
# Louisiana Board of Drug and Device Distributors

## VR-DAY
## Verification Readiness Exercise
## November 19, 2024


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# Introduction

Enacted in 2013, the Drug Supply Chain Security Act (DSCSA) is a U.S. federal law designed to enhance the security and integrity of the pharmaceutical supply chain, thereby protecting patients from counterfeit, contaminated, or otherwise harmful drugs. The law establishes a framework for tracking and tracing prescription medications throughout the supply chain. It requires manufacturers, repackagers, distributors, third-party logistics providers, and dispensers to share transaction data, maintain product traceability, and implement product identifier verification processes to authenticate drug legitimacy. It also allows for access by authorities including federal and state regulators.

The mission of the Louisiana Board of Drug and Device Distributors (the Board) is 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

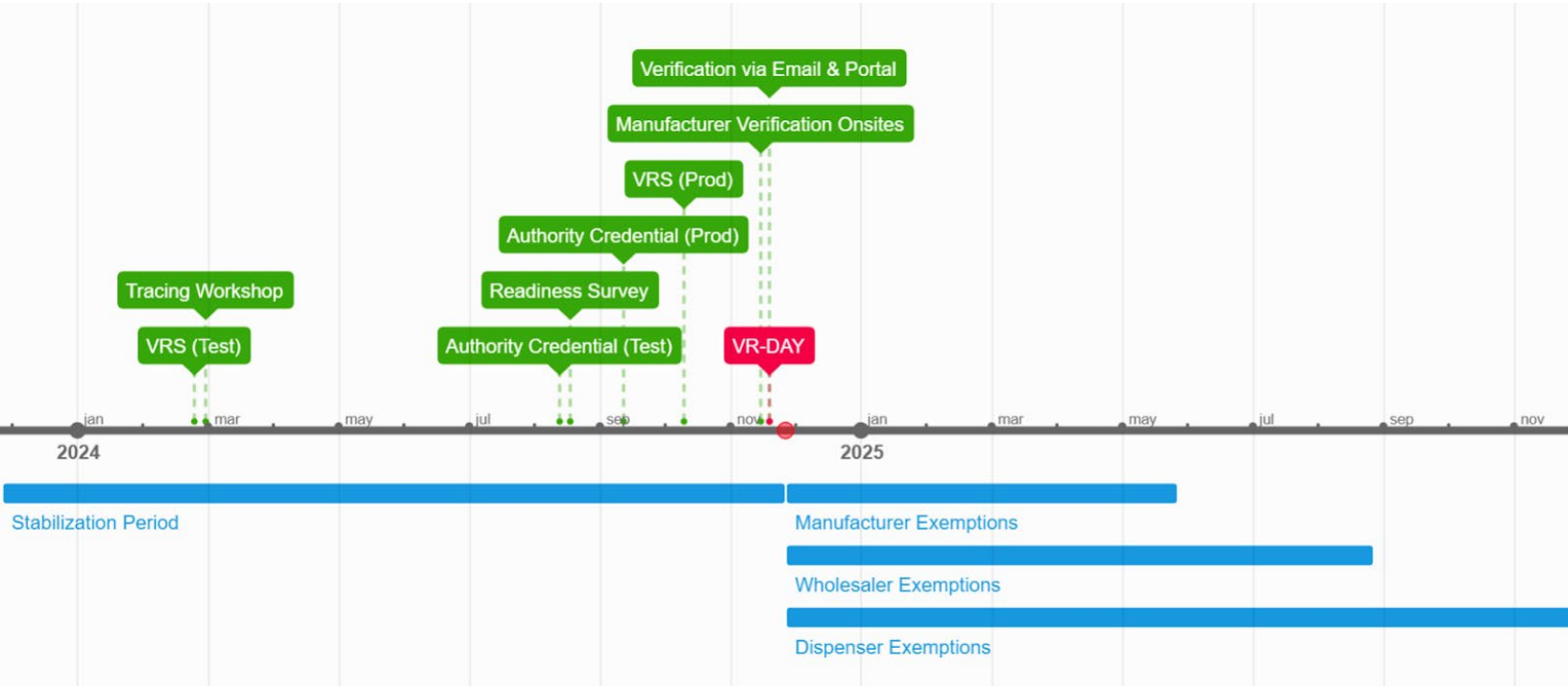
legend drugs or legend devices within and into the state of Louisiana. Part of the Board's mandate is to ensure that licensees establish, maintain, and adhere to a number of written policies and procedures that align with the requirements of the DSCSA. To support this mission, the Board intends to make use of the enhanced drug distribution security (EDDS) network under the DSCSA as per §203. In addition to enhancing patient safety, these efforts also serve to protect brand integrity, so all legitimate parties are aligned to work together.

Interoperability under the DSCSA can only be accomplished through collaborative effort. To evaluate these capabilities in a real-world setting, the Board conducted Verification Readiness (VR) Day – an industry readiness exercise to provide DSCSA stakeholders including the Board a safe space to undertake a real-time series of product verifications and observe the results, while preserving stakeholder anonymity as much as possible.

# Background

Under the DSCSA, Authorized Trading Partners (ATPs) in the pharmaceutical supply chain are required to exchange product compliance information, including drug verification and tracing data. These exchanges of information often take place between "indirect" trading partners with no prior business relationship and varying levels of sophistication, as well as between trading partners and state and federal authorities. This is especially important in the course of suspect and illegitimate product investigations, when authorities may need to quickly reach the appropriate point of contact.

While many DSCSA requirements (including product identifiers and ATP confirmation) are already in effect, the full set of DSCSA requirements comes into effect this month with the end of the FDA stabilization period apart from exemptions for connected trading partners. Over the course of 2024, the Board has been active in advancing the use of the EDDS to enable more effective inspections and empower trading partners to more easily respond to routine requests. This included an industry tracing exercise, Readiness Survey, and the VR-Day Exercise.



## DSCSA Tracing

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

On February 29, 2024 in Washington DC, the Board participated in DSCSA Trace Interoperability Pilot Demo Day – an exercise hosted by the Center for Supply Chain Studies (C4SCS) with FDA and industry stakeholders in attendance. During this live exercise in collaboration with a manufacturer and dispenser, the Board modeled a suspect product investigation that resulted in the unmasking of a counterfeit product. Critically, this test exercise included trading partners completely outside the State of Louisiana, so the Board needed to leverage EDDS interoperability to get answers quickly and effectively.

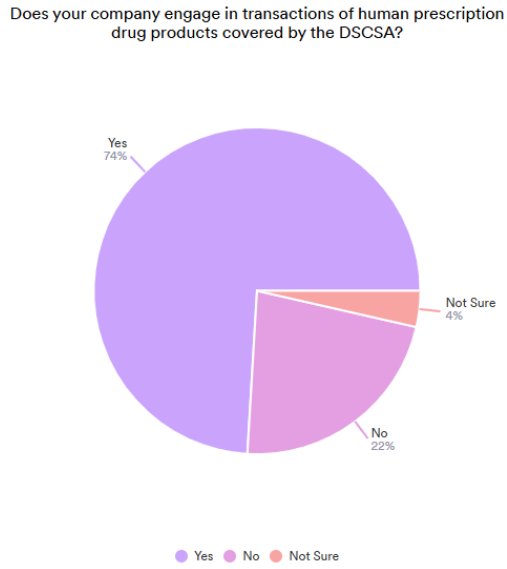
Using PDG-compliant trace requests and our OCI-compliant Authority credential, we submitted the requests electronically, allowing trading partners to validate our identity and respond promptly with confidence. In doing so, we became the first regulator in the nation to leverage the EDDS for a suspect product trace.

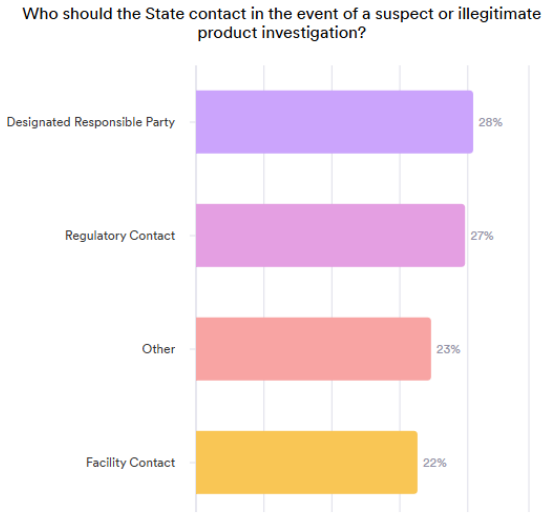
## The Board's DSCSA Readiness Survey


In August 2024, the Board undertook an effort to update licensees on steps being taken to leverage the DSCSA interoperable EDDS system, to enhance and streamline the Board's efforts to protect patient safety.

This included a Readiness Survey with all active licensed legend drug distributors to confirm DSCSA contact information, policies & procedures, and other key insights.

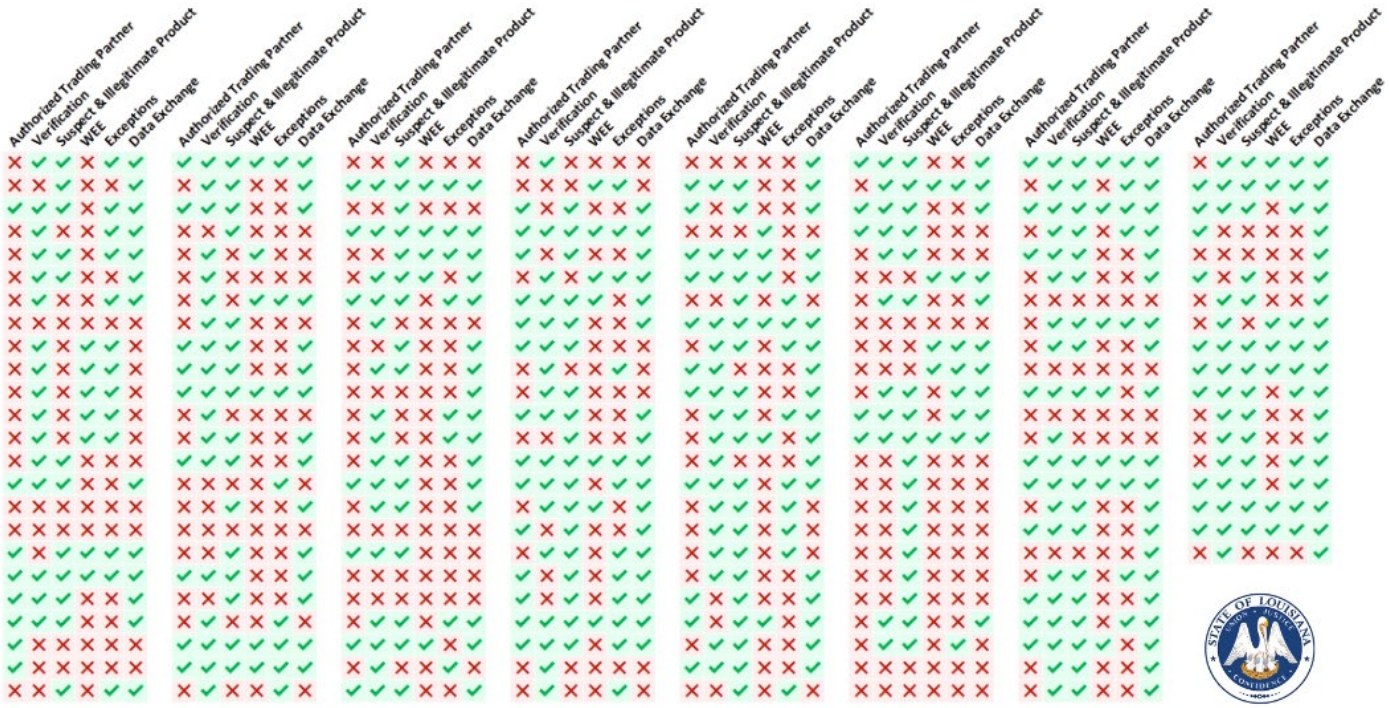
The Board received responses from licensees in 40 states as well as Canada and Puerto Rico.




## Policies & Procedures

As part of this effort, the Board requested that trading partners provide their DSCSA policies and procedures ahead of upcoming license reviews and inspections. The graphic below illustrates a representative sample of DSCSA policy & procedure coverage. Each row of six represents the document(s) submitted by a single facility.



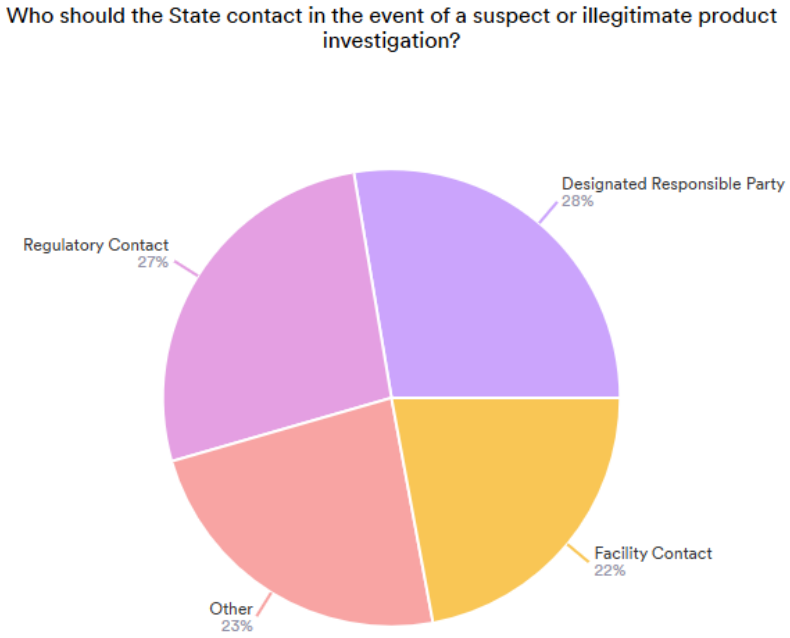

On a per-facility basis, the policies and procedures reviewed by the Board reveal the following coverage of key DSCSA compliance topics:

- 77% of respondents cover Suspect & Illegitimate Product

- 75% cover Product Identifier Verification
- 74% cover Data Exchange (e.g. EPCIS, T2/T3)
- 45% cover Exceptions (e.g. Missing Data)
- 43% cover Authorized Trading Partners (ATPs)
- 29% cover Waivers, Exemptions & Exceptions (WEEs)

### DSCSA Points of Contact

As the issuing body for all manufacturers and wholesalers selling or shipping into the state of Louisiana, the board has multiple touchpoints for each licensed facility, including a designated responsible person, facility contact, and regulatory contact. During the course of the Readiness Survey, the board asked licensees to indicate their preferred contact for suspect or legitimate product investigations. Notably, there was a relatively even split among the three contacts, as well as nearly a quarter of all facilities identifying a fourth preferred point of contact for DSCSA-related inquiries.




The full report can be found at https://regulator.id/la/readiness-survey.

## DSCSA Product Verification

Under the DSCSA enhanced drug distribution security requirements, trading partners must have "systems and processes for verification of product at the package level, including the standardized numerical identifier." This often involves a downstream trading partner such as a wholesaler or dispenser sending the request to the manufacturer or repackager responsible for the product identifier – the NDC, serial number, lot, and expiry date required to be on human prescription drug packages by the DSCSA. (More details about these requirements can be found on the FDA's website.)

### Introduction to Verification Router Service (VRS)

To enable interoperable product verification, a major component of the EDDS is the Verification Router Service (VRS), an industry-sponsored network of solution provider systems designed to automate verification requests and

responses. The VRS enables verification of product identifiers for suspect or illegitimate product investigations, exception processing, status checks and saleable returns. While the use of the VRS is not mandated by law, many trading partners make use of the network due to business and operational efficiencies. The Board intends to leverage these capabilities in support of its efforts to keep patients safe from contraband drugs.

During the VR-Day exercise, the Board welcomed Ms. Jaidalyn Rand of the Healthcare Distribution Alliance (HDA), the organization hosting the VRS Working Group. Ms. Rand covered the history of the VRS including its key development milestones since its inception:

- VRS Pilot & GS1 LVMS 1.0 (2018)
- VRS & ATP Credential FDA Pilots (2019)
- GS1 Lightweight Verification Messaging Standard (LVMS) 1.2 & Credential Testing (2022)
- GS1 LVMS 1.3 & Credential Production (2023)
- First Regulator on VRS (2024)

At a minimum, all VRS requests must consist of the following elements:

- the product identifier, i.e. the GTIN (which encompasses the NDC), serial number, lot, and expiry date;
- the GS1 Global Location Number (GLN) of the requesting party;
- the contact information of the requesting party, i.e. email address, phone number, or both;
- the context of the request, i.e. saleable return, suspect or illegitimate product investigation, exception verification, or status check; and
- whether the product is in the control or possession of the requesting party.

According to the GS1 LVMS Implementation Guideline, "initially, VRS implementations utilize Requestor and Responder Global Location Numbers (GLN)s for confirming ATP status. Subsequently, the pharmaceutical supply chain stakeholders added the verifiable ATP credential approach in demonstrating that a trading partner's identity and authorized trading partner status have been digitally verified. Requestor and responder GLNs will continue to be a part of DSCSA verification requests and responses defined in this guideline, even when ATP verifiable credential is included." While the use of verifiable credentials is not mandated by law, many trading partners choose to be digitally authenticated for operational efficiencies over the VRS.

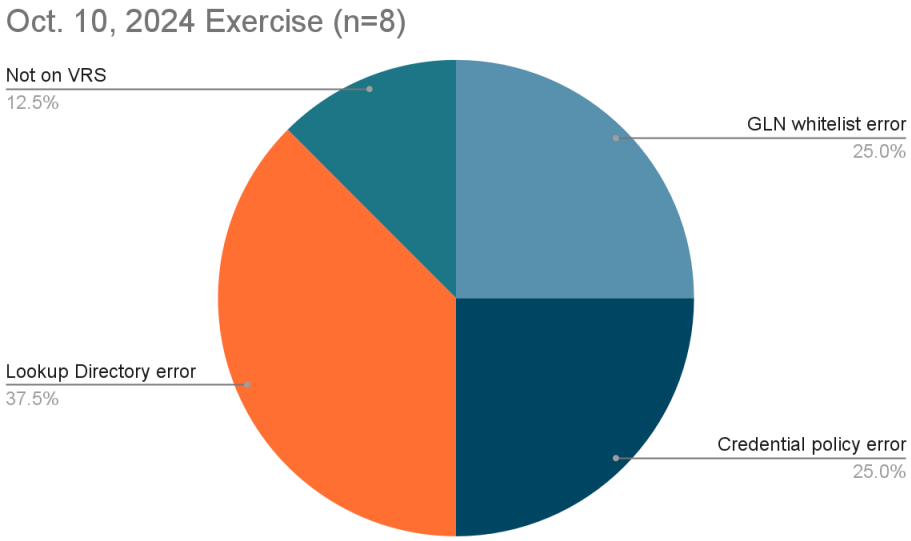
More information about the VRS can be found on HDA's website, PDG Blueprint Chapter 4, and in the GS1 Implementation Guideline.

## February 2024 Exercise

In February 2024, as part of the tracing exercise moderated by the Center for Supply Chain Studies under FDA observation, the Board first made use of the VRS testing service to evaluate its utility in support of suspect or illegitimate product investigations. The Board learned that by performing a verification request in advance of initiating a trace request, participants can nearly instantaneously confirm all-electronic contact information and gain quick insight into drug status.

## October 2024 Exercise

On October 10, 2024, the Board conducted a limited exercise (n=8) with several manufacturers to gauge the effectiveness of the VRS verification in production.




As shown in the chart above, 12.5% of requests were sent to manufacturer(s) not on the VRS, who were then asked to respond through a manual method. Of the other requests conducted, 25% blocked the request due to the Board's GS1 GLN being unrecognized, 25% were routed to manufacturers whose VRS provider(s) did not process the Board's Authority credential, and the remainder encountered issues with the VRS lookup directories. These results were reported to the trading partners and solution providers involved.

Although this first exercise in a production environment did not generate useful information about the drug packages in question, the fact that 7 of 8 packages generated a response motivated the Board to continue its efforts by scheduling a larger series of exercises, including VR-Day.

## November 2024 Manufacturer On-Sites

To prepare for the VR-Day Exercise, the Board conducted courtesy visits and onsite readiness exercises at two manufacturer sites in Louisiana who volunteered to participate. This involved a review of participating manufacturers' DSCSA policies & procedures (P&Ps), a review of prior product identifier verification activity, and the Board submitting verification requests. The Board principally focused on P&Ps related to verification requests, and how each facility would authenticate the requestor.

Manufacturer 1 has multiple lines of products, and had received 3 verification requests prior to that day's exercise from one of their known distributors. Their policies and procedures are kept in-house, with a digital version and 2 binders kept on site. The P&Ps are known by the staff, are easily accessible, and contain vital information such as relevant definitions and the steps their facility performs to comply with DSCSA requirements.

Manufacturer 2 manufactures mostly vitamins and supplements but has one product that falls under DSCSA. This was their first verification request received. Their P&P was developed from a template provided by their solution provider. This is a viable starting point for constructing P&P. As a general note, facilities must make sure that the SOPs are specific to the steps the facility follows to comply with requests.

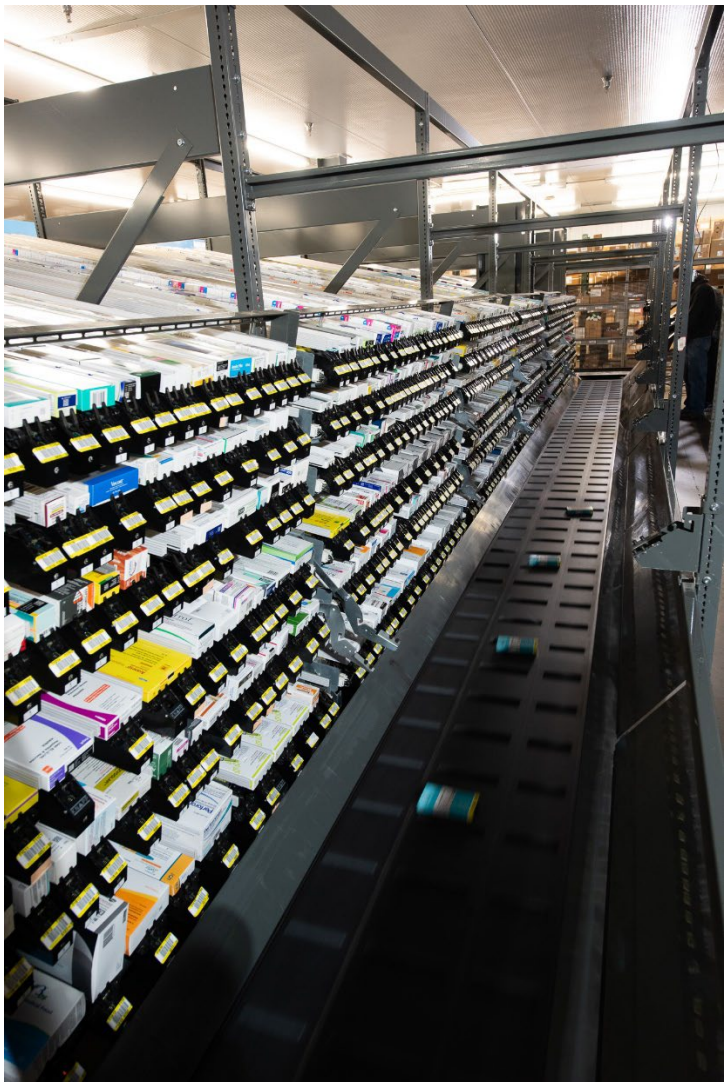
For the interoperable portion of the exercise, 4 verification requests were submitted via the VRS. As neither manufacturer makes use of the VRS, in both cases the facility representative received two emailed requests from the Board with the ability to respond via the Board's web-based portal. The facility representative then went into their systems and verified the product identifiers requested, then accessed the link in the email to respond via the Board's portal. They received an email confirming their response was received, and the Board portal was then updated with their response.

Of the 4 verification requests, 3 were successful and 1 was quarantined for further investigation, which is outside the scope of this report. While there are multiple ways a facility can comply with regulations to respond to a verification request, these were the specific steps followed in this exercise. Overall, the November 2024 Manufacturer On-Sites provided a valuable learning opportunity for the Board and licensees prior to the main VR-Day Exercise.

# VR-Day Exercise

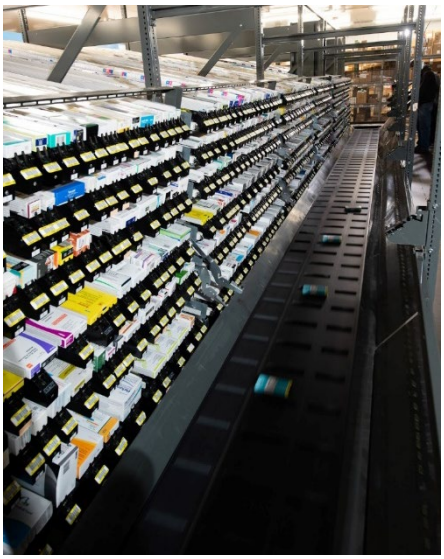
## Introduction & Acknowledgements

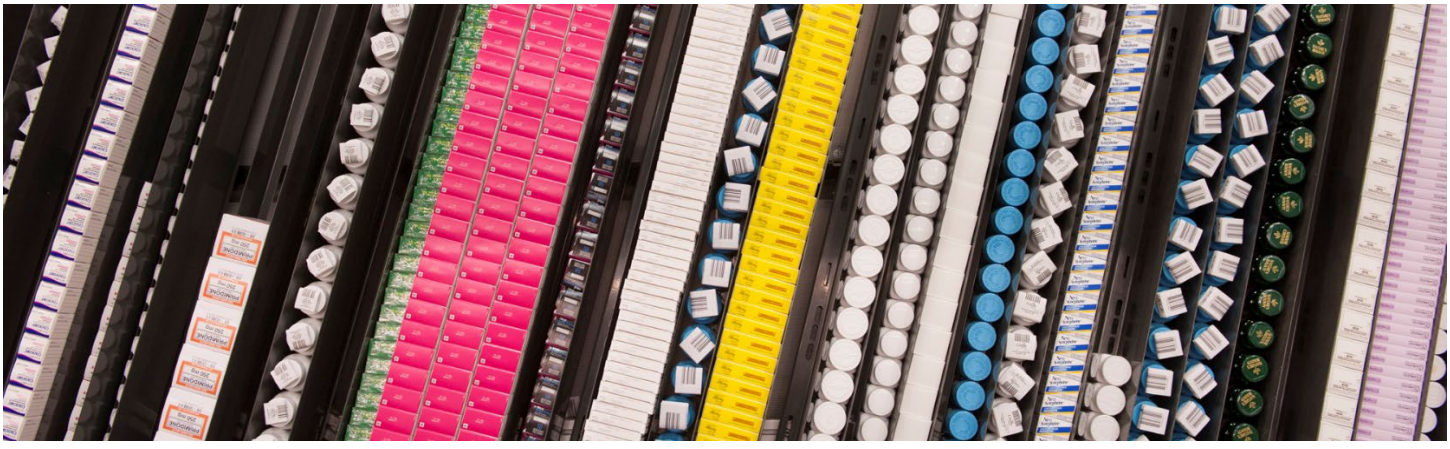
The VR-Day Exercise was an interoperable drug verification readiness exercise to provide DSCSA stakeholders including the Board an opportunity to undertake a real-time series of verifications and observe the results. This exercise was conducted over 3 days with the final day being a hybrid in-person and virtual event. Speakers at the event were George Lovecchio, Executive Director at the Board; Victoria Bienvenu, Compliance Manager at the Board; and Jaidalyn Rand, Director, Industry Relations at Healthcare Distribution Alliance (HDA). The event was conducted with support from Ben Taylor, Todd Barrett, and Alex Colgan (LedgerDomain) and Marc Blekkink (Movilitas). Special acknowledgements to NABP's onsite observers and our hosts at Louisiana Wholesale and Morris & Dickson. Thank you to everyone who attended in person and virtually.




*"At SOLA Pharmaceuticals, patient safety is our priority. We're advancing procedures and verification systems to combat illegitimate drugs, ensuring every product is safe and of the highest quality. Collaborating with the Louisiana Board of Drug and Device Distributors and LedgerDomain, we're testing these enhancements in real-world scenarios to strengthen reliability."*

*– Rebecca Risher, SOLA Pharmaceuticals*





*Photos courtesy of Morris & Dickson, Louisiana Wholesale, Sola Meds, and Medecor.*

# Exercise Parameter Development

## HDA VRS Taskforce Review

Prior to the exercise, the Board reviewed its intentions with the VRS Taskforce hosted by HDA, soliciting feedback from HDA and solution providers to maximize learnings and minimize disruptions to members. It was agreed that the Board would confirm its control over the inventory and would mark each request as a "status check" but to simulate real world conditions, that manufacturers not be notified in advance. As part of the overall readiness exercise, the Board advised that the use of GLNs and credentials would be evaluated.

## Manufacturer Selection

Prior to the exercise, the Board selected 60 leading manufacturers for the exercise to ensure a meaningful cross-section of manufacturers, based on likely inventories. Participating wholesalers then added in selected additional manufacturers that were material to their operations.

## Inventory Selection

Participating wholesalers selected genuine drug packages prior to the exercise. In addition to ensuring that each manufacturer was represented, the wholesalers also ensured that:

- All products were human prescription drugs.
- No products were in shortage.
- No products were controlled substances.
- As few products as possible were subject to temperature controls.

# Methodology

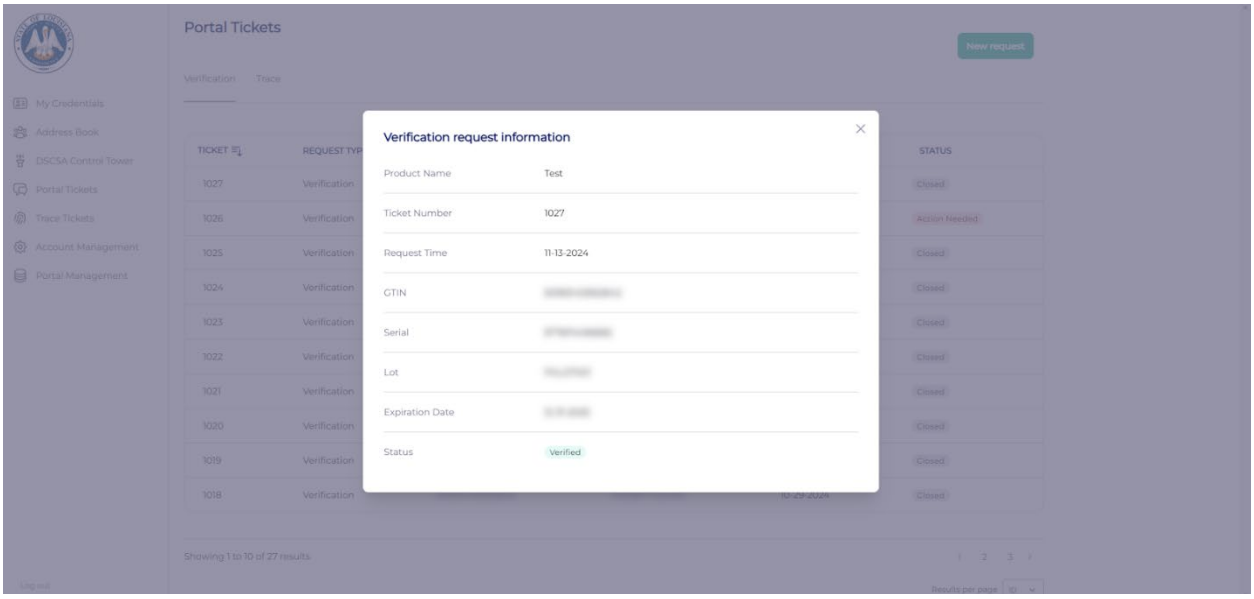
The objective of the VR-Day Exercise is to assess the verification readiness of the VRS network involving different scenarios for GLNs and credentials. Four flights were conducted in all for this exercise, in consecutive order:

| Flight | Requestor | GLN | Credential |
|---|---|---|---|
| 1 | Wholesaler 1 | Wholesaler (Shared) | N |
| 2 | Wholesaler 1 | Wholesaler (Shared) | Y |
| 3 | Board | Board (Shared) | Y |
| 4 (Main) | Board | Board (Not Previously Shared) | N |

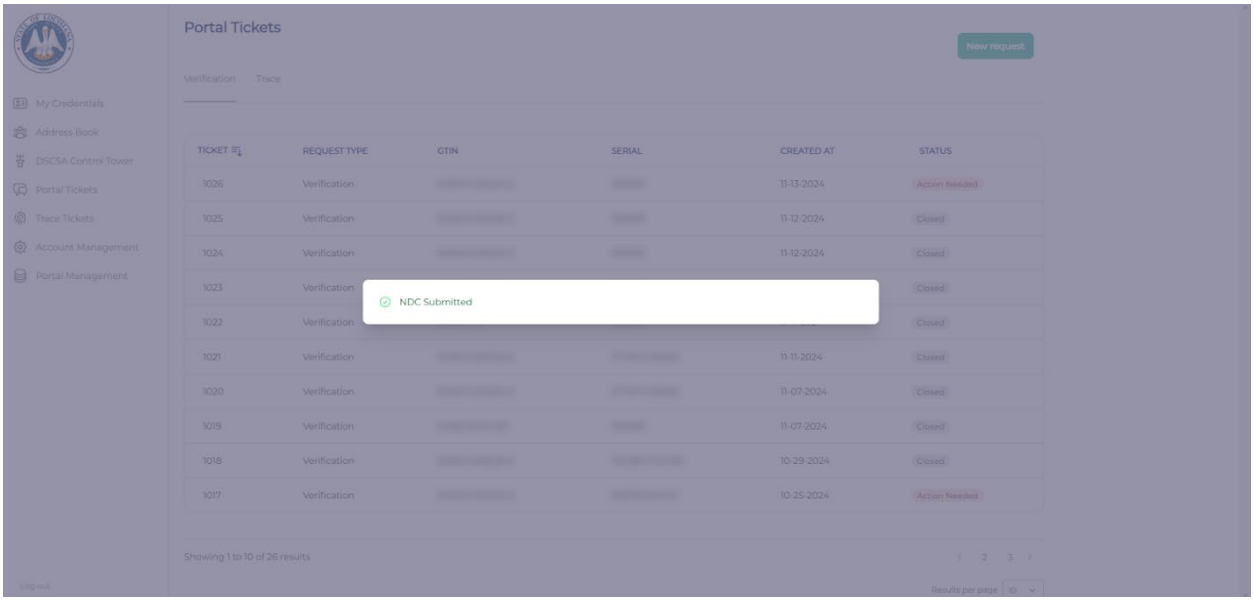
In all instances, verification requests were submitted with "DSCSA status check" and an attestation that the product was in the control or possession of the requesting party.

The outcomes for the verification testing were (1) VRS True, (2) VRS False, and (3) No Response.

In Flight 4, packages that had no responses from the VRS system were further investigated.




Automatic emails requesting responses via the Board's web portal were sent to points of contact on file.

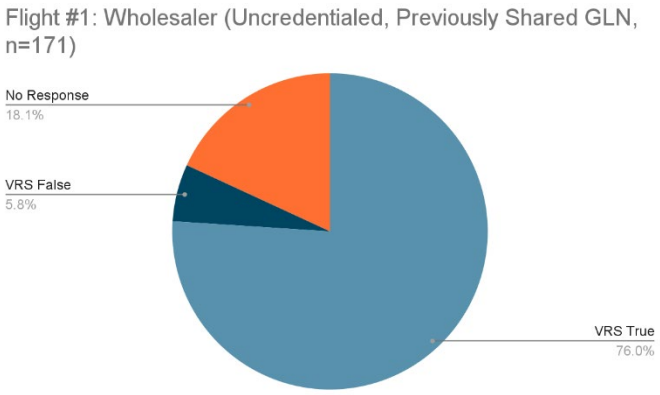


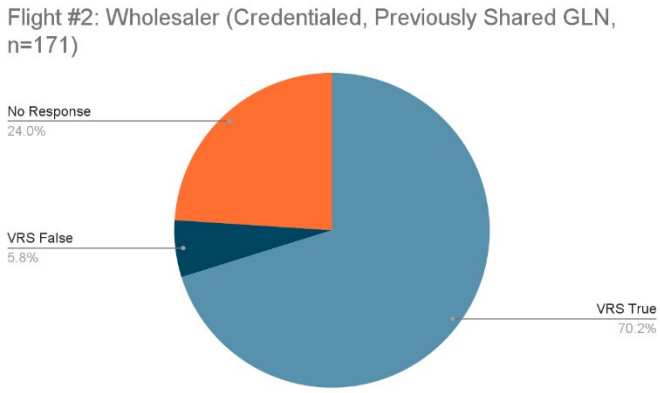

During the course of the exercise, all products were in possession or control of the Board. Products were held until all learnings from this exercise were cleared and the Board notified the participating wholesalers when packages could be re-introduced into the supply chain.

# Product Verification Flight Results

## Flights 1 & 2: Wholesaler

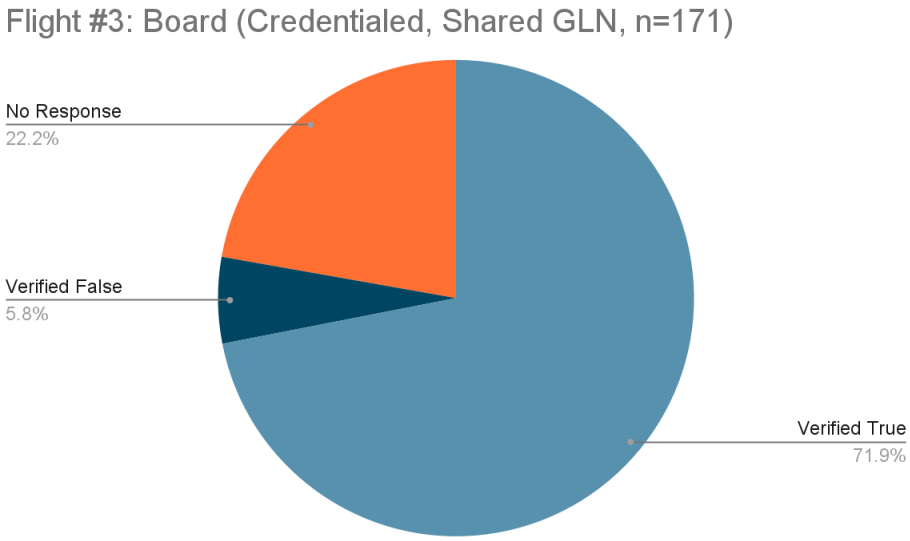
One of the participating wholesalers (Wholesaler 1) sent two flights of verification requests via the VRS as a control. One flight used OCI-compliant ATP credentials, and one did not use credentials. In each flight, the same 171 saleable units were scanned, and the wholesaler's GLN (which had been previously shared and was known to all their suppliers) was used.



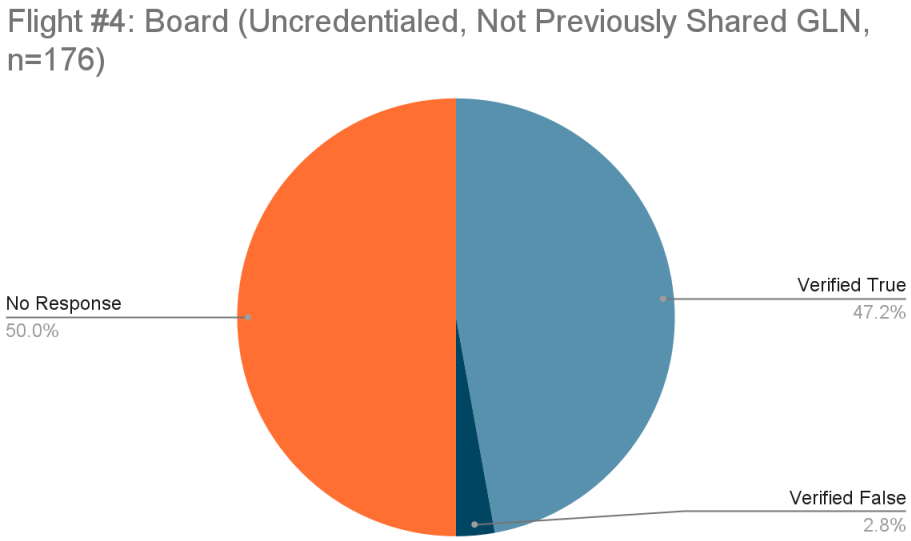

## Flight 3: Board

The Board submitted a flight of credentialed requests using the Board's OCI-compliant Authority credential and previously shared GLN. This involved the same inventory as the prior two flights.




## Flight 4: Board (Main VR-Day Exercise)

The main VR-Day Exercise consisted of a single flight of verification requests from the inventory of both wholesalers (the original 171 from Wholesaler 1, and 5 from Wholesaler 2) totalling 176 packages submitted. For this flight, the Board made use of a GLN that had not previously been shared, in order to understand the potential impact of GLN "allow listing" policies on requestors. In this case, based on error reports received, nearly all of the packages that verified "true" in Flight 3 and did not verify in Flight 4 were the result of GLN-related rejections.



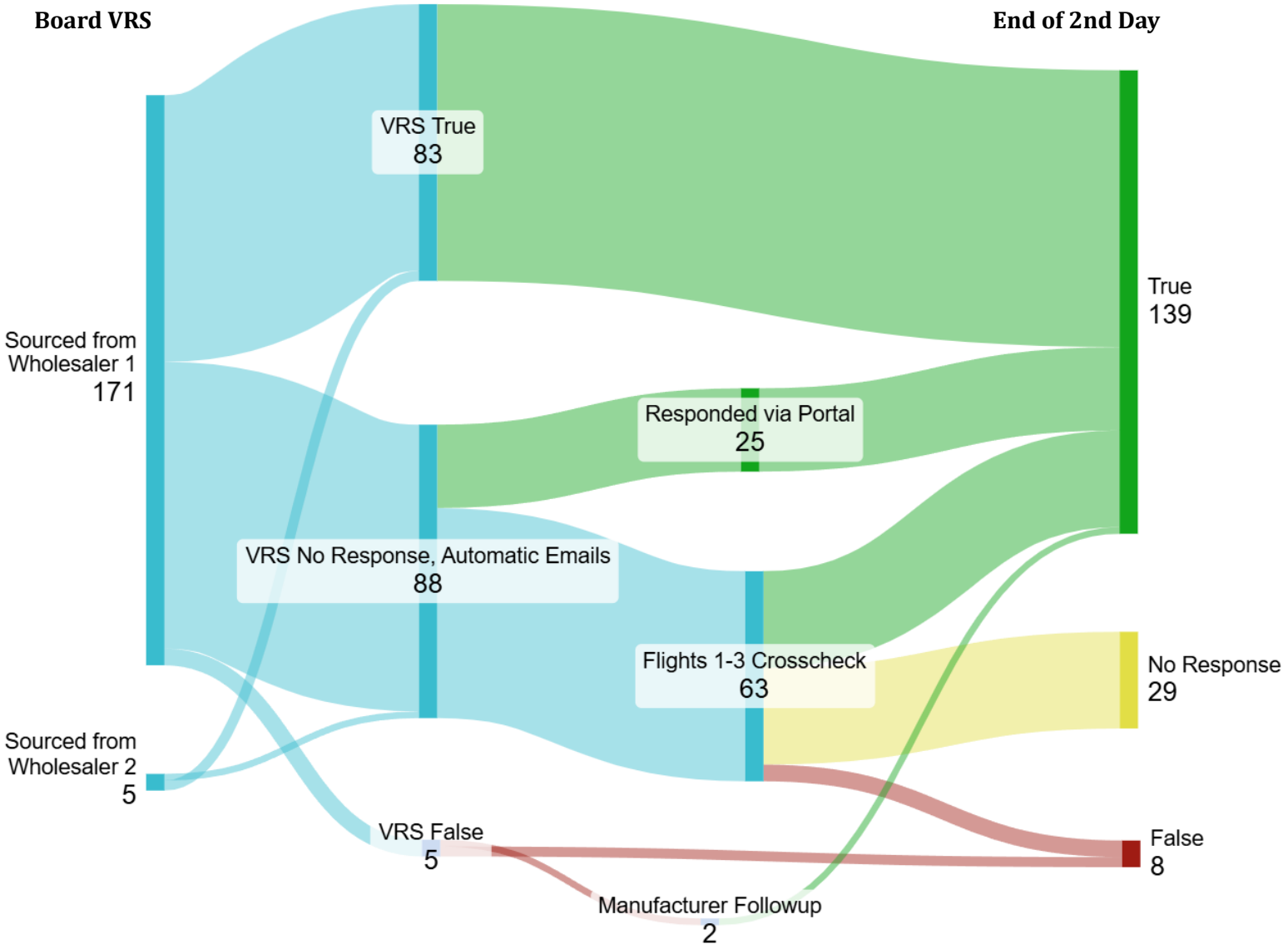

## Final Results

| | **Flight 1: Wholesaler** Uncredentialed, Previously Shared GLN | **Flight 2: Wholesaler** Credentialed, Previously Shared GLN | **Flight 3: Board** Credentialed, Previously Shared GLN | **Flight 4: Board** Uncredentialed, Not Previously Shared GLN |
|---|---|---|---|---|
| VRS True | 130 (76%) | 120 (70%) | 123 (72%) | 83 (47%) |
| VRS False | 10 (6%) | 10 (6%) | 10 (6%) | 5 (3%) |
| No Response | 31 (18%) | 41 (24%) | 38 (22%) | 88 (50%) |
| Total | 171 | 171 | 171 | 176 |

In Flight 4, the Board sent 176 requests. 88 received VRS responses and 88 no responses.

For the 88 packages that did not receive a VRS response from that flight, emails were automatically sent to manufacturers. Over the following 24 hours, the Board received 25 responses from manufacturers, who verified packages where the VRS had not provided a response. Separately, the Board received a followup communication regarding 2 packages where VRS "false" responses had been sent in error. This left 63 requests unresolved or 36% that required followup.

In order to ascertain a more precise number of unresolved VRS requests, package status information was cross-checked against information provided in Flights 1, 2, and 3. Subsequent analysis revealed that among those 63 packages, 32 packages had received valid VRS responses in Flight 3, and 2 packages had received valid VRS responses in Flights 1 and 2. This left 29 packages that had an unknown verification status.




At the end of this entire exercise, out of 176 requests sent by the Board, verification status was obtained for 84%.

# Conclusion

The Louisiana Board of Drug and Device Distributors always endeavors to enhance the security of the pharmaceutical supply chain and has taken the position that the DSCSA law affords the Board new tools to raise its game and that of its licensees. Through the use of the EDDS system, collaboration with industry stakeholders, and initiatives like VR-Day, the Board can make good on this potential and share learnings to the betterment of all. This empowers manufacturers and repackagers to ensure the integrity of their brands, wholesalers to ensure that product moves safely and effectively, and ultimately pharmacists and patients to better trust in the integrity of the supply chain.

Key findings from these efforts underscore both progress and challenges in achieving DSCSA interoperability. The VR-Day Exercise provided actionable insights into the current state of readiness among trading partners. With an impressive 82% of product identifier verification requests ultimately yielding valid and nearly instantaneous responses via the VRS network, it is clear that the foundations for fully interoperable PI verification are fully in place.

The remaining 18% requiring manual email follow-up emphasizes the importance of continued engagement with trading partners. In the event that manufacturers do not use VRS, have set block policies, or are experiencing technical issues, The Board has an email fallback system which auto-generates a credentialed email with a human-readable request for product verification and a link to the Board's portal. (All-electronic methods are dramatically faster and easier to log than Board inspectors needing to call an 800 number!)

We also learned that procuring a GLN is not enough – we need to exchange full contact information with trading partners. While regulators are not included in the ATP confirmation requirements, we for one will hold ourselves to that standard with an annual confirmation to all ATPs and fellow regulators.

Building on these results, the Board is better equipped to refine its policies and inspection procedures, enhance collaboration with stakeholders, and make use of the interoperable EDDS. As we shared at the VR-Day meeting, Board staff has drafted a new inspection checklist with a DSCSA section which is currently being reviewed by our main Board. We hope that these efforts provide a model for other jurisdictions as we work together to reinforce public trust in the safety and integrity of prescription medications.

Finally, we would like to thank our participating Board Members – Chairman Mike Davis, Scott Irelan of Morris & Dickson, and Chad Gielen of our host Louisiana Wholesale – as well as speaker Jaidalyn Rand of HDA and in-person observers Tim Stearns (HDA) and Greg Jones and Mark Karhoff (both NABP). We are grateful for the participation of licensees for our courtesy calls including Keith LaNasa and Rebecca Risher of Sola, Lindsey Venable of Medecor, Rustin Holbert of Morris & Dickson, and Buddy Ryder of Louisiana Wholesale.

Finally, while the Board does not endorse any solution providers, we extend our thanks to the verification (Movilitas, SAP, TraceLink, LSPedia, rfxcel, Systech, and Optel) and credentialing (LedgerDomain and Spherity) solution providers who participated in the planning, execution, and audit of the four flights.

# Addendum: VR-Day 2 (May 5, 2025)

## Introduction & Acknowledgements

On May 5, 2025, the board and participating organizations reconvened to conduct VR-Day 2, a follow up exercise to gauge industry progress ahead of the manufacturer deadline under the FDA's phased approach to DSCSA compliance. As always, the Board remains committed to making use of the latest tools to collaborate with industry, while accommodating the full range of interoperable approaches.

Special acknowledgements to Victoria Bienvenu at the Board. This event was supported by Ben Taylor, Todd Barrett, Alex Colgan, and Marc Blekkink.

## VR-Day 2 Interoperability Exercise

### Inventory Selection

The VR-Day 2 exercise involved three sets of inventory: (1) the 171 product identifiers provided by Wholesaler 1 in the original VR-Day Exercise, (2) 56 packages representing a standard order placed by a retail pharmacy, and (3) 9 randomly selected packages selected from Wholesaler 2's returns department.

### Manufacturers & Repackagers

In total, 73 manufacturers and repackagers received verification requests during the exercise. Sixty of these had received requests during the original exercise.

## Methodology

The objective of the exercise was twofold: (1) assess changes in responses to verification requests over time, and (2) gauge verification readiness based on an inventory sampling with greater randomization. Four flights were conducted in all for this exercise, in consecutive order:

| Flight | Requestor | GLN | Credential |
|---|---|---|---|
| 1 | Board | Board (Shared) | Y |
| 2 | Wholesaler 1 | Wholesaler (Shared) | Y |
| 3 | Board | Board (Shared) | Y |
| 4 | Board | Board (Shared) | N |

In all instances, verification requests were submitted with "DSCSA status check" and an attestation that the product was in the control or possession of the requesting party.

The three outcomes for the verification testing were VRS True, VRS False, and No Response. In Flights 3 and 4, packages that had no responses from the VRS system were further investigated.

# Product Verification Flight Results

## Flight 1: Board (VR-Day 1 Rerun)

As part of its benchmarking efforts, the Board submitted a flight of credentialed requests using the Board's Authority Credential and previously shared GLN, using the same inventory (n=171) as the original VR-Day One Flight 3. The results of this flight compared to the earlier flight are shown below.

| | **VR-Day 1 Flight 3** Credentialed, Previously Shared GLN | **VR-Day 2 Flight 1** Credentialed, Previously Shared GLN |
|---|---|---|
| VRS True | 123 (72%) | 126 (74%) |
| VRS False | 10 (6%) | 14 (8%) |
| No Response | 38 (22%) | 31 (18%) |
| Total | 171 | 171 |

Reasons for VRS False in the Flight 1 exercise included "no reason provided" (5), "GTIN/serial match" (8), and "manufacturer policy" (1). Reasons for No Response in the Flight 1 exercise included "400 (Bad Request)" (2), "400 (Verification Contact Error)" (4), "403 (Forbidden)" (3), "404 (GTIN not found)" (18), "502 (Bad Gateway)" (4), and "invalid expiry date" (1).

## Flight 2: Wholesaler (Retail Order)

One of the participating wholesalers (Wholesaler 1) sent one flight of verification requests for the replicated retail pharmacy order (n=56) via the VRS as a control, using their ATP Credential and previously shared GLN. Of these packages, 45 (80%) returned as Verified, 2 (4%) returned as Not Verified, and 9 (16%) returned as No Response. Reasons for VRS False included "no reason provided" (2). Reasons for No Response included "403 (Internal Error)" (1) and "404 (GTIN not found)" (8).

## Flight 3: Board (Retail Order)

The Board submitted a flight of credentialed requests for Wholesaler 1's replicated retail pharmacy order (n=56) using the Board's Authority Credential and previously shared GLN. The exact same results were encountered when compared to Flight 2.

In the 48 hours following the live exercise, emails were received from manufacturers clarifying their responses. For those manufacturers where no valid response was received, the Board made use of its portal to send secure emails with verification messages and its GLN to named points of contact. This enabled 4 products to be verified by manufacturers not participating in the VRS, reflecting the Board's commitment to supporting a range of approaches.

## Flight 4: Board (Returns)

Finally, the Board submitted a flight of credentialled requests for the packages randomly selected from Wholesaler 2's returns department (n=9) using the Board's Authority Credential and previously shared GLN.

## Final Results

| | **Flight 1: Board** Credentialed, Previously Shared GLN, Rerun | **Flight 2: Wholesaler** Credentialed, Previously Shared GLN | **Flight 3: Board** Credentialed, Previously Shared GLN | **Flight 4: Board** Credentialed, Previously Shared GLN |
|---|---|---|---|---|
| VRS True | 126 (74%) | 45 (80%) | 45 (80%) | 6 (67%) |
| VRS False | 14 (8%) | 2 (4%) | 2 (4%) | 2 (22%) |
| No Response | 31 (18%) | 9 (16%) | 9 (16%) | 1 (11%) |
| Total | 171 | 56 | 56 | 9 |

## Further Considerations

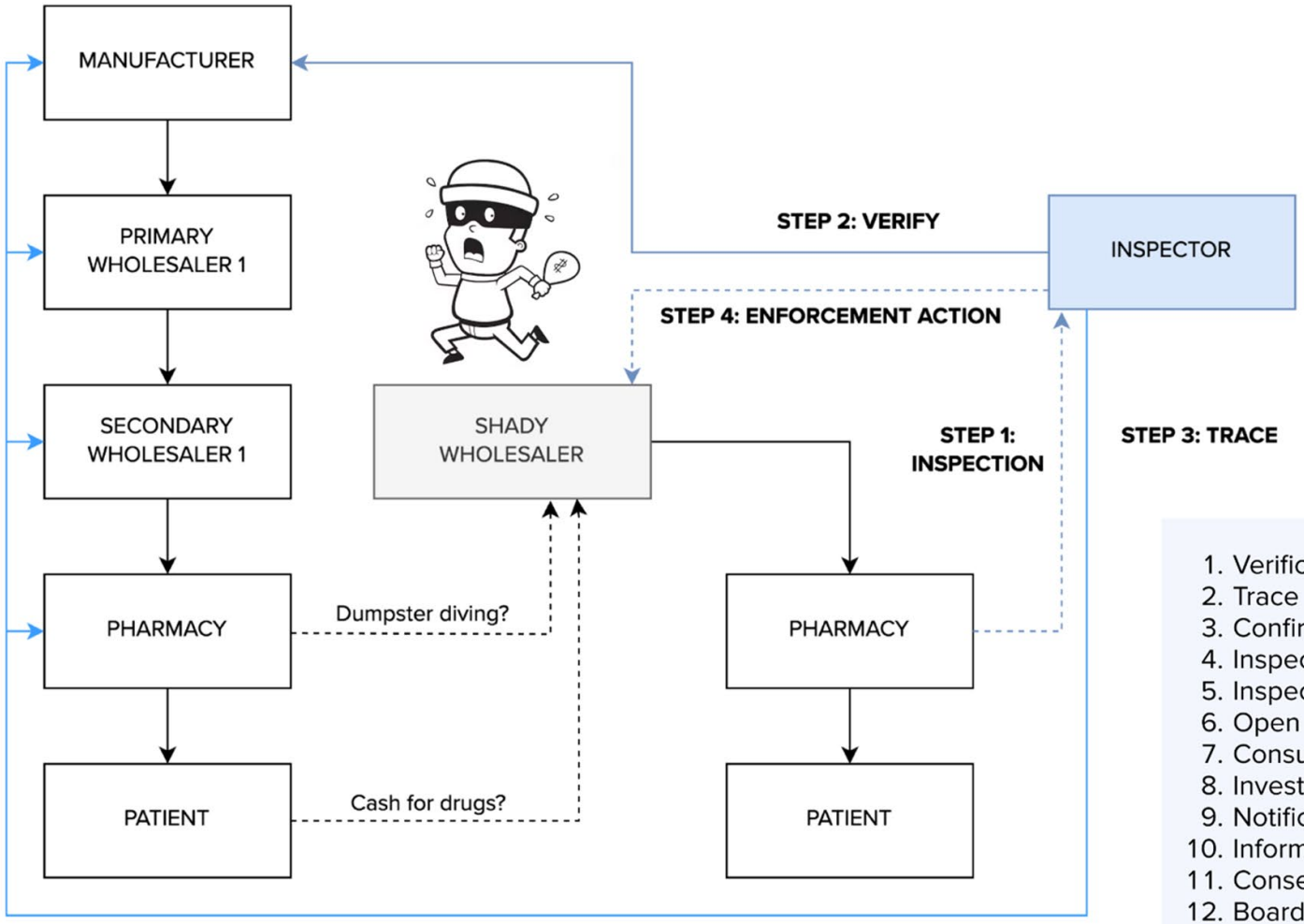
- We are pleased to report that a perfect match between the verifications performed by Wholesaler and those performed by the Board. This represents a significant improvement from VR-Day 1, where GLNs, credentials, and other factors led to major discrepancies in responses.
- During the same 24-hour period, our solution provider informed us that their service routed 12,064 VRS messages (requests and responses).
- We do see room for improvement on our side by ensuring that barcode parsing be passed through directly without excess post-scan interpretation.
- We observed some expired packages return “not verified” due to their expired status. While this is a valid response under the GS1 standard as expired packages are not suitable for re-distribution, we encourage manufacturers to be ready to provide fuller responses, as the Board’s activities may involve auditing or investigating expired products.
- Finally, we also reviewed your VRS response contact data with Louisiana's own master data and again saw good agreement.

## Conclusion

**Electronic, interoperable verification is a key element of the DSCSA, and Board continues to make use of the latest tools to collaborate with industry stakeholders to ensure that product moves safely and effectively, ultimately enabling pharmacists and patients to better trust in the integrity of the supply chain. With that in mind, whether you use VRS with GLNs and credentials, email, or even your trusty fax machine, the Board is willing to meet stakeholders where they are with a range of methods and approaches.**

In this exercise, we saw benchmarked VRS responses go from 78% to 84% and credential and GLN whitelist issues essentially disappear. In verifying a replicate order of a randomly selected tote from a retail customer order (n=56) selected by Wholesaler 1, a VRS response rate of 84% was also seen. Finally, verifying a random flight of saleable returns (n=9) from Wholesaler 2, we made use of our new scanner with genuine packages and demonstrated its use.

In closing, we are pleased to share our generic process flow and verification report for investigations to set expectations. Every investigation is different, but hopefully this transparency will enable all of us to better protect patients.




1. Verification
2. Trace
3. Confirmation of ATP
4. Inspection/review of P&Ps
5. Inspection report
6. Open case
7. Consult with Board attorney
8. Investigation
9. Notification
10. Informal conference (aka pretrial)
11. Consent agreement
12. Board hearing
13. Appeal
14. Referral for criminal prosecution
15. Drinks at Bon Temps

## Verification request information

| | |
|---|---|
| Ticket Number | 1575 |
| Request Time | 05-02-2025 (Friday) 03:20:49 p.m. |
| Request Method | Auto |
| GTIN | 50363402922642 |
| Serial | 9T76FKA96692 |
| Lot | PKLOT001 |
| Expiration Date | 12-31-2025 |
| Ticket Status | Open |

## Verification response information

| | |
|---|---|
| Verification Method | Auto |
| Verification Status | Verified |
| Response Timestamp | 05-02-2025 (Friday) 03:20:44 p.m. |

R Request sent to VRS

UUID: 91f6fef9-a955-4f05-a9e6-32887625f719
Sender: [redacted]
Email: [redacted]
Phone: 222-222-2222

Response from VRS

Timestamp: 05-02-2025 (Friday) 03:20:44 p.m.
UUID: 91f6fef9-a955-4f05-a9e6-32887625f719
Email: [redacted]
Phone: 011234567890
GLN: 0867923000032