Navigating DSCSA: Choosing a Compliance Approach for Dispensers



Next month, the FDA will begin enforcing the Drug Supply Chain Security Act (DSCSA) for dispensers. Yet with little time before the March 1 enforcement deadline, some hospitals and pharmacies are placing themselves at risk by not having a solution in place to ensure regulatory compliance.

The new requirements will impact the operations of every organization, from single-unit pharmacies to pharmacy chains and hospitals. DSCSA introduces a national standard for prescription drug safety that combats counterfeiting, diversion, and other illicit activities—while ultimately protecting patient lives. But the law - in effect for dispensers since July 1, 2015 - also introduces complex compliance requirements that challenge both staffing and system resources throughout the supply chain.

In this article, we'll first take a look at the phases of DSCSA requirements for dispensers. We'll then examine how the new requirements impact your operations. Finally, we'll outline important notes for you to consider as you decide how your business will respond to the rapidly approaching enforcement deadline.

DSCSA Dispenser Requirements

There are three phases of requirements for dispensers, beginning with the ones

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that took effect in 2015.

Initial Requirements

As of last July 1, dispensers must receive lot-level documentation—known as Transaction History, Transaction Information, Transaction Statement, or T3—for every product they purchase. There is a verification requirement, as well, stipulating that dispensers must retrieve, analyze, and provide T3 within two business days during suspect product investigations and recalls. They must also quarantine and investigate any product identified as suspect, and notify the FDA and their trade partners. Lastly, dispensers must retain product compliance documentation for at least six years.

Future Requirements

Serialization requirements come into play in 2020, mandating that dispensers purchase and sell only serialized drug products. Verification mandates evolve at this point, also, with enhanced requirements around verifying lot numbers and serial numbers at the package level.

In 2023, the final phase rolls out with package-level traceability requirements.

Impact on Your Pharmacy Operations

DSCSA's complex requirements will touch several areas of your business. From product receipt through product resale, let's take a brief look at a few ways in which the regulations will necessitate change.

Product Receipt

DSCSA mandates that you receive compliance documentation for the prescription products you buy. Now instead of just checking that a shipment you've received matches your purchase order, you will also need to confirm that your supplier has sent the appropriate T3. That adds a step to your receiving procedures and also forces you to think through where things happen within your organization. Is

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product sent to multiple stores or distribution centers? And will all the compliance documentation be sent to one central office? Which staff at what locations will be able to access T3?

Beyond that, what operating procedures will you put in place for the inevitable times when there is a mismatch between compliance documentation and incoming product? If you receive 120 units of a drug but the T3 only accounts for 100, you have 20 excess units that are not properly documented. You need a process to temporarily quarantine that product, keep track of it, and resolve the discrepancy with your supplier.

Resales, Loans, and More

As a pharmacy or hospital, you may assume that you fall solely under DSCSA's dispenser requirements. But if your business conducts the common practices of reselling, loaning, bartering, or donating product to other dispensers, you are likely subject to the same requirements that are applicable to wholesale distributors, as well. That means that you typically need to provide the correct compliance documentation on the outbound side, something you do not need to worry about if you purely dispense to patients.

This has repercussions on your receiving procedures. In order to track down the correct T3, you will want to have a record of the lot number. But if you originally received the product from a wholesaler who purchased it directly from the manufacturer, the wholesaler may not have provided it to you. If you know that you'll be reselling product, you'll want to consider structuring your intake procedures so that you track down and enter lot number during product receipt. Trying to figure out what product belongs to which T3 once you've co-mingled inventory isn't operationally efficient, and mismatching product and T3 puts you out of compliance.

Data Management

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DSCSA brings with it a new set of regulated documents that must be received, stored and kept easily accessible, which introduces a host of challenges. How will you connect with all your suppliers to receive the documentation? For the first several years, some T3 will come to you electronically and others will come via paper. How will you manage both formats, and how will you centrally store all T3 in order to quickly get to it in the event of an inquiry or investigation?

Achieving Compliance: What Are Your Options?

As the clock runs down to March 1, let's look at four potential approaches to compliance along with their drawbacks and advantages.

Putting Faith in Paper

Some dispensers hope to get by with a homegrown solution, typically one that revolves around paper. That involves requesting paper T3 from each of your suppliers, then organizing and storing a growing amount of documentation.

Drawbacks: Managing DSCSA through paper is not scalable. Even for a small business, the piles of T3 will quickly grow. Where will you store it for the required six years? And more importantly, how will you organize it such that you can respond to a product investigation within the tight two-business day timeframe? Investigators may request information based on a range of different factors, e.g., by date, product name, NDC, supplier name, etc., so you'll need a flexible way to locate documents based on the request. If you can't locate the specified compliance documentation in time, you put your business at risk for penalties. And in the end, paper is a short-term fix. By 2017, manufacturers must send T3 in electronic form and in 2023 the industry will transition to electronic, interoperable data exchange requirements. At minimum, documentation for all product you buy directly from the manufacturer or receive during drop shipment will come electronically in two years. So, relying on paper today would ensure that you have continuous change and churn in your pharmacy operations for years to come.

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Advantages: With paper, you avoid the expense of a third-party compliance solution, but how much do you actually save? A homegrown approach comes with its own costs, most notably staff resources. Can you spare half of an employee's time to copy, file, order, and search your paper repository? What about offsite backups of this compliance documentation? And will you switch to new suppliers if a current one refuses to send paper due to the complexity it causes them?

Relying on Suppliers

Your wholesale distributor partners may offer you portal access to T3 for product you've purchased through them, suggesting that you can avoid the need for your own in-house compliance solution.

Drawbacks: If you're like most dispensers and hospitals, you work with at least five suppliers, and potentially many more. Relying on wholesaler portal access to your T3 means that you're managing multiple logins and interfaces for multiple portals which can be overwhelming, especially if you're scrambling to respond to a product investigation. And if you resell or loan a product, how will your pharmacy personnel quickly know which portal to access for that product? In addition, what kind of guarantee do you have from your wholesalers that they will store your data for the required six years? What happens to that documentation if you stop doing business with them?

Even if you're willing to deal with the risks associated with entrusting your compliance to your wholesale distributor partners, you still need a plan for drop shipments. How will manufacturers deliver that T3 directly to you?

Advantages: This approach, like paper, saves the cost of a third-party compliance solution. But if your business deals with more than a few suppliers, manages drop shipments, or resells product, a portal-only approach comes with more risk than you're probably willing to take.

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Doing Nothing

Some dispensers feel they are too small to ever attract the attention of the FDA, so they see no need to address the current DSCSA requirements.

Drawbacks: You may think the FDA won't come after your neighborhood operation, but there is more to enforcement than the FDA. State boards of pharmacy and government agencies will conduct their own DSCSA inquiries, and accreditations could be at stake. In addition, an investigation that begins with one of your upstream partners could easily extend to all of the trading partners of that business, which might include your pharmacy. Suspect product investigations involving counterfeit, adulterated, stolen or fraudulently sold or diverted products will involve a wide variety of dispensers and suppliers, no matter their size.

Even if you could fly under the radar and avoid addressing DSCSA, would you really want to introduce that risk to your business when the end game is all about protecting drug integrity and patient health?

Choosing a Third-Party Platform

There are several third-party systems available to help you manage DSCSA compliance.

Drawbacks: Though typically a small investment, third-party platforms do come with a price tag. Additionally, some are better than others, so it's critical to do your due diligence before making your selection.

Advantages: The best DSCSA compliance solutions have been custom-built to meet the regulations and the complex network data exchange requirements DSCSA creates for dispensers. The right solution provider will not just sell you some software, but act as your DSCSA partner, simplifying compliance and minimizing the time it takes away from your day-to-day operations.

A top solution provider offers:

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- One central repository for all your documentation, regardless of your number of suppliers
- Access to that central repository from multiple store, hospital, or distribution center locations
- Easily configured connections to all of your trade partners
- Facile management of paper and electronic formats
- Comprehensive search capabilities to instantly find any compliance document
- Functionality to help track exceptions and quarantined product
- A scalable solution that will accommodate growing needs
- A tried and true system that is already being relied upon by hundreds of your peers
- A self-paced learning environment full of courses about all of the aspects of compliance under DSCSA and how to simplify compliance within their pharmacy workflow
- Provider expertise in regulatory affairs and solution updates as the requirements evolve

Making the Right Choice

DSCSA embraces drug and patient protection and over time, introduces a sophisticated technological approach to safeguarding the supply chain. Complying with DSCSA is an opportunity to embrace the future of the supply chain while also preserving the age-old patient-centric priorities of the pharmacist. The law introduces complexities right out of the gate and requires an increasingly digital state over time. Given that, pharmacies and hospitals should strongly consider a technological approach to this law. While paper, wholesaler dependencies, and looking the other way may be appealing, investing in a technology platform custom-built for the law is the best way for dispensers to efficiently achieve compliance, safeguard their daily operations, and take their commitment to drug integrity and patient safety to the next level.

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