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Rx Supply
Chain Advisors

Tying Up the Loose Ends for DSCSA

September 10, 2024

Today’s Agenda & Speakers

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- Interoperability
- Portals
- Data Exchange and Exceptions Management
- Authorized Trading Partners (ATPs)
- Drop Shipments, Marketplaces, 340B
- Waivers, Exceptions & Exemptions (WEEs)
- Regulatory Policies & Practices
- Action Plan + Q&A

What are the blind spots today, and what can you do?

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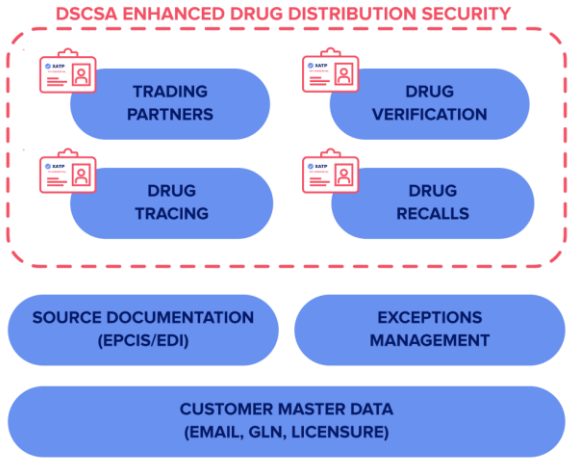
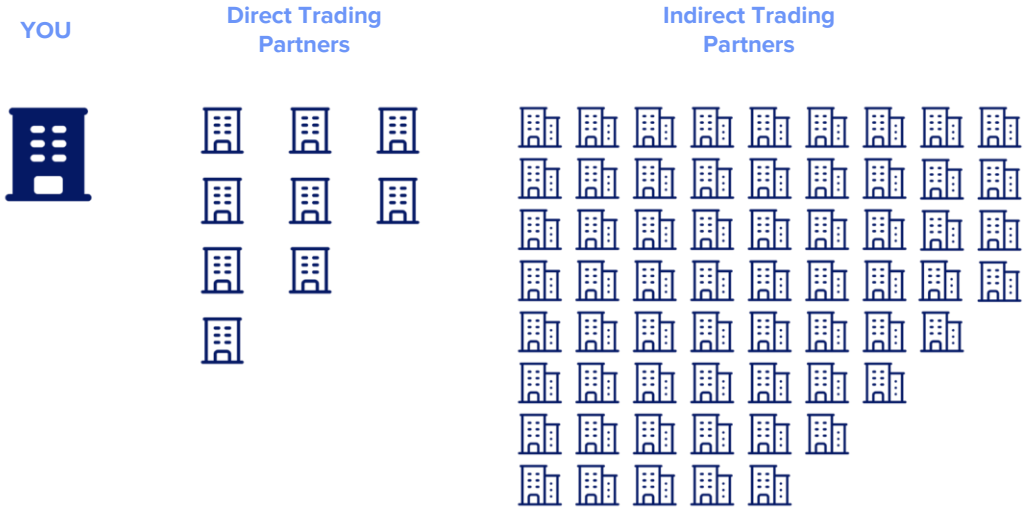
Federal DSCSA Law Calls for Interoperable Solution

November 27, 2023 deadline, 1-year “stabilization” nearly over





DSCSA unique today – requires real-time, indirect partner communication
>200,000 sites, >30,000 entities, no centralized authority

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Latest Insights from HDA Traceability

- FDA has received >300 Waiver, Exception and Exemption (WEE) applications – more than half from dispensers
- >200 applications were sent to FDA by the August 1 deadline and will get a response by November 27
- When asked about shortages resulting from lack of EPCIS data, Dr. Verbois recommended seeking an exemption until the issue is resolved
- State regulators shared that only half of all licensees have even partial DSCSA policies
- *“Everyone needs to rat out on their trading partners”*

Most stakeholders won’t hear about their WEE applications until November or beyond… so for the next 90 days, it’s time to buckle down!

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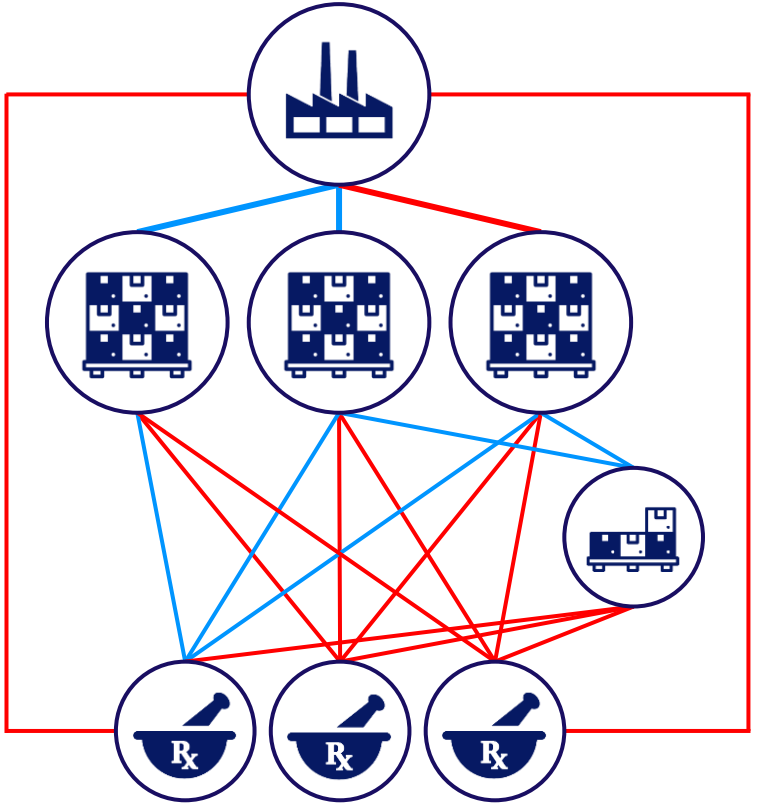
Portals & Networks

- Data Exchange (TI & TS)
- Tracing
- Verification
- Exceptions
- Lookups



Wholesaler & Manufacturer portals are an accepted way to receive product data, but don't cover all cases

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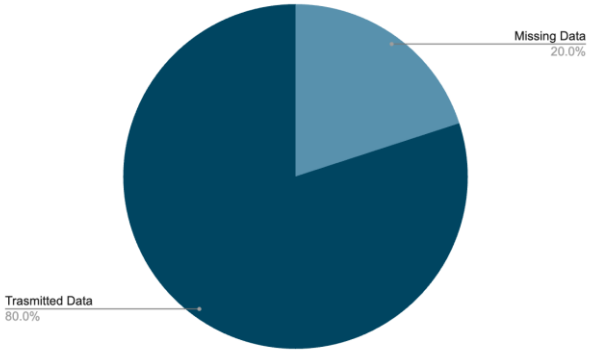
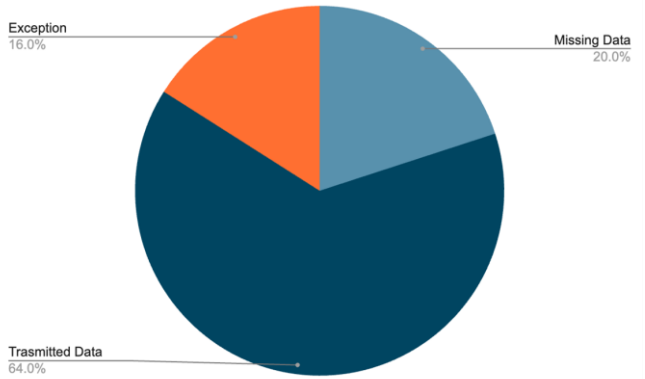
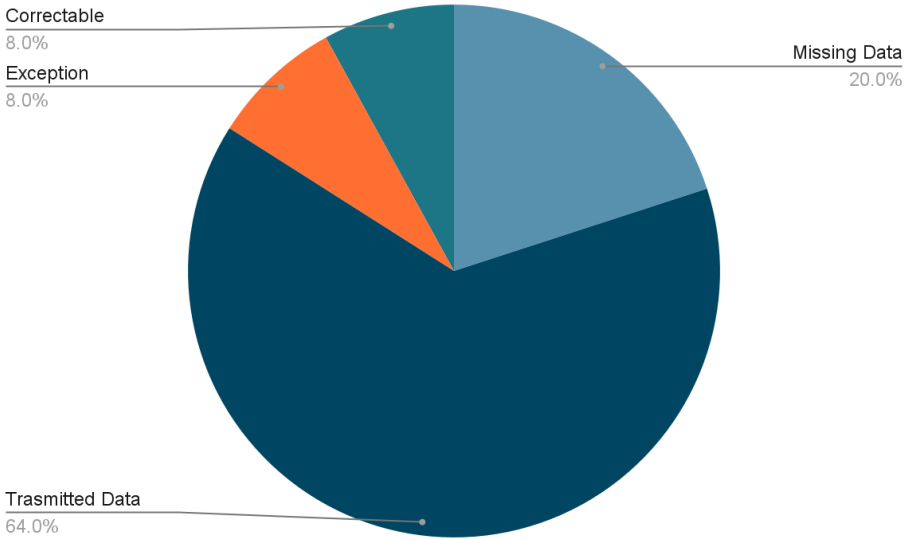
Projected Data Exchange Status November 2024







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Managing DSCSA Exceptions

CATCH the Errors

COLLABORATE on Root Cause

CORRECT the Errors

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Exception Root Causes

- File timing
- Missing data elements
- Customer master data
- Product master data
- Aggregation & sequencing
- Business logic

As file formatting issues fade, industry pulling together to address the most common issues

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Authorized Trading Partner (ATP) Confirmation

Foundational requirement, now “all electronic”

- **Identity:** *this is really Bob*
- **Representative:** *Bob really does represent Regional Wholesaler Inc.*
- **Authorized:** *Regional Wholesaler Inc. has a valid license*
- **Monitored:** *Regional Wholesaler Inc. has a valid license… TODAY*
- **Logged:** *electronic confirmation stored in 6-year auditable archive*

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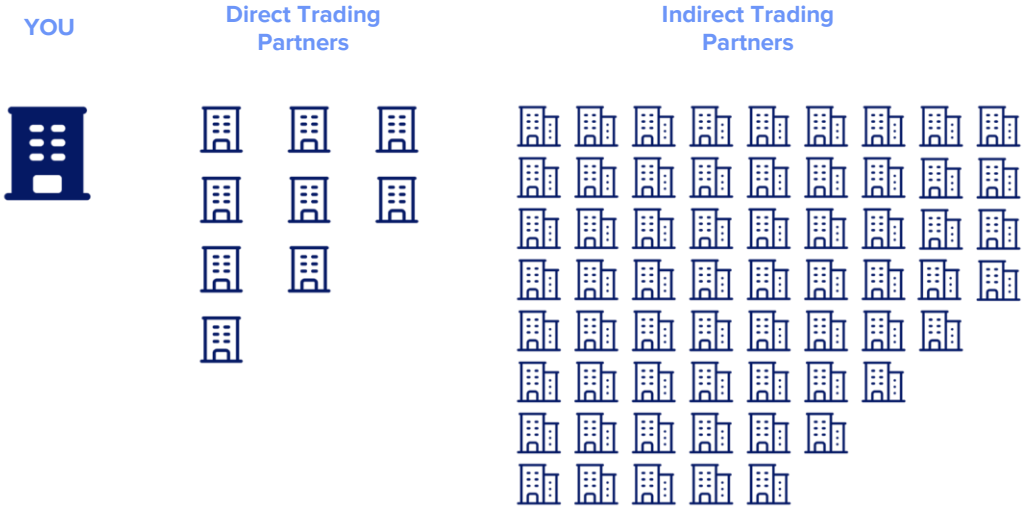
Indirect Trading Partners

When does “authorized trading partner” matter?



- Mandatory for direct trading partner transactions (including exception resolution)
- Mandatory for tracing & investigations
- Best practice for verification, required by some manufacturers

OCI-compliant ATP Credentials the only recognized method to prove ATP status over interoperable networks including email

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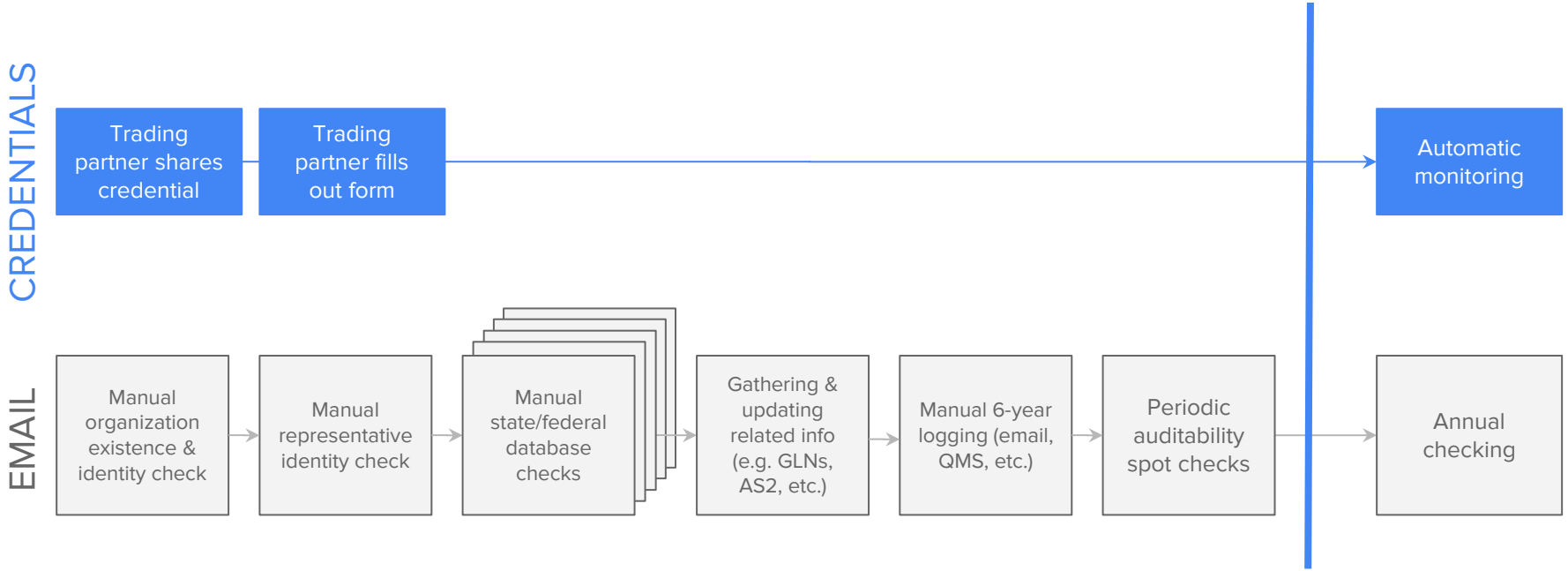
Electronic ATP Confirmation: Credentials vs Email



With verifiable credentials, third party does proofing for everyone
With trusted emails, you're burdened to perform your own diligence

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Drop Shipments & Marketplaces

	Manufacturers	Wholesaler/Marketplaces	Health Systems & Pharmacies
Product Flow	Manufacturers - Health Systems & Pharmacies		
Data Flow	SoldFrom GLN	Sold Via (Not a Standard)	SoldTo GLN & ShipTo GLN

Incomplete customer data, indirect relationships

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340B Implications

	Condition	Covered Entity	Contract Pharmacy
BillTo/ShipTo	Product Flow		Wholesaler - Dispenser
	Data Flow	SoldTo GLN	ShipTo GLN
Alternative Distribution	Product Flow	Wholesaler - Covered Entity	Covered Entity - Dispenser
	Data Flow	SoldTo GLN & ShipTo GLN	* ShipFrom - ShipTo

Covered entities need to become wholesalers and send data

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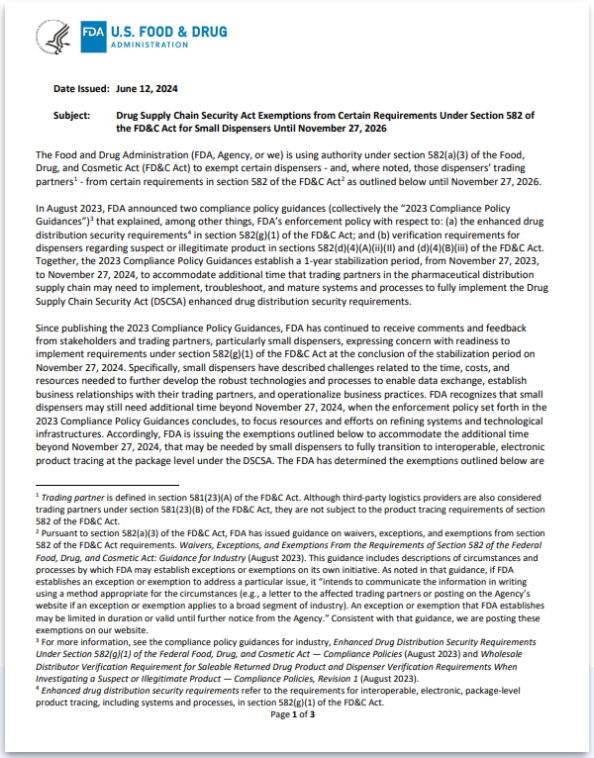
Waivers, Exceptions & Exemptions (WEEs)



U.S. FOOD & DRUG ADMINISTRATION

Date Issued: June 12, 2024

Subject: **Drug Supply Chain Security Act Exemptions from Certain Requirements Under Section 582 of the FD&C Act for Small Dispensers Until November 27, 2026**

The Food and Drug Administration (FDA, Agency, or we) is using authority under section 582(a)(3) of the Food, Drug, and Cosmetic Act (FD&C Act) to exempt certain dispensers - and, where noted, those dispensers' trading partners[1] - from certain requirements in section 582 of the FD&C Act[2] as outlined below until November 27, 2026.

In August 2023, FDA announced two compliance policy guidances (collectively the "2023 Compliance Policy Guidances")[3] that explained, among other things, FDA's enforcement policy with respect to: (a) the enhanced drug distribution security requirements[4] in section 582(g)(1) of the FD&C Act; and (b) verification requirements for dispensers regarding suspect or illegitimate product in sections 582(d)(4)(A)(ii)(II) and (d)(4)(B)(iii) of the FD&C Act. Together, the 2023 Compliance Policy Guidances establish a 1-year stabilization period, from November 27, 2023, to November 27, 2024, to accommodate additional time that trading partners in the pharmaceutical distribution supply chain may need to implement, troubleshoot, and mature systems and processes to fully implement the Drug Supply Chain Security Act (DSCSA) enhanced drug distribution security requirements.

Since publishing the 2023 Compliance Policy Guidances, FDA has continued to receive comments and feedback from stakeholders and trading partners, particularly small dispensers, expressing concern with readiness to implement requirements under section 582(g)(1) of the FD&C Act at the conclusion of the stabilization period on November 27, 2024. Specifically, small dispensers have described challenges related to the time, costs, and resources needed to further develop the robust technologies and processes to enable data exchange, establish business relationships with their trading partners, and operationalize business practices. FDA recognizes that small dispensers may still need additional time beyond November 27, 2024, when the enforcement policy set forth in the 2023 Compliance Policy Guidances concludes, to focus resources and efforts on refining systems and technological infrastructures. Accordingly, FDA is issuing the exemptions outlined below to accommodate the additional time beyond November 27, 2024, that may be needed by small dispensers to fully transition to interoperable, electronic product tracing at the package level under the DSCSA. The FDA has determined the exemptions outlined below are

[1] *Trading partner* is defined in section 581(23)(A) of the FD&C Act. Although third-party logistics providers are also considered trading partners under section 581(23)(B) of the FD&C Act, they are not subject to the product tracing requirements of section 582 of the FD&C Act.

[2] Pursuant to section 582(a)(3) of the FD&C Act, FDA has issued guidance on waivers, exceptions, and exemptions from section 582 of the FD&C Act requirements. *Waivers, Exceptions, and Exemptions From the Requirements of Section 582 of the Federal Food, Drug, and Cosmetic Act: Guidance for Industry* (August 2023). This guidance includes descriptions of circumstances and processes by which FDA may establish exceptions or exemptions on its own initiative. As noted in that guidance, if FDA establishes an exception or exemption to address a particular issue, it "intends to communicate the information in writing using a method appropriate for the circumstances (e.g., a letter to the affected trading partners or posting on the Agency's website if an exception or exemption applies to a broad segment of industry). An exception or exemption that FDA establishes may be limited in duration or valid until further notice from the Agency." Consistent with that guidance, we are posting these exemptions on our website.

[3] For more information, see the compliance policy guidances for industry, *Enhanced Drug Distribution Security Requirements Under Section 582(g)(1) of the Federal Food, Drug, and Cosmetic Act — Compliance Policies* (August 2023) and *Wholesale Distributor Verification Requirement for Saleable Returned Drug Product and Dispenser Verification Requirements When Investigating a Suspect or Illegitimate Product — Compliance Policies, Revision 1* (August 2023).

[4] *Enhanced drug distribution security requirements* refer to the requirements for interoperable, electronic, package-level product tracing, including systems and processes, in section 582(g)(1) of the FD&C Act.

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Blanket exemption for small dispensers includes:

- Requirement to verify proportionate amount of suspect or illegitimate drug products
- Electronic data exchange
- Serialization-level data
- Serialization-level traceability

It does not include exemptions for:

- Lot-level data exchange
- Authorized Trading Partners (ATPs)
- Other verification requirements
- Other suspect and illegitimate drug requirements

Don't get caught in the gaps!

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Regulatory Policies & Practices

Policy	Overview
ATP	Authorized trading partners must hold valid licenses, comply with applicable licensure reporting requirements, and **only engage in transactions (and certain interactions) with other authorized entities**
Tracing	Manufacturers, repackagers, wholesale distributors, and dispensers **maintain and provide transaction information, history, and statements for each sale** of prescription drugs to ensure traceability throughout the supply chain
Verification	Be able to **verify the product identifier with the original manufacturer** in the event of saleable return processing or suspect & illegitimate product investigations
Suspect Product Investigations	Promptly quarantine and investigate suspect products, verify their authenticity, **notify the FDA and immediate trading partners as applicable, and request traceability information from trading partners as applicable**
Data Retention	Maintain records of transaction information, history, statements, and suspect product investigations **for at least six years**
Data Exchange	Securely, electronically, and interoperably **exchange transaction information and statements, including unique identifiers for each package**

Regulatory Policies & Practices

Policy	Overview
Receipt Confirmation	Purchasing trading partners **develop and use systems and/or processes to confirm electronic data** in the transaction information and transaction statement is for the product received
Managing Exceptions	**Develop and use systems and/or processes to catch and identify DSCSA data issues,** collaborate and communicate exceptions with trading partners, and implement corrective measures
Quarantine and Return	Purchasing trading partners develop and use systems and/or processes to **physically and systematically quarantine product with data exceptions** and investigate to clear the exception or return the product to the purchaser
Emergent Dispensing	Purchasing trading partners develop and use systems and/or processes to perform a **risk assessment of product with data exceptions** and weigh the potential risk to patients versus absolute adherence to DSCSA data requirements (may include verification?)
Drop Shipments	Manufacturers provide serialized T2 data directly to the recipient pharmacy, ensuring compliance with transaction data exchange even when the wholesaler does not physically handle the product
340B	Distinct pathways for electronic, serialized product data exchange for 340B vs. non-340B shipments
First Responder Resupply	First responder resupply requirements exempt transactions involving medications provided to ambulance services and other first responders from the standard transaction information, history, and statement requirements

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Keep Your Eyes on the Ball

- Get your ATP Credential
- Review your portals & capabilities
- Triple-check your policies & procedures
- Be ready by November 27

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Thanks for Joining Us Today!

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Credentials at ledgerdomain.com/buy

Example SOPs at ledgerdomain.com/sops