The Drug Supply Chain Security Act (DSCSA)

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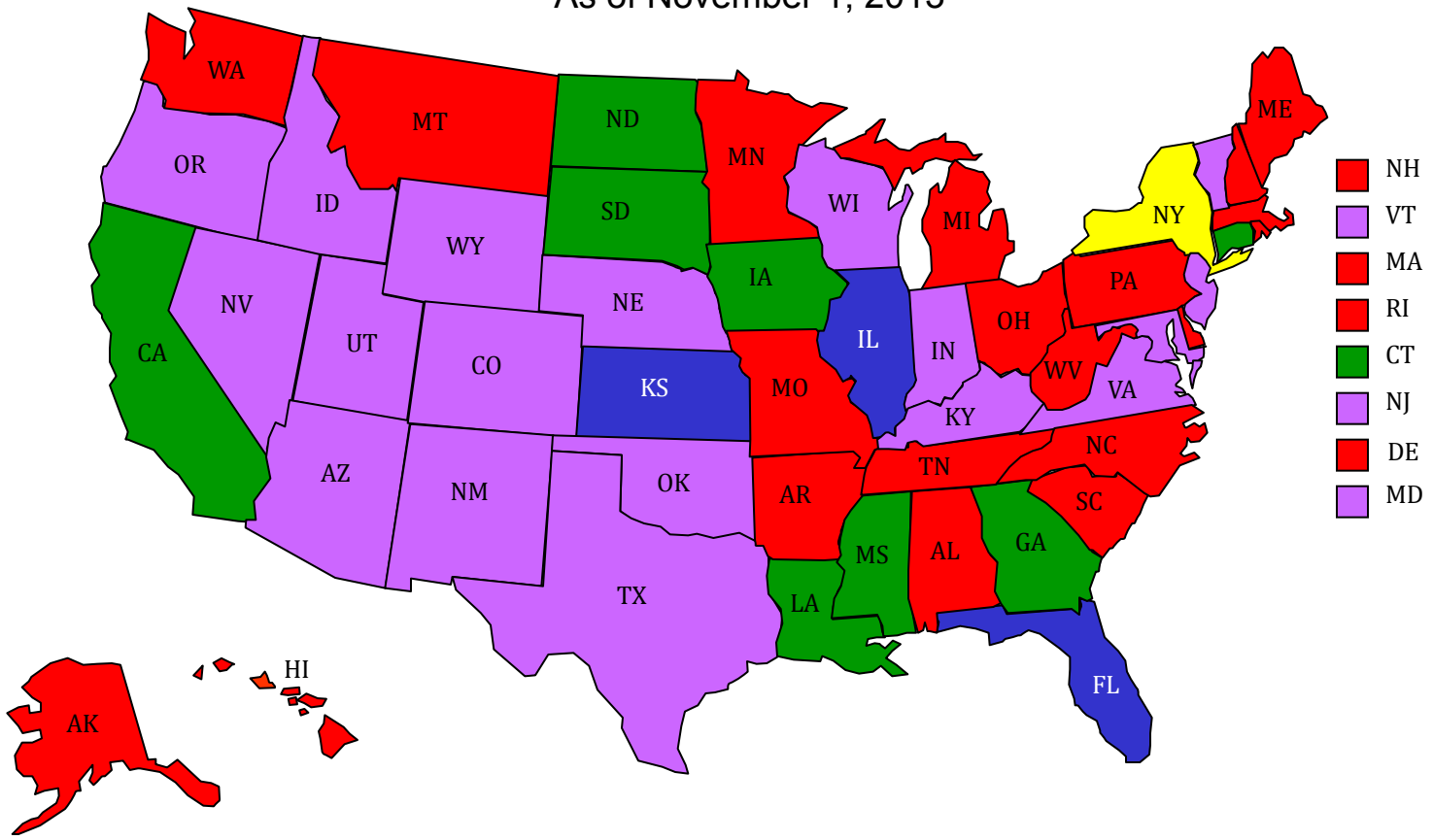
2013 HDA Map of State Pedigree Legislation/Regulations

As of November 1, 2013



20	No Legislation or Regulations
1	Proposed Legislation
8	Enacted Legislation
3	Enacted Legislation, Rules In Development
18	Final Rules Adopted

Main Concepts

- Unique Serialization of product at the unit level
- Product and package defined, only Rx drugs approved for use in the U.S.
- Firmly established the definition of “Authorized Trading Partner”
- 10-year phase in of electronic, interoperable systems for the exchange of transaction data [currently transaction information (TI), transaction history (TH) and transaction statements (TS)] to enable the tracing of prescription medicines throughout the pharmaceutical supply chain.
- Applies to transfers of OWNERSHIP, not custody or possession
- Established new processes / requirements for identifying suspect and illegitimate products in the supply chain.
- Uniform National Licensure Standards for wholesalers and 3PLs
- Role of state regulators

Final Enhanced Drug Distribution Security (EDDS)Requirements

- **Manufacturers must, for each covered package sold,**
  - Possess data with each package's unique serial number aggregated to the unique serial number on a sealed case.
  - Send the aggregated data (including serial numbers for each package sold) in an EPCIS event file in a B2B exchange with its customer (collectively referred to as "serialized data").
  - Send serialized data that is complete and accurate.
- **Wholesalers**
  - Must receive serialized data for each purchase from the manufacturer.
  - Must provide serialized data to its customers for each sale (either posted to a portal or sent in an EPCIS event file).
- **Dispensers can't purchase covered products unless they receive serialized data from the supplier.**
- **All providing/receiving, for all serialized data, for all trading partners, required on November 27, 2023 ****

Trading Partner Readiness Concerns

- **Manufacturers**
  - Many haven't aggregated and/or aren't ready for EPCIS.
  - If they are sending serialized data, it's often incomplete or inaccurate.
- **Wholesalers**
  - Cannot lawfully purchase products unless the manufacturer sends serialized data.
  - Cannot easily provide complete serialized data to customer if they didn't receive serialized data from manufacturer.*
  - Are concerned about volume of serialized data they will be providing.
  - ***Cannot*** concurrently use both current system of receiving/sending lot-level data (typically in an ASN) ***and*** EPCIS with the PI in the TI for DSCSA compliance.

**Questionable as to whether providing serialized data without having received it from manufacturer is in compliance in the first instance.*

Consequences for Lack of Readiness

- **If trading partners can't provide and receive serialized data, products can't legally move through the supply chain.**
- Supply disruptions and exacerbation of shortages
- Penalties under the FD&C Act

EPCIS Q4 2022 Highlights

Since HDA began collecting data in 2021, there have been significant strides regarding EPCIS implementation, onboarding and connecting to partners as transaction data move downstream.

This final edition of the survey was conducted in the fourth quarter of 2022, and participants included manufacturers, distributors, repackagers and 3PLs. The topline findings from this latest survey include:

- **From 51 percent in the third quarter, there was a slight increase in planned connections between manufacturers to distributors deemed "in-process/complete." The number rose to 56 percent by the end of the fourth quarter.**
- **Manufacturer participants report they face crucial obstacles in establishing connections through EPCIS. The top three challenges associated with implementation include onboarding length of time, employee knowledge and information technology-related issues.**
- **The industry reports EPCIS adoption is beneficial for "meeting GS1/DSCSA compliance," "standardization" and "efficient data capture/transfer."**

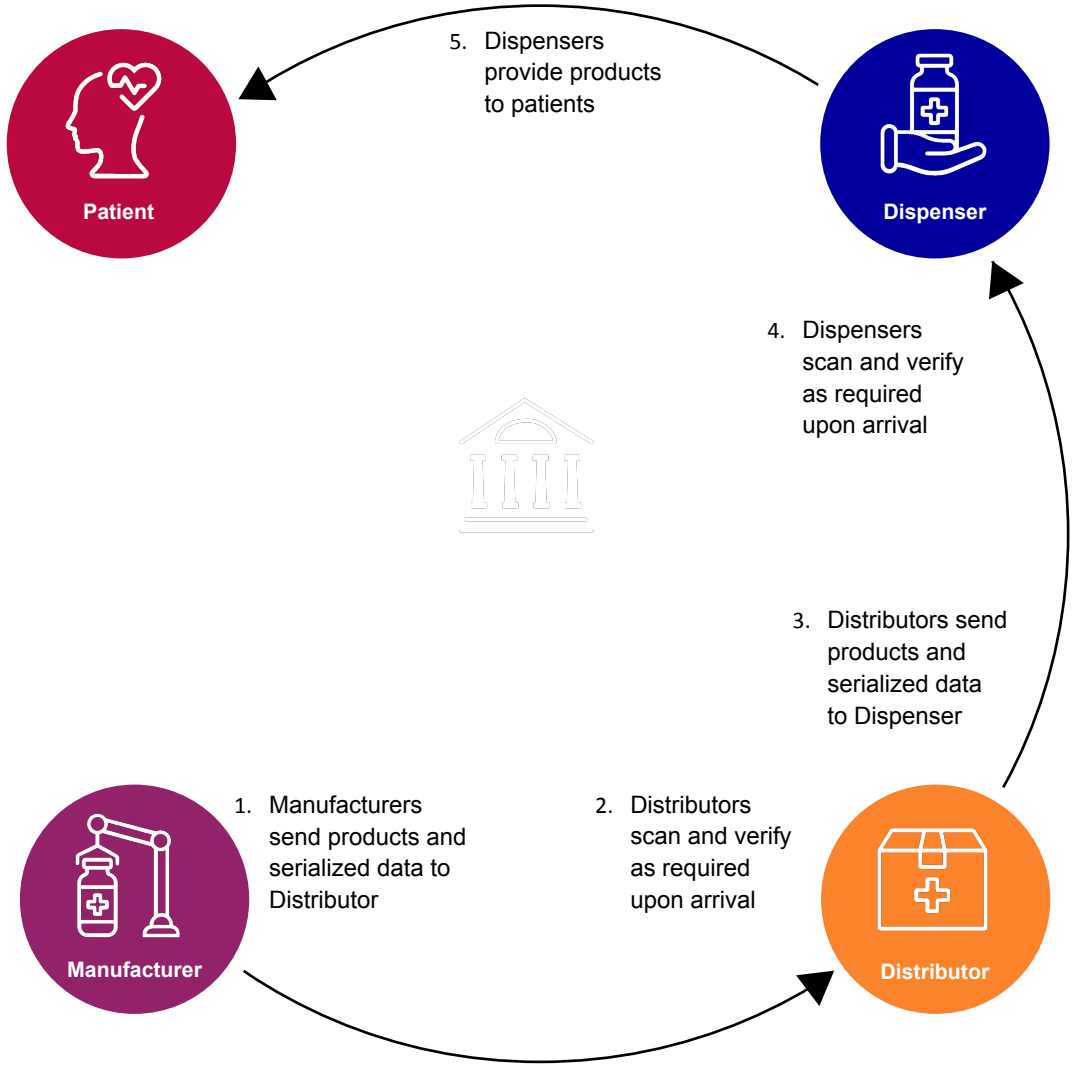
United States Prescription Drug Supply Chain

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.



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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 the 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

Transitional Inventory

- 95% of respondents will have transitional inventory as of Nov. 27. 16% of respondent are not yet sure what they will do about providing TI to their customers for that inventory.
- 84% do plan to provide some sort of TI. 63% of respondents plan to create a “pseudo” EPCIS commissioning event, while 31% plan to provide lot level TI.
- Of the respondents planning to create a pseudo EPCIS commissioning event:
    - 80% will capture item level PIs on individual packages when they sell individual packages
    - 40% will capture the PI for homogenous cases and only include that case identifier in the TI.
    - 30% plan to open homogenous cases and capture the PIs on each package in the case, then return the items to the case and include the package level PIs in the TI.

Electronic Connections

- When asked how many manufacturers each company needs to exchange serialized data with to support DSCSA, answers ranged from 620 to 90. On average, our members need to connect with 248 manufacturers, but the top five responses averaged 469. The bottom five were still over 108.
- How many electronic connections **exist now** with those manufacturers? The range was from 300 to 10, and the average was just 74.
- When asked how many electronic connects are **in process**, members reported an average of 75, with the range from 455 at the high end to just 3 on the low side. Top 5 respondents were working on nearly 200 connections at this time. These in process connections represent an average of 33% covered product, though responses range from 100% to less than 1%.
- How many manufacturers have not started efforts to establish a connection? The average across responses was 140 manufacturers have not started, with the range from 245 to 52. Top 5 responses averaged 224 and bottom 5 was 52. **On average, the manufacturers that have not started represent 42% of covered SKUs, with the range from 69%-20%**.

EDDS Compliance Policy

- Issued on August 25, 2023 – effective immediately, though comments can be submitted.
  - Posted on FDA guidance page
  - "FDA does not intend to take action to enforce" the requirements of §582(g)(1), *Enhanced Drug Distribution Security*, until November 27, 2024.

> This guidance is not intended to provide, and should not be viewed as providing, a justification for delaying efforts by trading partners to implement the enhanced drug distribution security requirements under section 582(g)(1) of the FD&C Act. FDA strongly urges trading partners to continue their efforts to implement necessary measures to satisfy these enhanced drug distribution security requirements.

Emphasis in original

Some additional observations

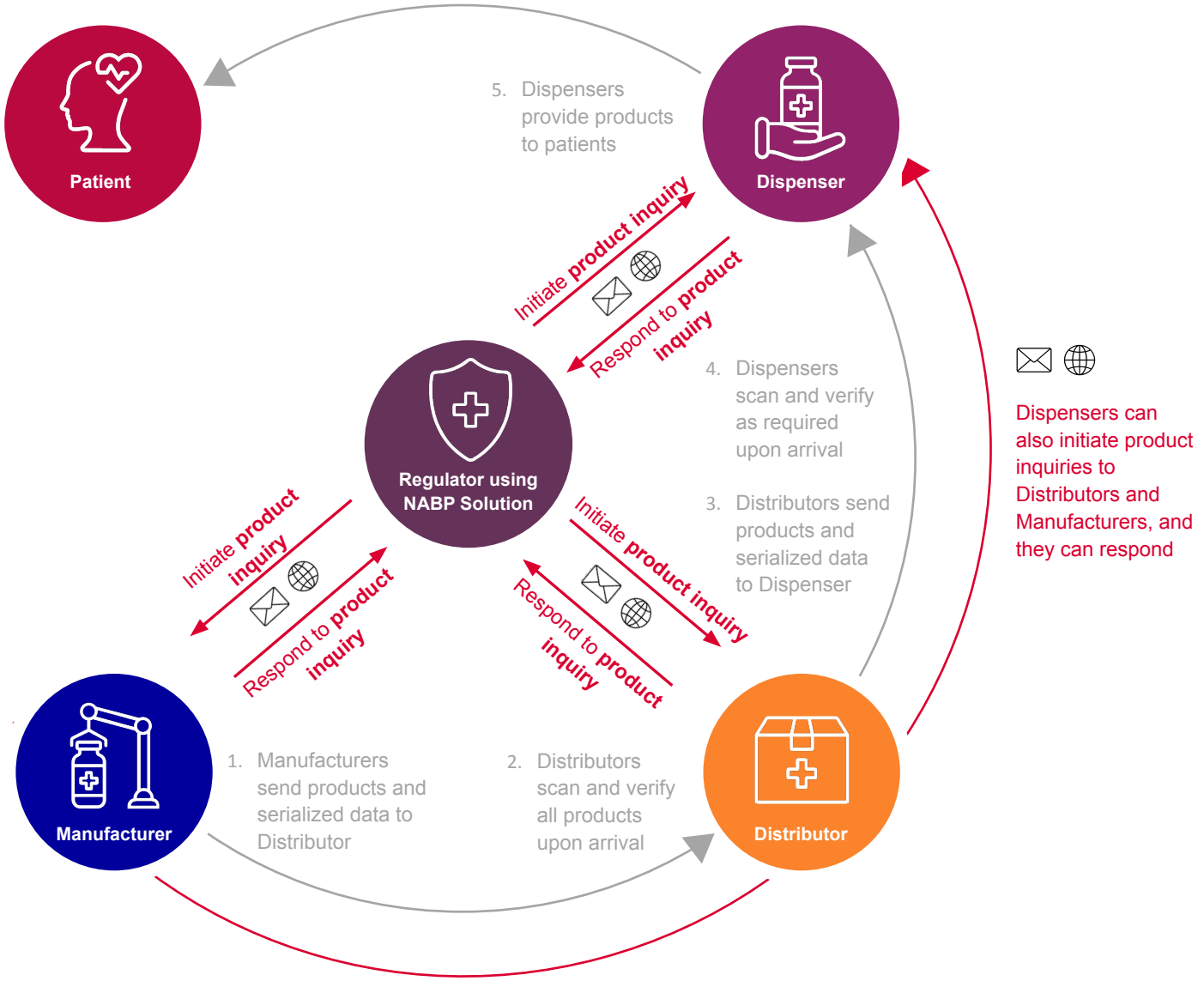
- FDA "generally expects trading partners to have the systems and processes in place to meet these requirements ***as of November 27, 2023***" NOT 2024!
- The additional time beyond November 27, 2023 is for "systems to stabilize and be fully interoperable for accurate, secure, and timely electronic data exchange."

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.



KEY

Receive email notification from the Pulse

Action in the NABP solution

Product Inquiry: product verification or product trace request

National Licensing Standard

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

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.**

Q&A

Thank you

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