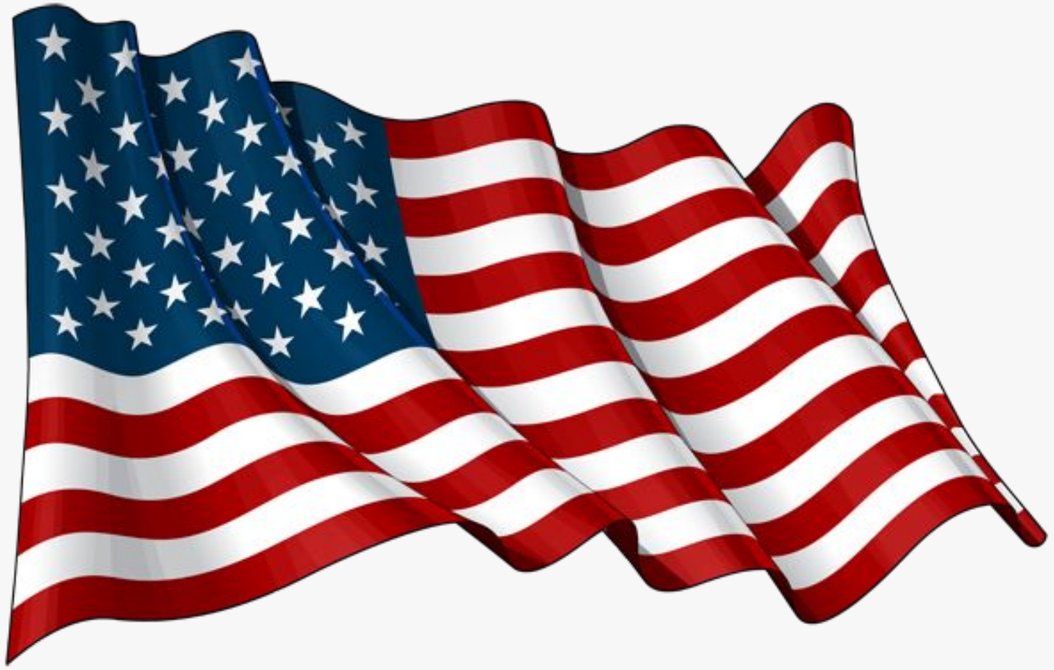
DSCSA Serialization for Distributors and Pharmacies

How to receive, track, investigate, store, and pass serialized product data downstream – and what regulators are looking for during inspections



Opening Remarks

The mission of the members 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 an into the state of Louisiana.

Antitrust Caution

During the course of today's webinar, discussions involving pricing, sales terms, territories, production volumes, or other aspects of competitive business practice must be avoided. Should any participant feel that statements or discussion are moving into such areas, they are encouraged to raise the concern immediately so that the conversation may be suspended until appropriate legal guidance confirms that the topics in question do not give rise to antitrust liability.

The Board recognizes the severity of the penalties that may be imposed where conduct is found to violate applicable antitrust law. Should the Board or any of its participants be implicated in a violation of federal or Louisiana state antitrust statutes, exposure may include both civil and criminal penalties – among them imprisonment, substantial fines, and attorney fees.

This policy statement unequivocally affirms the Board's commitment to free and fair competition as contemplated by the antitrust laws, and the Board intends to take all necessary and proper measures to ensure that no such violations occur in connection with its activities.

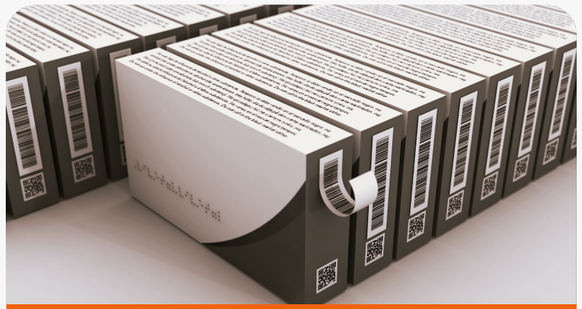
The Board is committed to interoperability across the drug and device distribution supply chain. However, this commitment does not constitute an endorsement of, or recommendation for, any single technology solution, platform, or service provider. Participants are encouraged to evaluate all available options independently and in consultation with their own legal and compliance counsel.

Agenda

1. Introduction and Core Concepts
2. Data Handling and Exchange
3. Compliance and Procedures
4. Investigation and Response
5. Risk Management and Next Steps

Introduction and Core Concepts

DSCSA: What Changed



From TH to serialized exchange

- Transaction History is sunset; stop relying on paper chain packets.
- The standard handoff is now **serialized TI + TS** electronically.

What “serialized TI” means

- Each package is identified by GTIN/NDC plus **serial, lot, expiry**.
- This is the data you must be able to store, search, and retrieve.

Operational impact for your team

- Receiving and shipping must match physical packs to the electronic file
- If you cannot identify exact packs transferred, you have a tracing gap

DSCSA Regulatory Requirements

Rolling deadlines for supply chain through Nov 2026

Domain	Requirements	Statutes
Authorized Trading Partners (ATPs)	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.**	§581(2)(A), §582(a)(3), see also verification and tracing sections
Data Exchange	**Securely, electronically, and interoperably exchange** transaction information and statements, including unique identifiers for each package.	§582(d)(1)(A), §582(g)(1)
Product Verification	Be able to **verify the product identifier** in the event of saleable return processing, suspect & illegitimate product investigations, or other circumstances.	§582(b)(4)
Tracing & Investigations	Promptly **investigate** suspect products, **verify their authenticity, notify the FDA and immediate trading partners** as applicable, and **request traceability information from trading partners** as applicable. Be ready to **respond to tracing requests from any ATP or federal/state regulator** while preserving confidential commercial information and trade secrets.	582(b)(4), §582(g)
Data Retention	Maintain records of transaction information, history, statements, and suspect product investigations for at least six years.	582(d)(1)(A)(iii), 582(d)(4)

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pdg Partnership for DSCSA Governance

BLUEPRINT

Core Data You Must Have

Transaction Information (TI) & Transaction Statement (TS) must accompany all non-exempt changes of ownership

You must be able to provide this source data for any human Rx product upon request

``(26) Transaction information.--The term `transaction information' means--

``(A) the proprietary or established name or names of the product;

``(B) the strength and dosage form of the product;

``(C) the National Drug Code number of the product;

``(D) the container size;

``(E) the number of containers;

``(F) the lot number of the product;

``(G) the date of the transaction;

``(H) the date of the shipment, if more than 24 hours after the date of the transaction;

``(I) the business name and address of the person from whom ownership is being transferred; and

``(J) the business name and address of the person to whom ownership is being transferred.

``(27) Transaction statement.--The `transaction statement' is a statement, in paper or electronic form, that the entity transferring ownership in a transaction--

``(A) is authorized as required under the Drug Supply Chain Security Act;

``(B) received the product from a person that is authorized as required under the Drug Supply Chain Security Act;

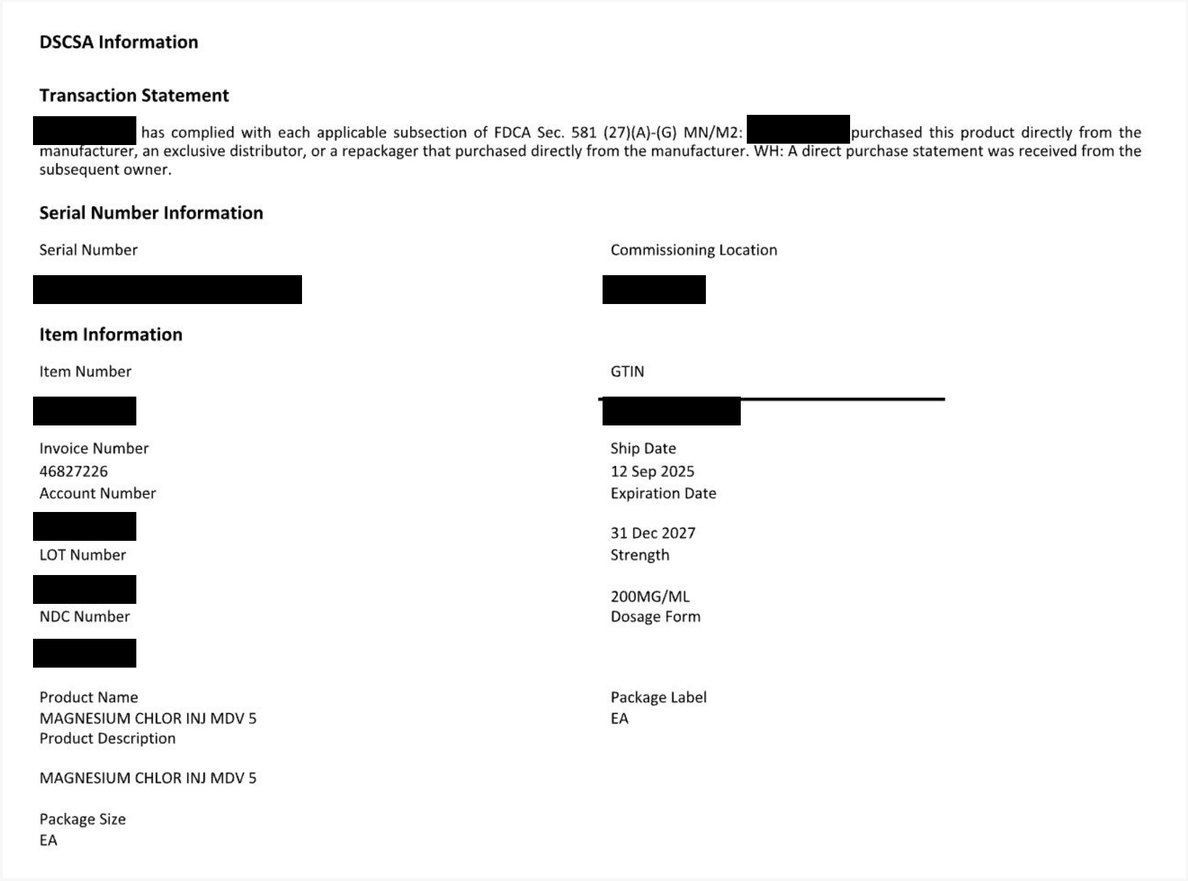
``(C) received transaction information and a transaction statement from the prior owner of the product, as required under section 582;

``(D) did not knowingly ship a suspect or illegitimate product;

``(E) had systems and processes in place to comply with verification requirements under section 582;

``(F) did not knowingly provide false transaction information; and

``(G) did not knowingly alter the transaction history.



DSCSA Information

Transaction Statement

[redacted] has complied with each applicable subsection of FDCA Sec. 581 (27)(A)-(G) MN/M2: [redacted] purchased this product directly from the manufacturer, an exclusive distributor, or a repackager that purchased directly from the manufacturer. WH: A direct purchase statement was received from the subsequent owner.

Serial Number Information

Serial Number
[redacted]

Commissioning Location
[redacted]

Item Information

Item Number
[redacted]

GTIN
[redacted]

Invoice Number
46827226
Account Number
[redacted]

Ship Date
12 Sep 2025
Expiration Date

31 Dec 2027
Strength

LOT Number
[redacted]

200MG/ML
Dosage Form

NDC Number
[redacted]

Product Name
MAGNESIUM CHLOR INJ MDV 5
Product Description

MAGNESIUM CHLOR INJ MDV 5

Package Label
EA

Package Size
EA

Data Handling and Exchange

Find Inbound Data

Use your EPCIS solution provider or wholesaler portal

- Transaction data is typically available online for each order/shipment.
- Confirm the correct ship-to/sold-to account is selected before downloading.

Know what to download

- Look for **EPCIS** files first; otherwise use portal TI+TS reports/exports.
- Some partners deliver data via EDI ASN 856 or downloadable spreadsheets.

Timing and ownership

- Data is often posted as orders are invoiced and shipped during the day.
- Save records per shipment so you can trace exact packages later.

Make it operationally repeatable

- Assign staff owners for portal access, downloading, and file naming.
- Store in a consistent folder path by date, supplier, and invoice/ASN.
- Policies & procedures for data handling & reconciliation

Receive Serialized Shipments

Pull the electronic records first

- For each shipment, retrieve TI + TS from your wholesaler portal at receipt.
- If EPCIS is available, save that file as your primary record.

Reconcile data to the physical shipment

- Confirm the shipment ID matches your downloaded TI/TS (or EPCIS).
- Scan and spot-check package serials against the file before shelving.

Trigger quarantine on exceptions

- Quarantine any mismatch, unknown serial, or unexplained overage immediately.
- 10-day window for exceptions management process (FDA recommendation)
- When appropriate, start a suspect-product review using the retrieved serialized records.

Outbound Serialized TI+TS

Pre-ship authorization check

- Confirm the customer is a duly licensed **Authorized Trading Partner** before releasing product.
- Keep proof of the check with the shipment record for retention.

Build outbound serialized TI

- Create TI for the exact packages shipped: GTIN/NDC, serial, lot, expiry.
- Include ship/transaction dates and clear From/To party details (GLN if used).

Send TI + TS electronically

- Transmit serialized TI plus your Transaction Statement; **EPCIS** is preferred.
- **Do not forward your supplier file unchanged; it does not reflect your ownership transfer.**

When Customers Lack EPCIS

Your obligation still applies

- Even if customers are not EPCIS-ready, you must send serialized TI+TS electronically.

Use a secure bridge method

- Send a machine-readable CSV or XML plus your TS as a separate file.
- Do not rely on paper pack slips as your only tracing record.

Minimum data to include

- For each package: GTIN/NDC, **serial**, lot, and expiry.
- For the transaction: ship/transaction date and clear From/To identifiers (GLN preferred).

Document and move forward

- Save the file sent, delivery reference, and customer acknowledgment for 6 years.
- Track each customer’s plan and timeline to move from bridge method to EPCIS.

Compliance and Procedures

ATP Checks

Trade only with ATPs

- Confirm supplier and customer are licensed and **authorized** to transact with state facility and federal licensing.
- If status is unclear, stop the shipment until resolved.

Verify at onboarding and ongoing

- Re-check licenses before purchase and before each sale/transfer.
- Include location identifiers (GLN when available) to avoid mismatches.

Document and retain evidence

- Save license lookups, screenshots, and verification date/time stamps.
- File records for **6 years** with inbound/outbound transaction data.

Why it matters

- Ownership & location changes over time can invalidate prior checks
- Weak ATP documentation increases risk during inspections and trace requests.

6-Year Record Retention

What you must retain

- Save inbound and outbound serialized **TI + TS**, plus any EPCIS files.
- Keep shipment support docs: invoices/ASNs, packing slips, BOLs, and emails.
- Archive dispenser acknowledgments or portal receipts that prove data delivery.

How to organize records

- Use a consistent folder structure: Inbound, Outbound, Verification, Returns, Investigations.
- File by ship date and shipment/invoice number for fast retrieval.

Retention and portal risk

- Retain DSCSA records for **6 years** and ensure they are searchable.
- If a wholesaler portal is your archive, export regularly before access ends.

Investigation and Response

Suspect Product Workflow

Recognize suspect triggers

- Treat counterfeit, stolen, diverted, or contaminated concerns as suspect.
- Prioritize any pack that fails a serial/2D scan or looks altered.

Quarantine immediately

- Physically segregate product and stop sale/distribution pending review.
- Document who quarantined, when, where stored, and reason code used.

Investigate using serialized data

- Pull inbound TI+TS/EPCIS to confirm what serials you received.
- Check outbound records to see whether any suspect serials shipped.

Speed depends on access

- Ensure staff can retrieve portal files quickly and retain them 6 years.
- If records are scattered, investigations and recalls slow down.

FDA Form 3911 Triggers

Trigger for FDA Form 3911

- Submit Form 3911 when you determine product is **illegitimate**.
- Use the package identifier data to pinpoint impacted serials quickly.

Who you must notify

- Notify your immediate trading partners and document time and method.
- Quarantine remaining inventory while notifications and checks occur.

Documentation for inspections

- Keep investigation notes, verification results, and all communications together.
- Archive records for **6 years** so they are retrievable on demand.

Recalls & Trace: Be Ready!

Recalls need data

- Search TI/TS records to find received, shipped, or transferred packs.
- GLNs help pinpoint the specific ship-from and ship-to locations

Be trace-ready on demand

- Respond quickly by pulling the shipment’s saved EPCIS or TI+TS file.
- Use invoice/ASN and ship date to find the right transaction record.

What a “full trace” includes

- Product details: drug name, NDC/GTIN, lot, and expiration date.
- Ownership details: From/To company name, address, and GLN when available.

Keep contacts current

- Maintain correct emails and digital addresses for trace requests and responses.

Speed comes from organization

- File records by date and shipment number; retain them for **6 years**.

Risk Management and Next Steps

Risk Areas

Unauthorized trading partners

- Buying from non-ATPs can invalidate the transaction before receiving.
- If licensure checks are skipped, you risk distributing noncompliant product.

Weak verification capabilities

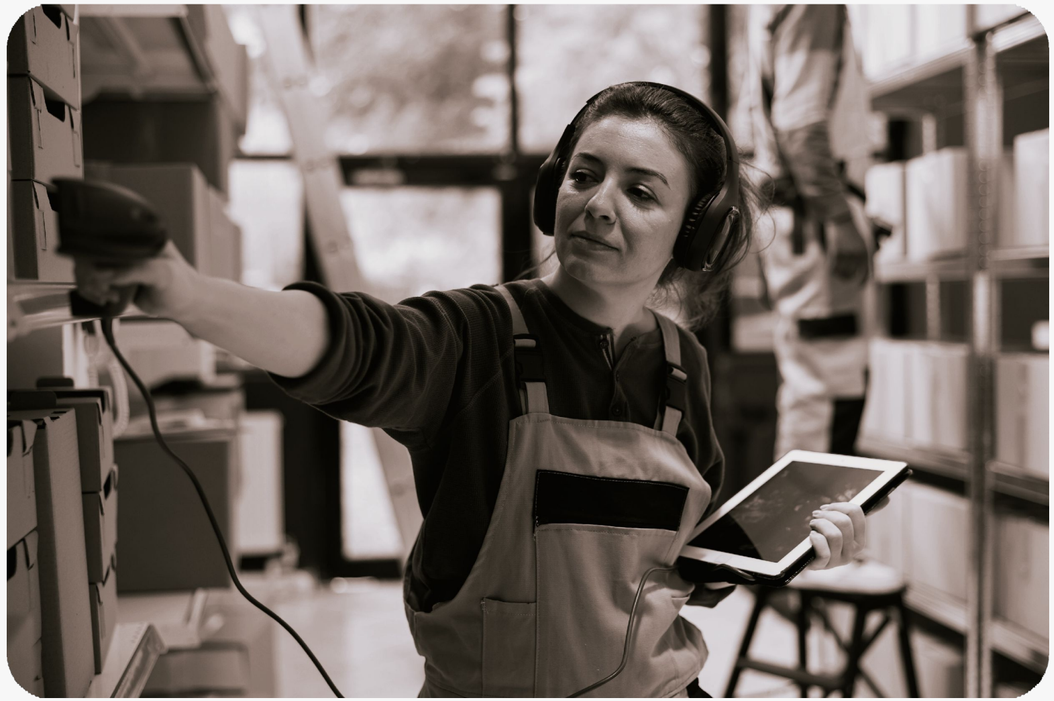
- If you cannot verify a package identifier, suspect cases stall.
- Slow verification delays quarantine decisions and downstream notifications.

Missing investigation records

- Enforcement repeatedly cites absent suspect-product investigation documentation.
- Keep files retrievable for **6 years** for audits and trace requests.

One gap triggers multiple failures

- Poor record control connects ATP, serialization exchange, recalls, and FDA reporting.



Steps to Implement

Map your data flows

- List every portal/file used for inbound EPCIS or TI+TS.
- Define where outbound serialized TI+TS is created and stored.

Align teams on one workflow

- Train receiving, pharmacy, distribution, compliance, and IT together.
- Assign owners for portal access, file retention, and trace responses.

Run an end-to-end test

- Download data, spot-check serials, and archive to 6-year folders.
- Transmit serialized TI+TS to a customer and confirm receipt.

Lock it into documented SOPs

- Write step-by-step procedures before recalls or investigations occur.

Q&A

DSCSA Education Series:

1. Tracking Serialized Data and Where to Find It ✅
2. "AI vs. Human Eye: Policies & Procedures and Data in 2026"
3. "Investigations in the Age of Enhanced Drug Distribution Security"

Need Help Getting Started?

- FDA DSCSA Resources
- PDG-FDA Town Halls
- DSCSA.Pharmacy Resource Center
- GS1 US Healthcare Standards
- Evaluate third-party EPCIS / DSCSA solution providers
- Ask your primary wholesaler what integration options they support