



The Global Language of Business

Best Practice Guidance for 340B Transactions and Drop shipments

Guideline

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Document Summary

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Document Title	Best Practice Guidance for 340B Transactions and Drop shipments
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Document Description	This guideline outlines best practices for 340B drug transactions and drop shipments, focusing on the consistent application of GS1 Standards to support regulatory compliance and efficient data exchange. It details ownership, data sharing, and documentation requirements for Covered Entities and Contract Pharmacies, and provides recommendations for managing comingled shipments and drop ship scenarios using standardized electronic formats.

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1 Introduction

This guide shall serve as an Industry resource for consistent application of GS1 Standards to facilitate the reliable exchange of data between parties for two (2) transaction types to meet regulatory and business requirements, including those of the U.S. Food and Drug Administration (U.S. FDA) Drug Supply Chain Security Act (DSCSA). The first section of this guide will review best practices for 340B replenishment transactions (Section 2). The second section will review best practices for Drop ship transactions (Section 3)

1.1 Terms for Clarity

- The **340B Drug Pricing Program** is a federally mandated program that requires drug manufacturers to sell outpatient drugs at discounted prices to Covered Entities for the manufacturers' drugs to be covered by Medicaid. [U.S. FDA letter on 340B and DSCSA [available here](#)]
 - Congress created the 340B Program in 1992 through the Veterans Health Care Act to enable health care providers that serve low-income and uninsured patients to purchase drugs at lower costs.
 - According to the United States Health Resources and Services Administration (HRSA), the administering agency of the 340B Program, the purpose of the program remains enabling covered entities to stretch federal resources to reach more eligible patients and provide more comprehensive services.
 - The physical replenishment of drug products under the 340B Drug Pricing Program is called the **340B Replenishment Program**. All references to 340B transactions in this document pertain solely to the product replenishment processes within this program.
- **Covered Entity:** A narrowly defined set of providers that treat primarily low-income and/or uninsured patients. When a Covered Entity places an order for medication under the 340B Replenishment Program from a supplier, that health system (Entity) maintains ownership of the product under DSCSA. If the Covered Entity is the dispensing pharmacy, the product will be in their possession. However, in many cases, the Covered Entity has a contractual relationship with a separately owned dispensing pharmacy (Contract Pharmacy). In those scenarios, although the product will not be in their physical possession as the medication is shipped from the Supplier to the Contract Pharmacy for dispensing, the Covered Entity maintains ownership of the product.
- **Contract Pharmacy:** A retail entity that provides prescription drugs to patients of Covered Entities under the 340B Drug Pricing Program. A Contract Pharmacy takes physical possession of a product under the 340B Replenishment Program but does not assume ownership, which is retained by the Covered Entity.
- **Drop shipment:** Drop shipping is a business model where a seller does not fulfill a customer order for products with inventory on-hand but instead transfers that customer order and shipment details to a manufacturer, distributor or other retailer, who then ships the products contained in the order directly to the seller's customer.

1.2 Role Definition

There are two primary roles we will refer to in the scenarios throughout this Guidance:

- **The Seller** who is the trading partner selling the product and releasing ownership of the product. This party would be identified by the source owning party GLN in the EPCIS file, the Sold From.
- **The Buyer** who is the trading partner purchasing the product. This party would be identified by the destination owning party GLN in the EPCIS file, the Sold-To.

2 340B Transactions

Under the 340B Replenishment Program, the Covered Entity (the Buyer) purchases 340B-Eligible outpatient products from a supplier (the Seller). That supplier (Seller) fulfills the order for the Covered Entity (Buyer) and ships the product from the order to either the Covered Entity (Buyer) or the Contract Pharmacy. The corresponding DSCSA TS and TI documentation goes to the 340B Covered Entity (Buyer) that purchased the product.

- If the Contract Pharmacy and Covered Entity have no relationship of common ownership, the Supplier shall only provide the required DSCSA TS/TI documentation to the Covered Entity, as the Covered Entity is the owner of the product shipped to the Contract Pharmacy. The Covered Entity determines if the Contract Pharmacy should have access to the DSCA TS/TI information. If access is granted, the Covered Entity should be responsible for ensuring there exists an agreement on the scope and method of disclosure of that information to include notification to the Seller permitting access.
- The Supplier is typically the Wholesale Distributor but could also be another party such as a Manufacturer or a Repackager. The product could be shipped as a drop shipment. Drop ship orders for 340B transactions will be handled in Section 3 (See Section 3).

2.1 Transaction Scenarios and Details

2.1.1 Various Options of Data Sharing Based on Trading Partners' Business Decision

For DSCSA, there is no transfer of ownership between the Covered Entity and the Contract Pharmacy. While there is no explicit regulatory requirement for TI/TS to be exchanged between the Covered Entity and the Contract Pharmacy, there may be business trading operational requirements in place for DSCSA transaction data to be sent to the Contract Pharmacy based on trading partner agreements.

Options		What agreements should be in place?	Who gets the TI/TS data
1	The Seller sends TI/TS data solely to the Covered Entity, the Buyer.	• Required by law for Covered Entity	Covered Entity
2	The Seller sends TI/TS data solely to the Covered Entity, the Buyer, and the Covered Entity sends TI/TS data to the Contract Pharmacy.	• Required by law for Covered Entity • Agreement between Covered Entity and Contract Pharmacy to share data	Covered Entity and Contract Pharmacy
3	The Seller sends TI/TS data to both the Covered Entity, the Buyer, and the Contract Pharmacy.	• Required by law for Covered Entity • Agreement between Covered Entity and Contract Pharmacy to share data • Written permission to Seller from Covered Entity to send TI/TS data to Contract Pharmacy.	Covered Entity and Contract Pharmacy

Notes:

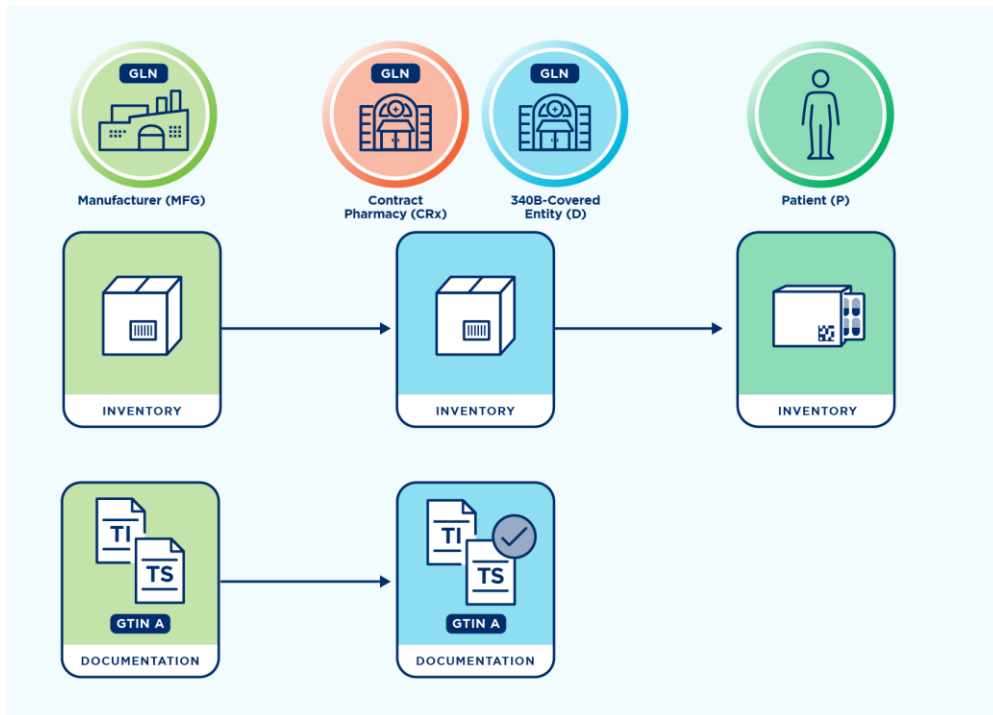
- The existence of an Agreement between parties does not equate to permission for sharing data; the Covered Entity shall provide written permission to Seller to provide the TI/TS to the Contract Pharmacy.
- There may be different types of agreements between the Covered Entity and Contract Pharmacy that dictate specific terms of what and how DSCSA information is provided to the Contract Pharmacy.
- There is no agreement required for the Covered Entity to send the TI/TS to the Contract Pharmacy but one may be in place to provide the necessary alignments between transaction parties.

- There may be scenarios where a Supplier may decide, absent an agreement to do otherwise, to not provide TI/TS to the Contract Pharmacy and only provide specific EPCIS event data (TI only).

2.1.2 340B Transactions involving parties under common ownership scenario

Under the 340B Replenishment Program, the Covered Entity (the Buyer) purchases the 340B-Eligible outpatient products from a supplier (the Seller). That supplier (Seller) fulfills the order for the Covered Entity (Buyer) and ships the product to a Pharmacy that is under the same common ownership as the Covered Entity. The corresponding DSCSA TS and TI documentation goes to the 340B Covered Entity (Buyer) that purchased the product.

Figure 2-1 340B Transactions Involving Parties Under Common Ownership



2.1.3 340B Transactions involving parties under different ownership scenario

Under the 340B Replenishment Program, the Covered Entity (the Buyer) purchases the 340B-Eligible outpatient products from a supplier (the Seller). That supplier (Seller) fulfills the order for the Covered Entity (Buyer) and ships the product from the order to the Contract Pharmacy. When the Contract Pharmacy receives 340B product, the corresponding DSCSA TS and TI documentation goes to the 340B Covered Entity (Buyer) that purchased the product.

The Contract Pharmacy has no relationship of common ownership with the Covered Entity in this scenario. As indicated in Section 2.1.1. above, for the Supplier to share the TI/TS with the Contract Pharmacy to enable the necessary reconciliation of the physical and electronic data there may be an agreement between the Covered Entity and Contract Pharmacy and the permission for that agreement should be communicated to the Supplier.

Figure 2-2A 340B Products Supplied by Wholesalers and Transactions Involving Parties Under Different Ownership Scenario

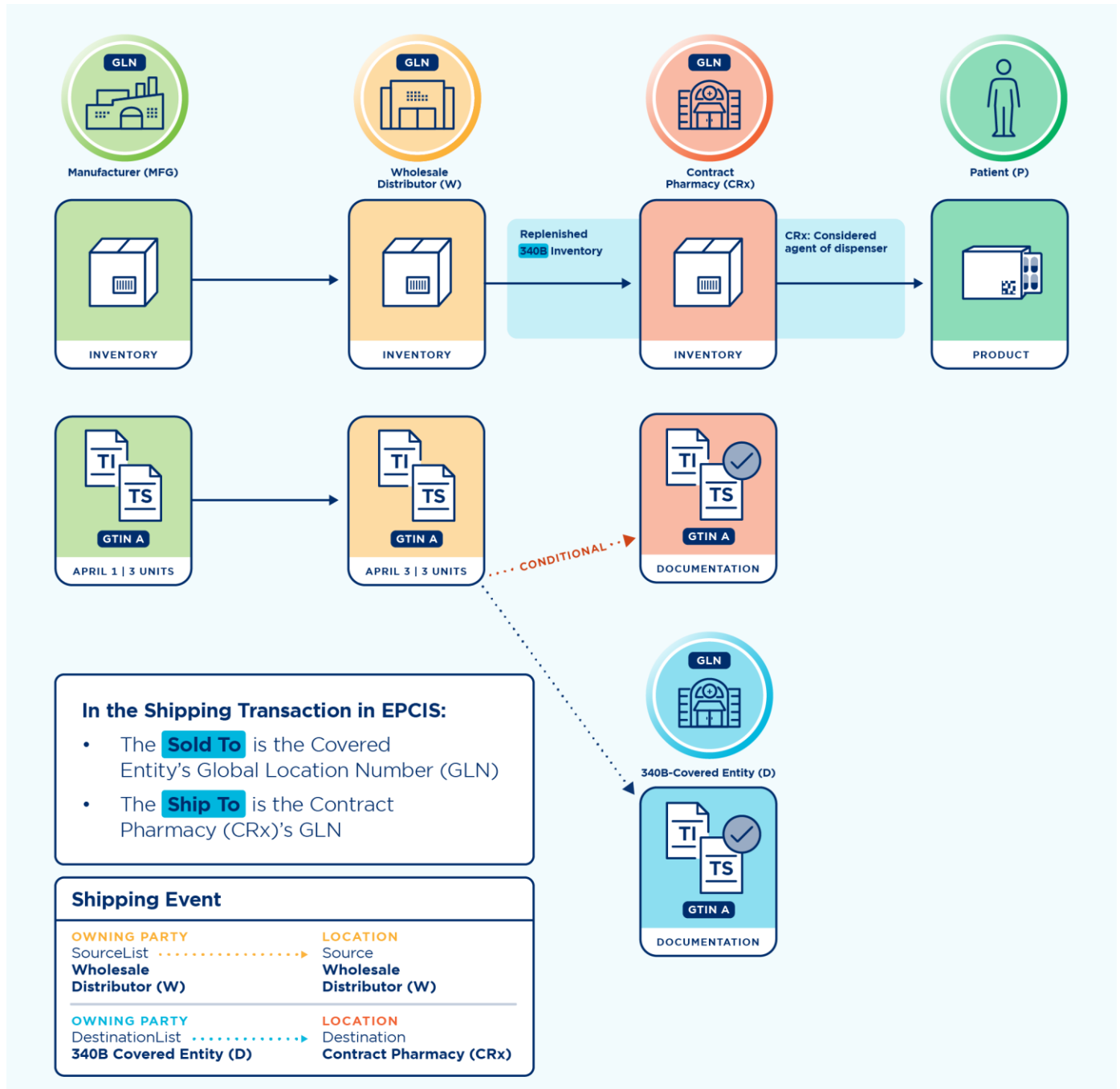
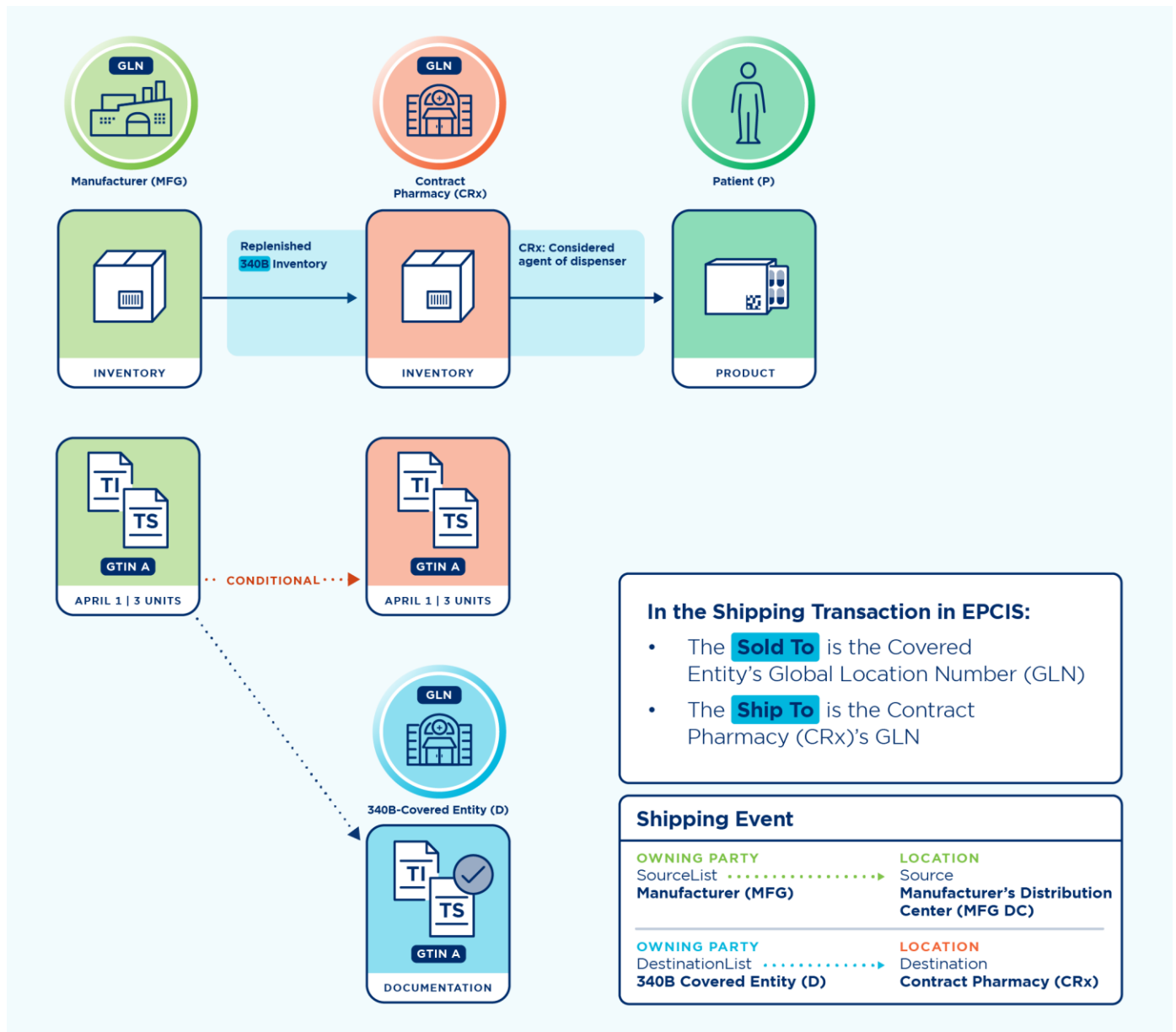


Figure 2-2B 340B Products Supplied by Manufacturers and Transactions Involving Parties Under Different Ownership Scenario

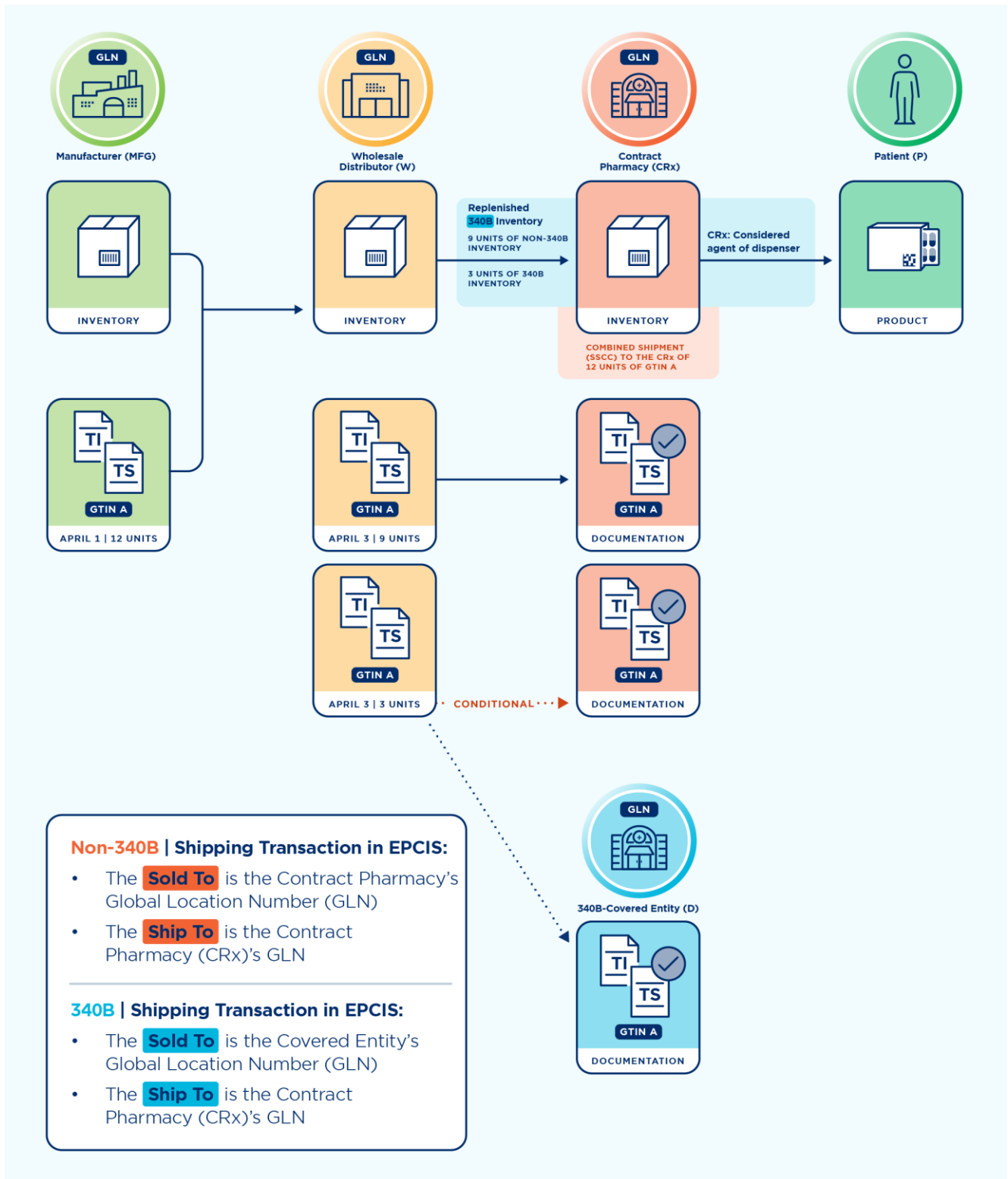


2.1.4 Comingled Shipping Containers

A Contract Pharmacy may receive a shipment from a Supplier that includes both 340B products and non-340B products in the same shipping container(s). These shipments are usually made by the Supplier to efficiently consolidate available logistics space. Although all products are shipped to the same location, ownership differs: 340B products are owned by the Covered Entity, while non-340B products are owned by the same receiving pharmacy (the Contract Pharmacy for 340B products).

- The TI/TS is different for these products as the owner is different per scenario.
- This requires 2 Sold-to GLNs for the same logistic unit.

Figure 2-3 Comingled Shipment Scenario Of 340B Products and Non-340B Products Shipped in the Same Shipment Container



2.1.4.1 Rationale:

- This process helps to ensure tote space is maximized while helping to reduce overall container volume for shipping.
- Sending the files to the appropriate owners maintains confidentiality. The files would reference the **same SSCC** at the level where the Purchase Orders ("PO") are combined.
- Each EPCIS document would only contain the information for the PO that is referenced in the urn:epcglobal:cbv:btt:po of the file.

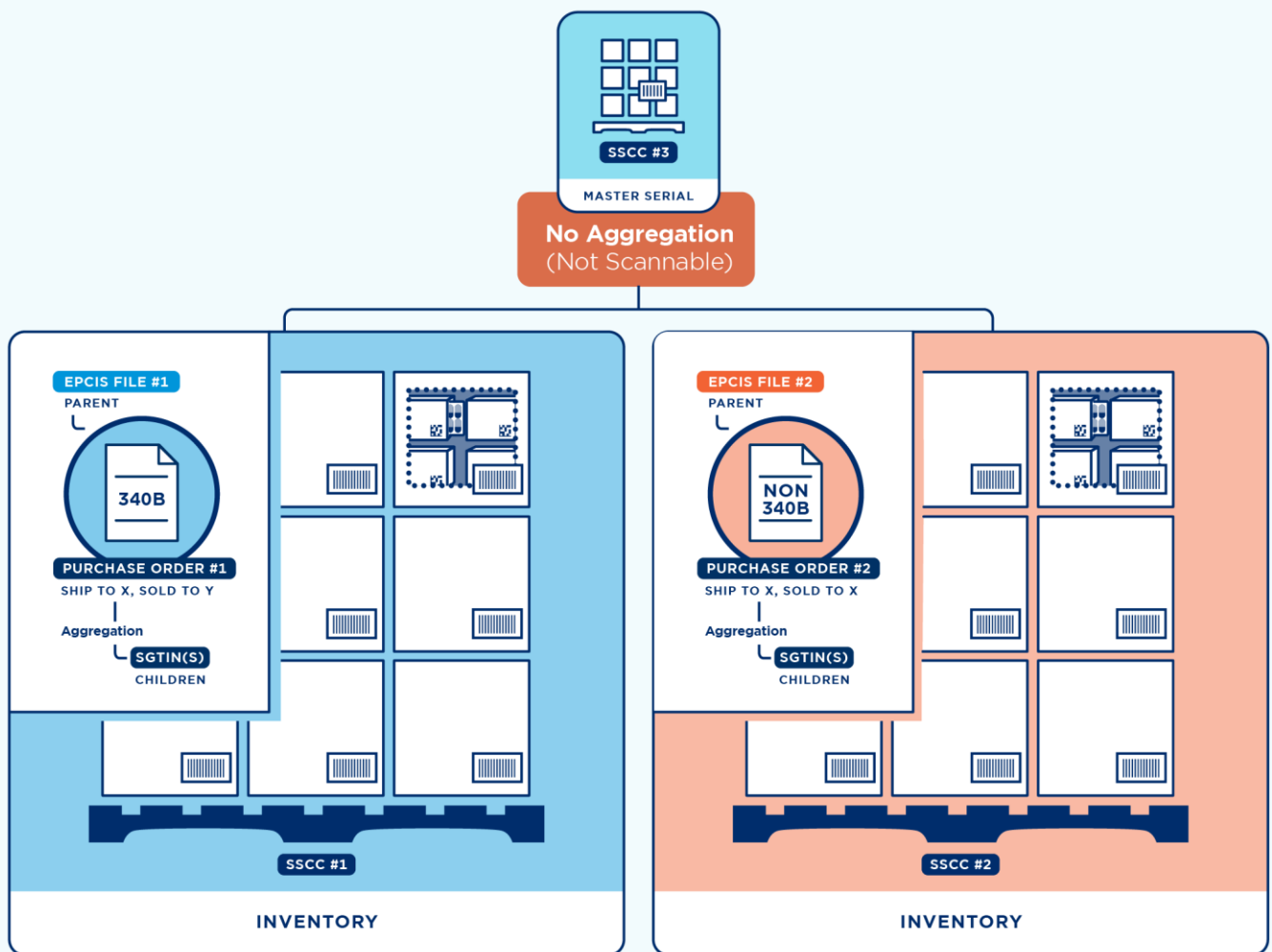
2.1.4.2 Key EPCIS considerations for comingled SSCC containing both 340B and non-340B products:

- The bizTransactionList of the Shipping event in the EPCIS document for the Covered Entity will list **ONLY the POs by the Covered Entity** and the **DESADVs** for the shipment of those products **owned by the Covered Entity and shipped to the Contract Pharmacy**.
- The bizTransactionList of the Shipping event in the EPCIS document for the Contract Pharmacy will list **ONLY the POs by the Contract Pharmacy** and the **DESADVs for the shipment** of those products **owned by the Contract Pharmacy and shipped to the Contract Pharmacy**
- The files will show different destinationList urn:epcglobal:cbv:sdt:owning_party.
- The EPCIS document for 340B products owned by the Covered Entity will show the Covered Entity as the destination owning party.
- The EPCIS document for non-340B products owned by the Contract Pharmacy will show the Contract Pharmacy as the destination owning party.
- The **Contract Pharmacy** is the **same ship-to location** for 340B products owned by the Covered Entity and the non-340B products purchased by the Contract Pharmacy. The EPCIS files will refer to the same destinationList urn:epcglobal:cbv:sdt:location, the Contract Pharmacy.
- Use **Transaction Events** to associate the specific EPCs belonging to PO and DESADV combination. This enables the reconciliation of EPCs to POs and DESADVs when there are multiple POs or multiple DESADVs.
- **DESADV (Despatch Advice) is the electronic dispatch notice which is a message that specifies details about the products sent.*

2.1.4.3 Option to Manage a Comingled Shipping Container

2.1.4.3.1 Two Separate EPCIS files and SSCC/Logistic Units with no Master SSCC/ Logistic Unit

Figure 2-4 Comingled Shipment Scenario Of 340B Products and Non-340B Products with a Non-Usable Master SSCC Logistics Unit that has no Associated Data



EPCIS Best Practice

Mark SSCC #3 as **not usable for scanning** for EPCIS system so it does not display an error. The P.O. will not be included but can include other transportation

- Wholesale Distributors electing to consolidate orders into a single **physical container/tote identified with an internal "master SSCC"** would **create separate EPCIS files** for the Covered Entity and the pharmacy physically receiving the order, the Contract Pharmacy.
 - A "Master" SSCC is used for the physical shipping unit only, it is not embedded into an EPCIS file
 - The SSCC would be identified on the outer container (SSCC#3 in the example above), but the SSCC scanned will not retrieve EPCIS data since SSCC#3 is not contained in any EPCIS data

file(s). Data shall be consumable by the supplier's operational system which supports the transportation process.

- To shield information for the 340B Covered Entities from the Contract Pharmacy, separate EPCIS documents are created for each owner of items in the consolidated tote.
 - Since the consolidated tote can contain both 340B and non-340B products, there will be an EPCIS document with TI/TS for each owner.
 - One EPCIS file for 340B product sold to the Covered Entity but shipped to the Contract Pharmacy.
 - One EPCIS file for the non-340B product sold and shipped to the Pharmacy that is also the Contract Pharmacy for the 340B products.
 - It is possible that the SSCC is unknown physically and only provided digitally. SSCCs in the shipping event of the EPCIS TI/TS document may appear in a scannable document inside the consolidated tote.
-  **Important:** For distributors and repackagers that choose this option to manage tote consolidation, the recommended practice is to have SSCCs (SSCC #1 & SSCC #2) that are scannable inside the container.
-  **Important:** Receivers should be prepared to scan each item in the tote if the SSCCs are not printed/provided with the tote. By scanning the item, relevant SSCC and TI/TS information should be digitally retrievable.
- Receivers need to prepare to have different POs and may have single or different Dispatch Notices (DESADV*s) across the same delivery.

2.1.5 Critical Aspects in Handling an Exception and/or Saleable Return

Effective communication between the Seller, Buyer, and Contract Pharmacy is crucial, especially when investigating and resolving exceptions or facilitating Saleable Returns. The Seller's obligation under DSCSA is to provide required information to the Buyer (the Covered Entity) but interactions with the Contract Pharmacy may be necessary. The Contract Pharmacy is as an agent of the Covered Entity in the case of a 340B transaction. Products related to exceptions or returns must be associated with the Covered Entity's purchase. Note that for DSCSA ownership transfer transactions, the "sold to" GLN is the key identifier, not the "ship to" GLN.

3 Drop Shipments

Under DSCSA a drop shipment refers to a transaction where a supplier (i.e. a manufacturer, wholesale distributor, repackager) directly ships a prescription drug product (as defined in the DSCSA) to a pharmacy or other authorized dispenser on behalf of a wholesale distributor (or other seller), while the payment and invoicing is handled by the seller that does not physically handle the product.

3.1 Background

Drop shipments are a common practice in the pharmaceutical supply chain because they can enhance efficiency and reduce costs particularly when items are out of stock or require expedient and/or special handling.

3.1.1 Transaction Information (TI) and Transaction Statement (TS)

3.1.1.1 Shipper's Responsibility

In a drop shipment, the manufacturer, repackager, wholesale distributor who physically ships the product is responsible for generating and providing the TI and TS data to the dispenser owning party. This data must be accurate and reflect the transaction details (See [Title II of the Drug Quality and Security Act § 582\(f\)](#)). See also draft guidance [Standardization of Data and Documentation Practices for Product Tracing Guidance for Industry §VI E](#).

3.1.1.2 Wholesale Distributor's Role

Wholesale distributors who don't physically handle (or store) the product in the transaction are typically exempt from the tracing requirements under DSCSA (See [Title II of the Drug Quality and Security Act § 582\(f\)](#)) in drop shipment scenarios. The order is still placed through the Wholesale Distributor as the business relationship is between the Manufacturer and the Wholesale Distributor.

3.1.1.3 Data Exchange

The DSCSA requires the electronic exchange of TI and TS data that includes details including product identification, serial numbers, lot numbers and transaction dates. This information is used to trace the drug product(s) through the supply chain. The Pharmacy (or other Dispenser) is responsible for receiving, verifying and storing the TI and TS data. This data must be exchanged electronically and in a standard format, such as Electronic Product Code Information System (EPCIS).

3.2 Problem

In a typical drop shipment scenario, the wholesale distributor is ordering product(s) from the manufacturer to ship directly to the wholesale distributor's customer. DSCSA has provisions enabling manufacturers to ship products ordered from the wholesale distributor directly to the wholesale distributor's customer by providing TI/TS directly to the wholesale distributor's customer. (See [Title II of the Drug Quality and Security Act § 582](#)). For transactions not involving 340B products, the TI/TS data provided includes the wholesale distributor as the Sold-To party and customer of the wholesale distributor location as the Ship-To location. While the non-340B TI/TS does not specify the wholesale distributor's Sold-To party, the Ship-To location is generally under the same organization as the wholesale distributor's Sold-To party (see table 4.2.1 below).

Table 3-1 Current Industry Model for Drop Shipments

Current Model for Drop Shipment	
Source Owning Party	Manufacturer Headquarters
Source Location	Manufacturer Warehouse
Destination Owning Party	Wholesaler Headquarters
Destination Location	Dispenser Pharmacy, generally under the same organization as Wholesaler's Sold-To party.

However, in a 340B drop shipment scenario, the wholesale distributor is ordering product(s) from the manufacturer to ship directly to the Contract Pharmacy and the Contract Pharmacy is the agent of the Covered Entity. The Covered Entity (not the Contract Pharmacy physically receiving the product) is the wholesale distributor's customer. Often, the Covered Entity is under different ownership than that of the Contract Pharmacy receiving the 340B product shipment.

The issue of the TI/TS data not explicitly including the wholesale distributor's Sold-To Party, the Covered Entity, requires a solution for the 340B drop shipment in this scenario.

3.3 Solution

To clarify that there are two ownership transfer transactions involved in a drop shipment and to explicitly identify the Sold-From and Sold-To parties for the two transactions, there should be two defined EPCIS transaction events. This enables explicit capturing of the two transactions pertaining to the product shipment:

- 1st transfer of ownership transaction is between Manufacturer and Wholesale Distributor
- 2nd transfer of ownership transaction is between Wholesale Distributor and the Wholesale Distributor's customer

By utilizing the existing EPCIS transaction event construct, the owners are not only explicitly defined, but it also serves as a mechanism for associating the Purchase Order (PO) pertinent for each transaction.

Moreover, this solution maintains a single shipping event to correctly reflect that there is only one physical shipment for a drop shipment transaction. In a drop shipment order, the Manufacturer is requested to ship the product directly to the Contract Pharmacy contracted by the wholesale distributor's customer. In this shipping event, the two POs involved in the two transactions can be defined using bizTransactionList.

3.3.1 Solution Benefits

- Leverages existing EPCIS and CBV standards with no additional U.S.-specific extensions required.
- Aligned with the approach for defining multiple POs.
- Captures ownership transfer information as EPCIS-compliant transaction events.
- Clearly identifies parties involved in 340B drop shipment transactions

3.4 Transfer of Ownership Transactions by Shipment Scenario

Table 3-2 Illustrating Transfer of Ownership by Shipment Scenario

Shipment Scenario #		Seller1	Buyer1	Seller2	Buyer2	Ship-From	Ship-To	# of Ownership Transfers	Is drop shipped	Is 340b drop shipped
1	Manufacturer (M) sells non-340B product to Customer (C) and Manufacturer (M) ships to Customer (C)	M	C	N/A	N/A	M	C	1	N	N
2	Wholesaler (W) sells non-340B product to Customer (C) and Wholesaler (W) ships to Customer (C)	W	C	N/A	N/A	W	C	1	N	N
3	Wholesaler (W) sells non-340B product to Customer (C) and Manufacturer (M) drop ships to Customer (C)	M	W	W	C	M	C	2	Y	N
4	Manufacturer (M) sells 340B product to Covered Entity (CE) and Manufacturer (M) ships to Contract Pharmacy (CRx)	M	CE	N/A	N/A	M	CRx	1	N	N
5	Wholesaler (W) sells 340B product to Covered Entity (CE) and Wholesaler (W) ships to Contract Pharmacy (CRx)	W	CE	N/A	N/A	W	CRx	1	N	N
6	Wholesaler (W) sells 340B product to Covered Entity (CE) and Manufacturer (M) drop ships to Contract Pharmacy (CRx)	M	W	W	CE	M	CRx	2	Y	Y

3.4.1 EPCIS Shipping Business Transaction Details representing non-340B Drop Shipment use case scenario #3

Table 3-3 EPCIS Transaction Event for Manufacturer/Repackager to Wholesaler Transaction-Non-340B Drop Shipment Use Case Scenario #3

This table shows how to populate the *first* Shipping Business Transaction Detail EPCIS transaction event for the ownership transfer transaction between Manufacturer/Repackager and Wholesaler.

Element	Usage	Type	Value	Reason
eventTime	Required	Timestamp	Date and time of event. (See Section 8.2.1) This should precede the date and time of the corresponding <i>Shipping</i> event.	The eventTime for the ownership transfer transaction between <i>Manufacturer/Repackager</i> and <i>Wholesaler</i> precedes the ownership transfer transaction between <i>Wholesaler</i> and its <i>Customer (C)</i> .
eventTimeZoneOffset	Required	String	Time zone offset in effect at the time and place where the event occurred.	EPCIS standard definition
recordTime	Optional	Timestamp	Date / time event was recorded in an EPCIS repository.	EPCIS standard definition
epcList	Required	List of URI	EPC Pure Identity URI for each object associated with the	EPCIS standard definition

Element	Usage	Type	Value	Reason
			business transactions listed in this event. If the EPC of a container is indicated, all of its contents are associated with the business transaction.	
action	Required	String	ADD	EPCIS standard definition
bizStep	Required	URI	urn:epcglobal:cbv:bizstep: shipping	CBV standard definition
disposition	Required	URI	urn:epcglobal:cbv:disp:in_transit	CBV standard definition. The disposition value "in_transit" is always paired with the bizStep "shipping" for forward logistics.
readPoint	Optional	URI	EPC Pure Identity URI for the GLN of the location at which the event took place. (See Section 8.2.2) This should match the readPoint of the corresponding <i>Shipping</i> event.	EPCIS standard definition
bizLocation	Omitted	URI	EPC Pure Identity URI for the GLN of the location where the objects are presumed to be following the event. (See Section 8.2.2)	For a <i>Shipping</i> event, this is unknown until a <i>Receiving</i> event occurs. Thus, bizLocation is always omitted in <i>Shipping</i> events.
bizTransaction List	Required	List of biz transactions	Business transactions governing this <i>Shipping Business Transaction Detail</i> event, which may include a purchase order, delivery number or an invoice (See Section 8.2.3 for details) Each transaction is represented as a pair of URIs: one URI for the type and one URI for the value. In a <i>Shipping Business Transaction Detail</i> event, only one business transaction of a given type shall be included.	Populate bizTransactionType= type="urn:epcglobal:cbv:btt:po"> with the wholesaler issued PO for the transaction between Manufacturer/Repackager and Wholesaler.
sourceList	Required	List of sources	Each source in the sourceList is a pair of URIs: one URI for the type and one URI for the value. The sourceList shall include one source of type urn:epcglobal:cbv:sdt:owning_party and another source of type urn:epcglobal:cbv:sdt:location. - The source value with source type of urn:epcglobal:cbv:sdt:owning_party is the EPC Pure Identity URI for the GLN of the transferring party. - The source value with source type of urn:epcglobal:cbv:sdt:location is	The Manufacturer/Repackager is the selling party for the transaction between Manufacturer/Repackager and Wholesaler. - Source value with source type of urn:epcglobal:cbv:sdt:owning_party is the EPC Pure Identity URI for the GLN of the Manufacturer/Repackager. The Manufacturer/Repackager's distribution center is the Ship-From location. - Source value with source type of urn:epcglobal:cbv:sdt:location is the EPC Pure Identity URI for the GLN of the Manufacturer/Repackager's distribution center.

Element	Usage	Type	Value	Reason
			the EPC Pure Identity URI of the ship-from GLN. Each GLN URI must match one of the companies in the company master data list.	
destinationList	Required	List of destinations	Each destination in the destinationList is a pair of URIs: one URI for the type and one URI for the value. The destinationList shall include one destination of type urn:epcglobal:cbv:sdt:owning_party and another destination of type urn:epcglobal:cbv:sdt:location. ■ The destination value with destination type of urn:epcglobal:cbv:sdt:owning_party is the EPC Pure Identity URI for the GLN of the transfer-to party. ■ The destination value with destination type of urn:epcglobal:cbv:sdt:location is the EPC Pure Identity URI of the ship-to GLN. ■ Each GLN URI must match one of the companies in the company master data list.	The Wholesaler is the buyer in the transaction between Manufacturer/Repackager and Wholesaler. ■ The destination value with destination type of urn:epcglobal:cbv:sdt:owning_party is the EPC Pure Identity URI for the GLN of the wholesaler. The Wholesaler Customer's location is the Ship-to location. ■ The destination value with destination type of urn:epcglobal:cbv:sdt:location is the EPC Pure Identity URI of the GLN for the Wholesaler Customer's location.

Table 3-4: EPCIS Transaction Event for Wholesaler to Customer Transaction – Non-340B Drop Shipment Use Case Scenario #3

This table shows how to populate the *second* Shipping Business Transaction Detail EPCIS transaction event for the ownership transfer transaction between Wholesaler and Wholesaler's Customer in use case scenario #3.

Element	Usage	Type	Value	Reason
eventTime	Required	Timestamp	Date and time of event. (See Section 8.2.1) This should precede the date and time of the corresponding <i>Shipping</i> event.	The eventTime for the ownership transfer transaction between <i>Wholesaler and Wholesaler's Customer</i> follows the ownership transfer transaction between Manufacturer/Re-packager and Wholesaler.
eventTimeZoneOffset	Required	String	Time zone offset in effect at the time and place where the event occurred.	EPCIS standard definition
recordTime	Optional	Timestamp	Date / time event was recorded in an EPCIS repository.	EPCIS standard definition

Element	Usage	Type	Value	Reason
epcList	Required	List of URI	- EPC Pure Identity URI for each object associated with the business transactions listed in this event. - If the EPC of a container is indicated, all of its contents are associated with the business transaction.	EPCIS standard definition
action	Required	String	ADD	EPCIS standard definition
bizStep	Required	URI	urn:epcglobal:cbv:bizstep: shipping	CBV standard definition
disposition	Required	URI	urn:epcglobal:cbv:disp:in_transit	CBV standard definition. The disposition value "in_transit" is always paired with the bizStep "shipping" for forward logistics.
readPoint	Optional	URI	EPC Pure Identity URI for the GLN of the location at which the event took place. (See Section 8.2.2) This should match the readPoint of the corresponding <i>Shipping</i> event.	EPCIS standard definition
bizLocation	Omitted	URI	EPC Pure Identity URI for the GLN of the location where the objects are presumed to be following the event. (See Section 8.2.2)	For a <i>Shipping</i> event, this is unknown until a <i>Receiving</i> event occurs. Thus, bizLocation is always omitted in <i>Shipping</i> events.
bizTransactionList	Required	List of biz transactions	Business transactions governing this <i>Shipping Business Transaction Detail</i> event, which may include a purchase order, delivery number or an invoice (See Section 8.2.3 for details) Each transaction is represented as a pair of URIs: one URI for the type and one URI for the value. In a <i>Shipping Business Transaction Detail</i> event, only one business transaction of a given type shall be included.	Populate bizTransactionType=type="urn:epcglobal:cbv:btt:po"> with the wholesaler customer's PO for the transaction between Wholesaler and Wholesaler's Customer.

Element	Usage	Type	Value	Reason
sourceList	Required	List of sources	Each source in the sourceList is a pair of URIs: one URI for the type and one URI for the value. The sourceList shall include one source of type urn:epcglobal:cbv:sdt:owning_party and another source of type urn:epcglobal:cbv:sdt:location. ■ The source value with source type of urn:epcglobal:cbv:sdt:owning_party is the EPC Pure Identity URI for the GLN of the transferring party. ■ The source value with source type of urn:epcglobal:cbv:sdt:location is the EPC Pure Identity URI of the ship-from GLN. ■ Each GLN URI must match one of the companies in the company master data list.	The Wholesaler is the selling party for the transaction between Wholesaler and Wholesaler's Customer. ■ The source value with source type of urn:epcglobal:cbv:sdt:owning_party is the EPC Pure Identity URI for the GLN of the Wholesaler. The Manufacturer/Repackager's distribution center is the Ship-From location. ■ The source value with source type of urn:epcglobal:cbv:sdt:location is the EPC Pure Identity URI for the GLN of the Manufacturer/Repackager's distribution center.
destinationList	Required	List of destinations	Each destination in the destinationList is a pair of URIs: one URI for the type and one URI for the value. The destinationList shall include one destination of type urn:epcglobal:cbv:sdt:owning_party and another destination of type urn:epcglobal:cbv:sdt:location. ■ The destination value with destination type of urn:epcglobal:cbv:sdt:owning_party is the EPC Pure Identity URI for the GLN of the transfer-to party. ■ The destination value with destination type of urn:epcglobal:cbv:sdt:location is the EPC Pure Identity URI of the ship-to GLN. Each GLN URI must match one of the companies in the company master data list.	The Wholesaler's customer is the buyer in the transaction between Wholesaler and Wholesaler's Customer, ■ The destination value with destination type of urn:epcglobal:cbv:sdt:owning_party is the EPC Pure Identity URI for the GLN of the Wholesaler's Customer. The Wholesaler Customer's location is the Ship-to location. ■ The destination value with destination type of urn:epcglobal:cbv:sdt:location is the EPC Pure Identity URI for the GLN of the Wholesaler Customer's location.

Table 3-5: EPCIS Object Event for the Non-340B Drop Shipment – Use Case Scenario #3

For quick reference, here's the table showing how to populate the Shipping EPCIS Object event capturing the non-340B drop shipment representing use case scenario #3.

Element	Usage	Type	Value	Reason
eventTime	Required	Timestamp	Date and time of event. (See Section 8.2.1).	EPCIS standard definition. For purposes of DSCSA, this is considered the shipping date (when bizStep = shipping).
eventTimeZoneOffset	Required	String	Time zone offset in effect at the time and place where the event occurred.	EPCIS standard definition
recordTime	Optional	Timestamp	Date/ time event was recorded in an EPCIS repository.	EPCIS standard definition
epcList	Required	List of URI	The EPC(s) of the outermost containers in the packaging hierarchy. Most likely, SSCCs of Cases or Pallets.	EPCIS standard definition
action	Required	String	OBSERVE	EPCIS standard definition
bizStep	Required	URI	urn:epcglobal:cbv:bizstep:shipping	CBV standard definition
disposition	Required	URI	urn:epcglobal:cbv:disp:in_transit	CBV standard definition. disposition value "in_transit" is always paired with bizStep "shipping" for forward logistics
readPoint	Optional	URI	EPC Pure Identity URI for the GLN of the location at which the event took place. (See Section 8.2.2)	EPCIS standard definition
bizLocation	Omitted	URI	EPC Pure Identity URI for the GLN of the location where the objects are presumed to be following the event. (See Section 8.2.2)	For a <i>Shipping</i> event, this is unknown until a <i>Receiving</i> event occurs. Thus, bizLocation is always omitted in <i>Shipping</i> events. (Note: source and destination elements in this event provide "Ship from/to" and "Transfer from/to" information.)
bizTransactionList	Optional	List of biz transactions	Business transactions governing this <i>Shipping</i> event, which may include a purchase order, delivery number or an invoice. (See Section 8.2.3 for details) Each transaction is represented as a pair of URIs: one URI for the type and one URI for the value. If more than one business transaction of the same type is included, then this event does <u>not</u> specify which objects in the epcList are associated with which business transaction. Optionally, the shipper may include one or more <i>Shipping Transaction Detail</i> events (Section 10.4.5) to associate specific objects with each business transaction.	List 2 POs <code>type="urn:epcglobal:cbv:btt:po"></code> involved in the transfer of ownership transactions for the drop shipment to align with the 2 transaction events included. 1. PO issued by Wholesaler for the transaction between Manufacturer/Repackager and Wholesaler. 2. PO issued by Wholesaler's Customer for the transaction between Wholesaler and Wholesaler's Customer. Continue to include delivery document(s) with <code>type="urn:epcglobal:cbv:btt:desadv"></code>

Element	Usage	Type	Value	Reason
sourceList	Required	List of sources	Each source in the sourceList is a pair of URIs: one URI for the type and one URI for the value. The sourceList shall include one source of type urn:epcglobal:cbv:sdt:owning_party and another source of type urn:epcglobal:cbv:sdt:location. ■ The source value with source type of urn:epcglobal:cbv:sdt:owning_party is the EPC Pure Identity URI for the GLN of the transferring party. ■ The source value with source type of urn:epcglobal:cbv:sdt:location is the EPC Pure Identity URI of the ship-from GLN. Each GLN URI must match one of the companies in the company master data list.	For the shipping object event, reflect the transaction between Manufacturer/Repackager and Wholesaler. In non-340B drop shipment use case, the Seller is the Manufacturer/Repackager. ■ The source value with source type of urn:epcglobal:cbv:sdt:owning_party is the EPC Pure Identity URI for the GLN of the Manufacturer/Repackager. The Manufacturer/Repackager's distribution center is the Ship-from location. ■ The source value with source type of urn:epcglobal:cbv:sdt:location is the EPC Pure Identity URI for the GLN of the Manufacturer/Repackager's distribution center.
destinationList	Required	List of destinations	Each destination in the destinationList is a pair of URIs: one URI for the type and one URI for the value. The destinationList shall include one destination of type urn:epcglobal:cbv:sdt:owning_party and another destination of type urn:epcglobal:cbv:sdt:location. ■ The destination value with destination type of urn:epcglobal:cbv:sdt:owning_party is the EPC Pure Identity URI for the GLN of the transfer-to party. ■ The destination value with destination type of urn:epcglobal:cbv:sdt:location is the EPC Pure Identity URI of the ship-to GLN. Each GLN URI must match one of the companies in the company master data list.	For the shipping object event, reflect the transaction between Manufacturer/Repackager and Wholesaler. In non-340B drop shipment use case, the Buyer is the Wholesaler, ■ The destination value with destination type of urn:epcglobal:cbv:sdt:owning_party is the EPC Pure Identity URI for the GLN of the Wholesaler. The Wholesaler Customer's location is the Ship-To location. ■ The destination value with destination type of urn:epcglobal:cbv:sdt:location is the EPC Pure Identity URI for the GLN of the Wholesaler Customer's location.

3.4.2 EPCIS Shipping Business Transaction Details representing 340B Drop Shipment - Use case scenario #6

Table 3-6: EPCIS Transaction Event for Manufacturer/Repackager to Wholesaler Transaction – 340B Drop Shipment Use Case Scenario #6

This table shows how to populate the first Shipping Business Transaction Detail EPCIS transaction event for the ownership transfer transaction between Manufacturer/Repackager and Wholesaler.

Element	Usage	Type	Value	Reason
eventTime	Required	Timestamp	Date and time of event. (See Section 8.2.1) This should precede the date and time of the corresponding <i>Shipping</i> event.	The eventTime for the ownership transfer transaction between <i>Manufacturer/Repackager</i> and <i>Wholesaler</i> precedes the ownership transfer transaction between Wholesaler and its Customer, the Covered Entity (CE).
eventTimeZoneOffset	Required	String	Time zone offset in effect at the time and place where the event occurred.	EPCIS standard definition
recordTime	Optional	Timestamp	Date / time event was recorded in an EPCIS repository.	EPCIS standard definition
epcList	Required	List of URI	- EPC Pure Identity URI for each object associated with the business transactions listed in this event. - If the EPC of a container is indicated, all of its contents are associated with the business transaction.	EPCIS standard definition
action	Required	String	ADD	EPCIS standard definition
bizStep	Required	URI	urn:epcglobal:cbv:bizstep: shipping	CBV standard definition
disposition	Required	URI	urn:epcglobal:cbv:disp:in_transit	CBV standard definition. The disposition value "in_transit" is always paired with the bizStep "shipping" for forward logistics.
readPoint	Optional	URI	EPC Pure Identity URI for the GLN of the location at which the event took place. (See Section 8.2.2) This should match the readPoint of the corresponding <i>Shipping</i> event.	EPCIS standard definition
bizLocation	Omitted	URI	EPC Pure Identity URI for the GLN of the location where the objects are presumed to be following the event. (See Section 8.2.2)	For a <i>Shipping</i> event, this is unknown until a <i>Receiving</i> event occurs. Thus, bizLocation is always omitted in <i>Shipping</i> events.

Element	Usage	Type	Value	Reason
bizTransaction List	Required	List of biz transactions	Business transactions governing this <i>Shipping Business Transaction Detail</i> event, which may include a purchase order, delivery number or an invoice (See Section 8.2.3 for details) Each transaction is represented as a pair of URIs: one URI for the type and one URI for the value. In a <i>Shipping Business Transaction Detail</i> event, only one business transaction of a given type shall be included.	Populate <code>bizTransactionType=type="urn:epcglobal:cbv:btt:po"></code> with the wholesaler issued PO for the transaction between Manufacturer/Repackager and Wholesaler.
sourceList	Required	List of sources	Each source in the sourceList is a pair of URIs: one URI for the type and one URI for the value. The sourceList shall include one source of type <code>urn:epcglobal:cbv:sdt:owning_party</code> and another source of type <code>urn:epcglobal:cbv:sdt:location</code>. - The source value with source type of <code>urn:epcglobal:cbv:sdt:owning_party</code> is the EPC Pure Identity URI for the GLN of the transferring party. - The source value with source type of <code>urn:epcglobal:cbv:sdt:location</code> is the EPC Pure Identity URI of the ship-from GLN. Each GLN URI must match one of the companies in the company master data list.	The Manufacturer/Repackager is the selling party for the transaction between Manufacturer/Repackager and Wholesaler. - The source value with source type of <code>urn:epcglobal:cbv:sdt:owning_party</code> is the EPC Pure Identity URI for the GLN of the Manufacturer/Repackager. The Manufacturer/Repackager's distribution center is the Ship-from location. - The source value with source type of <code>urn:epcglobal:cbv:sdt:location</code> is the EPC Pure Identity URI for the GLN of the Manufacturer/Repackager's distribution center.
destination List	Required	List of destinations	Each destination in the destinationList is a pair of URIs: one URI for the type and one URI for the value. The destinationList shall include one destination of type <code>urn:epcglobal:cbv:sdt:owning_party</code> and another destination of type <code>urn:epcglobal:cbv:sdt:location</code>. - The destination value with destination type of <code>urn:epcglobal:cbv:sdt:owning_party</code> is the EPC Pure Identity URI for the GLN of the transfer-to party. - The destination value with destination type of <code>urn:epcglobal:cbv:sdt:location</code> is the EPC Pure Identity URI of the ship-to GLN. Each GLN URI must match one of the companies in the company master data list.	The Wholesaler is the buyer for the transaction between Manufacturer/Repackager and Wholesaler. - The destination value with destination type of <code>urn:epcglobal:cbv:sdt:owning_party</code> is the EPC Pure Identity URI for the GLN of the Wholesaler. The Ship-to location is the Contract Pharmacy. - The destination value with destination type of <code>urn:epcglobal:cbv:sdt:location</code> is the EPC Pure Identity URI for the GLN of the Contract Pharmacy.

Table 3-7: EPCIS Transaction Event for Wholesaler to Covered Entity Transaction – 340B Drop Shipment Use Case Scenario #6

This table shows how to populate the second Shipping Business Transaction Detail EPCIS transaction event for the ownership transaction between Wholesaler and Covered Entity.

Element	Usage	Type	Value	Reason
eventTime	Required	Timestamp	Date and time of event. (See Section 8.2.1) This should precede the date and time of the corresponding <i>Shipping</i> event.	The <i>eventTime</i> for the ownership transfer transaction between <i>Wholesaler</i> and <i>Covered Entity</i> follows the ownership transfer transaction between <i>Manufacturer/Re-packager</i> and <i>Wholesaler</i> .
eventTimeZoneOffset	Required	String	Time zone offset in effect at the time and place where the event occurred.	EPCIS standard definition
recordTime	Optional	Timestamp	Date / time event was recorded in an EPCIS repository.	EPCIS standard definition
epcList	Required	List of URI	- EPC Pure Identity URI for each object associated with the business transactions listed in this event. - If the EPC of a container is indicated, all of its contents are associated with the business transaction.	EPCIS standard definition
action	Required	String	ADD	EPCIS standard definition
bizStep	Required	URI	urn:epcglobal:cbv:bizstep: shipping	CBV standard definition
disposition	Required	URI	urn:epcglobal:cbv:disp:in_transit	CBV standard definition. The disposition value "in_transit" is always paired with the bizStep "shipping" for forward logistics.
readPoint	Optional	URI	EPC Pure Identity URI for the GLN of the location at which the event took place. (See Section 8.2.2) This should match the readPoint of the corresponding <i>Shipping</i> event.	EPCIS standard definition
bizLocation	Omitted	URI	EPC Pure Identity URI for the GLN of the location where the objects are presumed to be following the event. (See Section 8.2.2)	For a <i>Shipping</i> event, this is unknown until a <i>Receiving</i> event occurs. Thus, bizLocation is always omitted in <i>Shipping</i> events.
bizTransactionList	Required	List of biz transactions	Business transactions governing this <i>Shipping Business Transaction Detail</i> event, which may include a purchase order, delivery number or an invoice (See Section 8.2.3 for details) Each transaction is represented as a pair of URIs: one URI for the type and one URI for the value. In a <i>Shipping Business Transaction Detail</i> event, only one business transaction of a given type shall be included.	For the transaction between <i>Wholesaler</i> and <i>Covered Entity</i>, specify the PO issued by Covered Entity with transaction <code>type="urn:epcglobal:cbv:btt:po"></code>.

Element	Usage	Type	Value	Reason
sourceList	Required	List of sources	Each source in the sourceList is a pair of URIs: one URI for the type and one URI for the value. The sourceList shall include one source of type urn:epcglobal:cbv:sdt:owning_party and another source of type urn:epcglobal:cbv:sdt:location. ■ The source value with source type of urn:epcglobal:cbv:sdt:owning_party is the EPC Pure Identity URI for the GLN of the transferring party. ■ The source value with source type of urn:epcglobal:cbv:sdt:location is the EPC Pure Identity URI of the ship-from GLN. Each GLN URI must match one of the companies in the company master data list.	The Wholesaler is the selling party for the transaction between Wholesaler and Covered Entity. ■ The source value with source type of urn:epcglobal:cbv:sdt:owning_party is the EPC Pure Identity URI for the GLN of the Wholesaler. The Manufacturer/Repackager's distribution center is the Ship-from location. ■ The source value with source type of urn:epcglobal:cbv:sdt:location is the EPC Pure Identity URI for the GLN of the Manufacturer/Repackager's distribution center.
destinationList	Required	List of destinations	Each destination in the destinationList is a pair of URIs: one URI for the type and one URI for the value. The destinationList shall include one destination of type urn:epcglobal:cbv:sdt:owning_party and another destination of type urn:epcglobal:cbv:sdt:location. ■ The destination value with destination type of urn:epcglobal:cbv:sdt:owning_party is the EPC Pure Identity URI for the GLN of the transfer-to party. ■ The destination value with destination type of urn:epcglobal:cbv:sdt:location is the EPC Pure Identity URI of the ship-to GLN. Each GLN URI must match one of the companies in the company master data list.	The Covered Entity is the Buyer in the transaction between Wholesaler and Covered Entity, ■ The destination value with destination type of urn:epcglobal:cbv:sdt:owning_party is the EPC Pure Identity URI for the GLN of the Covered Entity. The Contract Pharmacy is the Ship-To location. ■ The destination value with destination type of urn:epcglobal:cbv:sdt:location is the EPC Pure Identity URI for the GLN of the Contract Pharmacy.

Table 3-8: EPCIS Object Event for the 340B Drop Shipment – Use Case Scenario #6

For quick reference, here's the table showing how to populate the Shipping EPCIS Object event capturing the 340B drop shipment representing use case scenario #6

Element	Usage	Type	Value	Reason
eventTime	Required	Timestamp	Date and time of event. (See Section 8.2.1).	EPCIS standard definition. For purposes of DSCSA, this is considered the shipping date (when bizStep = shipping).
eventTimeZoneOffset	Required	String	Time zone offset in effect at the time and place where the event occurred.	EPCIS standard definition
recordTime	Optional	Timestamp	Date/ time event was recorded in an EPCIS repository.	EPCIS standard definition
epcList	Required	List of URI	The EPC(s) of the outermost containers in the packaging hierarchy. Most likely, SSCCs of Cases or Pallets.	EPCIS standard definition
action	Required	String	OBSERVE	EPCIS standard definition
bizStep	Required	URI	urn:epcglobal:cbv:bizstep:shipping	CBV standard definition
disposition	Required	URI	urn:epcglobal:cbv:disp:in_transit	CBV standard definition. disposition value "in_transit" is always paired with bizStep "shipping" for forward logistics
readPoint	Optional	URI	EPC Pure Identity URI for the GLN of the location at which the event took place. (See Section 8.2.2)	EPCIS standard definition
bizLocation	Omitted	URI	EPC Pure Identity URI for the GLN of the location where the objects are presumed to be following the event. (See Section 8.2.2)	For a <i>Shipping</i> event, this is unknown until a <i>Receiving</i> event occurs. Thus, bizLocation is always omitted in <i>Shipping</i> events. (Note: source and destination elements in this event provide "Ship from/to" and "Transfer from/to" information.)
bizTransactionList	Optional	List of biz transactions	Business transactions governing this <i>Shipping</i> event, which may include a purchase order, delivery number or an invoice. (See Section 8.2.3 for details) Each transaction is represented as a pair of URIs: one URI for the type and one URI for the value. If more than one business transaction of the same type is included, then this event does <u>not</u> specify which objects in the epcList are associated with which business transaction. Optionally, the shipper may include one or more <i>Shipping Transaction Detail</i> events (Section 10.4.5) to associate specific objects with each business transaction.	List 2 POs <code>type="urn:epcglobal:cbv:btt:po"></code> involved in the transfer of ownership transactions for the drop shipment to align with the 2 transaction events included. - PO issued by Wholesaler for the transaction between Manufacturer/Repackager and Wholesaler - PO issued by Covered Entity for the transaction between Wholesaler and Covered Entity Continue to include delivery document(s) with <code>type="urn:epcglobal:cbv:btt:desadv"></code>

Element	Usage	Type	Value	Reason
sourceList	Required	List of sources	Each source in the sourceList is a pair of URIs: one URI for the type and one URI for the value. The sourceList shall include one source of type urn:epcglobal:cbv:sdt:owning_party and another source of type urn:epcglobal:cbv:sdt:location. ■ The source value with source type of urn:epcglobal:cbv:sdt:owning_party is the EPC Pure Identity URI for the GLN of the transferring party. ■ The source value with source type of urn:epcglobal:cbv:sdt:location is the EPC Pure Identity URI of the ship-from GLN. Each GLN URI must match one of the companies in the company master data list.	For the shipping object event, reflect the transaction between Manufacturer/Repackager and Wholesaler. In the 340B drop shipment use case, the Seller is the Manufacturer/Repackager. ■ The source value with source type of urn:epcglobal:cbv:sdt:owning_party is the EPC Pure Identity URI for the GLN of the Manufacturer/Repackager. The Manufacturer/Repackager's distribution center is the Ship-from location. ■ The source value with source type of urn:epcglobal:cbv:sdt:location is the EPC Pure Identity URI for the GLN of the Manufacturer/Repackager's distribution center.
destinationList	Required	List of destinations	Each destination in the destinationList is a pair of URIs: one URI for the type and one URI for the value. The destinationList shall include one destination of type urn:epcglobal:cbv:sdt:owning_party and another destination of type urn:epcglobal:cbv:sdt:location. ■ The destination value with destination type of urn:epcglobal:cbv:sdt:owning_party is the EPC Pure Identity URI for the GLN of the transfer-to party. ■ The destination value with destination type of urn:epcglobal:cbv:sdt:location is the EPC Pure Identity URI of the ship-to GLN. Each GLN URI must match one of the companies in the company master data list.	For the shipping object event, reflect the transaction between Manufacturer/Repackager and Wholesaler. In 340B drop shipment use case, the Buyer is the Wholesaler, ■ The destination value with destination type of urn:epcglobal:cbv:sdt:owning_party is the EPC Pure Identity URI for the GLN of the Wholesaler. The Contract Pharmacy is the Ship-To location. ■ The destination value with destination type of urn:epcglobal:cbv:sdt:location is the EPC Pure Identity URI for the GLN of the Contract Pharmacy.

3.4.3 EPCIS XML Examples

XML Examples illustrating use of proposed transaction events for expressing the two changes of ownership transactions in Drop shipment scenarios can be [found here](#).

- Use Case Scenario #3: Non-340BDropShip SellerExch1-R1_2.xml – aligns with GS1 US DSCSA Implementation Guideline R1.2
- Use Case Scenario #3: Non-340BDropShip_SellerExch1-R1_3.xml – aligns with GS1 US DSCSA Implementation Guideline R1.3

- Use Case Scenario #6: 340BDropShip_SellerExch1-R1_2.xml – aligns with GS1 US DSCSA Implementation Guideline R1.2
- Use Case Scenario #6: 340BDropShip_SellerExch1-R1_3.xml – aligns with GS1 US DSCSA Implementation Guideline R1.3

The following are the ONLY 3 differences in the example XML files:

- The XML examples aligned with GS1 US DSCSA Implementation Guideline R1.3 have 2 extra extension segments compared to the XML examples aligned with GS1 US DSCSA Implementation Guideline R1.2.

1. 118 | | | | | `<gs1ushc:guidelineVersion>GS1 US DSCSA R1.3</gs1ushc:guidelineVersion>`
2. 348 | | | | | `<gs1ushc:dropShipment>true</gs1ushc:dropShipment>`
3. In GS1 US DSCSA Implementation Guideline R1.3, NDC is expressed as 10-digit NDC with dashes with US_FDA_NDC as the additionalTradeItemIdentificationTypeCode.

```

38 | | | | | <VocabularyElementList>
39 | | | | | <!-- master data for lowest saleable unit -->
40 | | | | | <VocabularyElement id="urn:epc:idpat:sgtin:030001.0012345.*">
41 | | | | |   <attribute
42 | | | | |     id="urn:epcglobal:cbv:mda#additionalTradeItemIdentification">0001-0123-45</attribute>
42 | | | | |     <attribute
42 | | | | |       id="urn:epcglobal:cbv:mda#additionalTradeItemIdentificationTypeCode">US_FDA_NDC</attribute>

```

- In GS1 US DSCSA Implementation Guideline R1.2, NDC is expressed in 11-digit format, with FDA_NDC_11 as the additionalTradeItemIdentificationTypeCode.

```

38 | <VocabularyElementList>
39 | <!-- master data for lowest saleable unit -->
40 | <VocabularyElement id="urn:epc:idpat:sgtin:030001.0012345.*">
41 |   <attribute id="urn:epcglobal:cbv:mda#additionalTradeItemIdentification">00001012345</attribute>
42 |   <attribute id="urn:epcglobal:cbv:mda#additionalTradeItemIdentificationTypeCode">FDA_NDC_11</attribute>
43 |   <attribute id="urn:epcglobal:cbv:mda#regulatedProductName">Epcistra</attribute>
44 |   <attribute id="urn:epcglobal:cbv:mda#manufacturerOfTradeItemPartyName">GS1 Pharma LLC</attribute>
45 |   <attribute id="urn:epcglobal:cbv:mda#dosageFormType">PILL</attribute>
46 |   <attribute id="urn:epcglobal:cbv:mda#strengthDescription">100mg</attribute>
47 |   <attribute id="urn:epcglobal:cbv:mda#netContentDescription">500 pills</attribute>
48 | </VocabularyElement>

```

4 Appendix

A.1 Glossary of Terms

Term	Acronym	Definition
Government Definitions:		
Drug Supply Chain Security Act	DSCSA	The Drug Quality and Security Act (DQSA) was enacted by Congress on November 27, 2013. Title II of DQSA, the Drug Supply Chain Security Act (DSCSA), outlines steps to achieve interoperable, electronic tracing of products at the package level to identify and trace certain prescription drugs as they are distributed in the United States. [Source: https://www.fda.gov/drugs/drug-supply-chain-integrity/drug-supply-chain-security-act-dscsa]
Transaction Information	TI	Information required by the DSCSA that describes the owning parties, the covered products, and dates that the activity took or is taking place. In an EPCIS document this information is spread throughout the file. Table 10-1 in Section 10 of the GS1 US DSCSA Implementation Guideline R1.3 maps DSCSA Data Attribute to relevant EPCIS segments. Sec. 581 “(26) Transaction information.--The term ‘transaction information’ means-- “(A) the proprietary or established name or names of the product; “(B) the strength and dosage form of the product; “(C) the National Drug Code number of the product; “(D) the container size; “(E) the number of containers; “(F) the lot number of the product; “(G) the date of the transaction; “(H) the date of the shipment, if more than 24 hours after the date of the transaction; “(I) the business name and address of the person from whom ownership is being transferred; and “(J) the business name and address of the person to whom ownership is being transferred. Source: (FDA.gov DSCSA text web document)

Term	Acronym	Definition
Transaction Statement	TS	An attestation by the seller of a covered product stating that they followed the directives set forth by the DSCSA. Table 10-1 in Section 10 of the GS1 US DSCSA Implementation Guideline R1.3 maps DSCSA Data Attribute to relevant EPCIS segments. Transaction Statement is also covered in Section 10.1. Sec. 581: “(27) Transaction statement --The ‘transaction statement’ is a statement, in paper or electronic form, that the entity transferring ownership in a transaction-- “(A) is authorized as required under the Drug Supply Chain Security Act; “(B) received the product from a person that is authorized as required under the Drug Supply Chain Security Act; “(C) received transaction information and a transaction statement from the prior owner of the product, as required under section 582; “(D) did not knowingly ship a suspect or illegitimate product; “(E) had systems and processes in place to comply with verification requirements under section 582; “(F) did not knowingly provide false transaction information; and “(G) did not knowingly alter the transaction history. Source: (FDA.gov DSCSA text web document)
Trading Partner Definitions:		
Manufacturer		A manufacturer is defined in section 581(10) of the FD&C Act to mean: [W]ith respect to a product -- (A) a person that holds an application approved under section 505 or a license issued under section 351 of the Public Health Service Act for such product, or if such product is not the subject of an approved application or license, the person who manufactured the product; (B) a co-licensed partner of the person described in subparagraph (A) that obtains the product directly from a person described in this subparagraph or subparagraph (A) or (C); or (C) an affiliate of a person described in subparagraph (A) or (B) that receives the product directly from a person described in this subparagraph or subparagraph (A) or (B).

Term	Acronym	Definition
Repackager		DSCSA defines repackager in section 581(16) of the FD&C Act as “a person who owns or operates an establishment that repacks and relabels a product or package for – (A) further sale; or (B) distribution without a further transaction.”
Wholesaler		DSCSA defines wholesale distributor in section 581(29) of the FD&C Act to mean “a person (other than a manufacturer, a manufacturer’s co-licensed partner, a third-party logistics provider, or repackager) engaged in wholesale distribution (as defined in section 503(e)(4) of the FD&C Act, as amended by [DSCSA]).”
Contract Manufacturing Organization	CMO	For the purposes of the DSCSA, a CMO is an entity that performs manufacturing operations for the NDA/ANDA/BLA holder or a co-licensed partner of the NDA/ANDA/BLA holder, to fulfill a contractual obligation with such manufacturer, but is not responsible for the introduction of the product into interstate commerce. [Source: http://pdsaonline.org/wp-content/uploads/2015/06/PDSA-Letter_DSCSA-QA_May-2014.pdf]
Third Party Logistics	3PL	DSCSA defines a 3PL in section 581(22) of the FD&C Act to mean: [A]n entity that provides or coordinates warehousing, or other logistics services of a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of a product, but does not take ownership of the product, nor has responsibility to direct the sale or disposition of the product.
Dispenser		The term dispenser, as defined in section 581(3) of the FD&C Act: (A) means a retail pharmacy, hospital pharmacy, a group of chain pharmacies under common ownership and control that do not act as a wholesale distributor, or any other person authorized by law to dispense or administer prescription drugs, and the affiliated warehouses or distribution centers of such entities under common ownership and control that do not act as a wholesale distributor; and (B) does not include a person who dispenses only products to be used in animals in accordance with section 512(a)(5).
GS1 Standards:		
GS1 Company Prefix	GCP	A GS1 Company Prefix is a unique string of 6–11 digits issued to your company by your local GS1 Member Organization.
Global Trade Item Number®	GTIN®	The Global Trade Item Number (GTIN) is the globally unique GS1 identification number used to identify “trade items” (i.e., products and services that may be priced, ordered, or invoiced at any point in the supply chain).
Serialized GTIN	SGTIN	An SGTIN is the combination of a GTIN and a unique serial number of up to 20 alphanumeric characters.
Global Location Number	GLN	The Global Location Number (GLN) is the globally unique GS1 Identification Number used to identify parties and locations.

Term	Acronym	Definition
Serialized Global Location Number	SGLN	The term SGLN refers to an EPC URI syntax for GLNs that is used in EPCIS. The SGLN syntax is capable of representing a plain GLN (without extension) or a GLN plus extension.
Serial Shipping Container Code	SSCC	The Serial Shipping Container Code (SSCC) is the globally unique GS1 identification number used to identify individual logistic units. A "logistic unit" is defined as an item of any composition established for transport and/or storage which needs to be tracked individually and managed through the supply chain.
Electronic Product Code	EPC®	The Electronic Product Code™ (EPC) is syntax for unique identifiers assigned to physical objects, unit loads, locations, or other identifiable entity playing a role in business operations.
Electronic Product Code Information Services	EPCIS	The EPC Information Services (EPCIS) standard defines a data model and a data-sharing interface that enables supply chain partners to capture and communicate data about the movement and status of objects in the supply chain.
Data Carriers and Barcode Related:		
GS1 DataMatrix		GS1 DataMatrix is a two-dimensional (2D) barcode which may be printed as a square or rectangular symbol made up of individual squares.
Universal Product Code	U.P.C.	A U.P.C. is a type of barcode. Specifically, a UPC-A is a barcode that can hold a GTIN-12, and is familiar from its use on consumer products in North America.
Human Readable Interpretation	HRI	Human Readable Interpretation (HRI) is the printed representation of the data encoded in a barcode (e.g., GS1 DataMatrix or GS1-128 barcode).
Human Readable Form		Human-readable refers to product identifiers on their packaging that can be read absent of requiring a machine.



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IAPMO

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