Shipments Under DSCSA: Unpacking the Complexities of Special Shipping Scenarios



When the **U.S. Drug Supply Chain Security Act** was ratified, it established new requirements for the exchange of serialized T2 data at each step of the supply chain. However, there are several unique shipment scenarios that can complicate the exchange of the necessary compliance data. This can disrupt shipment and receiving processes, even leading to costly delays.

We caught up with Dan Walles, Global Manager of Traceability & Compliance at TraceLink, to discuss how the Enhanced Drug Distribution Security (EDDS) requirements of the DSCSA impact shipments and what you need to do to handle these scenarios.

How does the DSCSA impact shipments?

Under the DSCSA, serialized T2 data must be sent to the recipient along with the physical product before the product can be sold or shipped further down the supply chain.

However, not all shipments are equal. While exchanging serialized T2 data with the physical product is straightforward in most scenarios, there are a few unique shipment use cases that can create some issues when it comes to sending the compliance data. Some of these scenarios include:

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- **Drop shipments:** When pharmacies need a product immediately, the wholesaler orders the product and **the manufacturer ships it directly to the pharmacy** without the distributor taking ownership of it. However, the manufacturer may not have a commercial relationship with the pharmacy, which makes it difficult to send the required T2 data.
- **340B:** Wholesalers sell drug products to 340B-covered entities but ship products to the 340B contract pharmacies that dispense these drugs on behalf of the covered entity. This can create complications in the chain of custody, as the covered entity maintains ownership of the product despite it being shipped to the contract manufacturer.
- **Returns:** Dispensers may send product back to the wholesale distributor and that product might be resold to another dispenser. Dispensers may also ship back products that have been identified as part of a recall. Knowing when you must comply with DSCSA during these scenarios has a direct impact on your operations.

What makes these shipment scenarios so difficult to navigate?

While each of these scenarios has its own unique challenges, the core issue shared between them is the lack of a commercial relationship between the relevant parties involved in the transaction.

With paper packing slips, you could always just attach the data to the packages being shipped. But when this serialization data needs to be exchanged electronically, your systems must be properly integrated with all other relevant stakeholders to ensure the data makes it to the right partner.

There are also situations where a party involved in the shipment may want access to the serialization and aggregation data to support their receiving processes.

What can the industry do to better manage these unique scenarios?

The challenge the industry faces is twofold:

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1. Many members of the industry have not thought through how these shipment scenarios are impacted by the new EDDS requirements of the DSCSA.
2. Many solutions used to handle the logistics of these shipment scenarios simply don’t have the technical architecture to accommodate these new workflows.

A network-based approach has a lot of value in these scenarios because it collects all the key stakeholders of the pharmaceutical supply chain onto a single platform. This makes it easy to integrate with partners even if you don’t normally have a close commercial relationship with them.

All it takes is a **single connection to the TraceLink network** and you can immediately begin sending critical compliance data to any other member on the network. Moreover, the TraceLink network is designed to make onboarding supply chain partners easy, so even if they aren’t on the network, they can be added quickly and at no cost.

If you’d like to know how TraceLink can help you handle these unique shipment scenarios and ensure your compliance, contact us today for a free consultation with one of our DSCSA experts.

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Contact TraceLink to learn more about DSCSA compliance!
Fill out the form to contact us now.

Thank you for contacting us; we’ll be in touch shortly.

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