5 Reasons Why Paper Creates Risk for Dispensers



The Drug Supply Chain Security Act (DSCSA) requires dispensers to receive their products with proper transaction documentation. But the question for many dispensers is this: Is my packing slip (or purchase order) enough to be in compliance with the law? The simple answer is, probably not.

If you haven't yet started receiving transaction history, transaction information, and transaction statement (TH, TI, TS, or T3 collectively) documentation in electronic format, your paperwork could be throwing you out of compliance and you don't even know it. Here, we unpack for you why all documentation is not equal, and offer you top considerations for moving from paper to electronic to ensure DSCSA compliancy.

1. The typical packing slip documents a shipment, not a history

The FDA allows paper as a mechanism for documenting DSCSA transactions during the initial phase of DSCSA implementation. But unless the paperwork has been appropriately modified to meet DSCSA regulations, it won't keep you compliant. For every product you buy, the law requires a transaction history for each change of ownership going back to the original manufacturer. The typical packing slip shows only transactions back to the supplier, so it does not provide a sufficient transaction history.

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2. Key regulatory data often goes missing

Even if your paperwork from your supplier does include information from the original manufacturer, that may not be enough. The T3 is not just about the product, but also about all the transactions it underwent. First, the T3 should be defining a unique product (as denoted by the National Drug Code or NDC), produced in a unique batch (as denoted by the lot number), sold by the manufacturer on a unique date (as denoted by the transaction date). Next, the T3 is supposed to document the unique changes of ownership for that product. It's this unique mix of NDC, lot number, transaction date and history of transactions that is the core of the transaction history. Any change to this mix should be represented on a separate TH. This creates one of two problems for dispensers receiving typical packing slips or purchase orders: legally required data fields may be missing, or any one line item on such a paper document may inappropriately comingle different lot numbers or original manufacturer sales dates or different paths through the supply chain.

3. You still need legal attestations about each product

In addition to transaction information and history, your supplier must supply a transaction statement for each product. The TS confirms that the entity transferring ownership of the product in this transaction is authorized to sell that product, is not knowingly selling you illegitimate product, and is in compliance with several other provisions of DSCSA requirements.

4. Validating paper documentation is your burden

The data you receive in the T3 will change depending on the path that the product has taken through the supply chain. Not just different supply chain transactions but also specific data fields in the document may or may not be included. If you receive a T3 that has a missing data field such as lot number, it's up to you to figure out why (Is the supplier not required to provide that piece of information? Have I received non-compliant DSCSA documentation for that product? Or, is this a

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potentially suspect product I am receiving?). When dealing with paper, the burden is fully on you to know if you've received valid compliance documentation for this unique product. On the other hand, an automated compliance system can cut the complexity of capturing and interpreting data for any product that comes into any of your locations, and prompt you about information you need to investigate.

5. Legal documents and business documents are fundamentally different

By law, you may only accept ownership of product if it has been provided with an accompanying T3. A T3 is a regulatory document; it's discoverable and can be used for legal processes governing the transactions under DSCSA. A packing slip or purchase order is designed for logistical and business purposes, so the handling and governance of such documents is different than a legal document covering regulatory processes like DSCSA. When it comes to paper documents like packing slips, issues such as error correction and archival are often managed in a manner than creates risk when used for regulatory purposes. Truly, such business documents are not intended to be DSCSA compliant.

DSCSA compliance impacts how you as a dispenser receive product and manage documentation. In its raw format, T3 information is not easily interpretable. A solution that's been purpose-built to understand both the regulations and the business context removes the burden of having to master all DSCSA compliance details.

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