State of DSCSA

Regulatory & Industry Update

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Louisiana Board of Drug & Device Distributors: DSCSA Report 2024

Hello everyone,

Under the U.S. Drug Supply Chain Security Act (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 appropiate point of contact.

On November 27th, 2024 the full set of DSCSA requirements will come into effect with the end of the stabilization period announced by FDA last year. More information about the interoperability requirements and enhanced drug distribution security (EDDS) network may be found on the FDA's website or in the Partnership for DSCSA Governance (PDG) Blueprint.

The mission of the Louisiana Board of Drug and Device Distributors 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.

In August 2024, the Board undertook an effort to update its 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 effort includes the following:

- We have prepared for the transition with a statutory framework, rule promulgation, and updated inspection procedures and training.
- We are actively conducting verification and trace activities as an authority under the DSCSA, including live exercises in collaboration with PDG and FDA.
- To participate in the EDDS network including the Verification Router Service (VRS), the State will make use of an OCI-compliant Authority Credential.

Finally, the Board conducted a survey with all active licensed legend drug distributors to confirm DSCSA contact information, policies & procedures, and other key insights. Today we are pleased to share the high-level results of this effort with fellow state and federal regulators as well as the nation's trading partner community.

By sharing these results, we hope to shine a spotlight on the incredible efforts undertaken thus far, and call attention to areas where work remains ahead of the deadline in less than seven weeks.

With warm regards from the Pelican State,

George Lovecchio
Executive Director, Louisiana Board of Drug and Device Distributors

Louisiana Board of Drug & Device Distributors: DSCSA Report 2024

Hello [redacted],

Under the U.S. Drug Supply Chain Security Act (DSCSA), pharmaceutical supply chain trading partners are required to respond to requests for information from state authorities in the event of suspect and illegitimate product investigations. As you are a licensee with the State of Louisiana, we're reaching out to provide a general update on our ongoing efforts to safeguard the life and health of citizens.

In addition, we ask you to confirm your trading partner information, including preferred contact information in the event of a suspect or illegitimate product investigation. **If we do not hear from you by August 20, we will contact your facility point of contact.**

CONFIRM YOUR INFORMATION

Or copy and paste the following link into your browser: [redacted]

DSCSA Interoperability

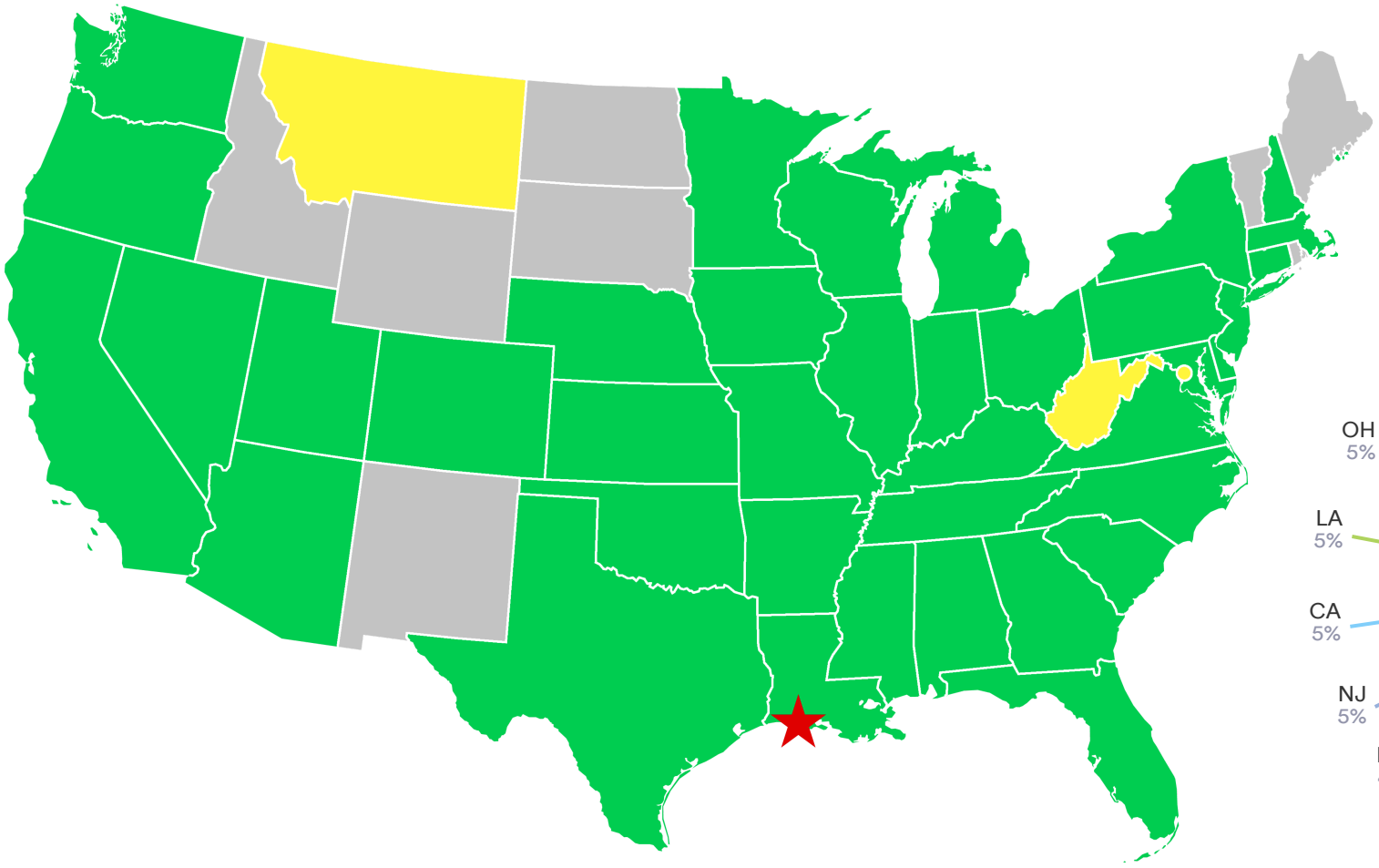
On November 27th, the full set of DSCSA requirements come into effect with the end of the stabilization period announced by FDA last year. More information about the interoperability requirements and enhanced drug distribution security (EDDS) network may be found on the FDA's website or in the Partnership for DSCSA Governance (PDG) Blueprint.

Our board has prepared for the transition with a statutory framework, rule promulgation, and updated inspection procedures and training. We are actively conducting verification and trace activities as an authority under the DSCSA, including live exercises in collaboration with PDG and FDA.

- Surveys were sent in rounds to Designated Responsible Person (DRP), facility, and regulatory points of contact in successive rounds.
- Response period open from August 13 – September 23, 2024.
- Survey emails included a test presentation of the Board's DSCSA Authority credential.

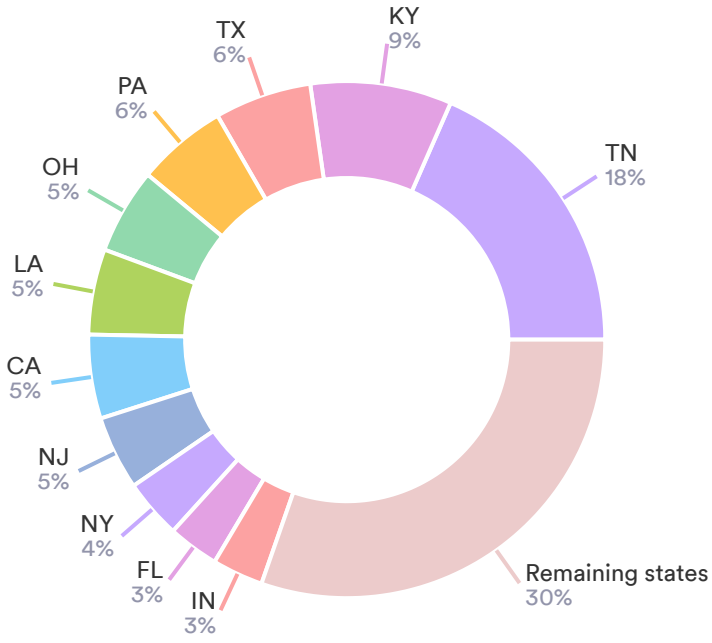
Responding Trading Partners

The Board received responses from licensees in 40 states, shown below in green, as well as Canada and Puerto Rico. No responses from licensees prior to report cutoff were received in the yellow states and Washington DC. The grey states are those with no facilities licensed in the State.



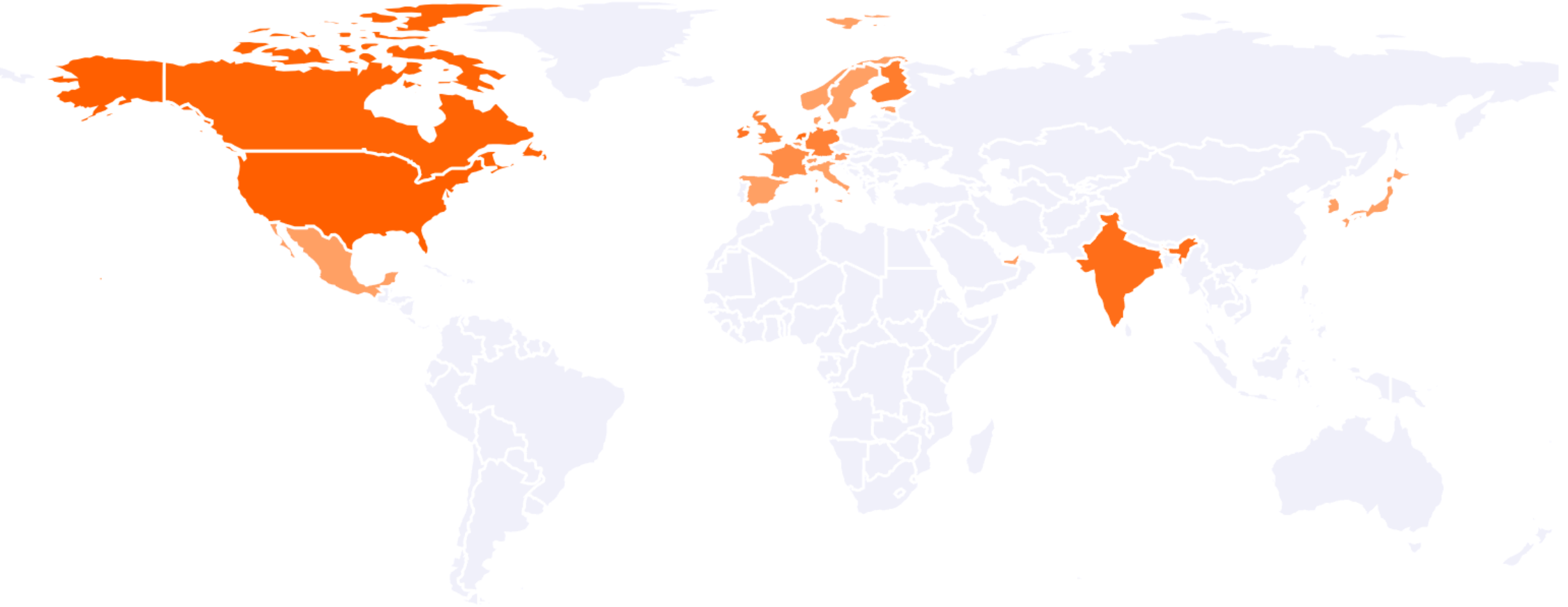
54%

Licensed Facilities Responded



Responding Points of Contact

With responses from DRPs, facility contacts, and regulatory contacts, the DSCSA community with licenses in Louisiana spans 4 continents and nearly 20 countries.



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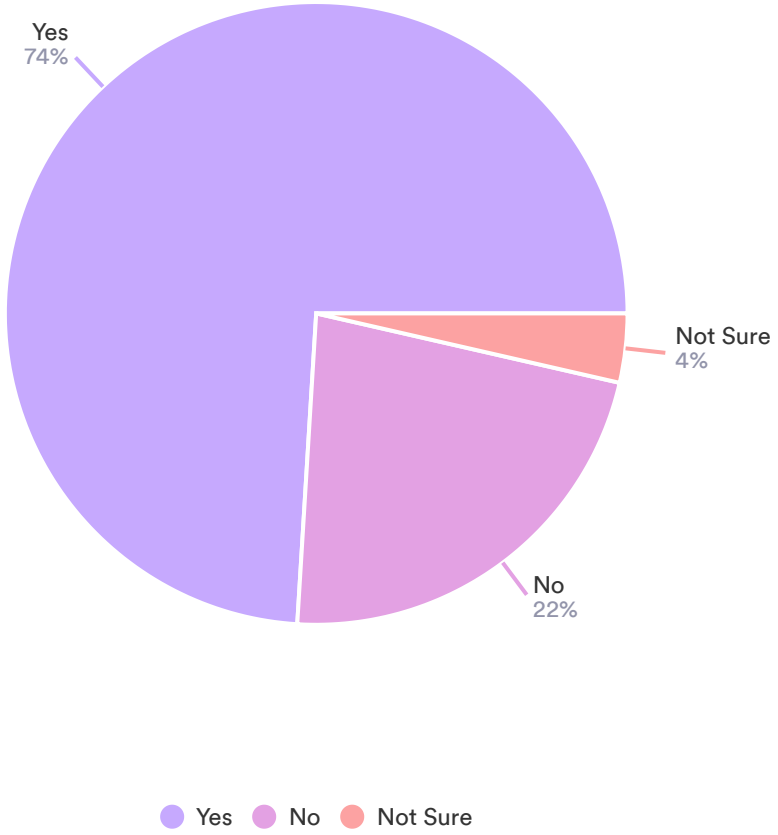
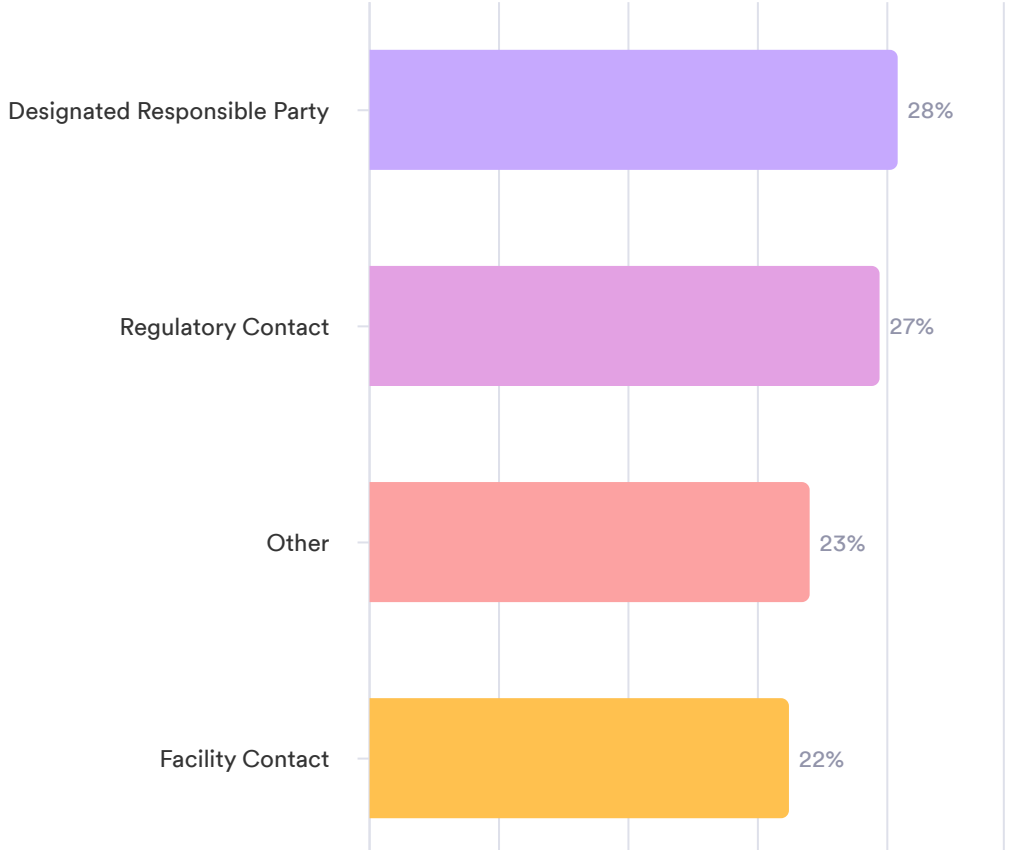
Does your company engage in transactions of human prescription drug products covered by the DSCSA?



Who should the State contact in the event of a suspect or illegitimate product investigation?



While the Board has 3 points of contact for each facility, nearly a quarter of all facilities identified another preferred point of contact for DSCSA-related inquiries!

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Policies & Procedures

The Board requested that trading partners provide their DSCSA policies and procedures ahead of upcoming license reviews and inspections. The word cloud below illustrates the density of DSCSA key words.

273

Facilities Provided Policies & Procedures

759

Individual Policy & Procedure Documents

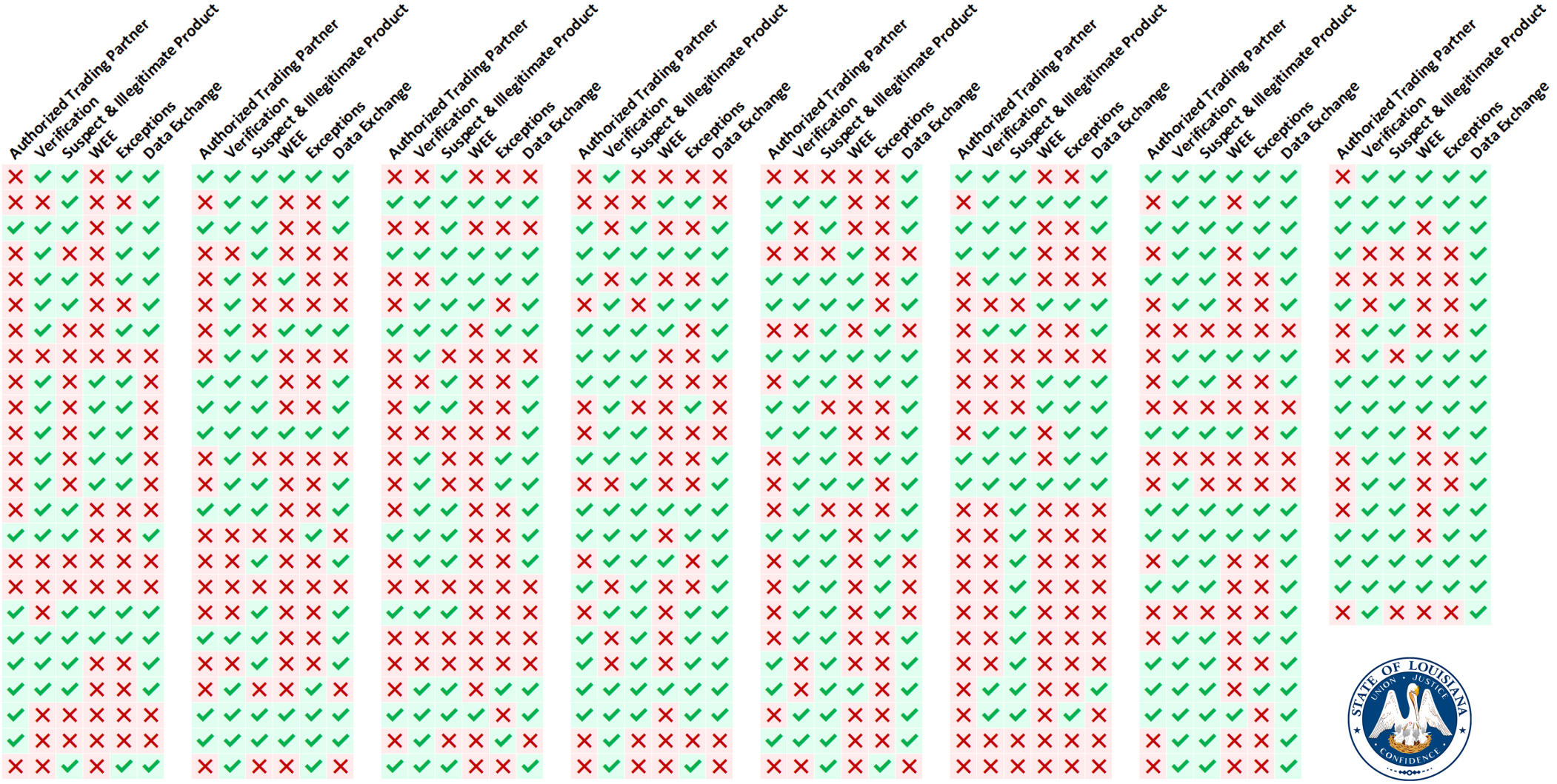
1.5M

Words

Louisiana Board of Drug & Device Distributors: DSCSA Report 2024

Policies & Procedures Heatmap

This graphic illustrates a representative sample of DSCSA policy & procedure coverage. Each row of six represents the document(s) submitted by a single facility.



Policies & Procedures

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

77%
Suspect & Illegitimate Product

75%
Verification

74%
Data Exchange (e.g. EPCIS, T2/T3)

45%
Exceptions (e.g. Missing Data)

43%
Authorized Trading Partners (ATPs)

29%
Waivers, Exemptions & Exceptions (WEEs)

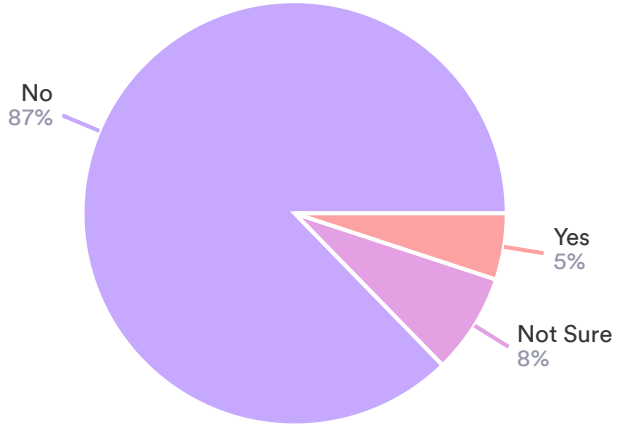
> *As many licensees are currently evaluating their policies & procedures ahead of the November 27 deadline, we would like to see moving toward 100% on all these points, although we appreciate the WEEs are a moving target. With the "electronic, interoperable" requirements coming into full effect, we have found a need to educate on Authorized Trading Parter validation and tracing, as many trading partners have outdated policies that don't reflect newer requirements, standards, and guidelines.*
>
> *Moving forward, we appreciate the use of digital credentials by our licensees, especially for the majority anchoring off an out-of-state license with faxes and photocopies. We've gotten our credential just like everybody else and it wasn't that hard.*

Waivers, Exemptions & Exceptions

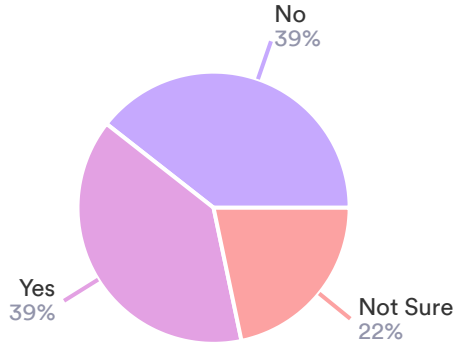
Under the DSCSA, trading partners unable to meet the enhanced drug distribution security requirements of section 582 of the FD&C Act by November 27, 2024, may request a waiver or exemption from those requirements. Although requests can be submitted at any time, FDA recommended trading partners submit a waiver or an exemption request by August 1, 2024.

- Submission dates range from June 6 to August 17, 2024
- Durations range from flu season to November 2026
- Tracing & verification requirements
- Some entities received confirmation that certain products are not covered by the law
- “We are asking for a WEE because [our largest customer] has asked for a WEE themselves.”
- “Approximately 15% of the medication volume that flows through [our wholesaler] does not have proper EPCIS data flowing from the manufacturer as of today and [our wholesaler] advises they are not expected to be ready by 11/27/24. [Our wholesaler] has also applied for a waiver/exemption.”
- Operational challenges (incomplete readiness of trading partners), lack of system capabilities to handle exceptions, and critical nature of timely access to medications for vulnerable populations.

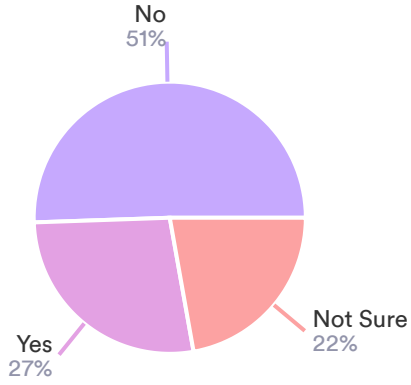
Has your company applied to the FDA for a Waiver, Exception, or Exemption (WEE) under the DSCSA?



Do you have policies and procedures in place to communicate with trading partners when selling product that is exempt from DSCSA requirements (e.g. grandfathered or covered under a WEE)?



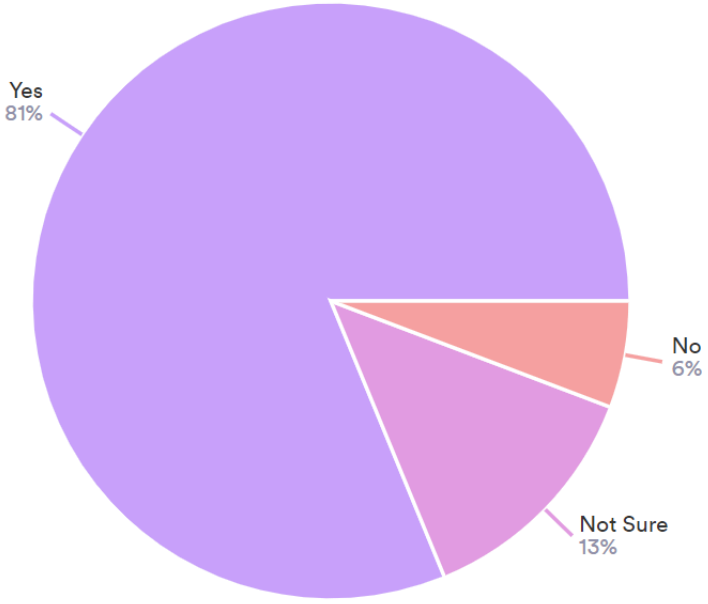
Do you have policies and procedures in place to communicate with trading partners about the WEE(s) that they may have been granted, including measures to assess the validity of their WEE(s)?



Tracing & Recalls

Under the final EDDS requirements of the DSCSA, trading partners must have "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 [...] in the event of a request by [the State] on account of a recall or for the purposes of investigating a suspect product or an illegitimate product."

In the event of a recall, do you have policies and procedures in place to promptly respond with the transaction information and transaction statement in a secure, interoperable, electronic manner upon request by the State of Louisiana?



In February 2024, the Board joined fellow regulators along with manufacturers, wholesalers, and dispensers to conduct an exercise in interoperable electronic tracing as required under the DSCSA.

Mapping the path of a suspect product through the pharmaceutical supply chain, we worked to unmask a counterfeit package and prevented it from reaching any patients. (Fortunately, since it was a test, Center for Supply Chain Studies founder Bob Celeste managed to avoid prison time!)

Critically, this exercise included trading partners completely outside the State of Louisiana, so we needed to rely on 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.

As we look forward, we're calling on trading partners to ensure that their recall processes are in line with their serialization-level systems.

Resources for Trading Partners

- U.S. Drug Supply Chain Security Act (DSCSA)
- FDA DSCSA Policies
- FDA Annual Licensure Reporting Requirements
- Open Credentialing Initiative (OCI)
- PDG Blueprint Chapter 1: Understanding of Compliance Requirements and Baseline Business Requirements
- PDG Blueprint Chapter 3: TI/TS Exchange Functional Design
- PDG Blueprint Chapter 4: Product Identifier Verification Functional Design
- PDG Blueprint Chapter 5: Tracing Architectural Functional Design
- PDG Blueprint Chapter 6: Credentialing and User Authentication
- PDG Tracing SOP Considerations
- Video: Tracing Interoperability Exercise

DSCSA is a nationwide effort unlike any we've seen before, and the Louisiana Board of Drug and Device Distributors is working hard to ensure our licensees are ready to meet the requirements and safeguard the life and health of all citizens.

We hope that by sharing the results of these efforts, fellow regulators and trading partners will have the opportunity to revisit their policies & procedures with fresh eyes and deliver a more seamless transition to enhanced drug distribution security.

We'll have more to share over the weeks and months ahead, and welcome your questions and comments. You can contact us at compliance@drugboard.la.gov, and we will endeavor to respond in a timely manner.

Ziggy is ready for a walk and the weather looks good (for now), so I'm off to enjoy the sunshine.

Your friendly neighborhood regulator,

George Lovecchio
Executive Director, Louisiana Board of Drug and Device Distributors