pulse™ by NABP

Report of the DSCSA State Regulator & Dispenser Tracing Pilot With the United States Pharmaceutical Supply Chain

NABP Members

Participants:

- Alaska
- Idaho
- Iowa
- Kansa
- Kentucky
- Maryland
- Massachusets
- North Dakota
- Ohio
- Virginia
- NABP Associates – Josh Bolin, Bill Cover, Gregg Jones, Eileen Lewalski, Justin Macy
- InfoNetworks – NABP Contracted Partner
- Ten Count Consulting – NABP Contracted Partner

Observers (Stay Informed):

- Food and Drug Administration (FDA)
- California
- Connecticut
- Florida
- Louisiana
- Minnesota
- Missouri
- Missippi
- Montana
- New Hampshire
- New York
- North Carolina
- North Dakota
- Pennsylvania
- Rhode Island
- South Dakota
- Tennessee
- Texas
- Utah
- Washington
- Wisconsin
- Wyoming

Industry and Organizations

Manufacturer Participants:

- Bristol Myers Squibb
- EMD Serono
- Eli Lilly and Company
- Genentech
- Ingenus Pharmaceuticals
- Johnson & Johnson
- Novo Nordisk
- Pfizer
- Sanofi

Distributor Participants:

- Cencora
- Capital Wholesale Drug Co
- Cardinal Health
- Hercules Pharmaceuticals
- McKesson
- Mutual Drug

pulse™ by NABP

Dispenser Participants

- Condo Pharmacy
- Indiana University Health
- Intermountain Health
- Rite Aid
- Thrifty White Pharmacy
- Sam's Health Mart
- Veterans Affairs (VA)
- Walgreens

Solution Providers

- Advasur Serialization Compliance Services
- Axway
- BirchOS
- ConsortiEX
- Gateway Checker
- SAP
- LedgerDomain
- LSPediA
- Movilitas.Cloud
- Optel Group
- RfXcel
- RxScan
- Systech
- TraceLink
- TrackTraceRx
- Trust.MED

Observers From Across Industry

- AAM
- Amgen
- Anda Inc
- American Pharmacists Association
- Apotex
- ArentFox Schiff LLP
- Auto-ID Solutions
- BBF Consulting
- Center for Supply Chain Studies
- CVS Health
- DHL
- Excel
- Excellis Health Solutions
- Gilead Sciences
- GS1 US
- Healthcare Distribution Alliance (HDA)
- Health Mart Pharmacy
- Hikma Pharmaceuticals
- IEEE
- InfiniTrak
- Inmar
- Insolate Technologies
- Medline Industries
- Mississippi Senior Care
- Morris & Dickson co.
- Murtagh Consulting
- National Community Pharmacists Association
- Novartis
- Open Credentialing Initiative
- OFW Law
- Partnership for Safe Medicines
- Partnership for DSCSA Governance (PDG)
- Providence Health Technologies
- PMC
- Precision Dose
- Premier RX Wholesale
- RO
- Sagent Pharmaceuticals
- Smith Drug Company
- StoreMed
- Transplant Pharmacy
- Uptown Pharmacy
- United States Pharmacopeia
- Value Drug Company
- Vantage Solutions
- Vizient
- Walmart

Executive Summary

NABP, working at the direction of its member state boards of pharmacy and other state regulators, undertook a second product tracing pilot to further align on requirements, systems, and integrations needed to comply with the November 27, 2023, Drug Supply Chain Security Act (DSCSA) requirements. This effort included:

1. A series of workshops to inform, assess, and outline the representative use cases required for all state regulators and the entities they oversee to meet the federal law requirements.
2. An industry-wide tabletop pilot to explore the use cases, identify findings and gaps, and develop a roadmap to implementation.

This pilot was the first time a significantly broad representation of industry leaders, including manufacturers, distributors, dispensers, solutions providers, and state regulators, participated and collaborated to explore DSCSA interoperability. This diverse group worked together over several weeks to better understand business requirements and determine gaps in the tools and processes required to support the industry.

The primary goals of Pulse by NABP™ are to facilitate the creation of a trusted ecosystem to exchange DSCSA-related data, such as product tracing requests and responses for serialized drug products as required by law. The network is expected to:

- be consistent with the Uniform National Policy (Section 585 of the Federal Food, Drug and Cosmetic Act) and FDA guidance;
- implement a uniform request/response standard for state regulators and trading partners to incorporate DSCSA requirements and FDA guidance;
- create an interoperable framework for state regulator and/or trading partner communication;
- ensure that only authorized regulators can access and make requests to authorized trading partners (ATPs);
- protect the confidential and/or proprietary information of participants; and
- focus on the most critical patient safety use cases.

Following the workshops and pilot project, NABP developed this report to outline the current state of DSCSA compliance within the industry and the proposed steps required to develop an interoperable framework for the industry. This document will be published on NABP's website and proactively shared with state regulators, boards of pharmacy, industry sectors, standards groups, professional trade organizations, solutions providers, and federal entities to implement and measure DSCSA compliance.

The key findings of the completed pilot were documented in the following areas:

- **Critical Industry Alignment** – There were five key findings (outlined below) related to the need for an authoritative trading partner information source, alignment of foundational identification data, expected adoption usage growth, reasonable technological barriers to product safety (especially for small independent pharmacies), and alignment on tracing messaging formats.
- **Standards and Best Practices Alignment** – there were 24 findings that were related to topics that should be shared with industry and worked with organizations such as PDG, GS1, HDA and other industry alignment groups.

- **General Findings** – There were 20 findings that provided insights for NABP, its state members, and regulatory groups in the further development of tools such as Pulse by NABP for DSCSA compliance.

As a result, NABP intends to continue development, testing, and industry alignment in the following critical areas:

Critical Finding	Finding Description
1. Trading Partner Directory	Confirmed as a key functionality needed in Pulse by NABP as identified by industry in the previous tracing pilot. State regulators need an authoritative directory (licenses, registrations, identifiers, and contact information) and functional application to engage with trading partners. All stakeholders need an aligned trading partner directory confirmed by data owners (who, where, and how to connect).
2. Expect Growing Tracing Volume	Expect average adoption times and request volumes to be established as paper transaction history sunsets and serialized transaction information data expands throughout supply chain.
3. Achievable and Aligned Security	There is a need for equitable technological approaches that will enable adoption from the most at-risk small dispensers. Most manufacturers highlighted the importance of reducing restrictions for requestors, while others highlighted the need for more technology-enabled security.
4. Foundational and Confirmed Data	Start with foundational state and federal license/registration data and allow actual trading partners (responsible) to confirm information, including identifiers assigned such as GS1's Global Location Numbers (GLNs). Based on follow-up data analysis in October 2023, NABP determined that around 6-7% of pharmacy dispensers do not have published GLNs for all locations, while most have multiple GLNs that have been created for the same locations.
5. Request/ Response Messaging	PDG drafted JSON message structures for product tracing requests and response work with some suggested improvements. NABP should continue to monitor as related functions are added to Pulse.

NABP expects to continue working with industry stakeholders and alignment groups as they continue to address these interoperability alignment findings.

The Journey Remaining to Complete DSCSA 2023 Requirements

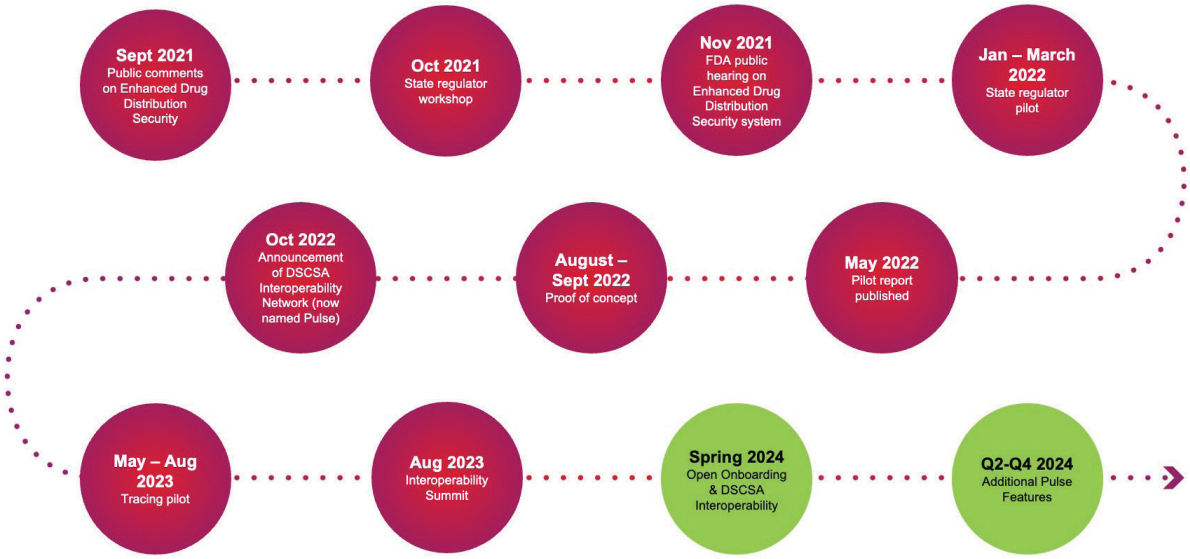
With the final DSCSA 2023 requirements now in effect and FDA confirming the need for more time with the recently announced stabilization period (effective through November 27th, 2024), there is significant work remaining for industry and state/federal agencies to fully develop, integrate, and stabilize the systems and processes required for compliance. These requirements raise several concerns for state regulators and the industry partners they regulate, including:

- ensuring that properly authorized direct and indirect trading partners are engaged for product purchases and exchange of data;
- exchanging required transaction information and related transaction statements as relevant product ownership events occur;
- establishing the systems and networkability necessary for supporting product tracing and product verification requirements; and
- ensuring the ability to demonstrate compliance with all required aspects of the law.

FDA also noted in a 2021 draft guidance titled Enhanced Drug Distribution Security at the Package Level Under the Drug Supply Chain Security Act that the enhanced system "should allow FDA and other federal and state officials to communicate with trading partners' individual systems and receive relevant information upon request."

With the announcement of the Pulse by NABP platform, NABP intends to initiate a trading partner directory based on state and federal license and registration information records in first quarter 2024. All trading partners will have the opportunity to claim system profiles related to their organization, which will be based on existing accreditations and licensure address confirmation processes. This process will include the ability to confirm contact and location identification information, including email addresses, GS1 GLNs, and other widely used identifiers.

How did we get here?



This diagram highlights the key events in NABP's process of engaging the industry and ensuring the Pulse by NABP platform is developed in an open and collaborative way to support the Association's mission.

Engaging State Regulators

NABP continues to hold regular meetings with state regulatory agents to provide updates on the readiness of the Pulse platform and the related trading partner directory, each of which can be utilized for DSCSA-related communications. Once the directory is operational, evolution of the network will move toward the planned enablement of product verification and product tracing for state regulators and the dispensers they regulate.

The efforts will continue to leverage the previously established use cases that were utilized as the basis for the tracing pilots and proof of concepts conducted. These scenarios include:

1. illegitimate and suspect product investigations;
2. fraudulent activity;
3. product recalls; and
4. routine compliance audits.

How Was the Pilot Conducted?

The goals of the pilot were developed with the engaged state regulators and reviewed by participants from across the supply chain. The goals included:

- **Basic Connectivity:** Conduct initial trial runs of trace messages in email and/or JSON message formats
- **Messages and Formats:** Explore industry needs for messaging exchange for DSCSA transactions including the Pulse by NABP trading partner directory
- **Technical Requirements:** Understand email or system-to-system communication necessary between trading partners and/or solutions providers
- **Identity and Authorization:** Economical, interoperable, and viable approaches for ensuring trusted, confidential, and secure messaging
- **Align Sectors, States, Solutions Providers, and Standards:** Understand additional needs or requests of stakeholders; provide feedback for industry work groups such as PDG & GS1

With these objectives in mind, the following use cases were developed for the pilot:

1	Explore State Regulator Trace Requests • Scenarios for key use cases (suspect/illegitimate products, fraudulent activity, recalls, and routine compliance) • Methods, message formats, and technology • Communication with trading partners directly and/or their solution/service providers
2	Explore Trading Partner Responses • Handling within each use case with various responders • Methods, message formats, and technology
3	Explore Dispenser Trace Requests • To support suspicious product investigation • Methods, message formats, and technology

In each of these use cases, the assumption for the pilot was that each scenario required a product trace request to be initiated. A product information trace request, as outlined in the DSCSA and FDA guidance, is the act of collecting transaction history and transaction statement records from all owners of the product, back to the original manufacturer who created the product identifier and related human- and machine-readable labeling.

The pilot was conducted over five months through weekly status meetings and working breakout sessions. The executed pilot included the completion of:

- 19 product tracing scenarios
- 26 full test runs
- 68 trace requests and responses

Detailed Findings

During the pilot, each participant was able to share feedback and highlight concerns to discuss with the pilot work group. After review in the work group meetings, this feedback was consolidated, updated, and formed the basis for the pilot findings.

NABP has agreed to address the most critical findings, which were highlighted in the executive summary. We appreciate and value the partnership and efforts of PDG and GS1 to take the lead on other findings and gaps. NABP is committed to collaborating with these and other industry organizations as each item is addressed.

Standards and Best Practices Alignment – there were 24 findings related to topics that should be shared with the industry and worked on with groups such as PDG, GS1, and other industry alignment groups.

Source	Description
State Regulator	**Soft Warning Message for Duplicate Requests:** It is unclear if some requests had been generated and ended up creating duplicates. Is it possible to give a soft warning if you have an active open request for that product, scan, and trace recipient combination?
State Regulator	**Clearer Indication of Trace Recipient:** User generated a trace request with the State Regulator and searched for profiles (licenses and GLNs) for a distributor and noticed multiple locations appeared. Unclear which one to send the trace to or if trace location will default based on company setup eventually?
Manufacturer	**Authority Checks:** Can it be assumed that trace requests will only come from regulators and pharmacies with valid licenses/IDs?
Manufacturer	**Authority Checks:** Can it be assumed that trace requests will only come from regulators and pharmacies with valid licenses/IDs?
Manufacturer	**Follow-Up to Requestor:** Once a trading partner submits a response to the trace, can we follow up with the regulators for more information on the investigation in the application and/or by email?
Manufacturer	**Negative Response:** There is a need for the ability to indicate that a National Drug Code/Global Trade Item Number/serial number did not match any transaction information on record.
Manufacturer	**Negative Handling:** A negative would likely lead to a possible investigation. This could either indicate a confirmed illegitimate or may be due to system issues or data entry.
Manufacturer	**Comments:** Could the response include the ability to comment if, for example, the responder feels it is important to provide supplemental information?
Manufacturer	**Electronic Product Code Information Services (EPCIS) 1.2 response:** Our solutions provider has an upcoming solution to generate transaction information/transaction statement (TI/TS) files following GS1 EPCIS Lightweight messaging standard R1.2. Is our assumption that the EPCIS file will be ingestible by Pulse?
Manufacturer	**3911 or Other Investigation Numbers:** Are trading partners expected to inform direct trading partners with form 3911s if a trace request was received?
Manufacturer	**Group Email Address:** Can we respond directly to the state regulator from a central company DSCSA mailbox we use to monitor and track DSCSA inquiries vs going into Pulse to upload TI/TS?

Manufacturer	**Security Info:** Trace request file went to spam and the address link was flagged by corporate security as needing additional clearance to utilize
State Regulator	**Invalid Traces:** If there are traces that are no longer valid, can requestors have the ability to cancel, void, revoke, or archive a trace request?
State Regulator	**Receipt Confirmation:** Is there a way to tell if a trading partner has reviewed the request?
State Regulator	**Repeat Request:** Is there a process to submit a repeat request if a response hasn't been received after a certain amount of time?
Manufacturer	**PDF File:** Is it possible to upload a PDF file as the trace response rather than a JSON file? At least initially, our system will generate a PDF trace response vs a JSON file.
Manufacturer	**Request download:** It would be helpful to have the ability to download the request.
Manufacturer	**Response Contact Information:** Include contact information in the response for follow-up by requestor (may be different than the request routing)
State Regulator	**Case Number:** Please add a field where state regulators can put in a "case number" that doesn't go with the request but remains visible under our "active requests" page. This is helpful when there are multiple requests made for various cases (inspections or investigations).
State Regulator	**Photos:** Add ability to upload .JPEGs/photos/documents and send with requests.
State Regulator	**Comments:** Can we add the ability to send comments with the trace request?
Dispenser	**Start Time of the Trace Request:** Is it possible to align on a required start time generally, or will response time always be determined on a case by case basis?
Manufacturer	**Incorrect Destination:** Received a trace request for another manufacturer. Is it possible to help prevent systematically?
Manufacturer	**Archiving:** Completed trace requests make it harder to manage queue. Is it possible to allow users to archive or filter to only see open requests?
Manufacturer	**Trace Request as Suspicious Product Indication:** There is concern on if a response should be given for a suspect product if the requestor is essentially saying "we have suspicious product," or should it go directly to an investigation? Would a tracing response at the manufacturer level happen without an investigation?

General Findings – There were 20 findings that provided insights for NABP and state member regulatory groups in the further development of tools for an interoperable approach to DSCSA compliance. These findings are consolidated into the following topics:

- advance dashboards and reports for monitoring and managing communication;
- provide the ability for trading partners to work with state or federal regulators to initiate trace requests when required for patient safety;
- provide email alerts and summaries to minimize the need to log in to the Pulse platform;
- advance integration to allow messages to be sent system to system for users to interact with as needed (moving beyond email will be required);
- more detailed error and warning messages to minimize misunderstanding; and
- better alignment on time zones and "starting event" for tracing response time tracking.

Next Steps

- NABP has initiated development and deployment plans to address the gaps identified during the pilot project. To help guide and inform the development process and to build on the collaborative efforts between trading partners and state regulators, NABP will convene an advisory group. The advisory group will be composed of trading partners and state regulators.
- NABP will convene regular meetings with Pulse Partner Program solutions providers to collaborate on development plans and to ensure that solutions providers are on a path toward interoperability for any required interactions with the platform, such as directory searches, license/ATP status checks, product tracing, or product verification messaging. In addition, this will allow NABP to coordinate testing and further exploration with solutions providers as systems evolve and integrate.
- NABP will continue to engage with PDG and GS1 to help inform standards development or to participate in future workshops, pilots, and other activities as necessary.

Considerations for State Regulators

- **Sunset of transaction history:** One of the most significant impacts of the transition to electronic interoperable tracing at the unit level is that the transaction history sunsetted as 2023 requirements were met. The impact for regulators is that this transaction history is no longer available for review at the time of inspection or investigation. This was the primary purpose of conducting a pilot that would facilitate the collection of the transaction information necessary to rebuild that transaction history.
- **DSCSA is an ownership law:** While transaction histories include information about the physical movement of product(s), the November 2023 requirements mandate the exchange of transaction information showing change of ownership of the product. States may independently request information about the physical movement of product, but that is not included under the DSCSA tracing provision.
- **Impact on compliance audits and inspections:** Given the sunsetting of the transaction history and other requirements under DSCSA, regulators should consider how they will ask trading partners to verify compliance with DSCSA. In particular, how will they verify that trading partners are "authorized" under DSCSA, and how will they prove that they have systems and processes in place to comply with DSCSA?

Considerations for FDA

NABP is grateful that representatives from the agency were able to attend meetings and webinars as observers, and the Association is hopeful that it provided insight into areas of needed attention.

- Consistency With Uniform National Policy and FDA Guidance: As referenced in previous public comments and presentations, any solution(s) that NABP builds(s) to facilitate state regulator communication with trading partners will be built in a manner that is consistent with DSCSA, as well as any final regulations.
- State-Federal Collaboration: While it is understood that FDA will pursue its own means of facilitating communications with trading partners, NABP maintains that state regulators must have their own independent means of consistent and efficient communications with trading partners to fulfill their regulatory obligations prescribed within DSCSA.
- 3911 Form Automation: Due to the expected importance of the 3911 form and its relationship to product status, we encourage the agency to consider automating integration to the 3911 forms. This would include interaction with state and other federal agents, along with facilitating communication to/from the manufacturers as product quality owners.
- Support Existing Investigation Processes: State and other federal agents are authorized to initiate product information requests and conduct investigations as outlined in DSCSA. These agents will be required to have independent access and maintain the ability to manage this collected data in order to carry out their daily responsibilities.
- Dispenser Engagement: While the engagement in DSCSA-related work groups continues to increase, there is still a common misunderstanding of the level of effort and time needed to comply with the requirements of DSCSA. FDA and the dispenser's trade groups can help to raise awareness through training and better communication of the expectations for 2023, as well as help develop better requirements for industry governance, standards groups (like PDG and GS1), and solutions providers.
- Regulator Learning Curve: DSCSA-related systems, processes, and data are still in the early stages, and we encourage all state and federal authorities to consider conducting and participating in pilots directly with stakeholders to better understand the current conditions and prepare for the significant attention needed for DSCSA 2023.