RESOURCES

340B Under DSCSA: How to Close the Gap Between Data Flow and Product Flow



For the past 30 years, the 340B Drug Discount Program has had a tremendous impact on patient health, improving access to affordable medications for vulnerable populations. The U.S. Drug Supply Chain Security Act indirectly supports this effort by improving supply chain traceability, ensuring the safety of medications flowing through the supply chain.

For 340B-covered entities, their contract pharmacies, and the wholesale distributors that send them product, the impact of the DSCSA's **serialized product data exchange requirement** on the products they dispense has been a constant source of confusion. We recently caught up with Dan Walles, General Manager of Traceability & Compliance at TraceLink, to discuss why 340B shipments are difficult to coordinate under the DSCSA and how to better handle these shipments in compliance with the law.

What happens in a 340B shipment?

What makes a 340B shipment unique compared to other shipment scenarios is the divergence of the physical product from product ownership. When a health system orders a 340B-covered medication from its wholesale distributor, the health system retains ownership of the product while the physical product is shipped to the contract pharmacy that dispenses it.

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This scenario requires the wholesale distributor to ship product to a different organization than the one that ordered the product and one that they may not have a regular commercial relationship with. Historically, this process hasn’t been overly problematic. The distributor can ship the product directly to the contract pharmacy, and the paper packing list featuring the DSCSA compliance information and all the product details can be included in the physical shipment for receiving purposes at the contract pharmacy.

How does DSCSA impact 340B shipments?

The Enhanced Drug Distribution Security (EDDS) requirements of the DSCSA, which went into effect on Nov. 27, 2023, add a degree of logistical complexity to the choreography of 340B shipments.

The EDDS requirements mandate the electronic exchange of serialized T2 product data at the unit level. This means that, under the updated regulations, using a paper packing list to convey compliance information is no longer allowed. And even if it were, the impracticality of printing packing slips that list hundreds or even thousands of serial numbers is readily apparent. Adding to this challenge is the fact that it can be time consuming for companies to integrate their enterprise systems with trade partners they don't have direct commercial relationships with to exchange serialized product data.

What can be done to close the gap?

With the DSCSA stabilization period coming to an end this year, all entities involved with shipping and receiving 340B products need to assess their processes to ensure compliance and operational efficiency. As they evaluate their approach, there are three critical considerations to keep in mind:

- The DSCSA was designed with the acknowledgment that each trade partner has unique processes and systems in place. This means trade partners may need to support multiple approaches for serialized T2 data exchange.

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- The exchange of T2 serialized product data isn’t just a compliance requirement. Many trade partners will want access to serialized product data and aggregation data to improve their receiving and operational processes.
- Many DSCSA solutions are not architected to support 340B shipment scenarios under the new requirements. This may give companies in the pharmaceutical supply chain a false sense of preparedness if they have not discussed 340B with their solution provider.

TraceLink's network-based approach supports 340B shipments and data exchange in compliance with the DSCSA by streamlining serialized T2 product data exchange. Because the TraceLink network connects wholesale distributors, 340B-covered entities, and their contract pharmacies through a single platform, it’s much easier for companies within the pharmaceutical supply chain to integrate with other trade partners that they don't have direct commercial relationships with.

TraceLink also supports the guidance given by both GS1 and PDG on T2 serialized data exchange scenarios for 340B shipments. For example, wholesale distributors may need to make T2 product data available via direct integrations and portals in support of scenarios like:

- Uploading T2 data to a portal, which can be accessed by both the covered entity and the contract pharmacy.
- Sending T2 data to the covered entity, and sending product and T2 data to the contract pharmacy.
- Sending T2 data to the covered entity, who passes it through to the contract pharmacy, and sending product to the contract pharmacy.
- Sending T2 data and product to the covered entity, who then sends product and T2 data to the contract pharmacy.

If you’d like to know how TraceLink can help you handle 340B shipments and ensure your compliance, contact us today for a free consultation with one of our

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DSCSA experts.

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