

## Monthly Pharmacy Closed Cases Jun/Jul 23

As of 2023-08-18 09:06:22 Mountain Standard Time/MST • Generated by Camille Farley • Sorted by Closed Date (Ascending)

### Filtered By

Date Field: Closed Date equals Custom (6/1/2023 to 7/31/2023)

Case Number	Closed Date	Professions	Profession Subtype	Complaint Types	Closure Code	Status
144105	6/1/2023	Pharmacy	Class A-Retail	Inspection	Administrative Action; Letter of Concern; Random Inspection	Closed
142809	6/1/2023	Pharmacy		Unlicensed Practice	Administrative Action	Closed
144250	6/2/2023	Pharmacy		Pharmacy Violation	Administrative Discretion	Closed
142291	6/2/2023	Pharmacy	Class E-Durable Medical Equipment	Inspection	New Inspection	Closed
144441	6/2/2023	Pharmacy	Class A-Retail	Inspection	Random Inspection	Closed
144183	6/5/2023	Pharmacy		Pharmacy Violation	Administrative Action	Closed
144213	6/5/2023	Pharmacy	Pharmacist	Drug Diversion	Referred to UPHP	Closed
142505	6/5/2023	Pharmacy	Class A-Retail	Pharmacy Violation	Administrative Action	Closed
144446	6/5/2023	Pharmacy	Class A-Retail	Inspection	Random Inspection	Closed
142956	6/5/2023	Pharmacy	Class B-Closed Door	Inspection	Letter of Concern; New Inspection	Closed
144412	6/7/2023	Pharmacy	Class A-Retail	Inspection	Letter of Concern; Random Inspection	Closed
142263	6/7/2023	Pharmacy	Class A-Retail	Inspection	New Inspection	Closed
143895	6/7/2023	Pharmacy	Class A-Retail	Inspection	New Inspection	Closed
144541	6/8/2023	Pharmacy	Class A-Retail	Inspection	Random Inspection	Closed
144488	6/9/2023	Pharmacy	Class A-Retail	Inspection	Voluntary Compliance	Closed
144614	6/12/2023	Pharmacy	Class C-Wholesaler	Inspection	Random Inspection	Closed
144616	6/12/2023	Pharmacy	Class A-Retail	Inspection	Random Inspection	Closed
144613	6/12/2023	Pharmacy	Class A-Retail	Inspection	Random Inspection	Closed
143163	6/12/2023	Pharmacy	Class A-Retail	Pharmacy Violation	Verbal Warning	Closed
144660	6/12/2023	Pharmacy	Class A-Retail	Inspection	Random Inspection; Verbal Warning	Closed
144548	6/12/2023	Pharmacy	Class A-Retail	Inspection	Random Inspection	Closed
144547	6/12/2023	Pharmacy	Class A-Retail	Inspection	Random Inspection	Closed
144549	6/12/2023	Pharmacy	Class A-Retail	Inspection	Random Inspection	Closed
144550	6/13/2023	Pharmacy	Class A-Retail	Inspection	Administrative Action; Letter of Concern; Random Inspection	Closed
144681	6/13/2023	Pharmacy	Class A-Retail	Inspection	Random Inspection	Closed
144709	6/14/2023	Pharmacy	Class A-Retail	Inspection	Letter of Concern; Random Inspection	Closed
141447	6/14/2023	Pharmacy	Class B-Narcotic Treatment Program	Inspection	New Inspection	Closed
144712	6/14/2023	Pharmacy	Class A-Retail	Inspection	Letter of Concern; Random Inspection	Closed
144663	6/15/2023	Pharmacy	Class C-Wholesaler	Pharmacy Violation	Letter of Concern	Closed
144723	6/15/2023	Pharmacy	Class A-Retail	Inspection	Random Inspection; Voluntary Compliance	Closed
144745	6/15/2023	Pharmacy	Class A-Retail	Inspection	Random Inspection	Closed
144742	6/15/2023	Pharmacy	Class B-Closed Door		No Jurisdiction	Information Only
144794	6/16/2023	Pharmacy	Class A-Retail	Inspection	Random Inspection	Closed
144684	6/20/2023	Pharmacy	Class A-Retail	Inspection	Letter of Concern; Random Inspection	Closed
144837	6/20/2023	Pharmacy	Class A-Retail	Inspection	Random Inspection	Closed
142936	6/20/2023	Pharmacy		Pharmacy Violation	Unfounded	Closed
144851	6/20/2023	Pharmacy	Class A-Retail	Inspection	Random Inspection	Closed
144845	6/21/2023	Pharmacy	Pharmacist	Incompetence/Negligence	Administrative Discretion	Information Only
144844	6/21/2023	Pharmacy	Pharmacist	Incompetence/Negligence	Administrative Discretion	Information Only
143205	6/21/2023	Pharmacy	Class A-Retail	Medication Error	Voluntary Compliance	Closed
140937	6/23/2023	Pharmacy	Class E-Animal Control	Inspection	New Inspection	Closed
144489	6/26/2023	Pharmacy	Class A-Retail	Inspection	Letter of Concern; Random Inspection	Closed
144993	6/27/2023	Pharmacy	Class A-Retail	Inspection	Random Inspection; Voluntary Compliance	Closed
145017	6/27/2023	Pharmacy	Class A-Retail	Inspection	Random Inspection	Closed
143528	6/27/2023	Pharmacy	Class B-Pharmaceutical Administration Facility	Inspection	New Inspection; Voluntary Compliance	Closed
144175	6/28/2023	Pharmacy	Class A-Retail	Incompetence/Negligence	Letter of Concern	Closed

143620	6/28/2023	Pharmacy	Class B-Pharmaceutical Administration Facility	Inspection	New Inspection	Closed
144869	6/28/2023	Pharmacy		Pharmacy Violation	Administrative Discretion	Closed
145038	6/29/2023	Pharmacy	Class A-Retail	Inspection	Random Inspection	Closed
144850	6/29/2023	Pharmacy	Class A-Retail	Inspection	Administrative Action; Letter of Concern; Random Inspection	Closed
145047	6/29/2023	Pharmacy	Class A-Retail	Inspection	Random Inspection; Voluntary Compliance	Closed
145048	6/29/2023	Pharmacy	Class A-Retail	Inspection	Random Inspection	Closed
140834	6/30/2023	Pharmacy	Class B-Pharmaceutical Administration Facility	Inspection	Letter of Concern; New Inspection	Closed
145120	6/30/2023	Pharmacy	Class B-Closed Door	Inspection	Random Inspection	Closed
143894	7/3/2023	Pharmacy	Class A-Retail	Unprofessional Conduct	Voluntary Compliance	Closed
143618	7/6/2023	Pharmacy	Class B-Pharmaceutical Administration Facility	Inspection	New Inspection	Closed
143628	7/6/2023	Pharmacy	Class B-Pharmaceutical Administration Facility	Inspection	New Inspection	Closed
143625	7/6/2023	Pharmacy	Class B-Pharmaceutical Administration Facility	Inspection	New Inspection; Voluntary Compliance	Closed
145207	7/6/2023	Pharmacy	Class C-Distributing	Inspection	Random Inspection	Closed
145212	7/7/2023	Pharmacy	Class A-Retail	Inspection	Administrative Action	Closed
145044	7/10/2023	Pharmacy	Class C-Manufacturing	Pharmacy Violation	Administrative Discretion	Closed
143865	7/10/2023	Pharmacy	Class E-Durable Medical Equipment	Inspection	New Inspection	Closed
145146	7/10/2023	Pharmacy		Pharmacy Violation	Letter of Concern	Closed
143626	7/10/2023	Pharmacy	Class B-Pharmaceutical Administration Facility	Inspection	Letter of Concern; New Inspection	Closed
143624	7/10/2023	Pharmacy	Class B-Hospital Clinic	Inspection	New Inspection	Closed
144443	7/11/2023	Pharmacy	Class C-Distributing	Inspection	New Inspection	Closed
145341	7/12/2023	Pharmacy	Class B-Branch	Inspection	New Inspection	Closed
144800	7/13/2023	Pharmacy	Pharmacist	Incompetence/Negligence	Unfounded	Closed
145377	7/13/2023	Pharmacy	Class A-Retail	Inspection	Random Inspection	Closed
145379	7/13/2023	Pharmacy	Class A-Retail	Inspection	Random Inspection	Closed
145338	7/13/2023	Pharmacy	Class A-Retail	Inspection	Random Inspection	Closed
145340	7/13/2023	Pharmacy	Class A-Retail	Inspection	Random Inspection; Voluntary Compliance	Closed
145343	7/13/2023	Pharmacy	Class A-Retail	Inspection	Random Inspection	Closed
144998	7/14/2023	Pharmacy	Class A-Retail	Inspection	Random Inspection; Voluntary Compliance	Closed
145405	7/14/2023	Pharmacy	Class C-Wholesaler	Inspection	Random Inspection; Voluntary Compliance	Closed
145409	7/14/2023	Pharmacy	Class E-Third Party Logistics Provider	Inspection	Random Inspection	Closed
145413	7/14/2023	Pharmacy	Class A-Retail	Inspection	Random Inspection	Closed
145412	7/14/2023	Pharmacy	Class A-Retail	Inspection	Random Inspection; Voluntary Compliance	Closed
144752	7/18/2023	Pharmacy	Class E-Veterinary Pharmaceutical Facility	Inspection	New Inspection	Closed
144843	7/19/2023	Pharmacy		Pharmacy Violation	Administrative Action	Closed
145496	7/20/2023	Pharmacy	Class A-Retail	Inspection	Random Inspection	Closed
145495	7/20/2023	Pharmacy	Class A-Retail	Inspection	Random Inspection; Voluntary Compliance	Closed
145494	7/20/2023	Pharmacy	Class A-Retail	Inspection	Random Inspection	Closed
145557	7/20/2023	Pharmacy	Class A-Retail	Inspection	Random Inspection	Closed
143637	7/20/2023	Pharmacy	Pharmacist	Ethical Standards	Unfounded	Closed
141326	7/25/2023	Pharmacy	Class B-Pharmaceutical Administration Facility	Inspection	New Inspection; Voluntary Compliance	Closed
145612	7/25/2023	Pharmacy	Class A-Retail	Inspection	Letter of Concern; Random Inspection	Closed
145308	7/27/2023	Pharmacy	Class E-Analytical Laboratory	Pharmacy Violation	Administrative Action	Closed
145314	7/27/2023	Pharmacy	Pharmacist	Ethical Standards	Voluntary Compliance	Closed
145403	7/28/2023	Pharmacy	Pharmacist	Incompetence/Negligence	Unfounded	Closed
145477	7/28/2023	Pharmacy	Class B-Pharmaceutical Administration Facility	Pharmacy Violation	Voluntary Compliance	Closed
145731	7/31/2023	Pharmacy	Class B-Hospital Clinic	Inspection	Letter of Concern; Random Inspection	Closed
145729	7/31/2023	Pharmacy	Class A-Retail	Inspection	Random Inspection; Voluntary Compliance	Closed
145737	7/31/2023	Pharmacy	Class A-Retail	Inspection	Random Inspection; Voluntary Compliance	Closed
142265	7/31/2023	Pharmacy	Class E-Veterinary Pharmaceutical Facility	Inspection	New Inspection	Closed
145042	7/31/2023	Pharmacy	Class C-Manufacturing	Pharmacy Violation	Letter of Concern	Closed
143621	7/31/2023	Pharmacy	Class B-Hospital Clinic	Inspection	New Inspection; Voluntary Compliance	Closed
<b>Total</b>	Count	97				

## Monthly Pharmacy Cases Received Jun/Jul

As of 2023-08-18 08:50:32 Mountain Standard Time/MST • Generated by Camille Farley • Sorted by Opened Date (Ascending)

### Filtered By

Date Field: Opened Date equals Custom (6/1/2023 to 7/31/2023)

Case Number	Opened Date	Professions	Profession Subtype	Complaint Types	Status
144505	6/6/2023	Pharmacy	Pharmacy Technician	Unlicensed Practice	Legal Action
144561	6/8/2023	Pharmacy	Class E-Veterinary Pharmaceutical Facility	Inspection	Under Investigation
144651	6/12/2023	Pharmacy	Class E-Veterinary Pharmaceutical Facility	Inspection	Under Investigation
144728	6/14/2023	Pharmacy	Pharmacy Technician	Substance Abuse	Under Investigation
144742	6/15/2023	Pharmacy	Class B-Closed Door		Information Only
144756	6/15/2023	Pharmacy	Class C-Manufacturing	Inspection	Under Investigation
144844	6/20/2023	Pharmacy	Pharmacist	Incompetence/Negligence	Information Only
144845	6/20/2023	Pharmacy	Pharmacist	Incompetence/Negligence	Information Only
145161	7/4/2023	Pharmacy		Unlicensed Practice	Under Investigation
145437	7/14/2023	Pharmacy	Pharmacy Technician	CSD Violation	Legal Action
145675	7/26/2023	Pharmacy	Class B-Closed Door	Incompetence/Negligence	Under Investigation
145799	7/31/2023	Pharmacy	Class A-Retail	Inspection	Under Investigation
Total	Count	12			

## Monthly Pharmacy Inspections Jun/Jul 23

As of 2023-08-18 08:31:12 Mountain Standard Time/MST • Generated by Camille Farley • Sorted by Inspection Date (Ascending)

### Filtered By

Show: All inspections

Date Field: Inspection Date equals Custom (6/1/2023 to 7/31/2023)

Case	Inspection Date	Inspection Classification	Inspection Type
144488	6/5/2023, 12:00 PM	Class A-Retail	Random
144489	6/5/2023, 12:00 PM	Class A-Retail	Random
142263	6/6/2023, 12:00 PM	Class A-Retail	New
144541	6/6/2023, 12:00 PM	Class A-Retail	Random
144548	6/6/2023, 12:00 PM	Class A-Retail	Random
144550	6/6/2023, 12:00 PM	Class A-Retail	Random
143895	6/7/2023, 12:00 PM	Non-Sterile Compounding	New
143895	6/7/2023, 12:00 PM	Class A-Retail	New
144549	6/7/2023, 12:00 PM	Class A-Retail	Random
144547	6/7/2023, 12:00 PM	Automated Pharmacy System	Random
144547	6/7/2023, 12:00 PM	Class A-Retail	Random
144613	6/7/2023, 12:00 PM	Class A-Retail	Random
144709	6/7/2023, 12:00 PM	Class A-Retail	Random
144614	6/8/2023, 12:00 PM	Class C-Wholesaler	Random
144616	6/9/2023, 12:00 PM	Class A-Retail	Random
140937	6/12/2023, 12:00 PM	Class E-Animal Control	New
144660	6/12/2023, 12:00 PM	Class A-Retail	Random
141447	6/13/2023, 12:00 PM	Class B-Narcotic Treatment Program	New
144681	6/13/2023, 12:00 PM	Class A-Retail	Random
144684	6/13/2023, 12:00 PM	Class A-Retail	Random
144712	6/14/2023, 12:00 PM	Class A-Retail	Random
144723	6/14/2023, 12:00 PM	Class A-Retail	Random
144745	6/14/2023, 12:00 PM	Class A-Retail	Random

144724	6/14/2023, 4:00 PM	Sterile Compounding	Random
144837	6/15/2023, 12:00 PM	Class A-Retail	Random
144837	6/15/2023, 12:00 PM	Automated Pharmacy System	Random
144850	6/15/2023, 12:00 PM	Class A-Retail	Random
144794	6/16/2023, 12:00 PM	Automated Pharmacy System	Random
144794	6/16/2023, 12:00 PM	Class A-Retail	Random
144851	6/20/2023, 12:00 PM	Class A-Retail	Random
144948	6/23/2023, 12:00 PM	Class C-Wholesaler	Random
143620	6/26/2023, 12:00 PM	Class B-Pharmaceutical Administration Facility	New
144998	6/26/2023, 12:00 PM	Class A-Retail	Random
144993	6/26/2023, 12:00 PM	Automated Pharmacy System	Random
144993	6/26/2023, 12:00 PM	Class A-Retail	Random
145017	6/26/2023, 12:00 PM	Automated Pharmacy System	Random
145017	6/26/2023, 12:00 PM	Class A-Retail	Random
145038	6/26/2023, 12:00 PM	Class A-Retail	Random
145038	6/26/2023, 12:00 PM	Automated Pharmacy System	Random
145047	6/26/2023, 12:00 PM	Class A-Retail	Random
145048	6/26/2023, 12:00 PM	Class A-Retail	Random
145212	6/26/2023, 12:00 PM	Class A-Retail	Random
145120	6/28/2023, 12:00 PM	Class B-Closed Door	Random
140834	6/29/2023, 12:00 PM	Class B-Pharmaceutical Administration Facility	New
144443	6/29/2023, 12:00 PM	Class C-Distributing	New
143618	7/5/2023, 12:00 PM	Class B-Pharmaceutical Administration Facility	New
143626	7/5/2023, 12:00 PM	Automated Pharmacy System	New
143626	7/5/2023, 12:00 PM	Class B-Pharmaceutical Administration Facility	New
143624	7/5/2023, 12:00 PM	Sterile Compounding	New
143624	7/5/2023, 12:00 PM	Non-Sterile Compounding	New
143624	7/5/2023, 12:00 PM	Automated Pharmacy System	New
143624	7/5/2023, 12:00 PM	Class B-Hospital Clinic	New
143628	7/5/2023, 12:00 PM	Class B-Pharmaceutical Administration Facility	New
143625	7/5/2023, 12:00 PM	Class B-Pharmaceutical Administration Facility	New
143625	7/5/2023, 12:00 PM	Automated Pharmacy System	New

143865	7/10/2023, 12:00 PM	Class E-Durable Medical Equipment	New
145338	7/11/2023, 12:00 PM	Class A-Retail	Random
145341	7/11/2023, 12:00 PM	Class B-Branch	New
145340	7/11/2023, 12:00 PM	Class A-Retail	Random
145343	7/11/2023, 12:00 PM	Class A-Retail	Random
145379	7/11/2023, 12:00 PM	Automated Pharmacy System	Random
145379	7/11/2023, 12:00 PM	Class A-Retail	Random
145412	7/11/2023, 12:00 PM	Class A-Retail	Random
145377	7/12/2023, 12:00 PM	Class A-Retail	Random
145409	7/12/2023, 12:00 PM	Class E-Third Party Logistics Provider	Random
145405	7/12/2023, 12:00 PM	Class C-Wholesaler	Random
144752	7/13/2023, 12:00 PM	Class E-Veterinary Pharmaceutical Facility	New
145413	7/13/2023, 12:00 PM	Class A-Retail	Random
145495	7/17/2023, 12:00 PM	Class A-Retail	Random
145494	7/17/2023, 12:00 PM	Automated Pharmacy System	Random
145494	7/17/2023, 12:00 PM	Class A-Retail	Random
145496	7/17/2023, 12:00 PM	Class A-Retail	Random
145729	7/17/2023, 12:00 PM	Automated Pharmacy System	Random
145729	7/17/2023, 12:00 PM	Class A-Retail	Random
145839	7/17/2023, 12:00 PM	Class A-Retail	Random
145839	7/17/2023, 12:00 PM	Non-Sterile Compounding	Random
142265	7/18/2023, 12:00 PM	Class E-Veterinary Pharmaceutical Facility	New
145731	7/18/2023, 12:00 PM	Sterile Compounding	Random
145731	7/18/2023, 12:00 PM	Class B-Hospital Clinic	Random
145859	7/18/2023, 12:00 PM	Class A-Retail	Random
145859	7/18/2023, 12:00 PM	Automated Pharmacy System	Random
145557	7/19/2023, 12:00 PM	Class A-Retail	Random
145574	7/19/2023, 12:00 PM	Class A-Retail	Random
145862	7/19/2023, 12:00 PM	Class A-Retail	Random
141326	7/20/2023, 9:00 AM	Class B-Pharmaceutical Administration Facility	New
145612	7/20/2023, 11:00 AM	Class A-Retail	Random
145612	7/20/2023, 12:00 PM	Non-Sterile Compounding	Random

145799	7/25/2023, 12:00 PM	Non-Sterile Compounding	Random
145799	7/25/2023, 12:00 PM	Class A-Retail	Random
143621	7/26/2023, 12:00 PM	Class B-Hospital Clinic	New
143621	7/26/2023, 12:00 PM	Sterile Compounding	New
145797	7/27/2023, 10:45 AM	Non-Sterile Compounding	Random
145847	7/31/2023, 12:00 PM	Class A-Retail	Random
<b>Total</b>	<b>Count</b>	93	

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## Monthly Pharmacy Citations Jun/Jul 23

As of 2023-08-18 08:31:22 Mountain Standard Time/MST • Generated by Camille Farley • Sorted by Date Issued (Asc

### Filtered By

Show: All citations

Date Field: Date Issued equals Custom (6/1/2023 to 7/31/2023)

Profession equals pharmacy

Date Issued	Case	DOPL Citation: Citation Number	Profession	Violation Type
6/1/2023	<a href="#">142505</a>	102655	Pharmacy	Pharmacy Violation
6/1/2023	<a href="#">144105</a>	102705	Pharmacy	Pharmacy Violation
6/13/2023	<a href="#">144550</a>	102733	Pharmacy	Pharmacy Violation
6/28/2023	<a href="#">144850</a>	102766	Pharmacy	Pharmacy Violation
6/28/2023	<a href="#">144850</a>	102767	Pharmacy	Pharmacy Violation
7/6/2023	<a href="#">145212</a>	102778	Pharmacy	Pharmacy Violation
7/19/2023	<a href="#">144843</a>	102806	Pharmacy	Pharmacy Violation
Total	Count	7		

:ending)



# DSCSA Update

Justin Macy, PharmD, JD  
Director of Innovation

## DSCSA Timeline

All state and federal serialization and pedigree laws were PREEMPTED. Eliminated “patchwork” of state laws and regulations.	Immediate November 27, 2013
New FDA standards (regulations). Replace 21 CFR Part 205 – GUIDELINES FOR STATE LICENSING OF WHOLESALE PRESCRIPTION DRUG DISTRIBUTORS (WDs). Adds regulations for Third-Party Logistics Providers (3PLs). Proposed rules released on February 4, 2022.	Effective two years after final rule for Wholesalers and 3PLs.
Required steps – Reporting of WDs and 3PLs, authorized trading partners, serialized products with 2D bar codes, product verification, suspect and illegitimate product actions.	Over 10 years
Electronic Interoperable System (tracing product to package level) for each trading partner.	Full Implementation November 27, 2023

# National Licensing Standards – Preemption

## Shift From 2014 Guidance

Proposed rule establishes a “floor” and a “ceiling” – meaning that state licensing structures that are not consistent with the proposed rules will be preempted (superseded).

## How High Is the Ceiling? How Low Is the Floor?

States with licensing structures that are “above the ceiling or below the floor” would be preempted, and facilities would instead need to obtain a federal license.

## Congressional Intent

Congress DID NOT, however, call for 50 identical licensing structures – it specifically rejected earlier drafts that called for identical licensing standards.

# Who Is the Licensing Authority?

## Distributor Licensing Process

Food and Drug Administration (FDA) plans to make information available to clarify who is the appropriate licensing authority in the wholesale distributor's state when the licensing authority is not FDA.

## 3PL Licensing Process

FDA intends to help stakeholders understand who the appropriate licensing authority is in the 3PL's state when the licensing authority is not FDA.

## Joint Regulatory Responsibility

Proposed rule frames the need for the National Licensing Standards as being critical to the protection of the supply chain but also recognizes the need for state-federal collaboration.

**Critical to focus on areas that truly impact patient safety.**

# What Comes Next

## State Comments

18 states submitted comments to the proposed rules for National Licensing Standards. ~20% of submitted comments were from states. NABP has been circulating its comments and state submissions.

## FDA Next Steps

Adoption of Final Rule on FDA's Unified Agenda for April of 2025

*This means that the earliest the rule would go into effect would be April 2027—if FDA hits that target date*

**Clarity on Licensing Authority Is CRITICAL for State Regulators AND Industry**

# Dispenser DSCSA Responsibilities Today

## Authorized Trading Partners

Do you have a process in place to ensure that you are only doing business with “authorized trading partners”?

## Receive, Store, and Provide Product Tracing Information

Do you have a process in place to ensure that you accept prescription drugs that are accompanied by the transaction information, transaction history, and transaction statement?

## Suspect and Illegitimate Product Handling

Do you have a process in place to ensure that you handle suspect and illegitimate product investigations properly? (FDA guidance on suspect and illegitimate products)

# NABP Inspection Observations

## NABP VPP

Conducted 1,198 inspections of pharmacies from June 2018-December 2022 through the Verified Pharmacy Program® (VPP®).

## Types of Pharmacies Inspected

Inspections were comprised of facilities engaged in interstate commerce and may perform sterile and nonsterile compounding.

## Scope of Inspections

VPP is akin to a regulatory inspection – it is not an accreditation. The inspection focuses on a specific area of practice, such as sterile or nonsterile compounding or specialty pharmacy. All inspections check for baseline compliance with DSCSA as it exists **today**.

# NABP Inspection Observations

## Documented Process for Establishing Status of Trading Partners

**79%** of pharmacies inspected have a documented process for establishing vendors of prescription drugs.

### HOWEVER...

**56%** of pharmacies inspected DO NOT routinely verify licenses of their trading partners; and

**61%** of pharmacies inspected DO NOT routinely check FDA's wholesale distributor database.

# NABP Inspection Observations

## Receive, Store, and Provide Product Trading Information

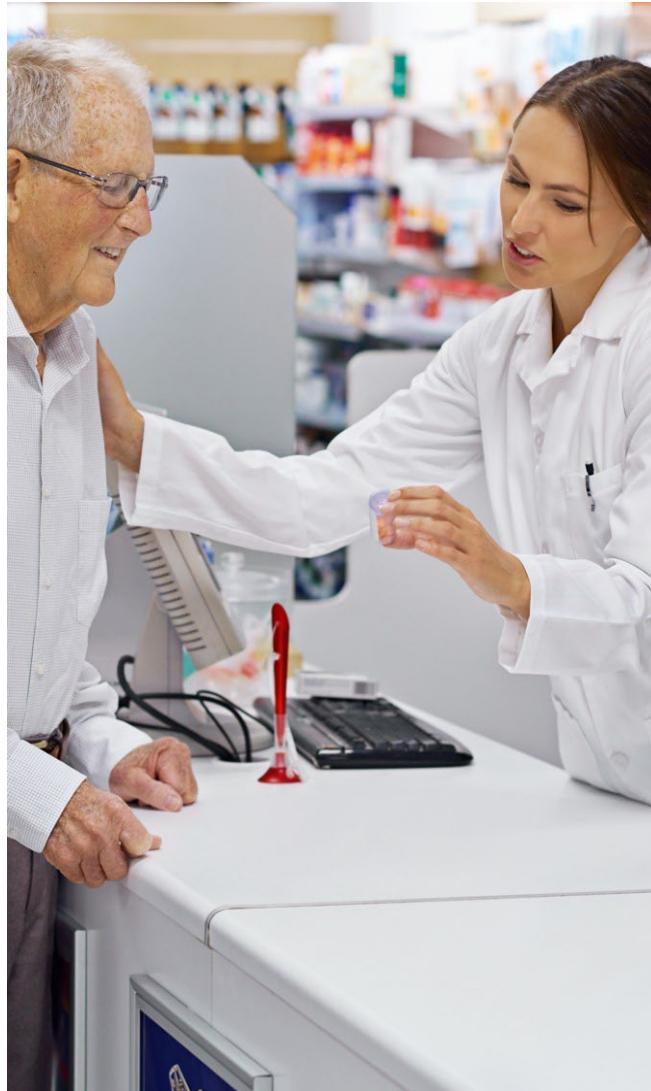
Do you have a process in place to ensure that you accept prescription drugs that are accompanied by the transaction information, transaction history, and transaction statement?

- **52%** of pharmacies inspected DO NOT routinely ensure that the transaction information, transaction history, and transaction statement are received prior to accepting shipments into inventory.

## Suspect and Illegitimate Product Handling

Do you have a process in place to ensure that you handle suspect and illegitimate product investigations properly?

- **16%** of pharmacies inspected DO NOT have a process to investigate suspect or illegitimate products.
- **8%** of pharmacies inspected have conducted a suspect or illegitimate product investigation.



# 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.

# What Next for Pharmacies?

**Establish detailed policies and procedures and how you will document training staff and how you prove you are following DSCSA requirements.**

**Determine how you are going to store product tracing information:**

- Wholesale Distributor(s)
- Solution Provider

**Determine how you are going to comply with product verification and product tracing requirements:**

- Manually
- Solution Provider
- Pulse, by NABP

# Supply Chain Ecosystem Under DSCSA

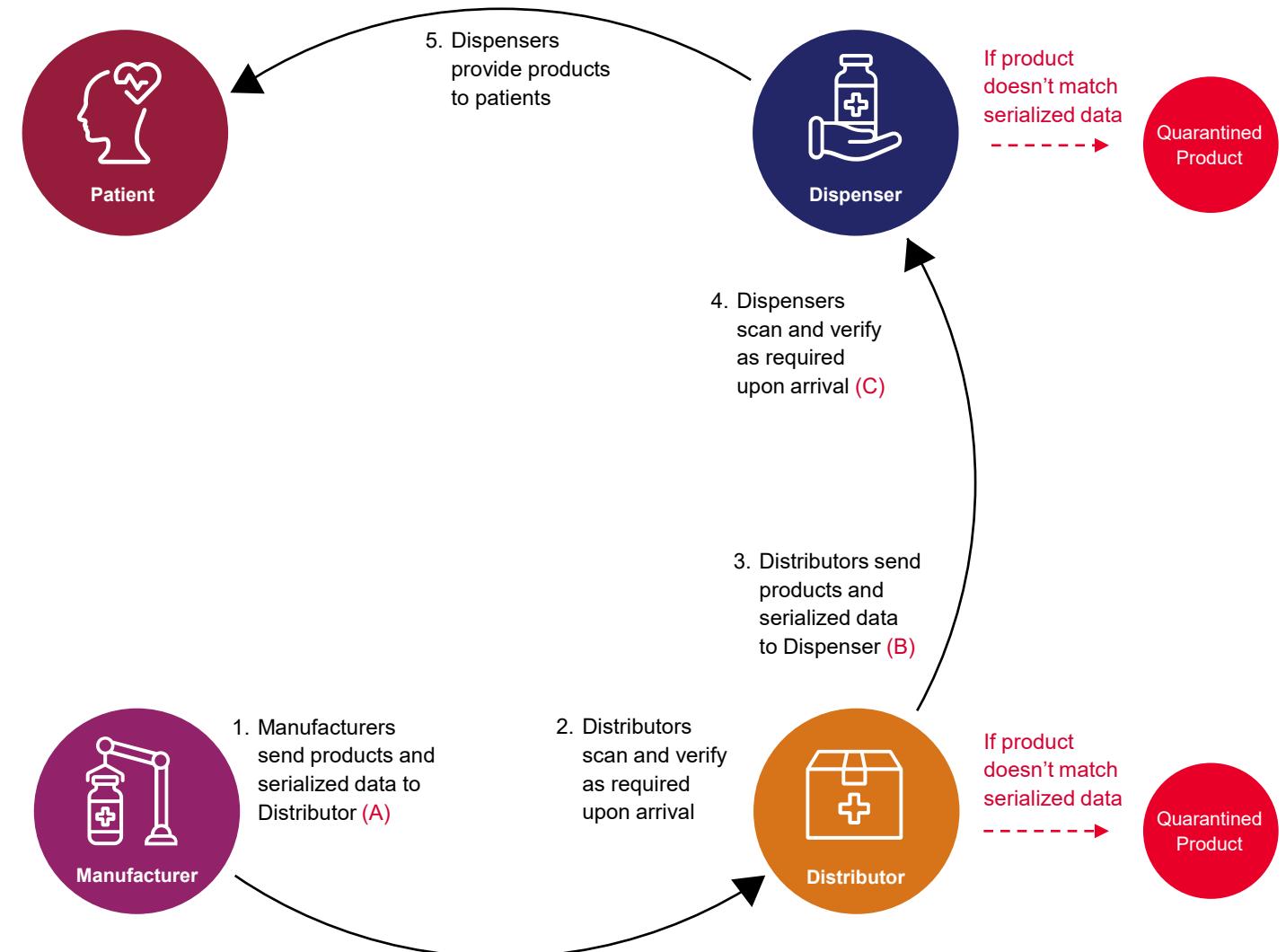
This ecosystem visualizes one way the product and product data moves throughout the supply chain from **Manufacturer** to **Patient** after November 27, 2023.

Under DSCSA, if a product does not match its serialized data or is suspicious in any way, it will be quarantined and investigated with appropriate actions outlined by DSCSA.

## KEY\*

- (A) A portion of manufacturers are not yet providing aggregated and serialized data to trading partners. If unable to make serialized data available upon change of ownership, they must hold until available.
- (B) Large national distributors expressed readiness to receive data and efforts beginning to share data, while more regional and local distributors are less prepared for 2023 requirements.
- (C) Some dispensers are exploring or able to receive DSCSA data, but most are either just beginning to understand DSCSA or not yet fully aware.

\*Based on NABP-conducted interviews in Q4 2022



# How did we get here?



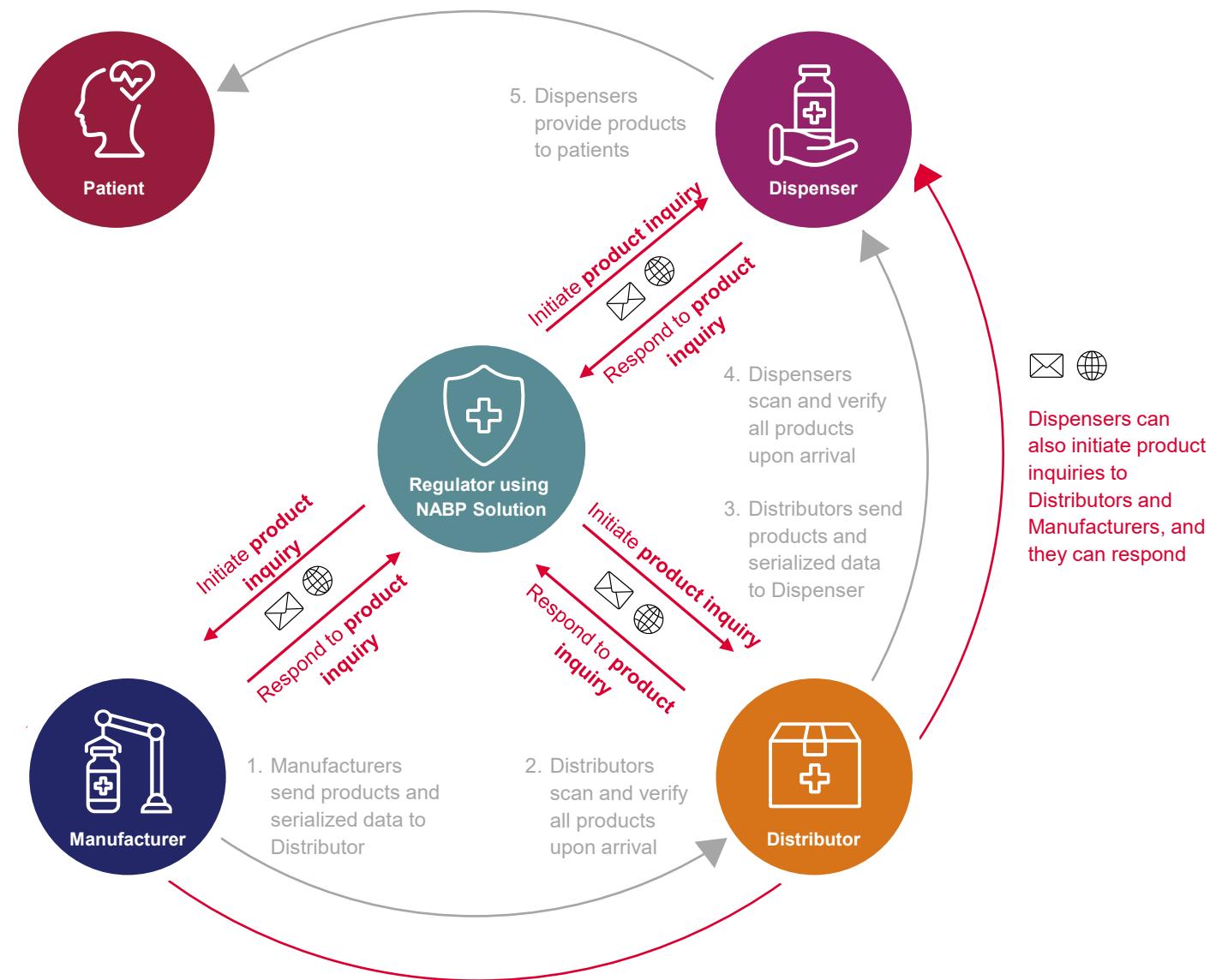
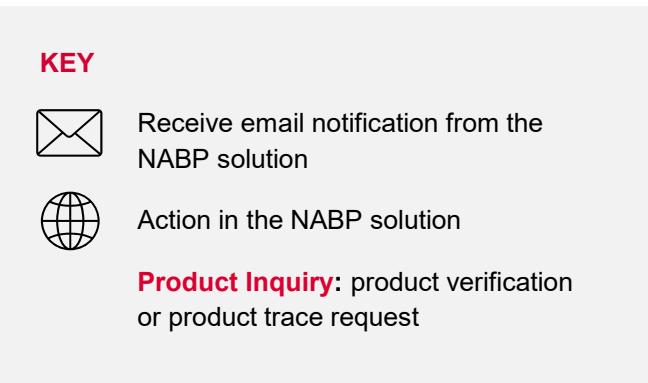
# 2023 Tracing Pilot Participants

	State Regulators	Primary Role: Manufacturer or Repackager	Primary Role: Distributor	Primary Role: Dispenser	Solution Providers	Trade, Standards, Other Orgs	Service Providers
2023 Tracing Pilot Participant	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. Ingenuis 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. Coffey County Hospital 2. Condo Pharmacy 3. Intermountain Health 4. Rite Aid 5. Sam's Healthmart 6. VA-Veterans Affairs 7. Walgreens 8. Thrifty White 9. Indiana University Health	1. Trust.MED 2. Advasur 3. Axway 4. Birch OS 5. ConsortiEX 6. Gateway Checker 7. LedgerDomain 8. LSPediA 9. Movalitas.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. KS BOP 7. ID BOP 8. OH 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

# Product Inquiries Through NABP's Solution

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.



# NABP's Goals

## **Support State Regulatory Community**

Equip the states with tools and resources to carry out their regulatory responsibilities.

## **Support Trading Partners in Meeting Compliance Obligations**

Provide accessible, inclusive tools that simplify DSCSA compliance, specifically for small dispensers.

## **Increase Participation in the Interoperable “System of Systems”**

The more widespread participation, the safer the supply chain will be.

## **Securely Support Interoperability**

Implement technological approach that is interoperable with other verification/trace ATP methods.

## **Protecting Patients and the Prescription Drug Supply Chain**

Patient safety and public health are at the heart of everything that NABP does every single day.

# What should boards be doing to prepare?

- Assess current Wholesale Distributor and 3PL laws for ways to streamline processes
- Evaluate current inspection report:
  - ATP Status
  - Product Verification
  - Product Tracing
  - Suspect/Illegitimate Product Investigations
- How boards will communicate DSCSA-related changes to regulated populations
- NABP Educational Sessions for Trading Partners and Regulators



## What's Ahead?

### When does Pulse launch?

Pulse will launch in summer 2023 prior to the DSCSA interoperability deadline of November 2023.

### How do I stay informed/involved?

Sign up for updates on our tracing pilot at [dscsapilot@nabp.pharmacy](mailto:dscsapilot@nabp.pharmacy)

Visit [pulse.pharmacy](http://pulse.pharmacy) to stay up to date.

### What can I expect moving forward?

Prior to Pulse's launch this summer, NABP will continue regularly sharing important educational materials and will setup onboarding and training sessions for boards.

# Useful Links

## How Pharmacies Can Prep Now for the November 2023 DSCSA Requirements

<https://nabp.pharmacy/news/blog/how-pharmacies-can-prep-now-for-the-2023-dscsa-requirements/>

## Demonstration of NABP DSCSA Interoperability Network

<https://www.youtube.com/watch?v=YrP41rlAgqo>

## Tracing Pilot Report

<https://nabp.pharmacy/members/programs-services/industry-information-networks/dscsa-state-regulator-network/>

## FDA DSCSA Law and Policies

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

**Pulse, by NABP** - [pulse.pharmacy](https://pulse.pharmacy)

**GS1 US** – [Identify/Obtain Global Location Number](#)



**NABP**  
National Association of  
Boards of Pharmacy

# Thank you