NABP
National Association of Boards of Pharmacy

Demystifying the DSCSA

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Learning Objectives

1. Identify dispenser requirements for compliance with the DSCSA
2. Explain the impact of FDA's "Stabilization Period" guidance
3. Recognize the shared federal-state regulatory responsibility for enforcing the DSCSA

DSCSA Summary

Components of Law

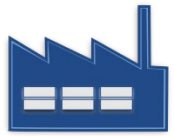
Part 2 of the DQSA (Drug Quality & Safety Act)

- Link to FDA Copy of DSCSA

Enacted Nov 27, 2013

- Intended to supersede a growing number of differing state laws
- Phases rolling out till Nov 2023 from manufacture to dispenser
- Facilitate 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	• T3 at the lot level (paper allowable) • Authorized TP • Suspect product handling & reporting	• Affix serial number • Provide T3 lot level (electronic) • Serial number retention and verification	• 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)	• Accept only serialized product • Suspect product reporting • Verification of serial numbers for suspect (Enforcement delayed to 11-27-23)	• 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/ Wholesaler	All Trading Partners

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“ceiling” – meaning that state licensing structures that are not consistent with the proposed rules will be preempted (superseded).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

FDA “Stabilization Period”- 1 Year

Not a delay, but a chance to increase adoption and stability!…but also a delay in FDA Enforcement...

FDA U.S. FOOD & DRUG ADMINISTRATION

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DSCSA compliance policies establish 1-year stabilization period for implementing electronic systems

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Drug Safety and Availability

Drug Alerts and Statements

Information about Nitrosamine Impurities in Medications

[August 30, 2023] FDA is announcing two compliance policy guidances establishing a 1-year stabilization period to accommodate additional time that trading partners in the pharmaceutical supply chain may need to adhere to Drug Supply Chain Security Act (DSCSA) requirements for electronic drug tracing at the package level.

Under the DSCSA, trading partners – primarily manufacturers, wholesale distributors, dispensers, and repackagers – are subject to certain requirements for enhanced drug distribution security.

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 for:

- 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

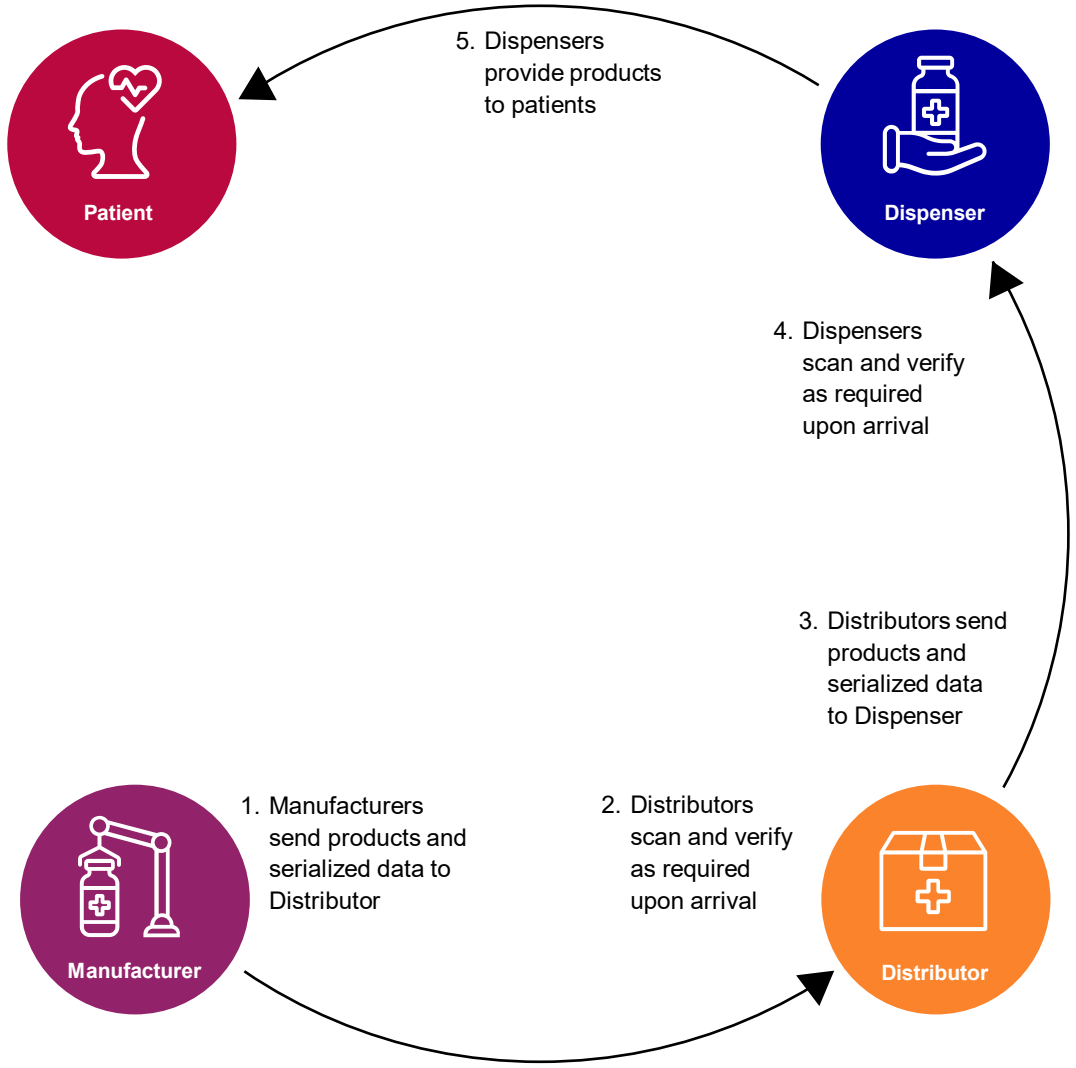
United State Prescription Drug Supply Chain

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.



The Problem

Because the supply chain is decentralized, tools are needed to achieve interoperability.

- Regulators need tools to communicate with trading partners
- Trading Partners are required to verify and trace products
- Trading Partners are required investigate suspect and illegitimate products

No single directory to connect the prescription drug supply chain.

Product Inquiries Through 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.

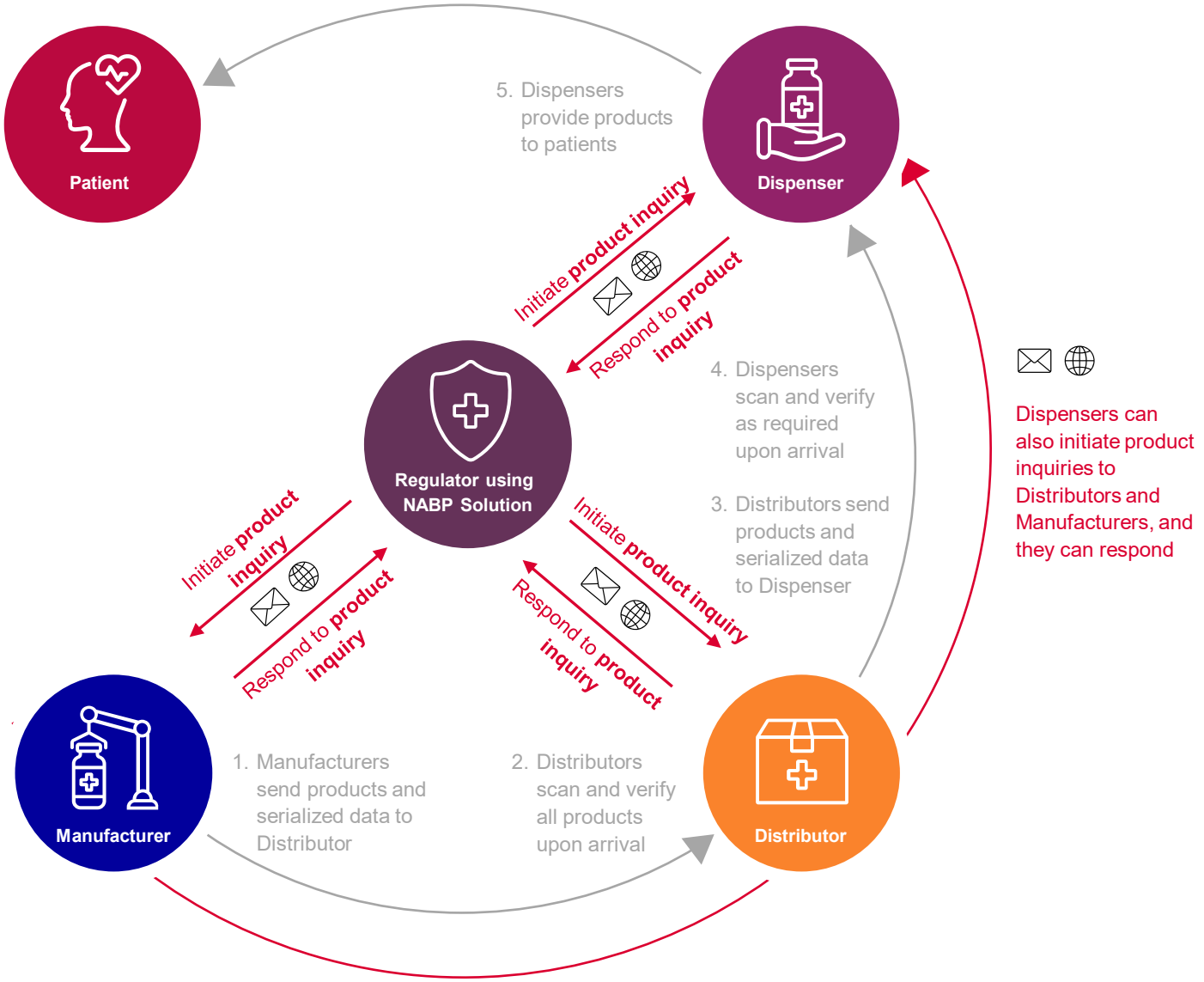
Trading Partners are identified by GLNs

Inquiries are initiated using SGTIN

KEY

- Receive email notification from the Pulse
- Action in the NABP solution

Product Inquiry: product verification or product trace request



NABP's DSCSA Solution Guiding Principles

Protect patients and the prescription drug supply chain

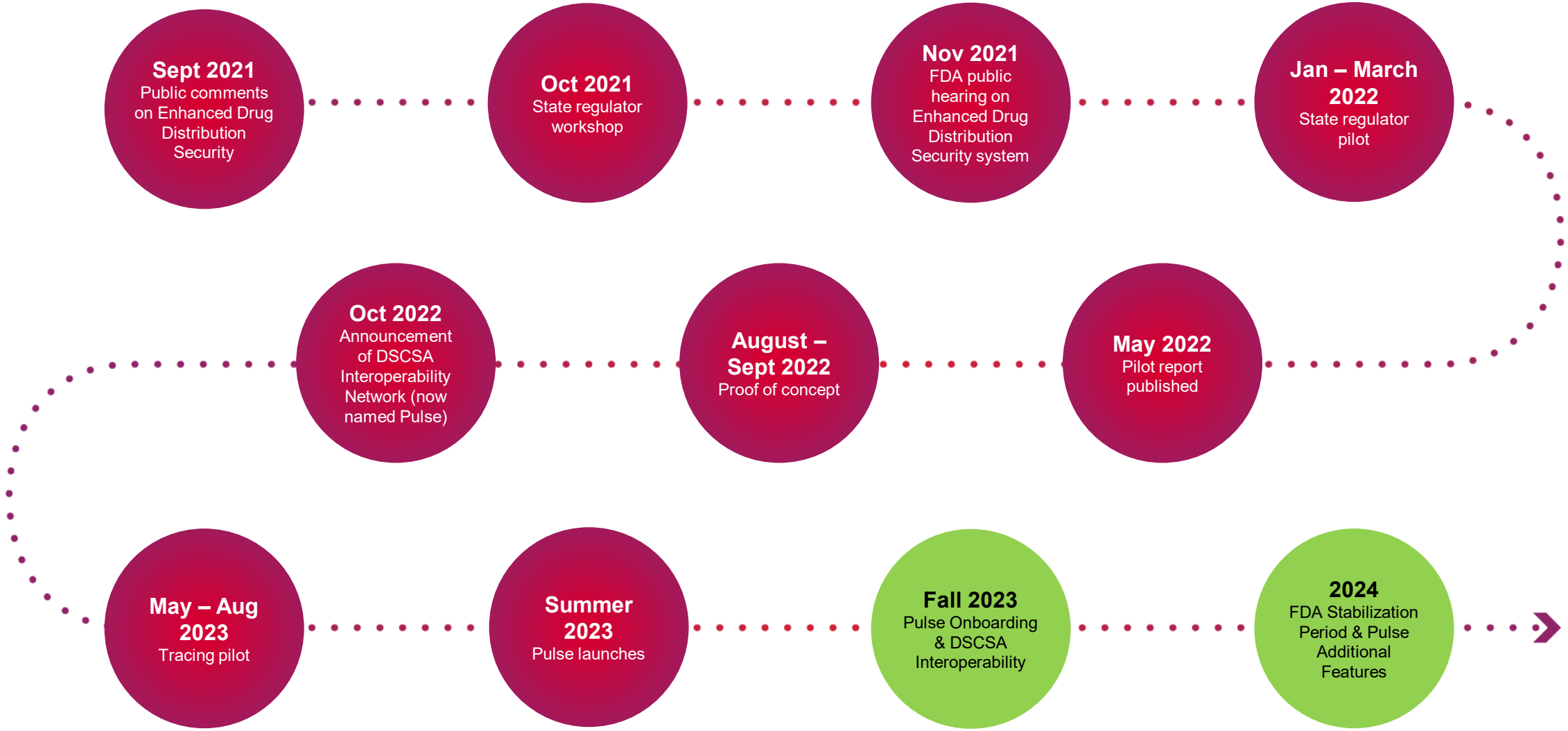
Support regulator communication with Trading Partners in a manner consistent with DSCSA

Support industry in meeting its compliance obligations under DSCSA, specifically small dispensers.

Technologically agnostic and interoperable with other verification/trace/ ATP methodologies

Increasing participation in the interoperable "system of systems" makes the entire supply chain more safe and secure

How did we get here?



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

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

How does Pulse support the Supply Chain?

Decentralized Integration Platform

Pulse supports Interoperability by serving as a decentralized integration platform that:

- Leverages GS1 Global Standards
- Empowers trading partners to maintain sovereignty and control over their own data
- Enables efficient and uniform requests for product information regulator during investigations
- Provides accessible tools to trading partners
- *Keeps the focus on the safety of the patient*

Owned and operated by a non-profit with 119-year history of protecting public health and patients.

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

Pulse by NABP™ Update

What to consider now

- Pulse is one part of a larger system of systems used by the industry
- With the FDA's "stabilization period" decision for DSCSA, there is a delay in enforcement for distributors and dispensers until November 2024 (manufacturers excluded)
- NABP continues to work in industry groups to establish standards and connections through the Pulse Partner Program
- The voluntary trading partner directory in Pulse is the critical to align the entire industry

What to expect next

- The stabilization period allows additional time for NABP to better align various industry data sources prior to open onboarding
- NABP is currently working to onboard the VA and select initial organizations in each sector
- NABP will work with state regulators to continue educating and guiding the organizations they regulate on DSCSA and Pulse onboarding
- The Pulse mailing list will be used to share upcoming webinars, round tables, and education sessions on DSCSA, Pulse by NABP, and next steps for claiming your profiles. We are excited for you to join us on this journey in the coming months

Questions?
Contact info@nabp.pharmacy

Not on our mailing list yet?
Sign up at nabp.pharmacy/pulse/sign-up/

DSCSA Components

Glossary

Term	Description
Aggregation	The process of building a relationship between a set of unique identifiers (serial numbers) linking individual salable units within a shipping case or pallet
DEA number	Registration number provided by Drug Enforcement Administration
DQSA	Drug Quality and Security Act – Includes title 1 related to compounding & title 2 is DSCSA
DSCSA	Drug Supply Chain Security Act
EPCIS	Electronic Product Code Information Services
GLN	GS1 Global Location Number
GTIN or SGTIN	Global Trade Identification Number or Serialized Global Trade Identification Number
GS1 Company Prefix	a unique string of digits issued to your company by your local GS1 Member Organization
Serialization	A unique product identification number that is encoded in a 2D Data Matrix bar code and affixed to the smallest unit of sale*
SSCC	Serial Shipping Container Code
TH, TI, TS	Transaction History, Transaction Information, Transaction Statement
T3	TH, TI, TS
VRS	Verification Router Service

DSCSA Components

Important Links

Group	Description	Description
FDA Copy of DSCSA Law	Copy of the DSCSA law as pass and signed into law. Note: There are other PDF versions if you search for DSCSA	https://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm376829.htm
FDA DSCSA	Page used by the FDA to communicate guidance, announce events and show progress towards implementation up to 2023 Interoperability	https://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/default.htm
GS1 US DSCSA Website	The core standards document of the GS1 system describing how GS1 barcodes and identification keys should be used.	https://www.gs1us.org/supply-chain/standards-and-regulations/drug-supply-chain-security-act
HDA Resources	Publications created by Healthcare Distribution Alliance that are meant to serve as a consolidation of requirements for distributors in the US market. Currently includes barcode guidelines and some DSCSA related webinars.	https://www.healthcaredistribution.org/resources
PDG	Partnership for DSCSA Governance, Inc. non-profit group building interoperability governance guidelines	https://dscsagovernance.org/
APhA, ASHP, HDA, NABP, NCPA, PDG, PDSA	Created a central place for dispensers to learn about the latest DSCSA	https:/dscsa.pharmacy/
NABP Pulse	NABP voluntary platform for DSCSA interoperability with state regulators and trading partners.	https://pulse.pharmacy/

Thank you