

Mastering DSCSA Compliance with SureCost: Your 5-Step Plan

Agenda

- Introductions
- What is DSCSA?
- Challenges Pharmacies Face
- Mitigate DSCSA Challenges with
SureCost DSCSA Compliance Packages
- Your 5-Step Plan to Ensure DSCSA
Compliance with SureCost

Introductions



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DSCSA

A Disclaimer

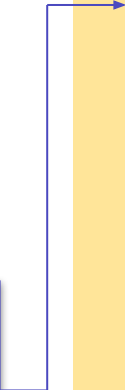
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What is DSCSA?

- Drug Supply Chain Security Act (DSCSA)
- Protect customers against pharmaceuticals that are counterfeit, tainted, or stolen
- The movement of prescription medications through the supply chain must be tracked and traced electronically by pharmaceutical producers, repackagers, wholesale distributors, and dispensers
- Effective November 27, 2023

What's changing for pharmacies?

TODAY

- Receive Lot level Product Tracing information “T3”, **IF the vendor sent it**, before receiving product
 - TI-Transaction information
 - TH-Transaction History
 - TS-Transaction Statement
 - Retain lot level compliance information in any format for a minimum of 6 years
- Quarantine and report suspect product within 24 hours
 - Respond to audit requests within 48 hours
- 

NOVEMBER 27, 2023

- Receiving Package Level Product Tracing information “T2” (TI-Transaction information, TS-Transaction Statement) in a historical interoperable standard (EPCIS) before receiving product
- 6 year data retention must be in electronic format
- Your receiving procedures are updated to check for suspicious product at the package level

DSCSA Traceable VS Non-Traceable

Traceable Items

- Rx items

Non-Traceable Items

- OTC items / Health & Beauty

The DSCSA exemption list is long...

even with some prescriptions

- Blood or blood components
- IV fluids
- Intracompany distribution between members of affiliate or within manufacturer
- Radioactive nucleotides for imaging

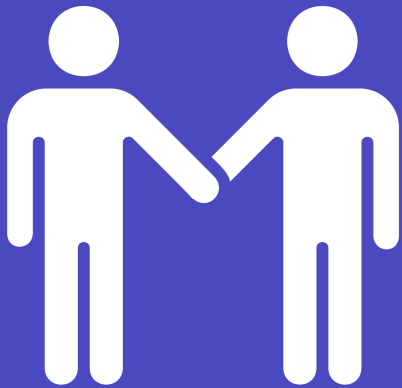
Please see Section 582 (24) of the DSCSA regs at www.fda.gov

DSCSA Compliance Challenges



Managing Data and Accuracy

- Use multiple tools and resources to capture, verify and store large amounts of data
- Must take the time to confirm the legality of drug products and identify their prior transaction history
- Although no regulation requirement to track transfers of items between pharmacy locations under the same ownership, there is still a chance of being audited
- Especially difficult for pharmacies that operate across multiple locations or have a high volume of transactions



Maintaining Vendor Relationships

- Must confirm that vendors, who are in charge of giving out crucial product tracking data, are sending correct and timely information
- In order to guarantee that the appropriate items are accessible when needed and to address any difficulties that emerge, pharmacies must be able to interact efficiently with their vendors.
- To recognize any problems or potential areas for improvement, pharmacies must assess and analyze vendor performance
- It is difficult when working with several vendors and manufacturers because it calls for the aggregation of data from various sources

Pharmacy Risks

Pharmacies have a higher risk of being subject to fees and fines if they're not:

- Consistent in managing compliance using one platform to connect the required touchpoints and data
- Holding their vendors accountable to adequately protect against counterfeit/illegitimate drugs—which is paramount to their ethical responsibility and readiness for audits

Mitigate DSCSA Challenges with **DSCSA** **Compliance** **Packages**

1. **Traceable Receiving**
2. **Traceable Transfers**
3. **Traceable Receiving & Transfers Bundle**

All packages:

- EPCS v1.2 data retrieval for all compliant vendors
- 6 year data retention of DSCSA barcode data
- Quarantine & reconciliation
- DSCSA reports

SureCost DSCSA Compliance 5-Step Plan

01

SureCost Mobile App

Start receiving with the free mobile app
today!

- Available on the Apple App Store and Google Play Store
- Make sure your entire team has an acceptable and reliable phone ready for PO receiving

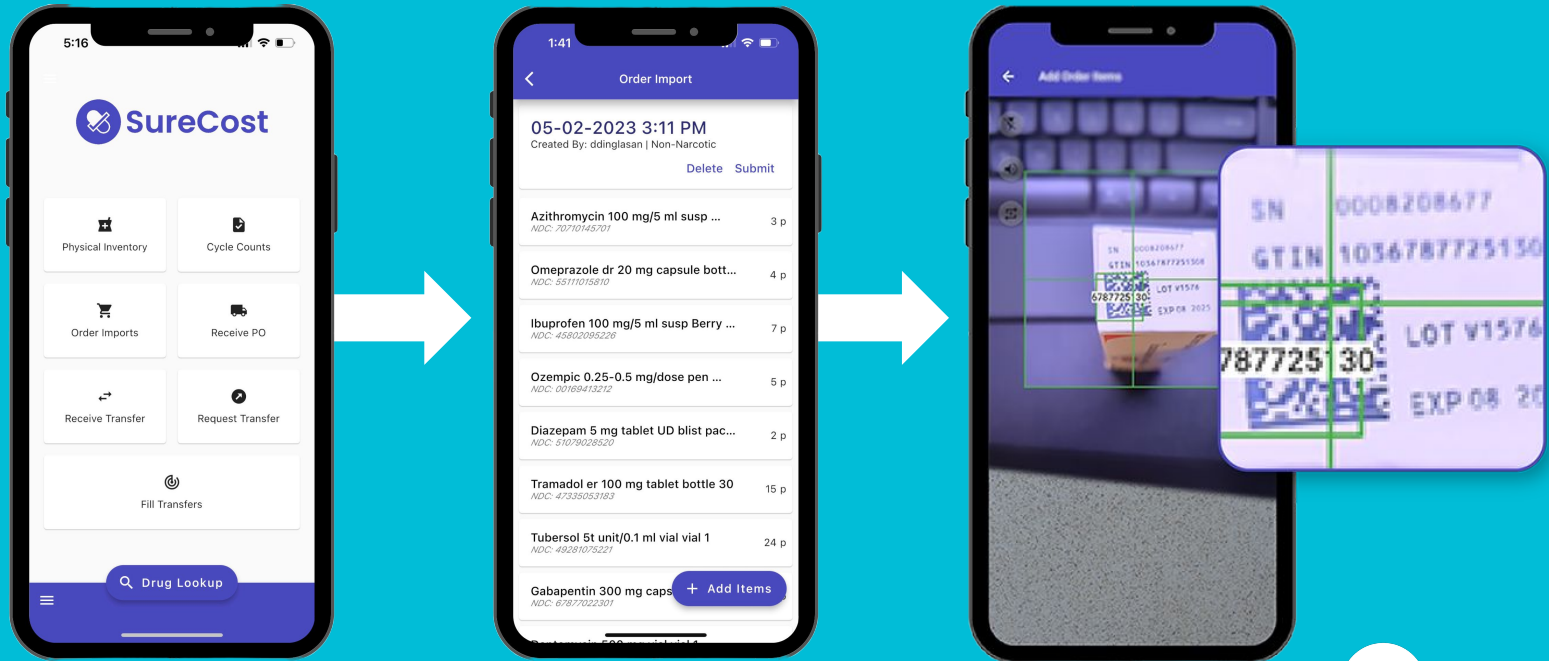
What If I Receive Elsewhere and Am Not Interested In Receiving In Surecost?

You'll be missing out on key advantages:

- Reconciliation between vendor EPCIS files and physically received products
- Quarantine suspect products and manage exceptions
- Efficient Case and Package level receiving on the fly

If not a good fit, you'll still have the ability for EPCIS file receiving, storage and reporting.

SureCost Mobile App



02

Global Location Numbers (GLN's)

- Obtain Bill To ***and*** Ship To GLN's for ***each of your pharmacy locations***
- Ways to obtain GLNs:
 - You have a few paths to obtain these:
 - [You can obtain them directly from GS1](#)
 - [AmerisourceBergen customers can follow their guide](#)
 - Some GPOs may be able to assist you with this

03

Send Us Your GLN

- Send us your GLN detail to support@surecost.com by **November 1st, 2023**
- Make sure to include the specific locations and whether they are a bill to or ship to GLN. Also includes GLNs if you have them.

04

Receiving SOPs

- Review or craft your receiving standard operating procedures
- [See our example](#)

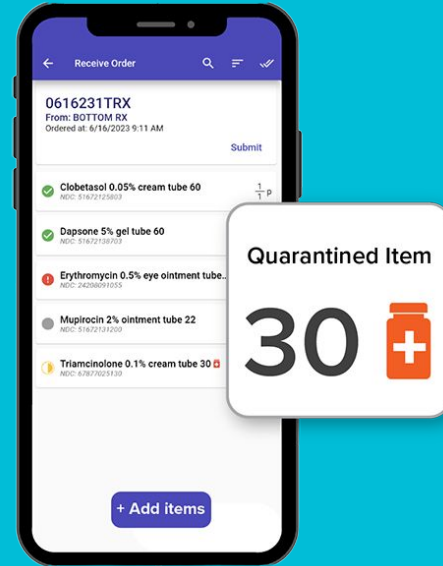
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Quarantine Process

- Identify an area where you'll “quarantine” or hold suspect products during receiving. Typically this would be a temporary holding area near your receiving area for any product that is suspicious looking or is flagged for invalid or missing data.
- What other steps to ensure they are ready for reconciliation SureCost page?

DSCSA Quarantine & Reconciliation

- If product identifier information doesn't match vendor's data, it is automatically flagged
- Reconciliation page that lists any flagged products and the ability to reconcile. The customer can obtain a new record from the vendor that matches, rescan the product if due to scanning/keying error, or manually remove the item from quarantine



Reconciliation



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Vendors Promos What's New Help Logout

Home **Purchasing** Formulary Products Inventory Reports Analysis Setup

Purchase Orders


This week Quarantined Items


PO #	Date	Submitted By	Type	Vendor	Sent	Ack	Shipped	Inv	Rec	Rec Submit	Item Count	Total Cost				
0523233TRX	05/23/2023 02:32 PM (EDT)	pmills (Support)	Standard	D2Pharmacy		✓			✓	✓	1	\$2.93	Detail	Receive	Reconcile	
0523233TRX	05/23/2023 09:30 AM (EDT)	pmills (Support)	Standard	D2Pharmacy		✓			✓	✓	1	\$17.72	Detail	Receive	Reconcile	
0523233TRX	05/23/2023 09:07 AM (EDT)	pmills (Support)	Standard	D2Pharmacy		✓			✓	✓	1	\$2.93	Detail	Receive	Reconcile	
ABC123RX5	05/22/2023 04:24 PM (EDT)	pmills (Support)	Standard	Pharmaplex		✓			✓	✓	1	\$440.42	Detail	Receive	Reconcile	



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Reconciliation

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VendorsPromosWhat's NewHelpLogout

HomePurchasingFormularyProductsInventoryReportsAnalysisSetup

FDA 3911
Reporting Guidance

Quarantine Item Reconciliation Detail

PO Number	Vendor	Date Added	Items	Last Updated	EPCIS Received
ABC123RX5	Pharmaplex	05/13/23	3	05/13/23 03:56	05/13/23 01:21

Item Description	Data Source	Added By	GTIN-14	Serial #	Lot #	Expiration	Event Status	Last Updated	Ignore/Process
Escitalopram 20mg tablet bottle RUG	Vendor EPCIS	System					Missing	05/13/23 01:21	<input checked="" type="checkbox"/>
Escitalopram 20mg tablet bottle RUG	Receiving	System	13549835468165	00456789111	BD5789	12/31/2024	Fully Received	05/13/23 01:21	


Item Description	Data Source	Added By	GTIN-14	Serial #	Lot #	Expiration	Event Status	Last Updated	Ignore/Process
Escitalopram 20mg tablet bottle RUG	Vendor EPCIS	System	13549835468165				Partial Match	05/13/23 01:21	<input checked="" type="checkbox"/>
Escitalopram 20mg tablet bottle RUG	Receiving	System	13549835468165	35004300571	BD5789	12/31/2024	Partial Match	05/13/23 01:21	

Item Description	Data Source	Added By	GTIN-14	Serial #	Lot #	Expiration	Event Status	Last Updated	Ignore/Process
Erythromycin 0.5% eye ointment tube 3.5 PER	Vendor EPCIS	System					Missing	05/13/23 01:21	<input type="checkbox"/>
Erythromycin 0.5% eye ointment tube 3.5 PER	Receiving	System	68463581468465	65004608081	BD5789	12/31/2024	Fully Received	05/13/23 01:21	

Reconcile

Reconciliation

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northwoods
PHARMACY

VendorsPromosWhat's NewHelpLogout

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PO Number	Vendor	Date Added	Items	Last Updated	EPCIS Received
ABC123RX5	Pharmaplex	05/13/23	3	05/13/23 03:56	05/13/23 01:21

Item Description	Data Source
Escitalopram 20mg tablet bottle RUG	Vendor E
Escitalopram 20mg tablet bottle RUG	Receive

Item Description	Data Source
Escitalopram 20mg tablet bottle RUG	Vendor E
Escitalopram 20mg tablet bottle RUG	Receive

Item Description	Data Source
Erythromycin 0.5% eye ointment tube 3.5 PER	Vendor E
Erythromycin 0.5% eye ointment tube 3.5 PER	Receive

Event Status	Last Updated	Ignore/Process
Missing	05/13/23 01:21	<input checked="" type="checkbox"/>
Fully Received	05/13/23 01:21	<input checked="" type="checkbox"/>

Event Status	Last Updated	Ignore/Process
Partial Match	05/13/23 01:21	<input checked="" type="checkbox"/>
Partial Match	05/13/23 01:21	<input checked="" type="checkbox"/>

Event Status	Last Updated	Ignore/Process
Missing	05/13/23 01:21	<input type="checkbox"/>
Fully Received	05/13/23 01:21	<input type="checkbox"/>

Reconcile

Caution

The following packages for PO# ABC123RX5 from Pharmaplex will be removed from quarantine. These items will be added to your available on hand quantities inventory:

Escitalopram 20 mg tablet bottle RUG:
00456789111
35004300571

Reason

Write details about why you have removed these items from quarantine.

Note: UserID, date, and time will be recorded.

SaveCancel



SureCost DSCSA Compliance 5-Step Plan

1. Set Up SureCost Mobile App
2. Obtain GLNs
3. Send SureCost Your GLNs
4. Establish Receiving SOPs
5. Establish Quarantine Process

Scan to **Book a Demo**
to see the DSCSA Compliance
Packages in Action!

Or go to:
https://hubs.la/Q01_6sj_0

