Louisiana Board of Drug and Device Distributors
Trace Readiness Week Report
January 2025

OVERVIEW

In November 2025, the Louisiana Board of Drug and Device Distributors (the "Board") conducted Trace Readiness Week (TR-WEEK) – a live, multi-party tracing exercise designed to assess the practical, end-to-end operation of DSCSA §582(g) requirements now in full effect.

While DSCSA is federal law, its day-to-day execution depends heavily on state regulatory authorities, who are empowered to request and assemble transaction information in support of investigations involving suspect or illegitimate product. States are often the first entities called upon to respond to real-world incidents, coordinate with law enforcement, and protect patients within their jurisdictions.

However, states cannot fulfill this role in isolation.

Effective tracing under DSCSA is inherently collaborative. It requires timely, accurate, and interoperable participation from manufacturers, repackagers, wholesale distributors, third-party logistics providers, dispensers, and regulators. This means well-maintained contact information, operational data systems, and a common understanding of the response requirements by all stakeholders. TR-WEEK was conducted to demonstrate this shared responsibility in practice.

AUTHORITY & TRACE METHODOLOGY

Under DSCSA, state regulatory authorities are empowered to request transaction information and transaction statements from Authorized Trading Partners (ATPs) to support investigations of suspect or illegitimate product. To carry out this exercise, the Board utilized tracing workflows aligned with the Partnership for DSCSA Governance (PDG) standards.

PDG is an industry-led governance body that develops standardized, interoperable trace processes and message formats designed to operationalize DSCSA requirements and enable timely, consistent product tracing across the pharmaceutical supply chain.

Reflecting the realities regulators encounter during actual investigations, responses were accepted through both machine-readable and human-readable formats.

TRACE ACTIVITY & RESULTS

Using real inventory and live systems, the Board leveraged its DSCSA solution to issue PDG-compliant trace requests to multiple trading partners: four manufacturers, a wholesale distributor, and a dispensing entity. These requests were issued via email and included human and machine-readable requests. Each trace request was acknowledged and fulfilled by the respective trading partners.

The responses were complete and consistent. Through the responses received, the Board successfully reconstructed the full chain of ownership of the product, from the point of manufacture through each subsequent change of ownership.

CONCLUSION

The PDG-compliant tracing activity enabled the Board to efficiently and accurately establish product lineage across multiple segments of the drug supply chain. The exercise demonstrated the practical effectiveness of DSCSA-aligned interoperability standards in supporting regulatory oversight and identifying potential violations of state and federal law.

Trading partners are reminded of their data retention and response obligations under both state and federal law. The Board will continue to leverage DSCSA authorities and industry standards to safeguard the pharmaceutical supply chain and protect the public health of Louisiana residents.

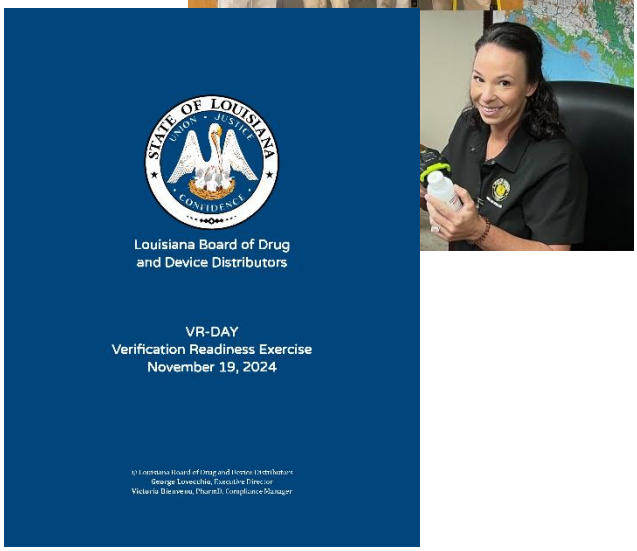
Louisiana Board of Drug and Device Distributors
Trace Readiness Report

BACKGROUND

DSCSA compliance and enforcement is a collaborative effort among federal, state, and industry stakeholders. As the final requirements have rolled into full effect over the last two years, the Board has been working closely with stakeholders as part of its mission to safeguard life and health and to promote public welfare of all citizens by the licensing and regulation of entities engaging in the distribution of legend drugs or legend devices within and into the state of Louisiana.

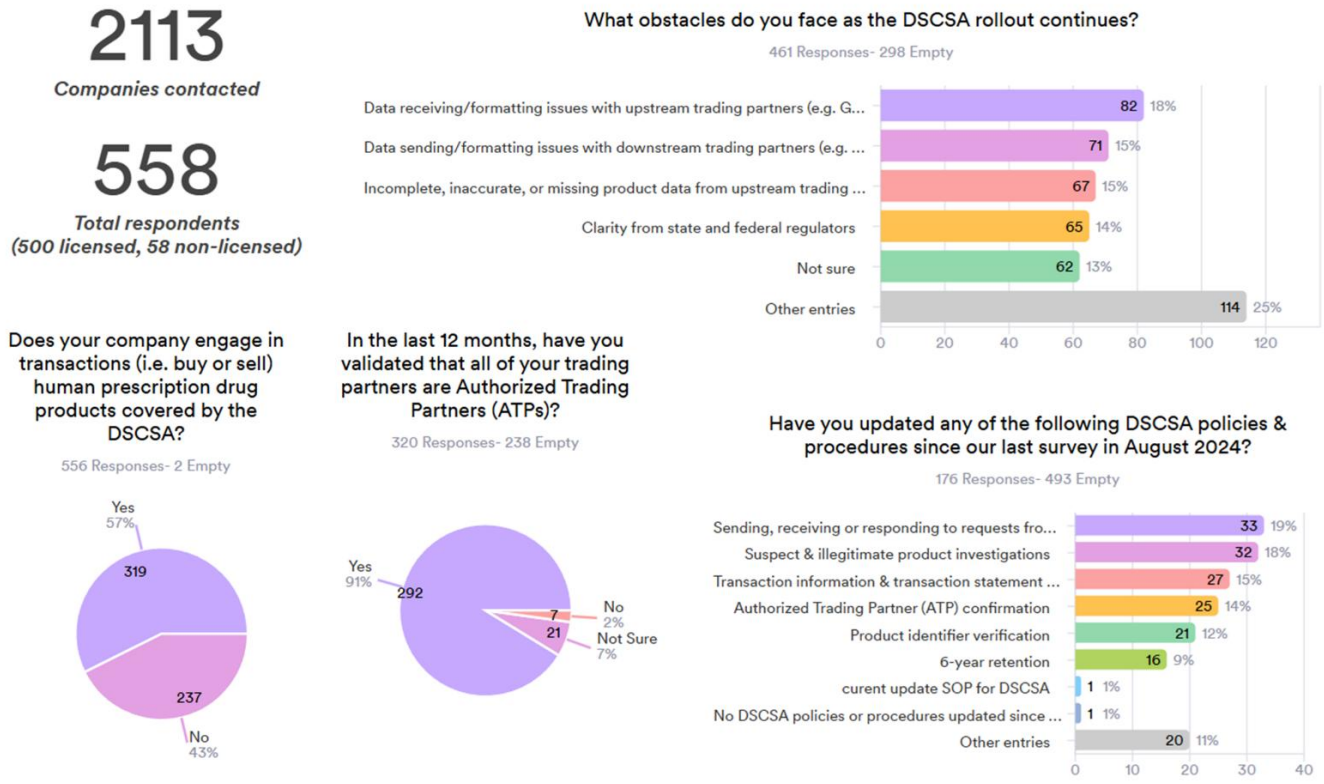
	WINTER 2024 Washington DC workshop under FDA observation	**SUMMER 2024** Survey outreach on WEERs and policies & procedures	**FALL 2024** VR Day 1 verification readiness exercise	**SPRING 2025** Survey outreach on DSCSA readiness & contacts	**SPRING 2025** VR Day 2 verification readiness exercise	**FALL 2025** Survey & TR Week tracing readiness exercise
ATP Confirmation	Credentialing	Credentialing	Credentialing & GLN	Credentialing, GLN & alternative methods	Credentialing & GLN	Credentialing, GLN & alternative methods
Policies & Procedures		☑ 77%		☑ Ongoing Progress		☑ Post-Implementation Consolidation
Verification			☑ 80%		☑ 84%	☑ VRS & Manual Fallback
Trace	☑ Live Exercise	☑ Tracing Contacts		☑ Ongoing Progress		☑ End-to-End Exercise & Discussion

More information about these efforts can be found in the VR-DAY reports, which cover multi-phase interoperable drug verification readiness exercises conducted in November 2024 and May 2025. The full report and videos can be accessed at regulator.id/la/vr-day.



Watch the TR-WEEK live session and download the slides

In fall 2025, the Board conducted its most recent DSCSA Readiness Survey to learn from stakeholders how the 582(g) requirements being in full effect were affecting policies, procedures, and operations.



Trading partners reported major policy updates on tracing & investigations. Serialization-level data formatting issues with upstream partners were still being encountered, and many downstream partners were still having connection issues.

Notably, 40% of respondents who indicated that they still face DSCSA compliance obstacles noted that lack of clarity from regulators was a key issue. Tracing remained an open question for most supply chain participants. While the Board has previously engaged in trace activity (both on its own accord and as part of inter-agency cooperation), the nature of these activities must remain confidential to avoid compromising active investigations. With that in mind, we resolved to address the matter with an open exercise.

DSCSA TRACING

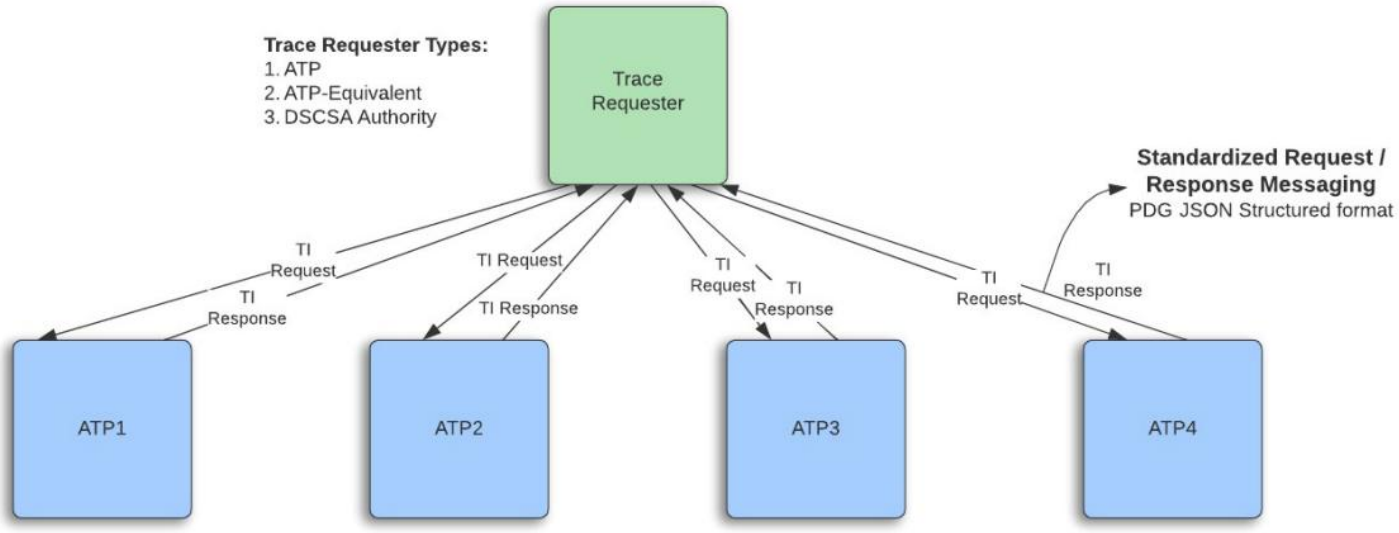
Under Section 582(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), DSCSA enhanced drug distribution security requirements, trading partners must meet the following "interoperable, electronic" requirements:

> *(D) The systems and processes necessary to promptly respond with the transaction information and transaction statement for a product upon a request by the Secretary (or other appropriate Federal or State official) in the event of a recall or for the purposes of investigating a suspect product or an illegitimate product shall be required.*
> *(E) The systems and processes necessary to promptly facilitate gathering the information necessary to produce the transaction information for each transaction going back to the manufacturer, as applicable, shall be required--*

(i) in the event of a request by the Secretary (or other appropriate Federal or State official), on account of a recall or for the purposes of investigating a suspect product or an illegitimate product; or
(ii) in the event of a request by an authorized trading partner, in a secure manner that ensures the protection of confidential commercial information and trade secrets, for purposes of investigating a suspect product or assisting the Secretary (or other appropriate Federal or State official) with a request described in clause (i).

To aid in the "electronic, interoperable" exchange of information required under 582(g), the Partnership for DSCSA Governance (PDG) has developed standardized, interoperable trace processes and message formats designed to operationalize DSCSA requirements and enable timely, consistent product tracing across the pharmaceutical supply chain. PDG is an industry-led governance body comprised of manufacturers, wholesale distributors, dispensers, and solution providers.

In practical terms, tracing takes the form of requests and responses which "roll up" or "roll down" the supply chain in order to construct a serialization-level transaction history of the product.



In carrying out its investigation, the Board utilizes these tracing workflows aligned with standards. Prior tracing activity has revealed the following:

- **Many teams are unfamiliar with their response obligations.** Trace outreach must be clear with citations and clear next steps for the receiver.
- **Appropriate contact data is critical.** Finding the right person at an organization to respond often takes significantly longer than the actual data retrieval.
- **Challenges with complicated Excel spreadsheets.** Multiple methods of response should be allowed; forms are preferred.
- **Consecutive tracing takes a week or more.** Trace requests can be run concurrently with multiple trading partners at once.
- **Data discrepancies & formatting errors.** Issues with source data are not unexpected as trading partners continue to stabilize their systems. Trading partners should respond with data as-is and trust to review.
- **Investigations may involve closed businesses.** Trading partners should review their long-term retention and response obligations after business closure.

SAMPLE TRACE REQUEST

Drug Tracing Request from Louisiana Board of Drug and Device Distributors

This is an official tracing request under the DSCSA from Louisiana Board of Drug and Device Distributors, located at 12091 Bricksome Avenue Suite B, Baton Rouge, Louisiana. Please respond within 24 hours or next business day. For more information about DSCSA tracing, please contact compliance@drugboard.la.gov or review the FDA's website.

REQUEST 1 Requestor Name: Louisiana Board of Drug and Device Distributors
Requestor Address: 12091 Bricksome Avenue Suite B
Requestor City: Baton Rouge
Requestor State: Louisiana

Submitted by Compliance, compliance@drugboard.la.gov 225-295-8567

Request ID: b65dd9be-6541-41f6-8984-1a3581f23d24
Request Timestamp: 2025-12-12T15:50:07.000Z
Investigation ID: SD001

Reason for Request: Compliance Audit
Suspect Description: Inquiring as part of trace readiness exercise. No active investigation is associated with this product.
Tracing Output Type: Transaction Information

GTIN: 00300245915023
Serial Number: 111M57WR0F3N42

REQUEST 2
Requestor Name: Louisiana Board of Drug and Device Distributors
Requestor Address: 12091 Bricksome Avenue Suite B
Requestor City: Baton Rouge
Requestor State: Louisiana

Submitted by Compliance, compliance@drugboard.la.gov 225-295-8567

Request ID: b65dd9be-6541-41f6-8984-1a3581f23d24
Request Timestamp: 2025-12-12T15:50:07.000Z
Investigation ID: SI001

Reason for Request: Compliance Audit
Suspect Description: Inquiring as part of trace readiness exercise. No active investigation is associated with this product.
Tracing Output Type: Transaction Information

To the left is a redacted trace request issued as part of TR-WEEK. Emails from the Board include a table of required information, which is provided later in this report.

Below is the machine-readable JSON that accompanies the trace email. The file includes a presentation of the Board's Authority credential as well as all the information required to retrieve the data and respond to the request.

{"tiRequestSet":{"tracingSchemaSetVersion":"2.0.0","tiRequestAuditReferences":{"tiRequestID":"b65dd9be-6541-41f6-
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12T15:50:07.000Z","tiRequesterInvestigationID":"SD001"},"tiRequestingPartyInformation":{"dscsaCredentialPresentatio
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RESPONDING TO A TRACE REQUEST

Trading partners with a PDG-compliant tracing solution may upload the JSON into their solution and issue an interoperable response to the endpoint specified in the file. For trading partners who lack a solution, the Board alternatively accepts submissions in Excel or tabular format. To make this easy, our trace request emails include an example table (see below) of the data required in the event of a Transaction Information request for a single product. Be sure to provide a full response for each transaction of the product (i.e. buying/receiving as well as selling/sending).

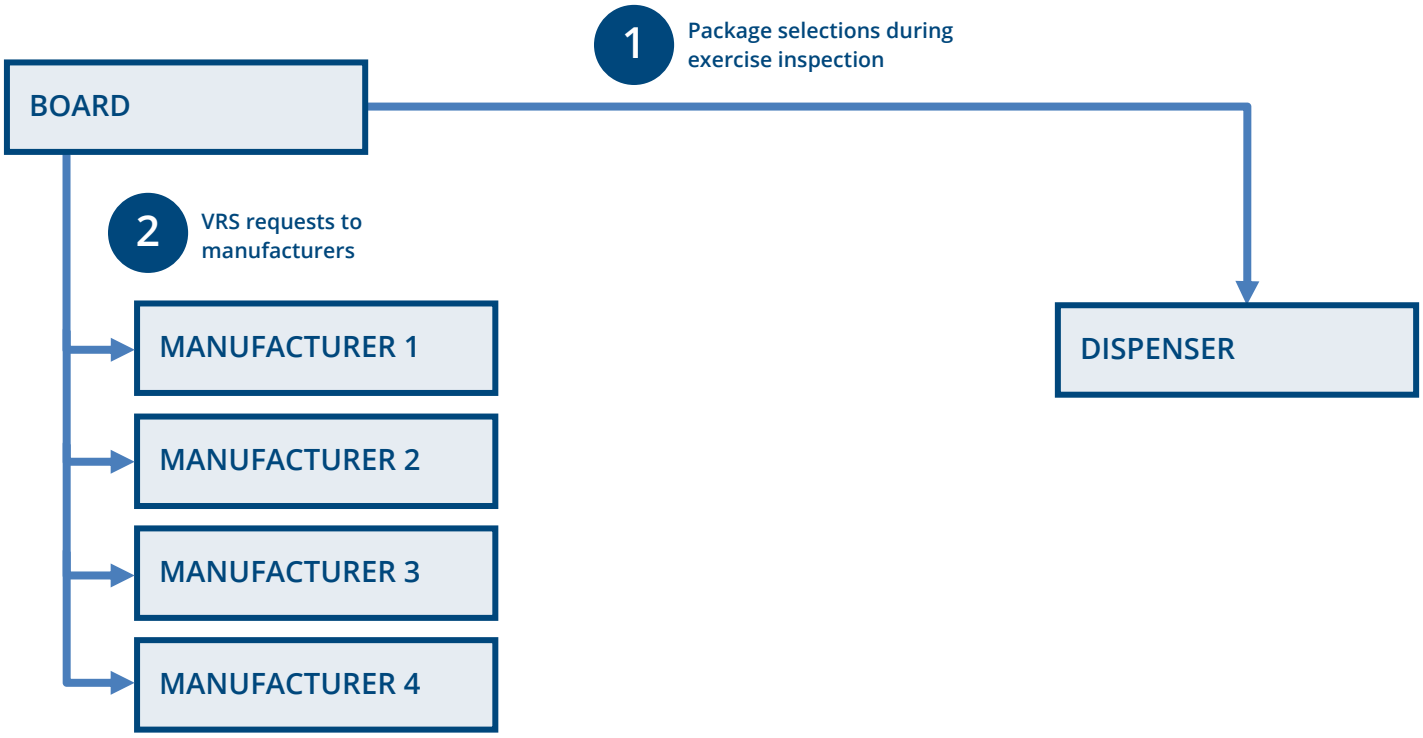
Louisiana Board of Drug and Device Distributors
Trace Readiness Report

Category	Field	Value	Description
Drug Information	Drug Name	ProTracin	Name of the medication.
	NDC	6015-2154-86	National Drug Code.
	GTIN	00360152154861	Global Trade Item Number.
	Strength	5mg	Concentration of the active ingredient.
	Dosage Form	Tablets	Physical form of the medication (e.g., tablet, capsule).
	Container Size	50	Number of dosage units per container.
	Number of Containers	1	Total number of containers in the shipment.
	Lot Number	M001-1	Batch or lot number of the product.
	Expiration Date	11-30-2026	Date after which the product should not be used.
Ownership From	Ownership From GLN	360152004869	Global Location Number identifying the previous owner.
	Ownership From Company Name	ArthiMax Pharma	Name of the company from which ownership is transferred.
	Street Address	808 Pine Road	Address of the company from which ownership is transferred.
	City	Summit	
	State / Province	NJ	
	ZIP / Postal Code	87127	
	Email Address	arthimax@example.com	
	Phone Number	1-123-122-1234	
	Digital Address (URI)	arthimax@example.com	Email address or API endpoint suitable for submitting trace requests and responses.
Ownership To	Ownership To GLN	812330250150	Global Location Number identifying the new owner.
	Ownership To Company Name	KC Pharmacy	Name of the company to which ownership is transferred.
	Street Address	202 Cedar Street	Physical address of the new owner.
	City	Gramercy	City where the new owner is located.
	State / Province	LA	State or province where the new owner is located.
	ZIP / Postal Code	70052	Postal code of the new owner's location.
	Email Address	kcpharma@example.com	Email contact for the new owner.
	Phone Number	1-321-221-4321	
	Digital Address (URI)	arthimax@example.com	
Other Info	Was this a drop shipment?	No	Indicates whether the shipment was a drop shipment directly to the end customer.
	PO associated with Transaction	XYZPO189	Purchase Order number related to the transaction.
	Transaction Statement	Seller has complied with each applicable subsection of FDCA Sec. 581(27)(A)-(G).	Statement asserting compliance with the law.
	Date of Shipment	12-04-2023	Date the product was shipped.
	Date of Transaction	[Leave blank]	The actual date of the ownership transfer. Leave blank if it was the same day as the shipment.
	Trace Request Recipient Email	requestor@example.com	Email address to which trace requests should be sent.
	Expiration Date	11-30-2026	Date after which the product should not be used.

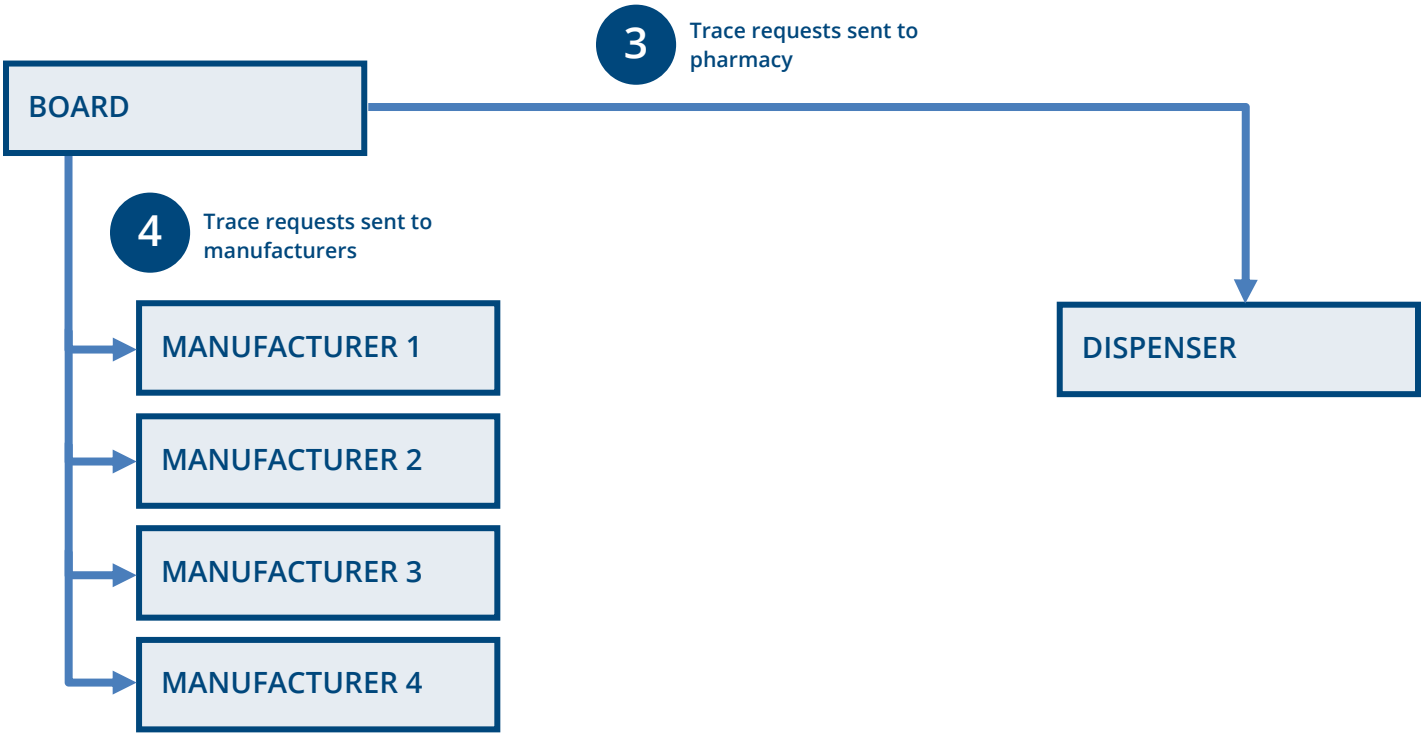
TR-WEEK TRACING EXERCISE

For the purposes of TR-WEEK, real-world inventory was randomly selected at a participating pharmacy originating from 4 manufacturers was used. None of the drugs used were in shortage or were controlled substances.

The Board first verified the packages via the Verification Router Service (VRS) as a status check. This confirmed that the manufacturers of record had commissioned barcodes consistent with those on the packages.

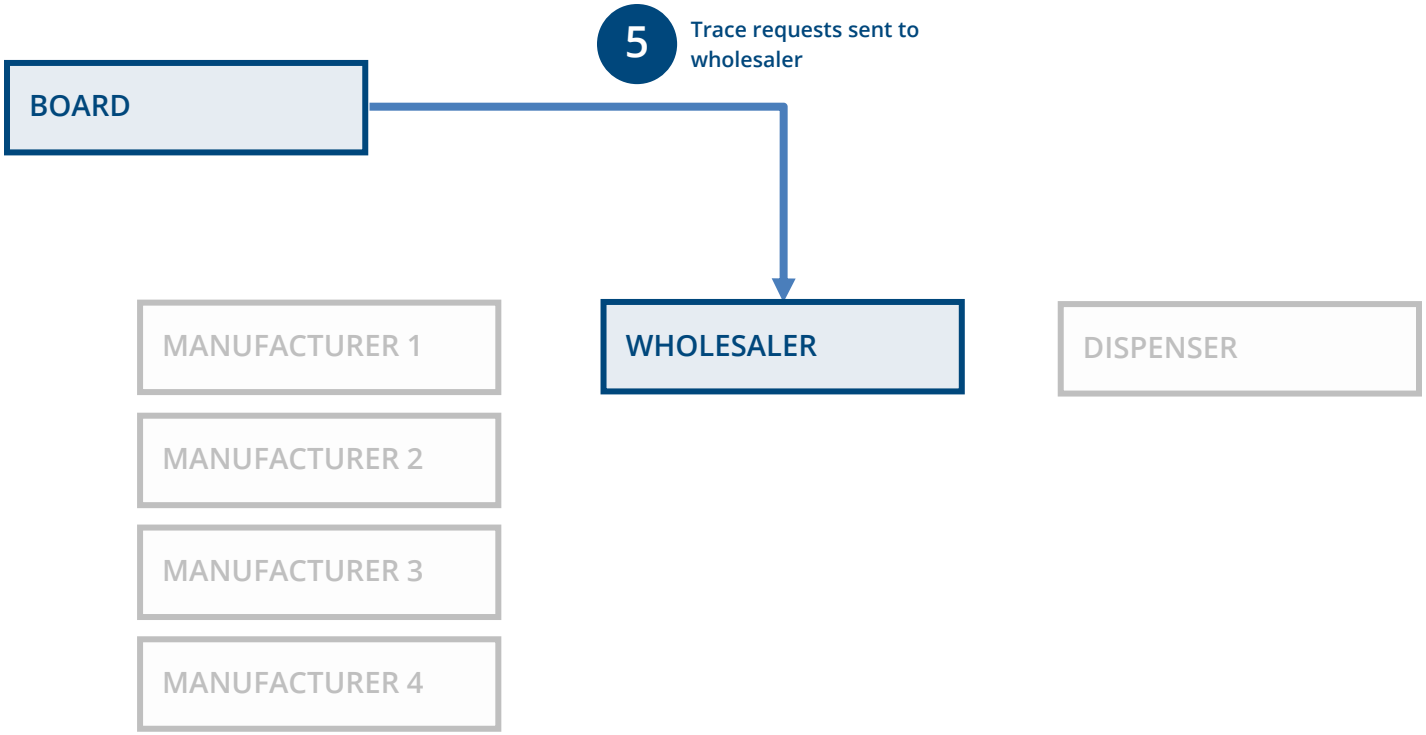


From there, trace requests were sent to the manufacturers and the pharmacy. This was run concurrently, not consecutively, in order to speed the process. The pharmacy received 4 trace requests, one for each package, while each manufacturer received a single trace request.



All five parties responded within the one business day indicated by FDA's Enhanced Drug Distribution Security guidance. All five indicated that these were the only transactions to which the products had been subjected (i.e. the manufacturers had not accepted them as returns at any time, and the pharmacy had not returned and later repurchased them).

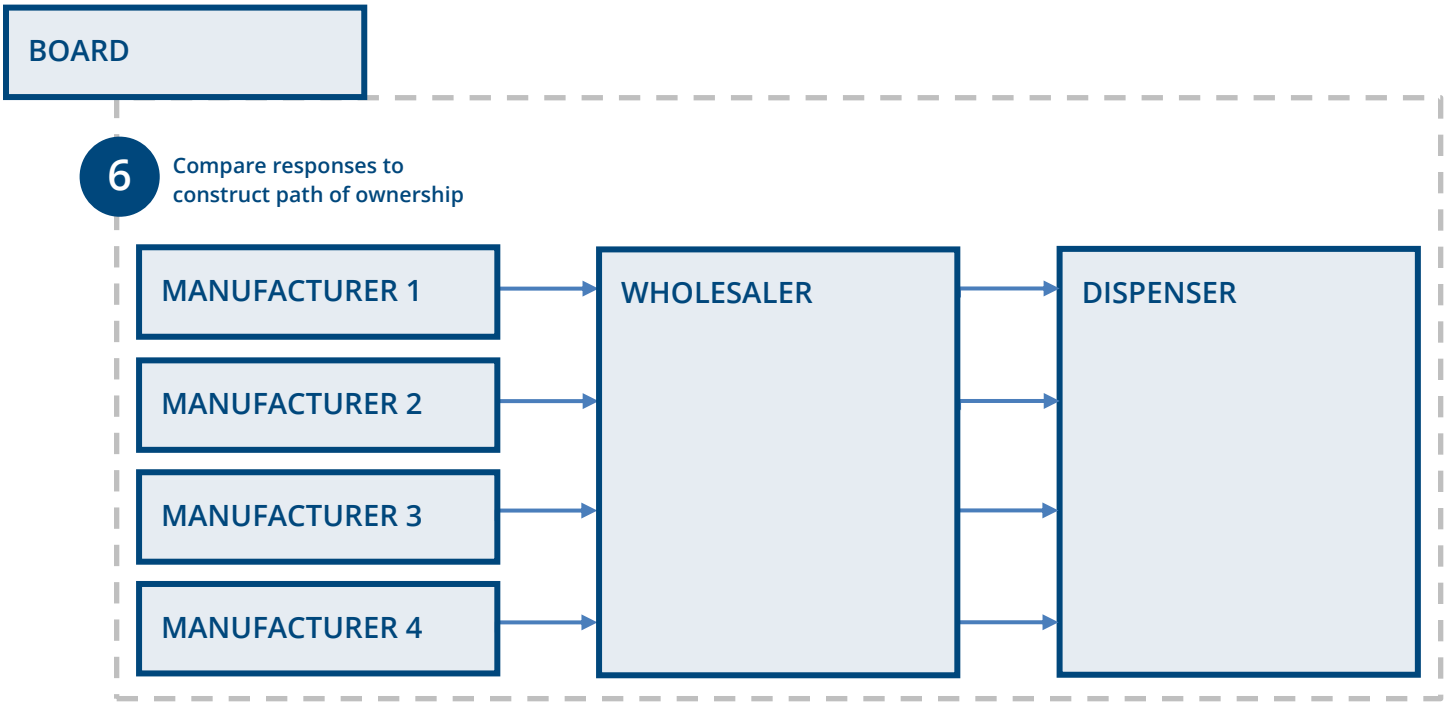
All trace responses indicated transactions with a single wholesaler. The Board directed the next round of trace requests to the wholesaler. Due to an apparent IT system delay, the trace responses were provided within two business days, as the wholesaler reported that the initial request did not appear in their email system until the day after it was sent.



The wholesaler provided two transactions per response: one for the purchase from the manufacturer, and one for the sale to the pharmacy. The wholesaler's responses indicated that the products were all purchased directly from the manufacturers and sold directly to the dispenser with no detours.

In total, six parties submitted responses, with one using two methods:

- Two used PDG-compliant JSON responses submitted via email.
- Three provided responses via email, directly populating the table provided by the Board in the trace request email.
- Two provided transaction reports generated in PDF format.



In summary, 12 trace requests were sent in total, revealing 8 distinct transactions (each described twice to enable cross-checking).

ANALYSIS & OUTCOMES

Upon reviewing all responses, the Board found that:

- **Minor data discrepancies continue to persist**. In one instance, two respondents disagreed on the entity-level GLN to be used to identify one of the parties involved in the transaction (though this did not turn out to be material from a compliance standpoint).
- One of the respondents encountered difficulties with the "container size" and "number of containers" requirements in the law and trace response specification. To clarify, container size is an open text entry; when drawing from EPCIS it is based on the net content description. "Number of containers," when the trace request is about an individual saleable unit, is always 1. (The number of containers would be higher for a homogenous case.)
- **Improvements to trace outreach resulted in faster and more effective responses.** One-third of respondents availed themselves of the Board's example response data.
- **JSON is an effective method for ensuring response completeness and consistency** under the PDG specification.
- **Appropriate contact data remains critical.** In multiple instances the trace request required internal referrals. Trading partners in possession of product to which they do not have ownership title should be ready to refer requestors to the appropriate responders.
- **Running trace requests concurrently with multiple trading partners at once is highly effective** and reduces investigation times.

CONCLUSION

Trace Readiness Week (TR-WEEK) demonstrated that interoperable, end-to-end tracing under DSCSA 582(g) is achievable today when regulatory authority, industry participation, and operational preparedness align. Using real inventory, live systems, and actual response workflows, the Board was able to reconstruct complete chains of ownership across multiple supply-chain segments within the timeframes contemplated by federal guidance.

The exercise also reaffirmed an essential principle of DSCSA implementation: state regulators play a central role in executing trace investigations, but they cannot do so without active, timely cooperation from Authorized Trading Partners. Tracing is a coordinated response obligation that depends on accurate contact information, retained records, internal readiness, and clear escalation paths within each organization.

TR-WEEK surfaced encouraging indicators of progress, including timely acknowledgements, complete responses, and successful use of both machine-readable and human-readable formats. As DSCSA enhanced enforcement continues, the Board will continue engaging with stakeholders through outreach, guidance, and future exercises to improve shared readiness, reduce uncertainty, and ensure that trace requests can be answered promptly and completely.

Safeguarding the pharmaceutical supply chain is a shared responsibility. When regulators and trading partners work together, we can protect patients and preserve trust in our nation’s drug distribution system.