

Managing Drop Shipment, 340B, and Other Special Network Product Flow Scenarios

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Session Objectives

- The “normal” healthcare supply chain is complex. When you include drop shipments, 340B, and saleable returns, the complexity increases substantially.
- DSCSA compliance for drop shipments, 340B, and saleable returns involves more than a “shipper” and “receiver.”
- A multienterprise network that can orchestrate supply chain processes across more than two partners substantially reduces the complexity and risk.



DSCSA and Drop Shipments

Challenges and Impact of DSCSA on Drop Shipments



DSCSA and Business Challenges

- The dispenser (DSP) orders a product from the wholesaler (WSD), but the wholesaler does not have it in stock.
- The wholesaler takes the order and orders the product from the manufacturer (MAH) with instructions to ship it directly to the dispenser.
- The manufacturer needs to provide the DSCSA-required serialized T2 information to the dispenser, but all the manufacturer has is the dispenser address.

The Industry is Discussing Multiple Approaches to Drop Shipments

Drop shipment options:

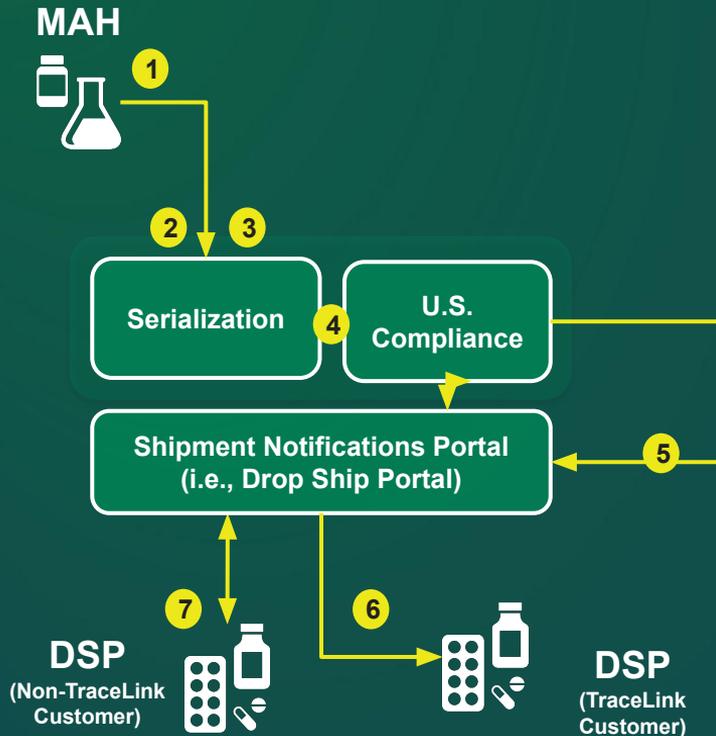
- Manufacturer sends serialized T2 to the dispenser.
- Manufacturer sends serialized T2 to the dispenser and wholesaler.
- Manufacturer sends serialized T2 to the wholesaler, and the wholesaler makes the serialized T2 available to the dispenser.

Via its drop shipment capability, TraceLink supports manufacturers sending serialized T2 to the dispenser. This ensures that both parties meet their DSCSA legal requirement.

TraceLink is working with the industry to support manufacturers in sending the serialized T2 to both the distributor and dispenser.

The GS1 Rx Secure Supply Chain group is spearheading this discussion.

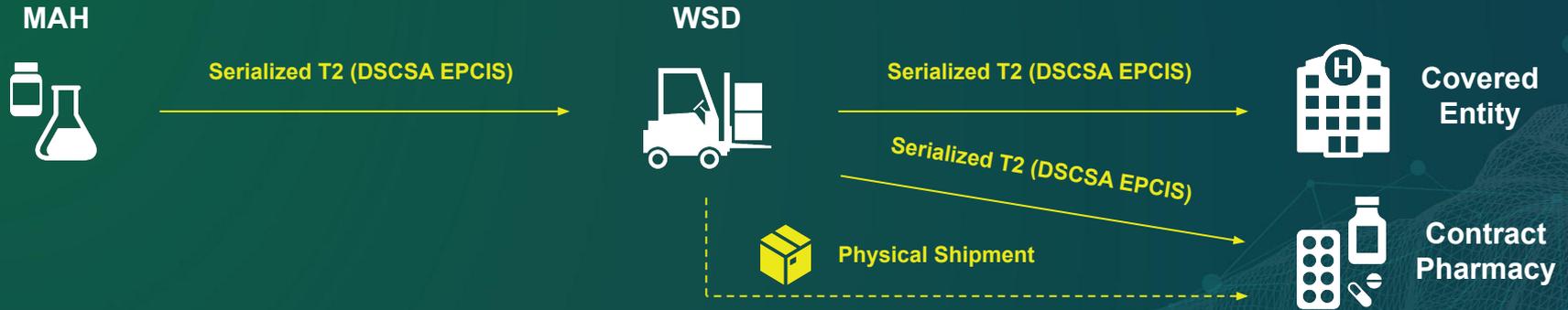
Solution Approach – MAH Sending To DSP



- 1) MAH creates a shipment and captures the serialization and aggregation data as usual.
- 2) MAH defines the shipment as a drop shipment through the user interface or within the integration transaction.
- 3) MAH defines the portal code and URL to access the drop shipment to be included on the packing slip.
- 4) The TraceLink solution detects that it is a drop shipment.
- 5) The solution sends the serialized T2 information to the Shipment Notification Portal.
- 6) If DSP is a TraceLink customer, the drop shipment will automatically appear in their U.S. Compliance application, where it can be received with other non-drop ship deliveries.
- 7) If DSP is NOT a TraceLink customer, DSP will access it through the portal at the URL included in the Packaging Slip.

DSCSA and 340B

Challenges and Impact of DSCSA on 304B Shipments



DSCSA and Business Challenges

- The 340B-covered entity takes ownership of the 340B product, even though it is shipped to the contract pharmacy.
- The covered entity must receive the serialized T2 information to maintain DSCSA compliance.
- The Contract Pharmacy will often request or require that the serialized T2 information be sent to them as well. With item-level traceability, there are two reasons for the request:
 - The Contract Pharmacy wants a record of serialized T2.
 - The Contract Pharmacy will need the serialization and aggregation data to optimize their receiving process.
- Sharing of information between the wholesaler and contract pharmacy requires written approval from the covered entity, as they are the product owner.

There Are Multiple Approaches to 340B Being Explored

340B options:

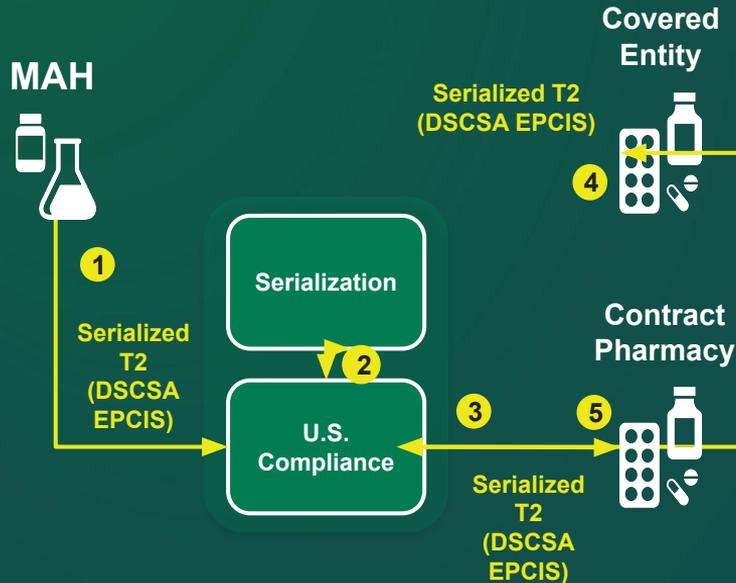
- The covered entity provides the contract pharmacy with a copy of the serialized T2.
- The wholesaler sends a copy of the serialized T2 to the contract pharmacy in addition to sending the serialized T2 to the covered entity.

The wholesaler only sends the serialized T2 to the covered entity. Providing the serialized T2 directly to the contract pharmacy requires written permission from the covered entity.

TraceLink is working with the industry to arrive at a common data model, but multiple scenarios will likely exist.

The GS1 Rx Secure Supply Chain group is spearheading this discussion.

Solution Approach – MAH Sending To DSP

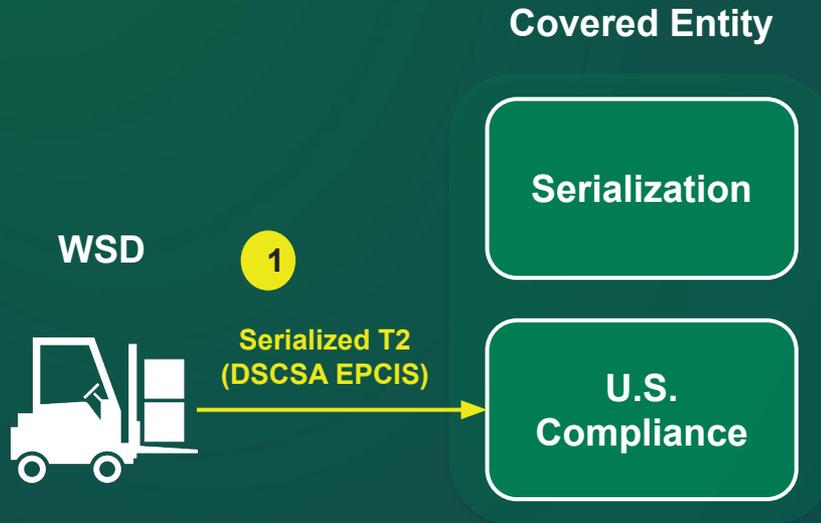


1. Wholesaler WSD receives serialized T2 from pharmaceutical MAH.
2. The wholesaler WSD prepares the 340B shipment and captures the serialization and aggregation information.
3. The wholesaler WSD sends the serialized T2 information to the covered entity and the contract pharmacy.
4. The covered entity receives the serialized T2 information and maintains that information in compliance DSCSA.
5. The contract pharmacy receives the serialized T2 information and uses it to facilitate the receiving process.

- NOTE: The contract pharmacy does not own the product and, therefore, is not required by law to receive and maintain the serialized T2.

Because the contract pharmacy is not the owner of the product, the covered entity must provide written permission for the wholesaler to send serialized T2 to the contract pharmacy.

Solution Approach: 340B - Covered Entity Perspective



1. The covered entity receives the serialized T2 transaction and maintains the transaction for the required data retention period.

At this point, both the wholesaler WSD and covered entity have met their obligations under DSCSA.

Key Takeaways

The supply chain has complex use cases that must be supported, or risk patient safety and business operations.

Supply chain stakeholders will need support for multiple approaches and interpretations. 340B scenarios are still under discussion to establish a best practice.

Drop shipments, 340B, and returns are three-party supply chain use cases.

- Unique requirements and solution needs for each party.
- Each party requires knowledge and information about the other party at the point of shipment.

Operating on the TraceLink network enables each party to have real-time awareness of each other to exchange the right information at the right time – securely and electronically.



Thank You