy 4. Mississippi Senior Care 5. Transplant Pharmacy 6. Uptown Pharmacy 7. Walmart | 1. Auto-ID Solutions 2. InfiniTrak 3. Inmar 4. Legisym 5. Spherity 6. Vantage Solutions | 1. APhA 2. AAM 3. GS1 US 4. HDA 5. IEEE 6. NCPA 7. OCI 8. PDG 9. Partnership for Safe Medicines 10. USP | 1. ArentFox 2. BBF Consulting 3. C4SCS 4. DHL 5. Excel 6. Excellis 7. Insolate 8. Murtagh Consulting 9. OFW Law 10. PMC 11. PHT 12. Storemed 13. Vizient |

Product Verification & Product Tracing Using Pulse by NABP

Because the US Supply Chain is decentralized, NABP created a mechanism to facilitate communication between regulators and trading partners.


This view visualizes how a product inquiry is made from a **Regulator** or **Dispenser**, and how trading partners can respond to the product inquiry using Pulse.


All services depicted in this map will be free for all participants.

Trading Partners are identified by GLNs

Inquiries are initiated using SGTIN

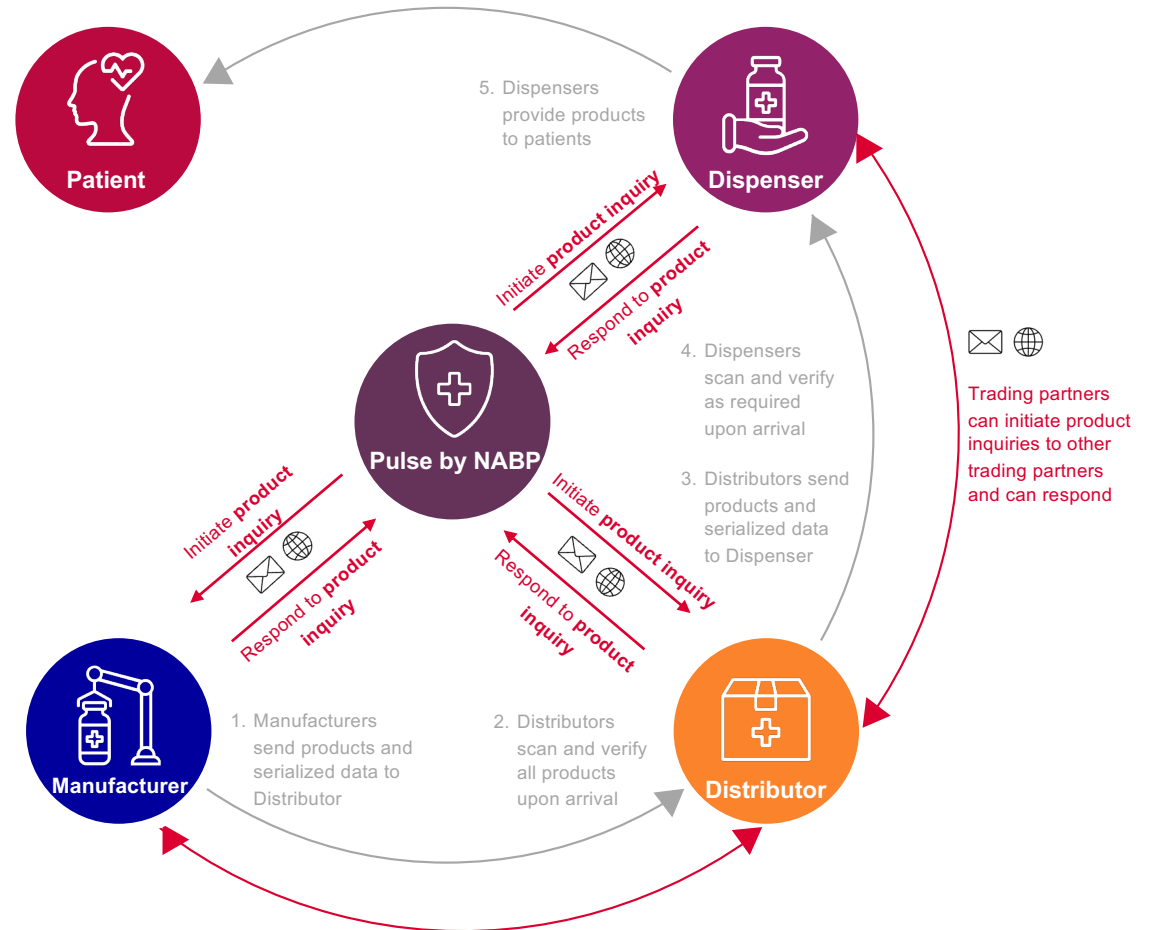
KEY

 Receive email notification from the Pulse by NABP

 Action in Pulse by NABP

Product Inquiry: product verification or product trace request

pulse
by NABP



What Did They Advertise?



Good morning, [REDACTED]

Here is what we have now on injectable insulins:

| | | | |
|----------------|-----|---------|--------------|
| OZEMPIC.25 | 285 | \$900 | 0169-4181-13 |
| OZEMPIC1 | 323 | \$900 | 0169-4130-13 |
| OZEMPIC2 | 24 | \$900 | 0169-4772-12 |
| TRULIC.75 | 209 | \$850 | 0002-1433-80 |
| TRULIC1.5 | 134 | \$900 | 0002-1434-80 |
| TRULIC3 | 83 | \$900 | 0002-2236-80 |
| TRULIC4.5 | 80 | \$900 | 0002-3182-80 |
| WEGOVY.50 | 0 | \$1,125 | 0169-4505-14 |
| WEGOVY1 | 0 | \$1,125 | 0169-4501-14 |
| WEGOVY1.7 | 0 | \$1,125 | 0169-4517-14 |
| WEGOVY2.4 | 0 | \$1,125 | 0169-4524-14 |
| WEGOVY.25 | 0 | \$1,125 | 0169-4525-14 |
| ZEPBOUND2.5 | 4 | \$1,125 | 0002-2506-80 |
| ZEPBOUND5 | 7 | \$1,125 | 0002-2495-80 |
| ZEPBOUND10 | 0 | \$1,125 | 0002-2471-80 |
| ZEPBOUND7.5 | 20 | \$1,000 | 0002-2484-80 |
| WEGOVY.25-SAMP | 11 | \$700 | 0169-4525-94 |

Please let me know if I can be of any assistance.

Here is what we have today:

| | | |
|--------------|-----|---------|
| MOUNJARO12.5 | 7 | \$1,020 |
| MOUNJARO5 | 12 | \$1,020 |
| MOUNJARO7.5 | 9 | \$1,020 |
| OZEMPIC.25 | 168 | \$900 |
| OZEMPIC1 | 163 | \$900 |
| OZEMPIC2 | 106 | \$900 |
| TRULIC.75 | 74 | \$900 |
| TRULIC1.5 | 59 | \$900 |
| TRULIC3 | 42 | \$900 |
| TRULIC4.5 | 23 | \$900 |

Suspect Product?



PULSE Product Verification System

Regulator Utilization By the Numbers...

- Over 120 state regulators + DEA are registered in Pulse
- Represents ~30 states
- 1600+ verification requests for suspect product investigations

FDA Connected Partner Exemption

Who is affected: Trading partners who have initiated their systems and electronic data connections, but who still face challenges with missing, incomplete, or inaccurate data.

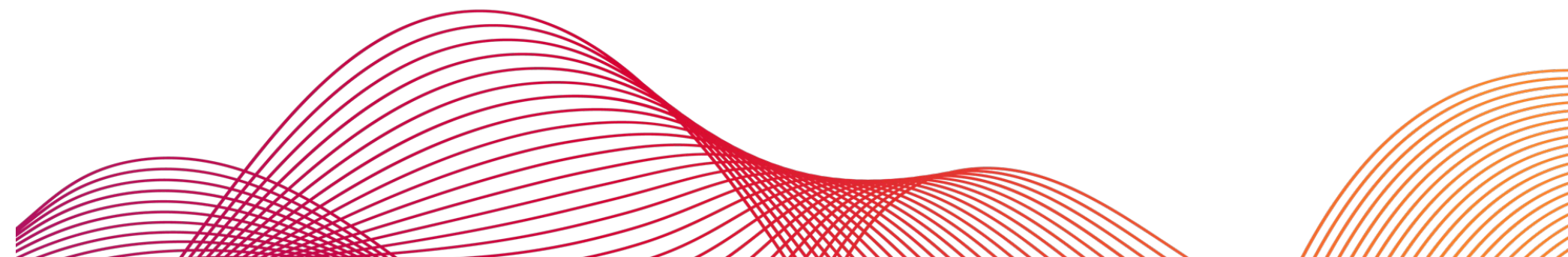
What is exempted: Key interoperable DSCSA requirements that were part of the previous stabilization period, like exchanging transaction information and transaction statements electronically, including product identifiers at the package level and certain verification request requirements.

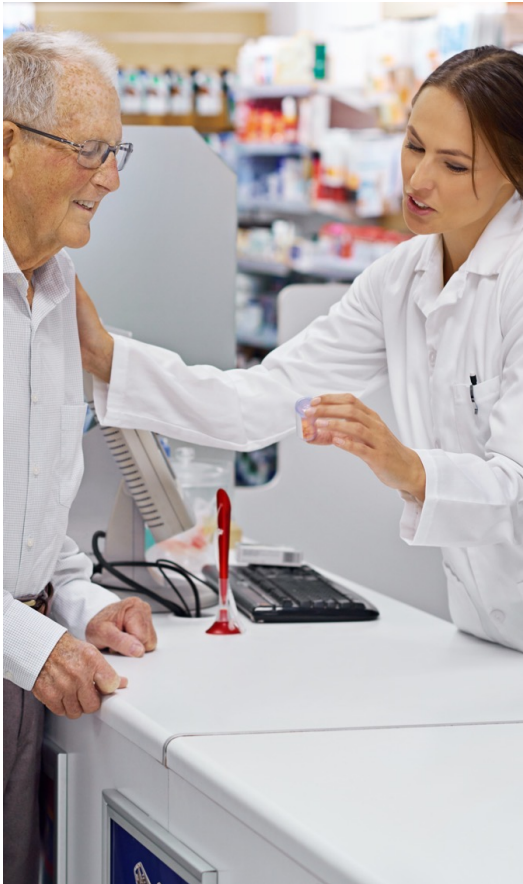
Timeline:

- For **manufacturers and repackagers**, exemptions last from November 27, 2024, until **May 27, 2025**.
- For **wholesalers**, exemptions are granted until **August 27, 2025**.
- For **dispensers with 26 or more full-time employees**, the exemption period extends until **November 27, 2025**.

Scope: These exemptions apply to specific requirements under Section 582(g)(1) of the FD&C Act. Other existing DSCSA obligations, remain in effect. Notably, trading partners who have not yet initiated the required systems and connections are not covered by these exemptions.

Pharmacy Obligations Under DSCSA





Dispenser Requirements

Authorized Trading Partners

Written policies and procedures that detail initial and ongoing process for trading partners, including:

- State licenses
- FDA database
- Frequency
- Last date checked
- Source

Product Identification

- Describe how pharmacy will verify the NDC, lot number, expiration date, and serial number
- Describe how product identifiers are evaluated
- Describe what happens when a product does not have identifiers

Product Tracing

Dispensers must provide and receive transaction information and transaction statements in a secure, electronic, and interoperable manner.

Receive transaction information

- Describe process to ensure that transaction information is received from trading partners prior to accepting items into inventory.

Store transaction information

- Describe process for storage of transaction information for a period not less than 6 years.
- Describe process for storing suspect or illegitimate product investigations for 6 years from end of investigation.

• Respond to regulators and trading partners

- Describe process for responding to a request for transaction information from a state or federal regulator or an authorized trading partner.

Suspect or Illegitimate Product Investigation

Dispensers must have processes in place to quarantine and investigate suspect or illegitimate product.

Suspect Product

Reason to believe a product is counterfeit, diverted, stolen, subject of fraudulent transaction, intentionally adulterated, or appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans.

Illegitimate Product

Credible evidence that shows a product is counterfeit, diverted, stolen, subject of fraudulent transaction, intentionally adulterated, or appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans.

Requirements

- Document
- Quarantine and ensure product does not enter supply chain
- Conduct product verification
- Complete and submit Form FDA 3911 within 24 hours

Distributors and Solution Provider Support for Dispensers

What can wholesale distributors do for their pharmacy customers?

- Wholesalers can store transaction information, but only for the products sold to that pharmacy (ie, via a portal or other electronic means).
- Wholesalers can provide standard operating procedures (SOPs) for how to use their solution.

What do pharmacies have to do themselves?

- Wholesalers CANNOT store information for products sold by other wholesalers.
- Wholesalers cannot conduct suspect and illegitimate product investigations (including product verification and tracing) for their pharmacy customer. This must be completed by the pharmacy purchasing the product.

Are pharmacies required to use a solution provider or a particular type of technology to comply?

- No, but the more upstream trading partners they have, the more complex compliance may become.

Affects of the DSCSA on Compounding

- Products are a subset of Prescription Drug
- Products are subject to tracing. Exemptions in Sec. 581 (24) Transaction definition.
- **Products do not include Drugs Compounded in compliance with sections 503A and 503B.**
- Compounded Drugs are not Products—they are not subject to the traceability requirements of the DSCSA

APIs



- APIs are Prescription Drugs but not Products
- API sellers are not required to provide Transaction Data (not subject to tracing)
- APIs must be sourced from authorized sources (FDA registered and State licensed)



APIs



- Prescription Drugs in finished form that are not considered “Products” are not required to have tracing data.
- **Products procured for use in compounding are required to be accompanied by tracing documents.**
- Some 503B outsourcing facilities are not receiving tracing documentation. Their finished dosage form does not require traceability, but the seller should be providing Transaction Documents

Four Operational Imperatives for DSCSA Compliance and to Minimize Threats to Patients

- 1) Know your prescription drug suppliers (sources).**
- 2) Know where your product tracing, also known as transaction information (data), is being stored and how to access it.**
- 3) Know what suspect product is, how to **identify it**, how to **investigate it**, and **what to do if it is deemed illegitimate**.**
- 4) Develop, update, and adhere to robust prescription drug purchasing policies and procedures (P&Ps) that accurately reflect your internal processes.**

DISPENSER GUIDE TO ACHIEVING Drug Supply Chain Security Act Compliance



Tools and Resources

FDA Resources – <https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/drug-supply-chain-security-act-law-and-policies>

Dispenser Education Web Page – www.dscsa.pharmacy

Dispenser Education Guide – Sign up at <https://pulse.pharmacy/about/sign-up/>

Serial Number Decommissioning Pilot Report – <https://pulse.pharmacy/resources/newsroom/serial-number-decommissioning-pilot-report/>

Prosper Africa Pilot Launch – <https://pulse.pharmacy/resources/newsroom/prosper-africas-tech-for-trade-alliance-announces-a-pharmaceutical-tracing-pilot-in-south-africa/>

Pre-Test Questions

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