Achieving & Maintaining DSCSA Compliance

HOW TO STAY DSCSA COMPLIANT BY IMPROVING YOUR PURCHASING PROCESS

DSCSA Then to Now

The FDA's focal point for audit and compliance is the T3 concept—comprising Transaction Information (TI), Transaction History (TH) and Transaction Statement (TS). TI embodies purchase specifics, acting like an invoice detailing origin, destination, and product identifiers. TH extends further upstream in the supply chain. As a pharmacy, your pertinent transaction information stems from distributors or direct manufacturers, while history may encompass multiple steps prior. The TS serves as a compliance declaration across all communications. This pertains to lot-level data, which must be upheld for six years regardless of the data's origin. Pharmacies are mandated to promptly isolate and report suspected products, responding to audit requests within specific timeframes—24 hours for technical literature and 48 hours for state or federal authorities.

So What's Changing in November 2024?
A notable shift is anticipated with the introduction of T2. This transition entails a departure from transaction history, prompted by the shift towards electronic data maintenance. While paper invoices were permissible previously, the new regulations mandate an electronic and interoperable format, primarily pointing to EPCIS as the standard meeting these criteria. Notably, the inherent historical structure of EPCIS aligns with these requirements, rendering the concept of transaction history redundant within the comprehensive historical system. With T3 evolving into T2 by November, the electronic storage of data at the package level, as opposed to the lot level, becomes essential, demanding the implementation of well-defined protocols to uphold these standards. A pertinent inquiry emerges concerning the identification of items subject to robust traceability, including a deeper exploration of traceable and non-traceable distinctions within prescription items, underscoring the need to clarify what precisely qualifies as a direct pathway and what falls outside this categorization.

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Navigating the DSCSA Complexities

A crucial aspect for pharmacies revolves around centralizing their purchasing activities, streamlining the process by eliminating the need for navigating multiple tabs. Even in cases of ordering from various compliant vendors, the opportunity exists to consolidate data and enhance precision. Rather than dispersing efforts across various tools, the emphasis lies in seeking solutions that create a singular hub for staff, seamlessly integrating data with trading partners. At the heart of DSCSA, precision is of utmost importance, transitioning from a mere identification of drugs and strengths to encompassing specific bottles with unique serial numbers. Consequently, the associated data's accuracy becomes pivotal, substantiating the movement of these elements within the compliance framework.

Spotlight on Traceable Items and Transfers
In broad strokes, it's easy to think of traceable items as being Rx-only items and non-traceable to be over-the-counter items. However, the complexity lies in the fact that even within prescription items, legal exemptions from traceability exist. These exceptions encompass diverse items such as blood fusion components, IV fluids, certain supplies and specialized medical equipment like radiology imaging tools. The range of exceptions can evolve, as evidenced by the inclusion of COVID-19 vaccines as traceable exceptions during the pandemic. The concept of associating prescription items with traceable and OTC items with non-traceable serves as a helpful framework for understanding the differentiation, but the nuanced landscape involves a broader array of exceptions within Rx items.

While specific traceability requirements don't apply to transfers within the same organization in most cases, the importance of data management in this context remains significant. The need to track and manage data around transfers persists. The centralization of data and the assurance of its accuracy are pivotal, providing a singular point of reference and readiness for potential audits. Despite the exemption from traceability requirements, managing transfer data effectively is crucial for maintaining operational integrity and audit preparedness.

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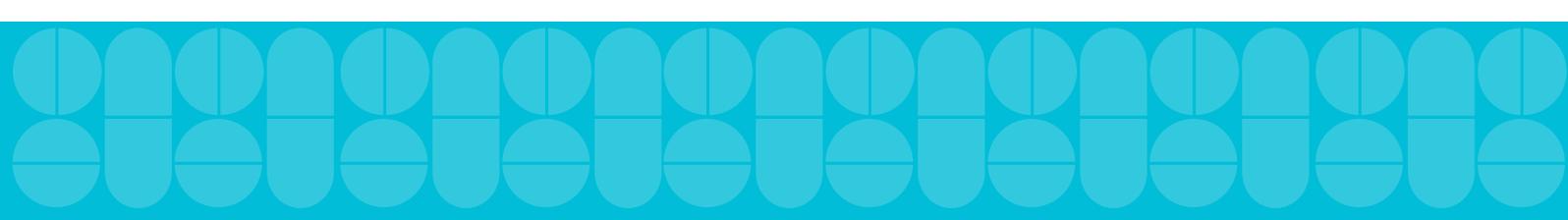
The Impact of Drug Shortages

Avoiding shortages is essential for providing reliable patient care and building patient confidence. While primary vendors are crucial, diversifying suppliers for transparency, pricing and addressing shortages is recommended. However, integrating multiple sources requires a streamlined approach to ensure compliance with DSCSA regulations. A comprehensive system is necessary to maintain consistency in processes across all suppliers, including primary and secondary ones. Demonstrating efforts to source from primary vendors and the need for secondary suppliers, especially when primary sources are out of stock, is vital for maintaining vendor relationships and compliance in primary vendor agreements. Real-time electronic information is essential for accurate pricing and product availability, along with monitoring tiered rebates compliance and generic compliance ratios. The complexity of managing these aspects necessitates a solution that will centralize and automate the process, ensuring accurate receipt validation, correct product pricing and even tracking specific serial numbers to align with vendor shipments. A unified solution is recommended to avoid employing multiple tools to address each step of the process.

The Risks of DSCSA Non-Compliance

Beyond the surface level of audit and financial risks, the core focus of DSCSA is patient safety and safeguarding the US supply chain. While compliance might present challenges, it's essential for the entire supply chain to adhere to these regulations, given that patient well-being is the ultimate priority. Ensuring patient protection, maintaining your brand's integrity and fostering patient trust are interlinked with adhering to compliance. By dedicating more time to patient care and assuring product availability, pharmacies enhance their value in the eyes of patients.

The SureCost DSCSA Compliance Packages

Ready to ensure DSCSA Compliance? Here's how SureCost helps your pharmacy

SureCost is a comprehensive solution that simplifies various aspects of pharmacy operations. Firstly, the importance of having a single, unified solution aids in aggregating and tracking information from different sources, streamlining the process and providing a central source of data for transparency, accuracy and price auditing. Product movements within a product group, even among generic equivalents, can be efficiently managed and monitored through such a centralized solution. Managing exceptions and multiple vendors becomes more straightforward, ensuring a cohesive approach to compliance and audit readiness.

By integrating technologies into a unified pharmacy management solution like SureCost, data flows seamlessly across various systems, enhancing the accuracy of dispensing data, utilization metrics and inventory management. The solution also enables efficient product optimization, avoiding stock overages and ensuring cost accuracy. Moreover, having access to accurate cost information is vital for evaluating reimbursement rates and understanding pharmacy margins, enabling more informed decision-making.

The SureCost DSCSA Compliance Packages are a reliable means to manage the complex DSCSA requirements. By consolidating data within a single platform, it becomes easier to ensure compliance, manage audits and maintain required records for the FDA's six-year retention period. Additionally, the solution's role in providing a single point of data aggregation for purchasing, inventory and patient management systems enhances operational efficiency and reduces the likelihood of discrepancies between various disjointed systems.

With SureCost, Get Your True Cost

SureCost ensures the provision of accurate true-cost information to pharmacies, encompassing both invoice prices and potential rebates, yielding a clear understanding of actual costs from source to recipient. While most pharmacies primarily rely on their primary vendors' catalog for cost basis, this might only capture a portion of the product range, particularly for generics, where cost variations significantly impact reimbursement outcomes. The software's seamless electronic integration facilitates easy access to accurate cost data, particularly from secondary sources.

Another key feature is streamlined accounts payable (AP) processes. Rather than navigating varied approaches to product-receipt confirmation, the software provides a single solution to capture received-product information, ensuring precise accounts-payable posting. This eliminates complexities, enhances payment accuracy and improves visibility into payment processes. Importantly, SureCost integrates with pharmacy procurement operations, effectively addressing DSCSA compliance requirements. It's an integrated solution where every step of the procurement process aligns, from expected orders to actual orders, shipments, invoices and received items. Moreover, it ensures accuracy at the bottle level, even verifying serial numbers, contributing to an efficient audit trail.

Lastly, SureCost serves as a centralized repository for PCAS documents, a vital element in today's pharmacy operations. Given the shift from editable X12 documents to XML documents like EPCIS, which contain comprehensive shipment information, SureCost facilitates barcode scanning, automatic recognition of accuracy and simplified audit preparations. In essence, SureCost streamlines cost management, accounts payable, DSCSA compliance and document integration, ensuring efficient and accurate pharmacy operations.

The Power of SureCost in Your Pocket

SureCost provides a mobile app available on both Google Play and the Apple Store, which provides significant advantages to busy pharmacies regardless of their market segment. The app addresses two primary aspects concerning DSCSA compliance: data management and physical product verification. The focus is on simplifying key tasks for busy pharmacy staff. The main entry point is the purchase order receiving process, using the app and the phone's embedded camera to efficiently scan 2D barcodes. These barcodes contain essential transaction information, such as G-10 identifier serial numbers, lot numbers and expiration dates.

The app operates across different platforms, catering to various users. For instance, floor staff utilizes mobile devices like phones or tablets, while supervisory roles access data through the web platform. The seamless integration ensures that data captured by the app is instantly available on the web platform. This integration extends to the reconciliation process, where discrepancies between received and expected data are identified. The app's quarantine feature provides the ability to isolate products for closer scrutiny.
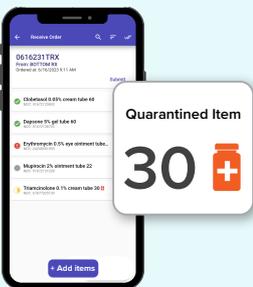
Access DSCSA Data for Audits in Seconds

Reports in SureCost provide valuable insights for inventory management. These reports provide the ability to quickly analyze data, such as identifying items that have been in stock for 30, 60, or 90 days, based on utilization. The system also tracks products that have been purchased, but not dispensed, as well as those that have been dispensed, but not purchased. These features are particularly useful for detecting potential issues like diversion, where purchased products aren't making their way to patients, indicating a possible problem.

Utilizing <u>SureCost's Inventory Management</u> solution enhances the monitoring process by incorporating actual inventory counts to identify any discrepancies. This comprehensive approach ensures that purchased items are accurately tracked from acquisition to dispensation. Furthermore, optimizing purchasing becomes more manageable with SureCost's platform. With the potential of primary and secondary vendors, understanding the broader marketplace's price and availability landscape is essential. SureCost streamlines this complex task, providing insights on how these factors impact primary vendor agreements and overall purchasing strategies. This integrated approach not only saves time, but also guarantees compliance with DSCSA regulations, efficient auditing of invoicing and seamless integration with accounts payable and pharmacy management systems. As an all-in-one solution, SureCost maximizes the efficiency and effectiveness of pharmacy purchasing processes.

Achieving and Maintaining DSCSA Compliance with CONSISTENCY, ACCOUNTABILITY and CONVENIENCE

Achieving and upholding compliance with DSCSA hinges on three fundamental factors: consistency, accountability and convenience. Consistency in processes greatly enhances compliance rates and efficiency. By standardizing procedures, regardless of whether they involve primary or secondary vendors, you establish a reliable method to optimize interactions and ensure adherence. SureCost's management of secondary vendors simplifies this process, promoting consistency and aiding in compliance efforts.

Once a consistent process is in place, tracking and measuring accountability becomes crucial. Identifying deviations from the established process, whether they involve discrepancies in product receipt or pricing, is vital. SureCost's features address these concerns, providing checks for pricing disparities, accurate receipt and invoice reconciliation. This enables swift identification of issues and fosters accountability across your operations.

When utilizing SureCost for purchasing, there's a symbiotic relationship with the receiving aspect. Reconciliation checks require precise receiving procedures through SureCost. SureCost's mission is to facilitate the seamless operation of your pharmacy and business while maintaining compliance. It achieves this by automating processes and capturing essential data needed for DSCSA compliance, ensuring that your pharmacy remains in motion while adhering to regulatory requirements.

Consistency   **Accountability**   **Convenience**

Ready to learn more about driving DSCSA compliance with SureCost solutions?

Book a Demo

Let's talk.

Book a 30-minute introductory meeting today

SureCost