NABP
National Association of Boards of Pharmacy

Report of the DSCSA State Regulator Pilot with the

UNITED STATES PHARMACEUTICAL SUPPLY CHAIN

NABP Members

Participants:

- CA – Michael Ignacio
- ID – Berk Fraser
- KS – Alexandra Blasi
- MA – Rick Geaney, John Murray, Samuel Penta
- ND – Mark Hardy
- OH – Jenni Wai
- NABP Associates – Josh Bolin, Bill Cover, Gregg Jones, Eileen Lewalski, Justin Macy, Neal Watson
- Ten Count Consulting – Mark Karhoff

Observers:

- Food and Drug Administration (FDA) – Daniel Bellingham, Lysette Desheilds, Connie Jung, Abha Kundi, Aaron Weisbuch
- KS – Shelly Rosebrook
- MA – Monica Botto, Michelle Chan, William Frisch, Joanne Trifone

Industry and Organizations

Manufacturer Participants:

- Apotex – Malinda Baumer, Stephen Coady, Fidel Hosein, Shivendra Mahendran
- EMD Serono – Sue Gleason, John Ryan
- Genentech – Kathy Daniusis, Vid Rajaram, Loretta Stipa
- Johnson and Johnson – Tristin Ault, Blaire Korman, April Sese
- Pfizer – Mike Mazur
- Sanofi – Arthi Nagaraj

Distributor Participants

- AmerisourceBergen – Ameer Ali, Kelly Lacy, Matt Sample
- Hercules Pharmaceuticals – Savannah Aronson, Eduardo Cedeno, Brianni Lyons, Tim Ward
- McKesson – Scott Mooney
- Premier Rx Wholesale – Joe Condo, Kyle Parker

Dispenser Participants

- Health Mart – Shane Wendel
- Mississippi Senior Care – Jamie Gunnells
- The Transplant Pharmacy – Jay Gulley
- Uptown Pharmacy – Max Peoples

- Walgreens – David Brown, Melva Chavoya
- Walmart – Asma Ishak-Mahdi

Trade and Standards Organizations

- American Pharmacists Association (APhA) – Ilisa Berstein
- GS1 – Andrew Meyer, Tracy Nasarenko
- Healthcare Distribution Alliance (HDA) – Anita Ducca, Justine Freisleben, Elizabeth Gallenagh
- Open Credentialing Initiative (OCI) – Brittany Payson
- Partnership for DSCSA Governance (PDG) – Eric Marshall

Observers From Across Industry

- Amgen – Natalie Helms
- ANDA Inc – Emily Hall
- ArentFox Schiff LLP – Brian Waldman
- Auto –ID Solutions – James Tucker
- BBF Consulting – Brian Files
- Bristol Myers Squibb – Diane Redler
- Cardinal Health – Maryann Nelson
- ConsortiEX – James Brunner, Tim Dornak, Gary Wyndham
- Center for Supply Chain Studies – Bob Celeste
- Excellis Health Solutions – Karyl Brown, Deana Kruopas
- Gilead Sciences – Rathna Arumugam, April Fitzgerald, Priya Gopal, Blaine Stroh
- InfoNetworks – Michael Palage
- InfiniTrak – Mark Tate, Mary Zervos
- LedgerDomain – Alex Colgan
- Legisym, LLC – David Kessler, Brittany Payson
- Eli Lilly and Company – Senthil Rajaratnam
- LSPediA – Ana Schleicher
- .Med Registry – Ray Fassett, Lloyd Mager
- Medline Industries – Mathew Price
- Morris & Dickson Co. – Vasu Darsi
- Novartis – Kevin Mackenzie, Dave Mason
- NC Mutual Drug – Mary Richard, Leslie Rucker
- OFW Law – Tish Paul
- Providence Health Technologies – Todd Barrett
- RfXcel – Kevin Smith
- Ro – Jeff Mesaros
- RxScan – Max Peoples, Rachel Reed
- Smith Drug Company – Brad Pine

- Spherity – Georg Juergens
- Storemed – Glenn Tamir
- The Partnership for Safe Medicines – Shabbir Safdar
- TraceLink – Elizabeth Waldorf
- TrackTraceRx – Randy Feldman, Chris Souza
- Ten Count Consulting – Mike Karhoff, Kyung Kim
- Value Drug Company – Julie Malone
- Vantage Solutions – Frank Guthrie

Executive Summary

NABP, working at the direction of its member state boards of pharmacy and other state regulators, undertook an effort to help outline the use cases and explore potential pathways needed for the industry to implement and enforce 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 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 tabletop pilot was instrumental in being the first time a significantly broad representation of industry leaders, including manufacturers, distributors, dispensers, 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 NABP's DSCSA efforts are to facilitate the creation of a network to exchange DSCSA-related data, such as transaction information of serialized drug products where required by law. The network is expected to:

- Be consistent with the Uniform National Policy (Sec. 585) and FDA guidance
- Create standard request/response protocol for state regulators incorporating 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 of authorized trading partners (ATPs)
- Protect confidential and/or proprietary information of participants
- 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 interoperability 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, solution providers, and federal entities to implement and measure DSCSA compliance.

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

- Clarification for State Regulators – There were eight findings outlined for state regulators to provide clarity in the upcoming phases.
- General Findings – There were 13 findings that provided insights for all industry stakeholders to use as they implement solutions and processes.
- Training Needs – There were eight areas of training highlighted as a necessity in helping state regulators, dispensers, and the larger industry sufficiently understand their DSCSA compliance requirements.
- Product Tracing Request and/or Response Template(s) – There were 23 recommendations made for improvements to the trace request and response spreadsheet form, which was used in the pilot and may be shared with standards groups for consideration.

The pilot project and workshops identified 18 broad solution or process gaps to be addressed by the industry. These gaps were divided into two main sections:

1. Gaps shared in the wrap-up workshop and by this report that should be recommended to PDG and/or GS1.
2. Gaps that NABP proposes to address in the next planned phases by making changes to detail(s), design(s), pilot project(s), prototype(s), and/or implementation.

As a result, NABP intends to develop solutions in the following areas:

Gap Name	Problem Description
Trace data exchange methods	Determine communication modes for users; may include standard messaging, email, and/or spreadsheets
Trading partner directory	There is **no** single directory in the whole industry and supply chain for all the ATPs; create and maintain a voluntary directory for industry
State regulator authorization	ATPs that receive trace requests desire proof that the requester is legitimate
Dispenser authorization	Similar to state regulators, the interoperable network should authenticate industry participants, whether part of a large or small organization
Product Global Trade Item Number (GTIN) to National Drug Code (NDC) crosswalk to manufacturers	There is a need to be able to correlate an NDC/GTIN to a manufacturer and have connection information for automated integration or manual forms of communication

NABP expects to provide more details as the next phases unfold and will continue to work with industry partners to ensure the supply chain is made more secure through this important federal mandate.

What Is DSCSA?

Enacted on November 27, 2013, Title II of the Drug Quality and Security Act (DQSA) is commonly referred to as DSCSA. Among its objectives, the law was passed to create a framework for facilitating the gathering of transaction data in the event of suspect, illegitimate, or otherwise potentially harmful products. It was also meant to harmonize the growing number of divergent state laws that had been enacted to secure the US prescription drug supply chain from criminal actors.

The law includes key milestone dates to enact requirements across the supply chain with the final milestone, related to creating enhanced drug distribution security at the saleable unit packaging level, scheduled to take effect on November 27, 2023. Initial milestones were heavily focused on ensuring that manufacturers and repackagers had proper human- and machine-readable labeling and data (including a standardized barcode with a unique product identifier), along with lot and expiration date for every saleable unit or homogeneous case. Subsequent milestones have outlined the sharing of related data, identification, and handling of suspicious product, and have established verification requirements, among other topics related to distinct aspects of the law. Industry stakeholders in these sectors have worked since the passing of the law to create the required standards, guidelines, and systems needed to ensure compliance. NABP has found the efforts taken to date by the industry-wide organizations such as GS1, PDG, OCI and HDA encouraging and is committed to leveraging the outcomes of this work and its related standards where possible in NABP's upcoming efforts.

The Journey Remaining to DSCSA 2023

With the final DSCSA 2023 requirements expected to go into effect in fewer than 19 months, there is significant work remaining for industry and state/federal agencies to explore, develop, integrate, and stabilize systems and processes required for compliance. These requirements raise a number of 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
- Collecting, storing, and sharing required transaction information and related transaction statements as relevant product ownership events occur
- Establishing systems and connectivity necessary for supporting product tracing and product verification requirements
- Ensuring the ability to demonstrate compliance with all required aspects of the law

FDA also noted in a recent 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.[i]"

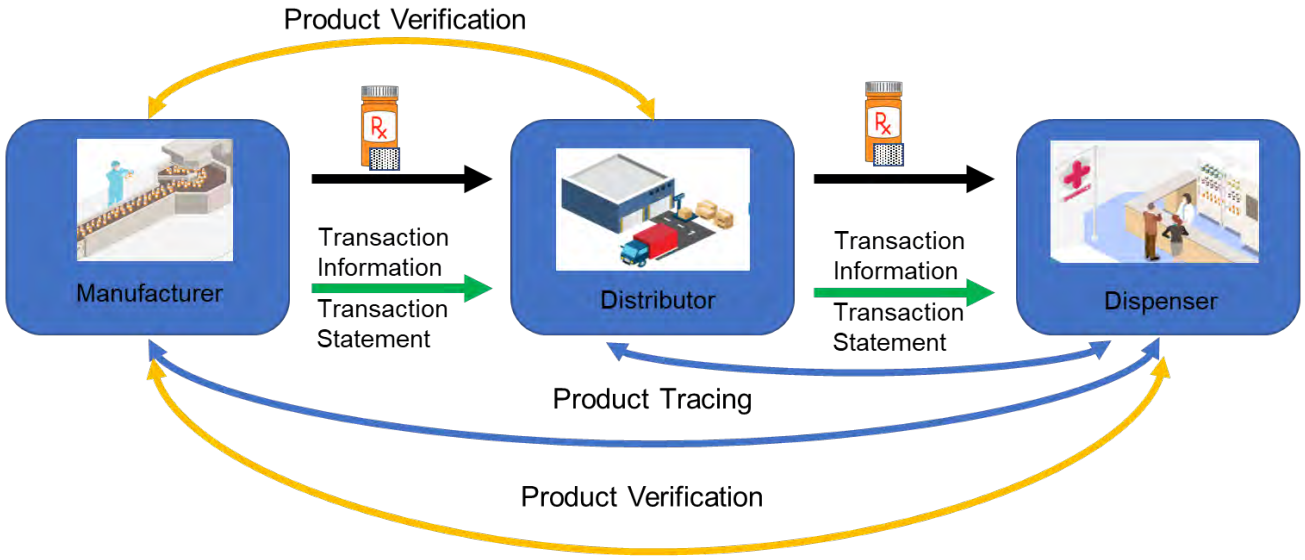
This challenge has been made more difficult by the coronavirus disease 2019, particularly in the dispenser sector, along with related workplace safety, well-being, and subsequent labor shortages.

NABP and its member boards of pharmacy have been made aware of increased inquiries from pharmacies with concerns about DSCSA compliance, including a lack of understanding of what will be required of pharmacies in November of 2023.

The Need for a Parallel State Regulator Interoperable Network

In response to these challenges, NABP has been working with associations and stakeholders representing the pharmacy community to begin developing training guidance and tools for DSCSA compliance. In addition, NABP plans to equip its member boards of pharmacy with guidance that can be used to educate their licensees. In exploring the currently planned connectivity across supply chain ATPs, NABP has developed the following diagram as an understanding of how the industry expects to share data and electronically interoperate:

Product and Data Flow – Typical Path Example

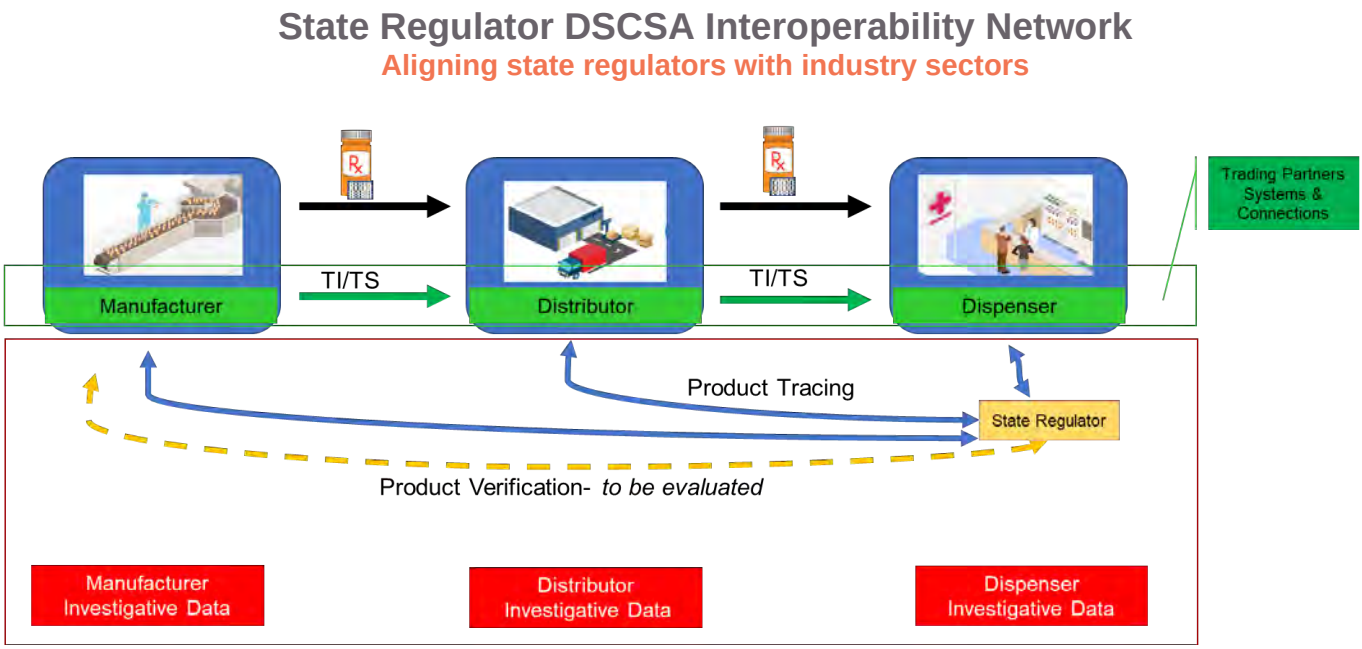


It is understood that this data may be exchanged via each trading partner's systems and direct integration with other ATPs' systems. To facilitate the data and electronic interoperability required for state regulators to perform activities outlined in DSCSA, NABP found that a parallel network is necessary. It is expected that this network will:

1. Be consistent with the Uniform National Policy (Sec. 585)
2. Incorporate a uniform request and/or response standard for state regulators incorporating DSCSA requirements
3. Create a common protocol for state regulator and/or trading partner communication

4. Ensure only authorized regulators can access and make regulator requests of ATPs
5. Protect confidential and/or proprietary information
6. Focus on the most critical use cases

NABP has developed the following diagram as the initial outline of the expected network interactions:



NABP expects to leverage existing systems where possible and currently provides secure credentialled connectivity to each state board of pharmacy. NABP is prepared to act as an intermediary to collaborate with FDA and other federal and state offices to further a consistent approach to DSCSA interoperability.

Engaging State Regulators

In the third and fourth quarter of 2021, NABP held a series of workshops with state regulators to educate them on expected requirements of DSCSA and to better understand the state regulators' needs for implementation of the November 27, 2023, requirements. This led to the creation of the NABP State Regulator DSCSA Use Cases to outline key activities in the following areas:

1. Illegitimate and suspect product investigations
2. Fraudulent activity
3. Product recalls
4. Routine compliance audits

To support these use cases, the workgroup confirmed that a State Regulator Interoperability Network is required to facilitate and align state authorities in their interactions with the broader supply chain ATPs. NABP was asked to help explore and define the functional requirements of such a network and to lead the effort in working with industry partners to develop the tools necessary for regulator interoperability.

It became apparent that a significant need to establish interaction with the broader industry and the development of a business-driven exploratory pilot would help facilitate these interactions.

The State Regulator DSCSA Tabletop Pilot

Upon completion of the State Regulator workshops, NABP reached out to industry groups and stakeholders to plan a DSCSA pilot. This pilot would be a technology-agnostic, tabletop effort to allow stakeholders to focus on understanding business requirements and identifying gaps in processes and primary system functionality.

The expectation was made that the pilot should focus on the area of greatest impact by exploring product tracing requests for state regulators in the event of suspicious product investigation.

The pilot project was open to any observing organization that operates within, or supporting, the US pharmaceutical supply chain. Participants were limited to supply chain stakeholders with ultimate responsibility for creating and sharing transaction business data to support DSCSA compliance requirements, along with state regulatory officials who are expected to ensure DSCSA compliance within their state. All meetings were conducted collaboratively, with agendas shared before the meeting and recordings with slide notes shared upon conclusion.

Weekly working meetings began with a virtual kickoff on January 25, 2022, and outlined the planned use cases, scenarios, and logistics of the pilot project. These meetings continued weekly until completion of the pilot on March 15, 2022, with a review of progress and discussion of the feedback received from participants.

Wrap-up meetings were held at NABP headquarters in Mount Prospect, IL on March 23, 2022, with an option for virtual participation. A final in-person review of the identified gaps took place on March 24, 2022, in Mount Prospect, IL. The in-person meetings included participants from across the supply chain – state regulators, professional trade organizations, and NABP associates, which allowed for informative discussions to help each group understand other groups' concerns, as well as explore areas for further collaboration to advance compliance and patient safety.

Feedback and updated slides from these meetings were used as the basis for this report to help establish an industry-wide understanding of the current and future expected landscape necessary to support the expected DSCSA interoperability requirements of November 27, 2023.

How Was the Tabletop Pilot Conducted?

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

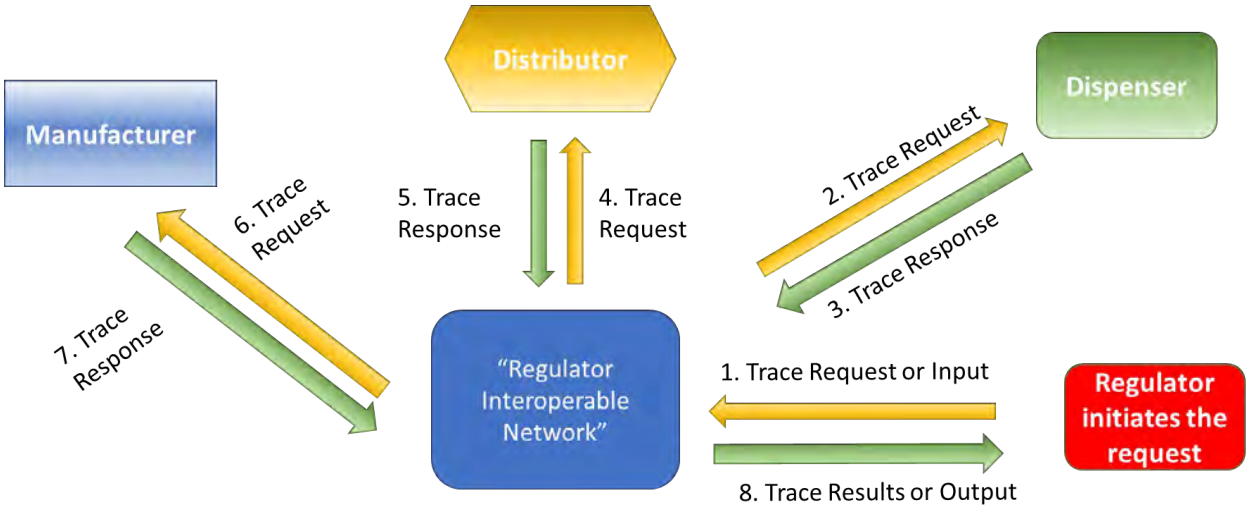
- Engaging key industry participants and stakeholders
- Communicating and solidifying the state regulator business use cases
- Performing functional and high-level technical evaluations of each use case
- Simulating messaging using existing standards or by framing new ones
- Understanding industry requirements for identity verification and credentialing
- Developing a roadmap of interoperability for state regulators

It was decided to focus on the most urgent and straight-forward portions of the interoperability use cases, particularly the illegitimate and suspect product investigations and the product tracing request required steps. The NABP-defined DSCSA State Regulator Use Cases included initiation of state regulator product trace requests based on the following:

1	[Regulatory authority] identifies suspect product at a retail pharmacy.
2	[Regulatory authority] is notified of illegitimate (counterfeit) product known to be in the supply chain.
3	[Regulatory authority] is notified of potential illegitimate product in reused packaging (bottles/boxes/labels).
4	[Regulatory authority] is investigating a patient-filed compliant of a suspicious product.

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 DSCSA and FDA guidance, is the act of collecting transaction information 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. An example path of a trace request is outlined in the diagram below. While future solution phases may enable other paths, this path demonstrates what a trace from a dispenser back to a manufacturer might look like:

Example Trace Request Routing



PDG provided fields, developed by the cross-industry organization, for the product trace request and response messages. These fields were added into a spreadsheet and included tabs for: Regulator Request, Universal Data Response, and Ownership Change Response. An example of each of these template pages is shown here:

State Regulator Request

	Data Entry	*Description*
Regulator State:		Enter the state you are representing
Regulator Name:		Enter your name
Regulator Email:		Enter your preferred email address
Regulator Phone:		Enter contact phone number for any questions
Regulator Attestation: (Suspect; Illegitimate; Recall)		Provide the reason for the product trace request
Suspect Circumstance Description:		Provide any information to responders you wish to share
SN:		Present in Barcode- Serial Number
GTIN:		Present in Barcode-GS1 Global Trade Identification Number
Lot:		Present in Barcode- Lot Number
Expiration Date:		Present in Barcode- Expiration Data

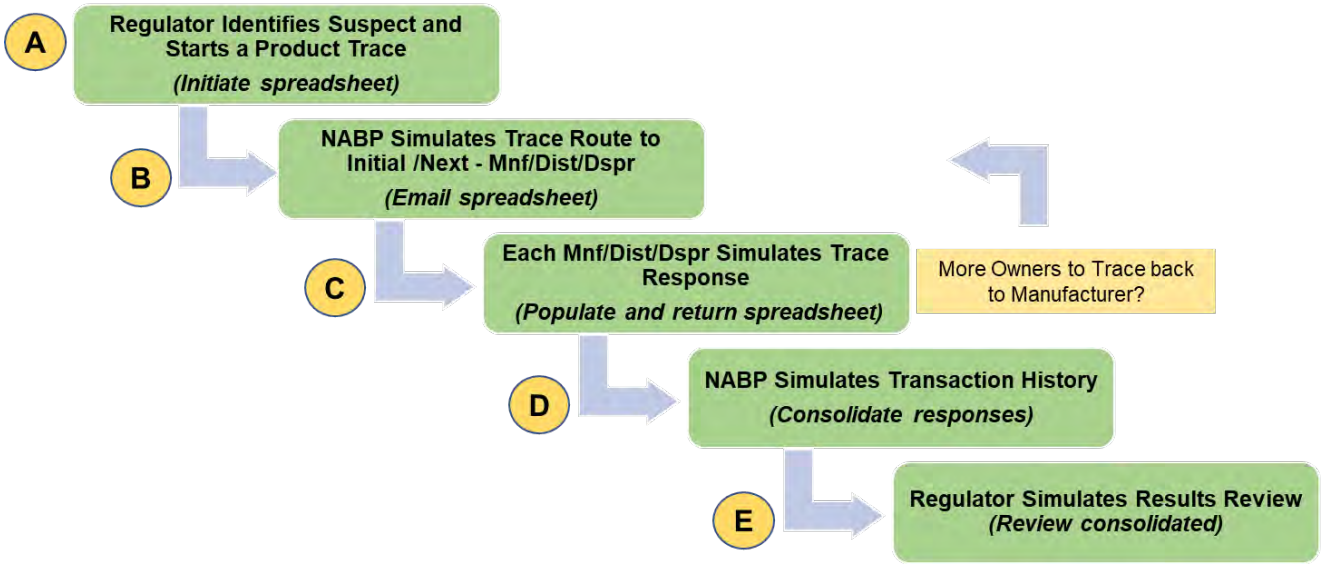
Universal Data Response

Field	Data for requested Unique Identifier
NDC	
GTIN (Saleable Unit)	
Serial Number (Saleable Unit)	
Lot Number	
Expiration Date	
Drug Name	
Strength	
Dosage Form	
Container Size	
Case GTIN (Homogeneous Case)	
Case Serial Number (Homogeneous Case)	

Ownership Change Response

	Ownership From Company Name	Ownership From Company Contact Info	Ownership From Other Identifier (identifier name-ID)	Ownership To Company Name	Ownership To Company Contact Method	Ownership To Other Identifier (identifier name-ID)	Transaction Statement	Date of Transaction	Date of Shipment	Transaction ID (PO#, Delivery, etc.)	Number of Containers
	Required	*Required*	*Optional*	*Required*	*Required*	*Optional*	*Required*	*Required*	*Optional if needed*	*Optional if available*	*Required*
Ownership Received (In Event)											
Ownership Sent (Out Event)											

The NABP pilot team agreed to simulate the Regulator Interoperable Network by sending the request to/from the state regulator, forwarding the request to each of the responders, and collecting and generating a simulated transaction history. The process for each use case and pilot run is outlined here:



The pilot was concluded with the following key statistics documented:

- Four use cases piloted
- 19 pilot runs
- 56 individual requests/responses
- 92 feedback items consolidated into key findings

Key Findings

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

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

Training – NABP will collaborate with state regulators, trading partners, and other associations to facilitate training and tools in these areas:

Area	Priority	Description
Dispenser DSCSA Training	Critical	The dispenser community needs detailed training in regulatory requirements to outline standards, tools, and possible paths to compliance.
State Regulator DSCSA	Critical	State regulators need detailed DSCSA training to use tools and to monitor compliance for the inclusion of industry alignment on interoperability portions.
Trace Exceptions	High	What steps should state regulators take when a tracing request fails, in part or in whole, to determine where issues reside (data, system, or actual suspect product)?
Suspicious Product Tracing	High	Clarity and flexibility are needed in outlining how a product might be determined to be suspicious or illegitimate. How should similar products be handled?
GTIN	High	Clarity of how NDC and GTIN correlate and are used and how to trace through investigation when GTIN is not available.
Communication	Medium	How regulators and dispensers should contact trading partners when an issue generates a trace request.
Manufacturer Communication	Low	Manufacturers indicate that they are not currently in communication with state regulators, so consideration of trading partner training is needed
Trace Response Handling	Low	Need to provide clear instructions to respond with exact matching product identifiers, rather than next closest serial number

General Observations

Area	Priority	Description
Timeline to DSCSA 2023	High	Many dispensers and state regulators believe there is still considerable time to prepare for DSCSA 2023 and do not understand the complexity and amount of work remaining to align, test, implement, onboard, and stabilize systems and data.

Expired Product or Aged Data	High	Tracing requests can be made even when product is expired, or data being traced is aging.
Response Handling	High	New procedures and systems are needed for responders to route trace requests internally; impact should be considered by each business.
Dispenser Returns	High	Dispensers do not need to provide T3 (Transaction Information, Statement & History) in non-saleable returns, this may vary for saleable returns and requires further industry alignment.
Duplicate Serial Number Monitoring	Medium	Responders might consider monitoring for excessive traces from various sources for the same GTIN and serial number.
Responder Data Gathering	Medium	Responder changes will be needed to join product, partner, and transaction information.
Trading Partner Fields	Medium	The pilot determined that variation in company name and address will produce challenges due to differences in data input. Because some companies use different divisions, reference different locations, change names, and go through mergers and acquisitions, variability in fields may occur.
Other Trace Scenarios	Medium	The industry will need to ensure that solutions can handle trace requests for fraudulent activity, product recalls, and compliance audits.
Shipment or Purchase Order Number	Medium	Shipment identifiers and purchase order numbers are helpful in confirming matches to transactions across trading partners.
Barcode Scanning	Medium	Barcode scanning to initiate trace requests can significantly reduce data entry errors if they are properly formatted and follow GS1 standards.
Regulator Inspections	Medium	Suspect product investigations are often difficult because contact information may be outdated or not from the appropriate source.
Data Requests	Medium	Requests to secondary trading partners may come without clear visibility of the requester and without vetting by a trusted party.
Tracing as One Tool	Low	Important reminder that tracing is a tool for researching ownership record data and should not be considered a product quality check.

Request/Response Template Findings

Feedback for Trace Request Template

	Data Entry	Description
Regulator State:		Enter the state you are representing
Regulator Name:		Enter your name
Regulator Email:		Enter your preferred email address
Regulator Phone:		Enter contact phone number for any questions
Regulator Attestation: (Suspect; Illegitimate; Recall)		Provide the reason for the product trace request
Suspect Circumstance Description:		Provide any information to responders you wish to share
SN:		Present in Barcode- Serial Number
GTIN:		Present in Barcode-GS1 Global Trade Identification Number
Lot:		Present in Barcode- Lot Number
Expiration Date:		Present in Barcode- Expiration Data

PDG Provided Starter Template

Field Name	Feedback	#
Regulator Email	E-mail and phone should be required to ensure able to contact in the event of further clarifications.	19
Regulator Attestation	Needs to be clarified, this seems to be more of a reason code. Will regulators provide "attestation" or "reason code"?	93
Suspect Circumstance Description:	Should requester include information such as why they believe the product is suspect?	94
GTIN	Clarity on when the case level trace is done which might trigger case ID in the response to be required.	51
Expiration Date	Need to consider details on differences in human readable vs machine readable formats and scenarios.	3, 35
*New	Need to determine what identifiers should be added to the request and response for routing and partner identification. GS1 Global Location Number, NCPDP, NABP e-Profile, etc.	72
*New	"NDC" and "product name" should be included in the request form or entry screen.	24, 62, 71
ALL	Include field level definitions with formats and outline required, suggested or optional.	27, 47

Trace Response Template

PDG Provided Starter Fields

Field	Data for requested Unique Identifier
NDC	
GTIN (Saleable Unit)	
Serial Number (Saleable Unit)	
Lot Number	
Expiration Date	
Drug Name	
Strength	
Dosage Form	
Container Size	
Case GTIN (Homogeneous Case)	
Case Serial Number (Homogeneous Case)	

Field Name	Feedback
NDC	"NDC" should be exchanged with dashes incorporated in 10-digit format.
GTIN	Should not be needed to respond to GTIN in the event of case trace request.
Container Size	Should clarify that this stays at saleable unit level even on case.
Case GTIN	Clarify as required in event of a case trace request or how it interacts with aggregation.
Case Serial Number	Clarify as required in event of a case trace request or how it interacts with aggregation.
ALL	Include field level definitions with formats and outline required, suggested or optional.
ALL	Clarify what fields must be exact data matches and when variability may be expected.

Trace Response Template

PDG Provided Starter Fields →

	Ownership From Company Name	Ownership From Company Contact Info	Ownership From Other Identifier (identifier name-ID)	Ownership To Company Name	Ownership To Company Contact Method	Ownership To Other Identifier (identifier name-ID)	Transaction Statement	Date of Transaction	Date of Shipment	Transaction ID (PO#, Delivery, etc.)	Number of Containers
	Required	*Required*	*Optional*	*Required*	*Required*	*Optional*	*Required*	*Required*	*Optional if needed*	*Optional if available*	*Required*
Ownership Received (In Event)											
Ownership Sent (Out Event)											

Field Name	Feedback
Ownership From/To Company Name	Need to consider that field may vary by business partner due to departments, business units and M&A timing.
Ownership From/To Company Contact Info	Needs to be divided into several fields for address (address lines, city, state, zip).
Ownership From/To Other Identifier	Need alignment on what identifiers should be used such as GS1 Global Location Number, NCPDP, NABP e-Profile, etc.
Date of Shipment	Further explanations and possible future training on when needed and how it differs from date of transaction.
Transaction ID	Need better clarity on scenarios where it may be strongly recommended or optional.
Number of Containers	Should always be 1 in the case of a trace request and response, even for case level.
ALL	Include field level definitions with formats and outline required, suggested or optional.
ALL	Field titles are a bit confusing as they do not line up with common DSCSA terms.

Gaps for NABP to Lead Solution Development

As highlighted in the executive summary section, these are the gaps that NABP has agreed to develop solutions for and will coordinate further with the industry, as needed, to develop, test, and/or implement.

#	Gap Name	Problem Description	Questions to Answer
G01	Trace data exchange methods	Determine modes for NABP to communicate with system users; may include standard messaging, email, and/or spreadsheets	How does NABP establish and publish consistent and flexible methods for ATPs to share information?
G02	Trading partner directory	There is **no** single directory in the whole industry and supply chain for all the ATPs	How does an ATP contact any direct or indirect ATP for DSCSA compliance?
G03	State regulator authorization	ATPs that receive trace requests desire to verify the identity of the requester	How does an ATP authenticate the credentials of those requesting sensitive information?
G04	Dispenser authorization	Similar to state regulators, the interoperable network should authenticate industry participants, whether part of large or small organization	How do dispensers, especially the considerable number of small pharmacies, prove they are authorized and authentic to direct and indirect trading partners?
G05	Product GTIN to NDC crosswalk to manufacturers	There is a need to be able to correlate NDC/GTIN to a manufacturer and have connection information for automated integration or manual forms of communication	If a product is found to have a GTIN and serial number but the last owner is unknown, how does the requester find or contact the correct manufacturer?

Gaps for PDG/GS1 to Lead - NABP to Participate

These items were identified as gaps for PDG and GS1 to review and determine how to further explore and mitigate. NABP will continue to interact with both PDG and GS1 in the coming phases to ensure the gaps are fully understood and to help provide input and support where needed in the resolutions.

Gap Name	Priority	Workshop Note
Transitory Product and Processes - Pre-2023 Data	High	How to identify and avoid risk of missing a counterfeit product and communicate a response?

Data Quality - Exact Match Fields	High	Which fields indicate a need for further verification, if not exact matches?
Data Quality - Variability Fields	High	How does the industry communicate variability and move towards industry alignment?
Case Level Tracing	High	What assumptions and limitations should be considered for other levels, such as inner packaging?
Trace Response Failure -Error Handling	High	What error messages and guidelines should be included to help with data entry, integration errors, or exempt messages?
GTIN/NDC Exemption Management	High	Can the industry help identify exempt products that do not require barcode or transaction data?
Saleable Returns Tracking	Medium	What assumptions or considerations should be included in tracing or verifying returns?
Drop-Ship Field Addition	High	What fields should be added to EPCIS and product trace request/responses to identify drop-shipped items?
GS1 Standard for Trace Request(s)/Response(s)	High	Industry should plan for an integrated message option.

Recommendations and Next Steps

NABP has initiated development 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 comprised of trading partners and state regulators.

NABP will convene regular meetings with solutions providers to collaborate on development plans and to ensure that solution providers are on a path toward interoperability with state regulators. In addition, this will allow NABP to explore opportunities to pilot, partner, or leverage existing work from within the solution provider community.

NABP will continue to engage with PDG and GS1 to help inform standards development or to participate in future pilots, as necessary.

Considerations for State Regulators

- **Sunset of transaction history:** One of the most significant impacts of the transition to the electronic interoperable tracing at the unit level is that the transaction history will sunset in November 2023. The impact for regulators is that that transaction history will no longer be 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 will mandate that transaction information showing change of ownership of the product be exchanged. States may independently request information about the physical movement of product, but that is not included under the DSCSA tracing provision.
- **Industry readiness for 2023:** The supply chain as a whole is at various levels of readiness for DSCSA. Some manufacturers are now sharing serialized transaction information and transaction statements with wholesalers in an electronic and interoperable manner. Some wholesalers are receiving transaction information and transaction statements from manufacturers, and some are beginning to explore sending information to their downstream trading partners (another wholesale distributor or dispenser). Very few dispensers are prepared to receive and store the information required by DSCSA. In addition to issues around readiness, data quality is also a significant transitional issue for trading partners.
- **Impact on compliance audits and inspections**: Given the sunset 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?

The following items were highlighted as areas that need greater clarity from state regulators. NABP plans to further explore these areas with its members as they address gaps in DSCSA 2023 implementation.

Area	Priority	Description
Trace Request Volume	Critical	How frequent are trace requests for suspect/illegitimate product(s) expected? How frequently do other requests such as recalls, or audits occur? How often for saleable unit versus case?
Image Sharing and Storage	High	Do we need to enable image sharing or other information related to the suspect product(s)? Should we clarify that a trace request is only a data check and separate those from a suspect product investigation?
Product Verification	High	Need to develop clarity for scenarios where product verification is required.
Direct Purchaser Statement	Medium	Do both the "direct purchaser statement" and "transaction statement" need to be included within electronic records? Should direct purchaser statement be added to the response template?

Fuzzy Information	Medium	Scenarios might include unable to provide GTIN, serial or lot number, and/or expiration date. Can these be handled manually outside a tracing system?
Transaction ID Field	Medium	Further insight needed from regulators on potential uses for "transaction ID" (PO/delivery/etc.); submit for industry consideration.
Paperwork Request Alignment	Medium	Trading partners highlighted that states have different requirements for ownership and possession tracking. Documents and formats should align.
Unknown Owner	Low	What scenarios might include product tracing where a single owner is unknown, such as a found-stolen product? May manufacturer requests start the trace process?

Considerations for FDA

NABP is grateful that representatives from the agency were able to attend meetings and webinars as observers and hopeful 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 build(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 likely pursue their 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.
- **DSCSA Timeline:** November 2023 compliance will likely take several years to develop, implement, and stabilize. In addition, product already in the supply chain may be moving without full chain-of-ownership transaction information or aggregation at the unique identifier (serial number) level. A timeline that highlights planned guidance and outlines the solution development by regulators, testing, and ramp-up phases would be beneficial.
- **Aggregation and Inference:** These requirements need to be more strongly suggested or mandated to facilitate required data sharing and product tracing. Without aggregation, it is likely that product tracing or data sharing will not be possible, which may lead to false suspect product alerts or product availability issues.
- **Transitory Product and Processes - Pre-2023 Data:** The current ability to rely on abbreviated transaction history sunsets in November 2023. Any product changing ownership in the supply chain prior to this date may be moving without product identifier-level transaction information. This could lead product trace requests to appear to have an incomplete transaction history (not going back to the original manufacturer), flagging the product, even though the product is safe and legitimate. This could cause false determination of a suspect or illegitimate product and an inability to differentiate safe from unsafe product. More collaboration within the industry is

needed to understand this issue more deeply, provide clarity in guidance on how to handle such product, and any interim approaches that may be acceptable and safe.

- **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 form. This would include interaction with state and other federal agents, along with facilitating communication to/from the manufacturers as product quality owners.
- **Supporting 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.
- **Stabilization Period Exception Handling:** There is growing concern that a significant portion of product in the supply chain may be unable to be moved in time immediately following November 27, 2023, when all stakeholders will be mandated to ensure perfect data before conducting any further transactions. We recommend FDA work with the industry to develop guidance that allows flexibility for the product to move if sufficient assurance can be provided that the product is safe and data issues are addressed as a condition of follow-up.
- **Dispenser Engagement:** While the engagement in DSCSA-related workgroups 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 solution 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.

[i] See FDA guidance for industry *Enhanced Drug Distribution Security at the Package Level Under the Drug Supply Chain Security Act* (June 2021). For the most recent version of the guidance, check the FDA guidance web page at https://www.fda.gov/regulatory-information/search-fda-guidancedocuments