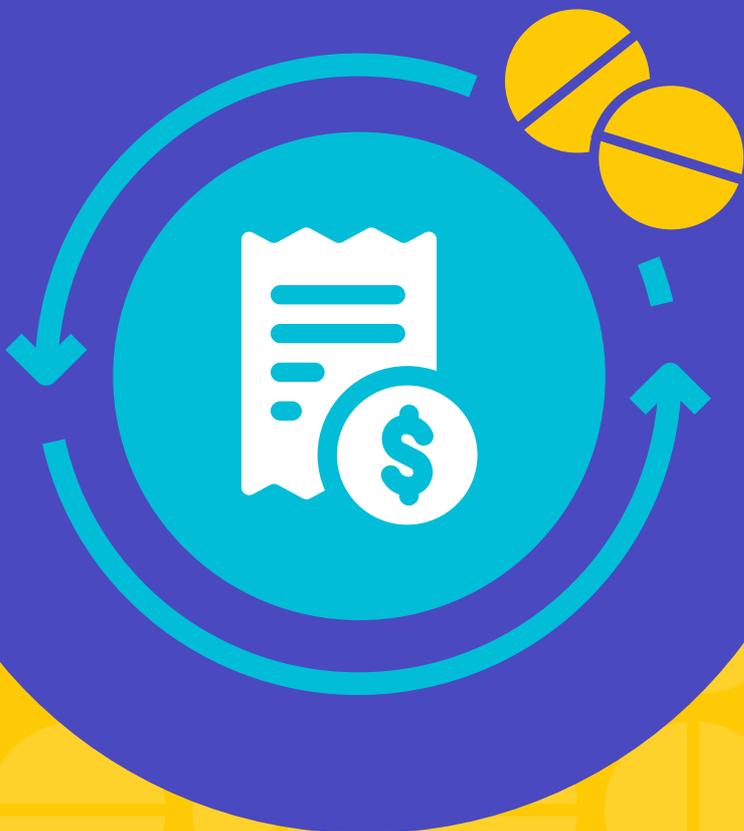


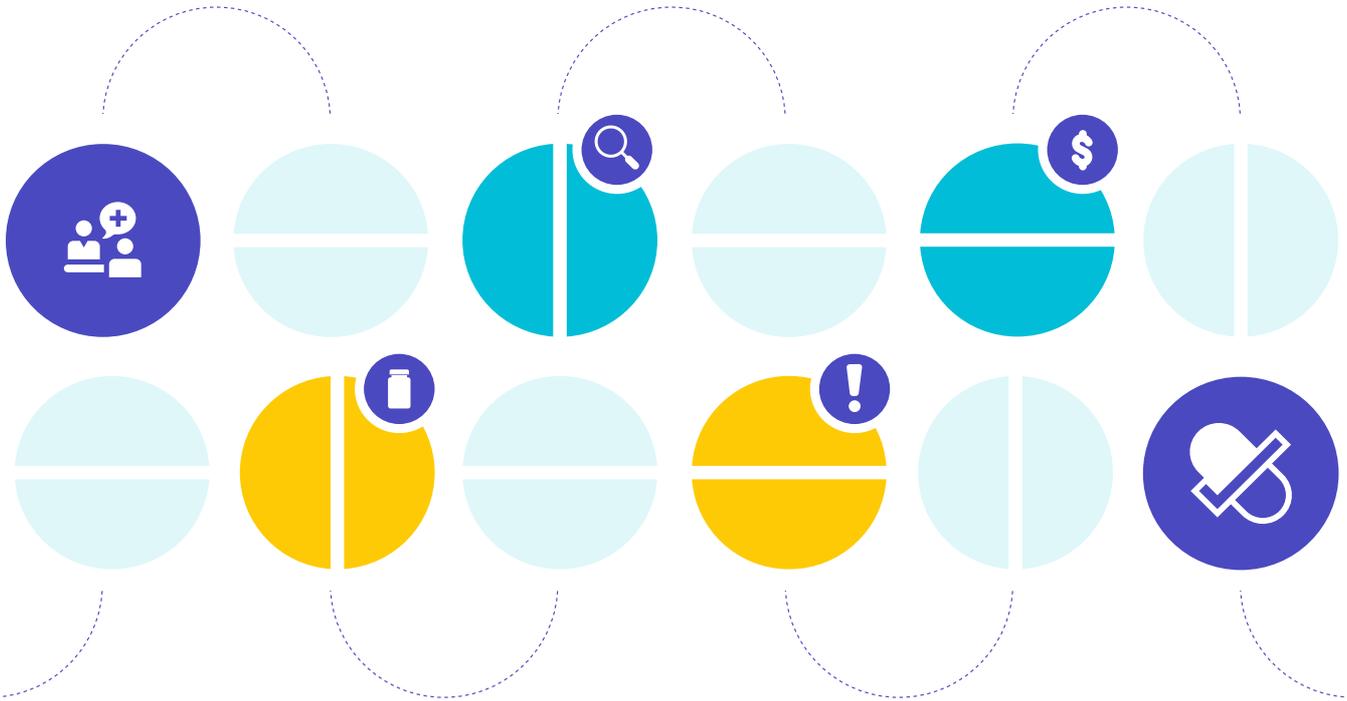


DSCSA: The Cost of Waiting and the Power of Preparation

Why SureCost's DSCSA Compliance Solution is the Right Tool For Right Now



You've probably heard that the FDA is implementing substantial updates to DSCSA.



Though enforcement of these new regulations is postponed until November 27, 2024, pharmacies should act now to prepare for these changes. Otherwise, they risk falling behind, failing to meet requirements and incurring costly penalties (and possible legal issues).

This white paper will walk you through upcoming DSCSA changes and explain why now is the time to respond. Finally, we'll show you how SureCost's DSCSA Compliance Package empowers your pharmacy to ensure compliance so you can concentrate on what counts: patient care and business strategy.

Updated DSCSA Requirements

DSCSA: A Bird's-Eye View

Drug Supply Chain Security Act compliance (DSCSA)

- Enacted in 2013 and enforced by the FDA
- Mandates tracking prescription drugs across the entire supply chain
- Implemented to ensure patient safety and secure safe chain of custody
- Regulates pharmacies, manufacturers and wholesalers
- Non-compliance entails audits, financial penalties, suspension or legal action

Previously, DSCSA compliance for pharmacies centered on lot-level product information. The major update concerning DSCSA is the requirement to **now trace and record package-level product tracing information**. Pharmacies are now responsible for checking products "right at their door." You may have heard the term "T2" for this data, meaning it encompasses both transaction information (TI) like invoice and transaction statement (TS) data.

To manage this data, **pharmacies must use a historical interoperable standard called “EPCIS” before receiving products.** This format has built-in historical capability; an auditor can pull details from any step in the supply chain. Pharmacies must **retain this data in an acceptable electronic format for six years.** The previous standard allowed paper formats, but you’ll now need the right technological resources to stay compliant. As we’ll see later, this requirement can make your job easier.

These updates also affect **returns for traceable products** (i.e., intended for redistribution). Specifically, these items must be homogenous cases in sealed packages. The wholesale distributor must verify the serial number with the GTIN or NDC.

What hasn’t changed? Pharmacies still have to **quarantine and report suspect products within 24 hours and respond to audits within 48 hours.** Examples include products that look like they’ve been subject to tampering or have mismatched identifiers.

What’s a Traceable Item?

Basically, if there’s a serial number on a prescription product—either in the vendor’s transaction or in the barcode—consider it a traceable item that you need to track for DSCSA compliance. Over-the-counter items and health/beauty products aren’t classified as traceable items (though no one will fault you for also tracking them).



Exemptions From Tracing

While many prescription products are classified as traceable items, there’s a long list of exemptions including:

- Blood or blood components for transfusion
- Compounded drugs complying with sections 503A or 503B
- Homeopathic drugs, marketed
- Intracompany distribution between affiliate or within a manufacturer
- Intravenous products
- Medical gases
- Radioactive drugs or biological products
- Radioactive nucleotides or drugs

The Impact on Your Pharmacy

Package-level verification by pharmacies is technically required now. But enforcement of the rule won’t take effect until **November 27, 2024.** That means the FDA isn’t actively auditing for these changes, and wholesalers won’t have to provide package-level data until that date.

These updates were initially supposed to take effect last year. Why the delay? Unsurprisingly, because there’s a lot to do! The FDA recognized that the entire supply chain needed more time to stabilize and develop full interoperability for accurate, secure and timely electronic data exchange.

That’s why they’re delaying enforcement of the rule. But there’s no reason to delay your preparation. In fact, it behooves your pharmacy to use this grace period and act now.

DSCSA is Delayed, So What?

Even with this delay, DSCSA’s challenges remain. If neglected now, issues with DSCSA compliance will quickly amplify.

SureCost is known for unifying purchasing and inventory to optimize buying decisions while streamlining workflows and ensuring compliance with vendors and other agreements.

You and your team will need to track and maintain vast amounts of data from various trade partners —while still running your pharmacy, including all locations.

Here's a very brief summary of all your pharmacy's responsibilities and all the variables under the new DSCSA regulations.

Manage T2 data



- Track each package
- Capture the information
- Confirm data's accuracy
- Store it for six years

Verify package-level info from and between:



- Your primary vendor
- Any secondary vendors
- Other trade partners
- Including returns on traceable products
- All pharmacy locations during transfers

Satisfy technical and administrative requirements:



- Use EPCIS format and reporting
- Keep six years of data on hand
- Quarantine suspect products
- Report within 24 hours
- Respond to audits within 48 hours

Maintain high-quality patient care and business operations



- Avoid delays in everyday pharmacy responsibilities
- Continue timely dispensing of products to patients
- Harness systems without overhauling current processes
- Prepare for drug shortages (more on that below)

As you can see, your pharmacy must be ready to handle a flood of data and new workflows affecting your vendor interactions, staff responsibilities and patient care. That means multiple robust processes and resources—including the right technology—integrated with your teams and existing systems.

Does November still feel that far away?

When it comes to DSCSA, the sheer wealth of data involved and the myriad parties involved, you don't want to silo your systems or rely on multiple processes. Handling all that data, even across just two sources, can lead to costly errors. You risk facing non-compliance and penalties and compromising patient safety and your peace of mind as a prescription provider and business stakeholder.

You want a DSCSA compliance solution that does the job and adds the least amount of work to your day. Ideally, you should incorporate a single process into your existing operations (instead of adding several new workflows to your job). That system will make it easier for you and your team to comply when the time comes. The technology you select now will make the difference between adaptation and scrambling.

A Single Solution for DSCSA Compliance

SureCost's DSCSA Compliance Package seamlessly integrates with those functions. Let's review five ways SureCost optimizes DSCSA as you harness smarter purchasing.

SureCost gives you a single source of truth for DSCSA-related data. From submitting purchase orders to receiving products—including DSCSA relevant data—and reconciling invoices, SureCost centralizes product information throughout the supply chain.

Consolidated DSCSA Data

Instantly log relevant information at receiving. SureCost facilitates prompt and accurate reporting, including scheduling regular reports in several formats, thereby minimizing the potential for penalties and damage to reputation. You can also quickly quarantine items if you suspect tampering or other issues and efficiently respond to audits within the requisite timeframe. These situations are stressful enough on their own; if the time comes, you want a solution to quickly and correctly furnish what you need.

For an extra level of protection, SureCost also enables you to track and quarantine non-compliance-traceable items. You can also decide if your pharmacy can benefit from optional features—including scanning traceable cases with like items and tote scanning cases/totes with mixed items.

Convenient EPCIS Implementation

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EPCIS is naturally historical. If an auditor pulled any transaction at any step in the supply chain, they could tie it anywhere, up or down, related to that item.”

Chase Ferguson, Product Manager at SureCost

EPCIS (Electronic Product Code Information Services) is the FDA's new requirement for DSCSA compliance. It's an electronic standard for tracking events in a supply chain. For pharmacies, when it comes to DSCSA, the critical event is your vendor shipping an item out their door and your pharmacy receiving it. With this update, paper processes are no longer allowed, and you'll need technology that meets the electronic requirements.

SureCost satisfies EPCIS requirements with a simple but powerful interface. This solution conforms to DSCSA's updated technical requirements. That includes EPCIS v1.2 data retrieval for all compliant vendors and rolling six-year retention of relevant data (with technical specifications listed in the side panel).

This solution automatically matches relevant data between your purchase order and received products. SureCost then creates the required historical records for this sequence of events while flagging discrepancies and similarly documenting actions related to suspect items. This includes the sequence of actions and staff members involved to show “how you got here.”

You can now quickly download and validate EPCIS files for any purchase order. With instant access to EPCIS files, you know you'll be ready to easily furnish data. Secure data storage ensures you always have the mandated six-year data repository on hand.

Mobile Capabilities for Where You Work

For further accessibility and convenience, the SureCost mobile app lets you quickly scan items from your portable device.

Capture the required DSCSA identifiers where you receive products. That data is now associated with the item back to its initial purchase order. You can view all the information in the app or through SureCost's desktop portal.

You're no longer tethered to a scanner or hustling between your desk and the receiving area. You go where the work is.



The SureCost mobile app is available to all SureCost customers for unlimited users on their team in both Android and iOS versions.

You spot discrepancies or potential suspect products immediately so you can reconcile issues at the source or initiate required protocols.

Accountability for Vendors and Your Pharmacy

When a potential issue in the chain of custody arises, you want to be able to immediately address the problem with the vendor through an efficient process.

SureCost automatically flags items at receiving while tagging the team members responsible for transactions like purchase orders, receiving or quarantine determinations. It then sends an alert if product identifier information doesn't match the vendor's data. You can then consult a reconciliation page listing all flagged products and the ability to reconcile.

If the issue is simply due to a numerical error or incorrect input, you can rescan the product or request an updated matching record from the vendor. You can initiate a quarantine before notifying the vendor and the FDA if needed. You can also use the "GS1 workbench" to test your trader partners' file standards. You can also use SureCost to track and quarantine non-compliance traceable items for an extra level of vendor accountability and audit protection.

SureCost works with all wholesalers and most secondary vendors, so all your purchasing data is in that single source (not segmented by who sent each product). That makes it a single source of truth for vendor remediation or external agency audits. You may also conduct your own internal investigations. Standard operating procedures like these enable self-accountability down to each action's who/what/when/why.

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It's vital to have a transparent relationship with your vendors while holding them accountable in an easy and smart way.

Calvin Hunsicker, Founder and Chief Product Officer at SureCost

Vendor Purchasing Compliance

SureCost lets you confirm vendors supply accurate DSCSA data, but it also checks contracted pricing and other terms. You want to catch overcharges, incorrect quantities, unexpected substitutions and other exceptions as soon as possible. You also need to calculate the cost to your business. That knowledge informs conversations with vendors about your pharmacy's needs and negotiations.

That's why you want easy access to flexible reporting and a robust data set through a single unified solution. You see what you expected to pay, how much you were charged and which vendors might have better purchasing options.

SureCost provides that insight along with tools for invoice reconciliation between purchase orders, received goods and accounts payable. Don't spend time marrying invoices or comparing multiple websites; keep the knowledge you need in one place.

These capabilities add up to making sure your pharmacy always:



Procures the right product



Collects necessary DSCSA data



Receives the right quantity



Pays the agreed-upon price



Getting items when you expected them

[Book a free DSCSA Consultation](#)

 SureCost

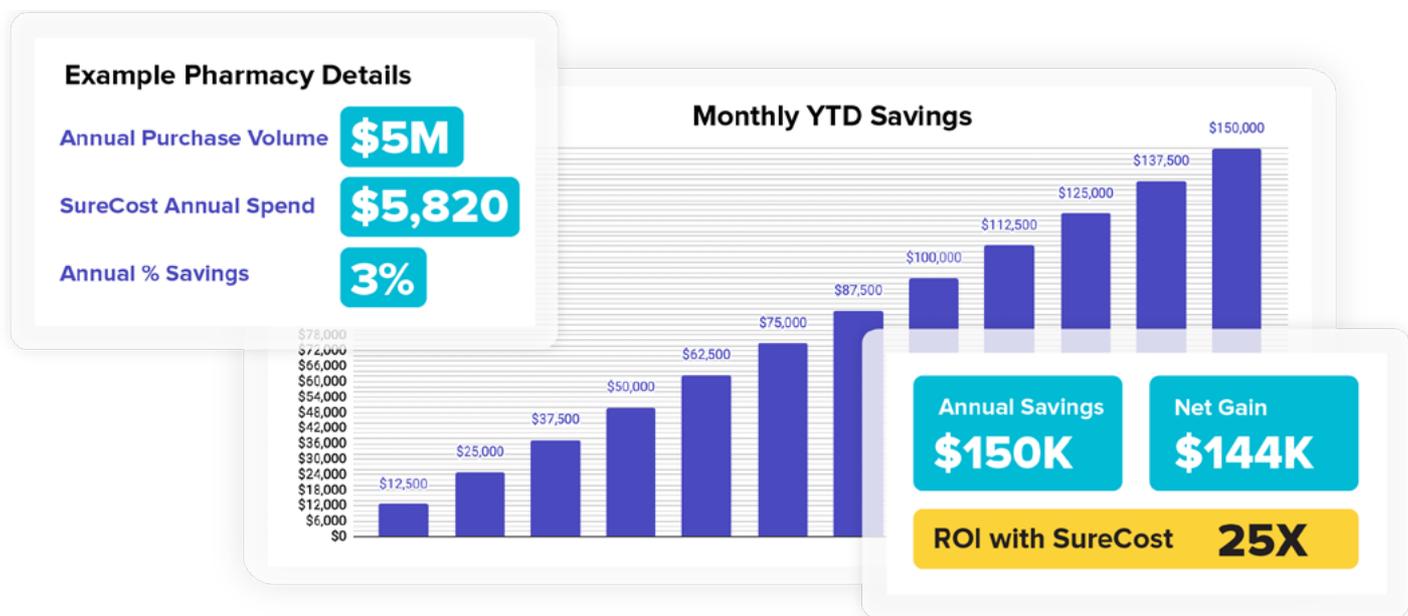
SureCost is also managed by a team of pharmacy professionals with over 75 years of collective experience as pharmacy professionals continuously innovating this solution and eager to ensure customer success.

Going Beyond With Integrated Inventory

While DSCSA has yet to require pharmacies to track items transferred internally across multiple locations for the same pharmacy, we strongly recommend doing so. It adds another level of security and accountability to the chain of custody. You want the ability to track a product across your entire organization down to its serial number.

SureCost captures and tracks relevant DSCSA data during inventory transfers while logging staff members and actions. That includes all inbound and outbound transfers for all locations—from the transfer request to the product reaching its destination. Using SureCost to manage inventory centralizes that information alongside all your purchasing and compliance data. It also enables easy access and reporting if you need to check your actual stock or investigate an issue.

The system flags non-matching traceable items when receiving an inbound transfer. You can also run and schedule reports in the same way as mandated items. Again, while not required by DSCSA, SureCost provides rolling six-year data retention of all transfer data. For extra vendor accountability and audit protection, you can quarantine and follow non-compliance traceable transferred items.



The Bottom Line

SureCost empowers pharmacies to consistently stay DSCSA-compliant. By automating the capture and storage of DSCSA data while streamlining purchasing and inventory, you can stay compliant while saving more and working smarter.

- SureCost is your all-in-one solution for purchasing, inventory and DSCSA compliance that:
- Consolidates all DSCSA data into a single source of truth
- Provides easy implementation of and access to EPCIS in case of audits
- Offers mobile functions that let you go where the work is
- Alerts you of DSCSA data issues while providing a quarantine and reconciliation process
- Adds another level of safety with DSCSA data for inventory transfers

Disclaimer

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