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GS1 Healthcare US

Addendum: Diagrams and XML Examples for Chain of Custody of Supply Chain Choreographies

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Document Summary

Document Item	Current Value
Document Title	Addendum: Diagrams and XML Examples for Chain of Custody of Supply Chain Choreographies
Date Last Modified	April 2024
Document Description	The purpose of this document is to establish the requirements and define specifications for capturing custody changes using Electronic Product Code Information Services (EPCIS) serialized data exchange for the U.S. market.

Log of Changes

Release Number – Date	Changes
Release 1.0 - March 2021	Release/publication
Release 1.2 – April 2024	Updated content to be in line with Applying GS1 System of Standards for DSCSA and Serialized Interoperable Traceability Implementation Guideline Release 1.3 and Addendum: Guidance and XML Examples for Supply Chain Choreographies in Serialized Item-Level Management.

1 Preface

1.1 Introduction

The purpose of this document is to establish the requirements and define specifications for capturing custody changes using Electronic Product Code Information Services (EPCIS) serialized data exchange for the U.S. market. Contract Manufacturers (CMOs), Contract Packagers (CPOs), Third Party Logistic (3PLs) and Reverse Logistics Providers (RLPs) are supply chain partners who perform services on behalf of manufacturers, repackagers and wholesalers. To facilitate operational serialized data exchanges between manufacturers, repackagers, wholesalers and their third-party supply chain service agents, the GS1 Healthcare US Rx Secure Supply Chain workgroup developed this implementation guideline to provide direction to the communication of chain of custody events between supply chain partners using EPCIS. Since chain of custody event information feeds the serialized traceability required by the Drug Supply Chain Security Act (DSCSA), the Chain of Custody EPCIS event data exchanges are designed to help enable and ease the formation of subsequent DSCSA events by helping to ensure that critical field data generated in the chain of custody events are populated and transmitted. EPCIS is a GS1 Standard that helps enable supply chain partners to capture event information about supply chain events (e.g., shipped; received; etc.), and to share that information with their trading partners securely and in near real-time.

This addendum introduces the end-to-end business scenarios for forward and reverse logistics in the pharmaceutical supply chain with third party agents of the manufacturers, repackagers, wholesalers, and dispensers. This addendum is complementary to the R1.0 Implementation Guideline Applying GS1 System of Standards to Pharmaceutical "Chain of Custody". It details the business processes for unregulated transactions between Trading Partners. It is intended to present the practical business scenarios in the pharmaceutical supply chain of custody events between manufacturers, distributors, dispensers, and their third-party supply chain agent: CMOs, CPOs, 3PLs and RLPs. For each business scenario, the specifics of the EPCIS event messages that are relevant for the third-party supply chain message exchange will be identified and illustrated with XML examples. You will be able to access and download the XML examples for forward distribution and reverse logistic scenarios through the below links. Each link will open a zip file with all the XML examples for each scenario.

- [Forward distribution scenarios](#)
- [Reverse logistics scenarios](#)

1.2 Document Information

This addendum was developed by GS1 US® and the Rx Secure Supply Chain Workgroup to assist the U.S. pharmaceutical industry in implementing the GS1 System of Standards to support traceability. It is based on the *GS1 General Specifications*, the *EPC Tag Data Standard (Version 2.0)*, the *EPCIS Standard (Version 1.2)*, and the *Core Business Vocabulary Standard (Version 1.2)*. It was developed using information obtained from a wide variety of members of the U.S. pharmaceutical supply chain from manufacturers, repackagers, wholesalers, and their supply chain trading partners along with pharmaceutical industry solution providers.



Important: As with all GS1 Standards and solutions, this guideline is voluntary, not mandatory. It should be noted that use of the words "must" and "require" throughout this document relate exclusively to technical recommendations for the proper application of the standards to support the integrity of your implementation.

1.3 Purpose

This document specifies how EPCIS can be leveraged as a standard for contracted third party agents such as CMOs, CPOs, 3PLs and RLPs to capture the operational product activities involved in the chain of custody of serialized pharmaceutical product transactions with their contracting DSCSA supply chain stakeholders: (e.g., Manufacturers, Repackagers, and Wholesalers.) It lists the specific set of EPCIS event attributes, XML examples with their respective usage requirements, and business rules applicable for CMOs, CPOs, 3PLs, and RLPs for each supply chain event involved in the Chain of Custody business information exchange.

By so doing, this document serves as an addendum to the Implementation Guideline 1.0 for managing the serialized Chain of Custody information exchanges and providing guidance to industry members about how to apply the GS1 System of Standards to their software solutions to support product serialization and item level traceability.

1.4 Scope

This addendum defines the EPCIS events (XML data format) to support business process for the contracted supply chain partners of the pharmaceutical manufacturers, repackagers and wholesalers, as they manage the business transaction and chain of custody of their serialized products at the item level. **It does not provide any guidance or advice regarding regulatory compliance.** Federal requirements for traceability in the pharmaceutical supply chain are specified in the 2013 Drug Supply Chain Security Act (DSCSA) and subsequent FDA Guidance(s). The specifications for applying GS1 System for DSCSA and Traceability are detailed in the [GS1 US DSCSA Implementation Guideline, R1.2](#) and [GS1 US DSCSA Implementation Guideline, R1.3](#).

This guideline reflects current industry best practices for managing the chain of custody for commercial serialized item traceability, prior to being placed into DSCSA commerce, or returns back from the pharmacy dispensers and healthcare providers.

2 EPCIS Events for Serialized Item Level Traceability

2.1 Chain of Custody Supply Chain Choreographies

To properly represent the specific activities and responsibilities of the agents and supply chain partners of the pharmaceutical manufacturers and wholesalers, we developed choreographies with business steps and electronic exchange of data with XML examples. This only includes Rx products to be serialized in accordance with DSCSA. There are a total of thirteen unique forward distribution scenarios which should encompass the majority of business cases to be executed by a Contract Manufacturer, Contract Packager, and Third-Party Logistics Provider on behalf of our manufacturer, repackager, wholesaler and dispenser. These supply chain choreographies represent forward distribution examples, and we will address the reverse logistic in section 2.2.

In this addendum we have one section focused on forward logistics and another focused on reverse logistics. Across the supply chain choreographies, there are 13 forward distribution and 4 reverse logistics scenarios. Each of the scenarios have 3 sub-sections of its own:

- The Physical and Data Flow Diagram,
- The Table of EPCIS messages exchanged by Sending and Receiving parties, and
- XML examples of the EPCIS messages exchanged by Sending and Receiving parties

2.2 Chain of Custody Forward Distribution Supply Chain Choreographies

These 13 forward distribution scenarios focus on the physical flow of products with the Chain of Custody Business Processes plus the data flows of Electronic Exchange between the supply chain trading partners.

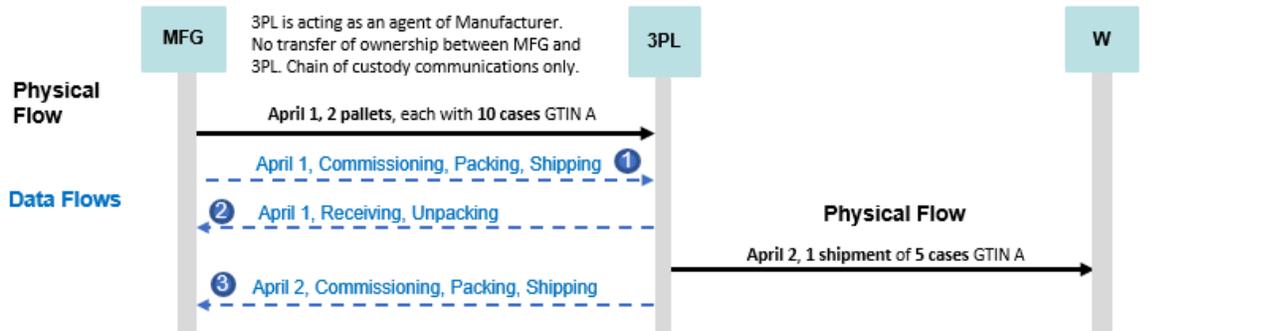
The XML examples for forward distribution scenarios can be accessed [here](#).

2.2.1 Manufacturer utilizes a 3PL for logistics service.

[MFG->3PL]->W

2.2.1.1 The Physical and Data Flow Diagram

In the diagram below the physical and data flows between the Manufacturers, 3rd Party Logistics Provider and the Wholesaler are depicted in the three steps.



	Chain of Custody Business Steps	Message Sending Party	Message Receiving Party	Chain of Custody Electronic Exchange
1	Manufacturer (MFG) ships product to 3PL on April 1	MFG	3PL	MFG sends EPCIS Commissioning, Packing, and Shipping data
2	3PL receives shipment from Manufacturer on April 1	3PL	MFG	3PL sends EPCIS Receiving and Unpacking data
3	3PL fulfills order and ships product to Wholesaler (W) on April 2	3PL	MFG	3PL sends EPCIS logistics Commissioning, Packing, and Shipping data, as applicable, to MFG

Note: Dates are shown for illustrative purposes only.

2.2.1.2 Table of EPCIS messages exchanged by Sending and Receiving parties

The schedule below details the EPCIS Sending and Receiving parties with each of the XML examples for the bizSteps for each attribute between the trading partners.

Scenario: 1. Manufacturer utilizes a 3PL for logistics services - XML Examples									
Scenario Step	EPCIS Sending Party	EPCIS Receiving Party	relevant CoC EPCIS Events	readPoint	bizLocation	sourceOwningParty	sourceLocation	destOwningParty	destLocation
1 Manufacturer (MFG) ships product to 3PL on April 1	MFG	3PL	Commissioning	MFG	MFG				
			Packing	MFG	MFG				
			Shipping	MFG	N/A (Omitted)	MFG	MFG	MFG	3PL
2 3PL receives shipment from Manufacturer (MFG) on April 1	3PL	MFG	Receiving	3PL	3PL	MFG	MFG	MFG	3PL
			Unpacking	3PL	3PL				
3 3PL fulfills order and ships product to Wholesaler (W) on April 2	3PL	MFG	Commissioning (SSCCs)	3PL	3PL				
			Packing	3PL	3PL				
			Shipping	3PL	N/A (Omitted)	MFG	3PL	W	W

Note: Dates are shown for illustrative purposes only.

2.2.1.3 XML examples of the EPCIS messages exchanged between parties.

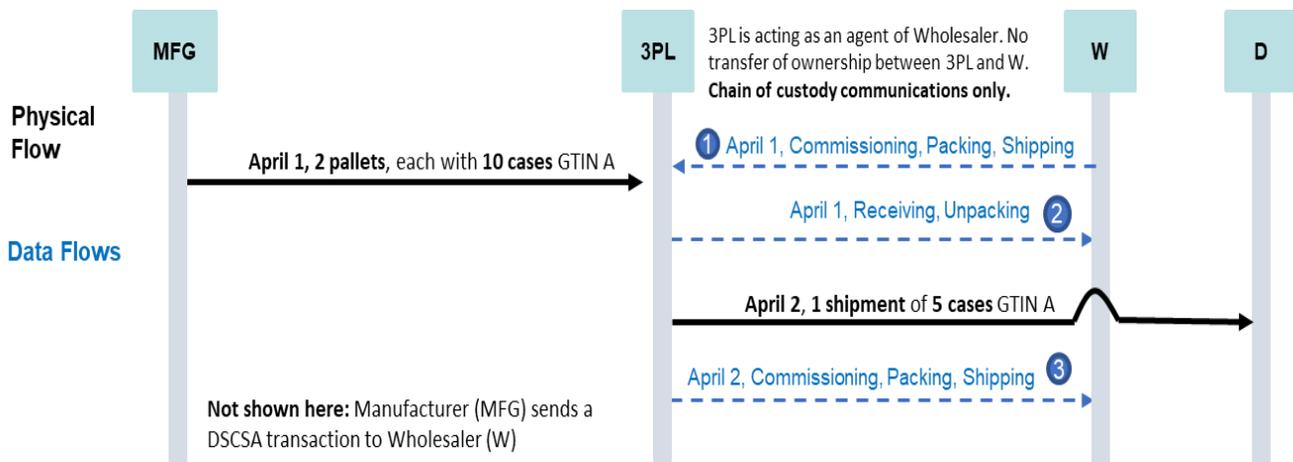
- The XML examples can be accessed [here](#).

2.2.2 Wholesaler utilizes 3PL for logistics services (Virtual Wholesaler)

The scenario below details the physical flow of products with the Chain of Custody Business Processes plus the data flows of Electronic Exchange between the supply chain trading partners.
MFG->[3PL->W]->D

2.2.2.1 The Physical and Data Flow Diagram

In the diagram below, the physical and data flows between the Manufacturers, Third Party Logistics Provider, the Wholesaler, and Dispenser are depicted in the three steps.



	Chain of Custody Business Steps	Message Sending Party	Message Receiving Party	Chain of Custody Electronic Exchange
1	Wholesaler (W) sends MFG-provided serialized data to 3PL on April 1	W	3PL	W sends MFG-provided EPCIS Commissioning, Packing, and Shipping data to 3PL
2	3PL receives shipment from Manufacturer on April 1	3PL	W	3PL sends EPCIS Receiving and Unpacking data to W
3	3PL fulfills order and ships product to Dispenser (D) on April 2	3PL	W	3PL sends EPCIS logistics Commissioning, Packing, and Shipping data, as applicable, to W

Note: Dates are shown for illustrative purposes only.

2.2.2.2 Table of EPCIS messages exchanged by Sending and Receiving parties

The schedule below details the EPCIS Sending and Receiving parties with each of the XML examples for the bizSteps for each attribute.

Scenario: 2. Wholesaler utilizes 3PL for logistics services (Virtual Wholesaler) – XML Examples									
Scenario Step	EPCIS Sending Party	EPCIS Receiving Party	relevant CoC EPCIS Events	readPoint	bizLocation	sourceOwningParty	sourceLocation	destOwningParty	destLocation
① Wholesaler (W) sends MFG-provided serialized data to 3PL on April 1	W	3PL	Commissioning	MFG	MFG				
			Packing	MFG	MFG				
			Shipping	MFG	N/A (Omitted)	MFG	MFG	W	3PL
② 3PL receives shipment from Manufacturer (MFG) on April 1	3PL	W	Receiving	3PL	3PL	MFG	MFG	W	3PL
			Unpacking	3PL	3PL				
③ 3PL fulfills order and ships product to Dispenser (D) on April 2	3PL	W	Commissioning (SSCCs)	3PL	3PL				
			Packing	3PL	3PL				
			Shipping	3PL	N/A (Omitted)	W	3PL	D	D

Note: Dates are shown for illustrative purposes only.

Grey fill indicates message is based on MFG-provided event data sent to W as part of DSCSA transaction.

2.2.2.3 XML examples of the EPCIS messages exchanged between parties.

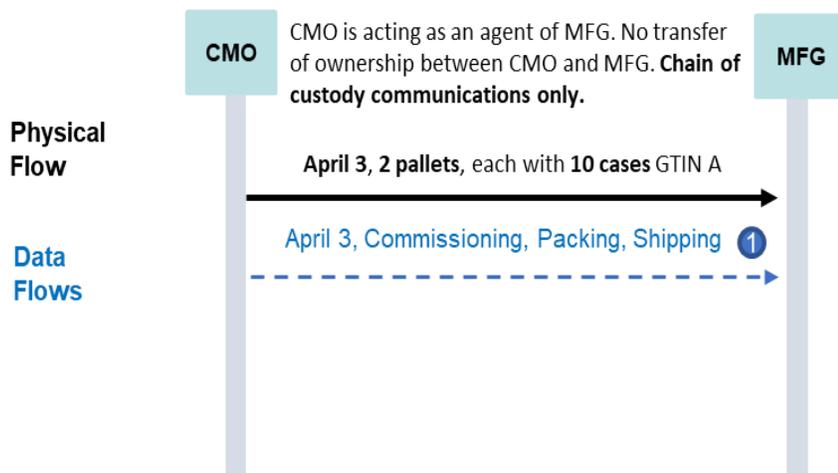
- The XML examples can be accessed [here](#).

2.2.3 Manufacturer utilizes Contract Manufacturer (with serialization)

The scenario below details the physical flow of products with the Chain of Custody Business Processes plus the data flow of Electronic Exchange between the supply chain trading partners.
[CMO->MFG]

2.2.3.1 The Physical and Data Flow Diagram

In the diagram below, the physical and data flows between the CMO and the Manufacturer are depicted in a single step.



	Chain of Custody Business Step	Message Sending Party	Message Receiving Party	Chain of Custody Electronic Exchange
1	Contract Manufacturer (CMO) ships product to Manufacturer (MFG) on April 3	CMO	MFG	CMO sends EPCIS Commissioning, Packing, Shipping events to MFG

Note: Dates are shown for illustrative purposes only.

2.2.3.2 Table of EPCIS messages exchanged by Sending and Receiving parties

The schedule below details the EPCIS Sending and Receiving parties with the XML example for the bizSteps for each attribute.

Scenario: 3. Manufacturer utilizes Contract Manufacturer (with serialization) – XML Examples									
Scenario Step	EPCIS Sending Party	EPCIS Receiving Party	relevant CoC EPCIS Events	readPoint	bizLocation	sourceOwningParty	sourceLocation	destOwningParty	destLocation
1 Contract Manufacturer (CMO) ships product to Manufacturer (MFG) on April 3	CMO	MFG	Commissioning	CMO	CMO				
			Packing	CMO	CMO				
			Shipping	CMO	N/A (Omitted)	MFG	CMO	MFG	MFG

Note: Dates are shown for illustrative purposes only.

2.2.3.3 XML example of the EPCIS messages exchanged between parties.

- The XML example can be accessed [here](#).

2.2.4 Manufacturer utilizes Contract Manufacturer/Packager and 3PL (Virtual MFG)

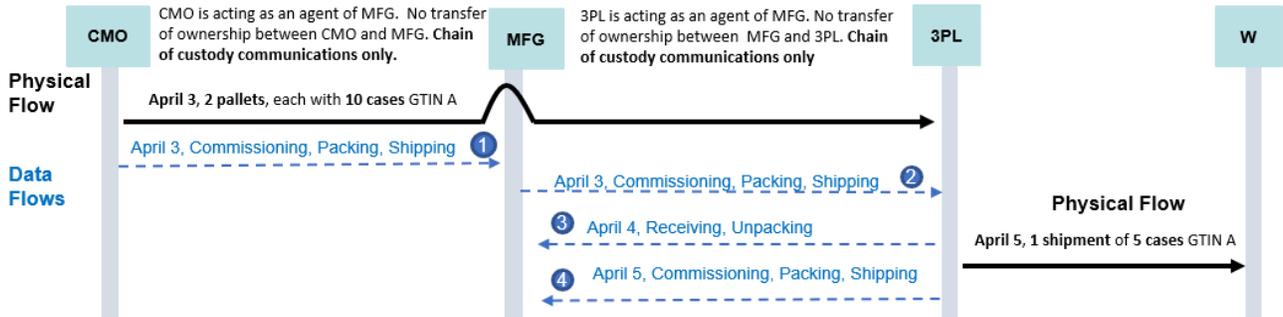
The scenario below details the physical flow of products with the Chain of Custody Business Processes plus the data flows of Electronic Exchange between the supply chain trading partners.

2.2.4.1 Manufacturer utilizes Contract Manufacturer and 3PL (Virtual MFG)

[CMO->3PL->MFG]->W

2.2.4.1.1 The Physical and Data Flow Diagram

In the diagram below the physical and data flows between the CMO, Manufacturer, Third Party Logistics Provider and the Wholesaler are depicted in the four steps.



	Chain of Custody Business Step	Message Sending Party	Message Receiving Party	Chain of Custody Electronic Exchange
1	Contract Manufacturer (CMO) ships product to 3PL on April 3	CMO	MFG	CMO sends EPCIS Commissioning, Packing, Shipping events to MFG
2	Manufacturer (MFG) sends CMO-provided serialized data to 3PL on April 3	MFG	3PL	MFG sends CMO-provided a copy of EPCIS Commissioning, Packing, and Shipping events to 3PL
3	3PL receives shipment from CMO on April 4	3PL	MFG	3PL sends EPCIS Receiving and Unpacking event to MFG
4	3PL fulfills order and ships product to Wholesaler (W) on April 5	3PL	MFG	3PL sends EPCIS logistics Commissioning, Packing, and Shipping events, as applicable to MFG

Note: Dates are shown for illustrative purposes only.

2.2.4.1.2 Table of EPCIS messages exchanged by Sending and Receiving parties

The schedule below details the EPCIS Sending and Receiving parties with each of the XML examples for the bizSteps for each attribute.

Scenario: 4.1. Manufacturer utilizes Contract Manufacturer and 3PL (Virtual MFG) – XML Examples									
Scenario Step	EPCIS Sending Party	EPCIS Receiving Party	relevant CoC EPCIS Events	readPoint	bizLocation	sourceOwningParty	sourceLocation	destOwningParty	destLocation
1	CMO	MFG	Commissioning	CMO	CMO				
			Packing	CMO	CMO				
			Shipping	CMO	N/A (Omitted)	MFG	CMO	MFG	3PL
2	MFG	3PL	Commissioning	CMO	CMO				
			Packing	CMO	CMO				
			Shipping	CMO	N/A (Omitted)	MFG	CMO	MFG	3PL
3	3PL	MFG	Receiving	3PL	3PL	MFG	CMO	MFG	3PL
			Unpacking	3PL	3PL				
4	3PL	MFG	Commissioning (SSCCs)	3PL	3PL				
			Packing	3PL	3PL				
			Shipping	3PL	N/A (Omitted)	MFG	3PL	W	W

Note: Dates are shown for illustrative purposes only.

Grey fill indicates message is based on event data provided from dataflow 1.

2.2.4.1.3 XML examples of the EPCIS messages exchanged between parties.

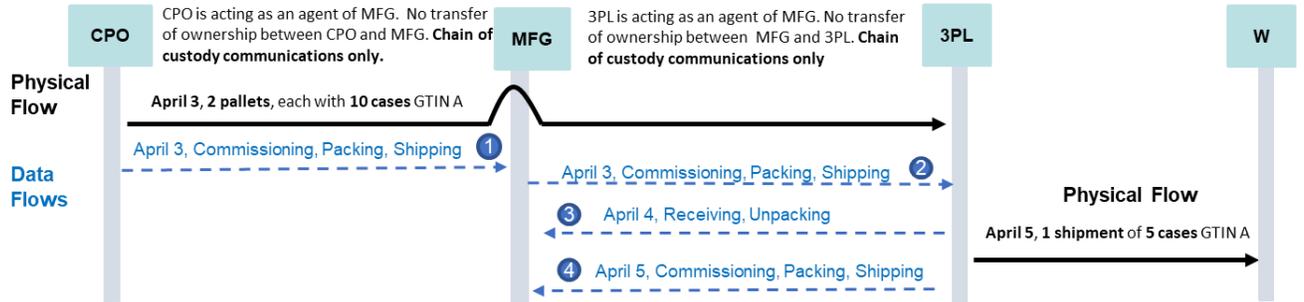
- The XML examples can be accessed [here](#).

2.2.4.2 Manufacturer utilizes Contract Packager and 3PL (Virtual MFG)

The scenario below details the physical flow of products with the Chain of Custody Business Processes plus the data flows of Electronic Exchange between the supply chain trading partners. [CPO->3PL->MFG]->W

2.2.4.2.1 The Physical and Data Flow Diagram

In the diagram below the physical and data flows between the CPO, Manufacturer, Third Party Logistics Provider, and the Wholesaler are depicted in the four steps.



	Chain of Custody Business Step	Message Sending Party	Message Receiving Party	Chain of Custody Electronic Exchange
1	Contract Packager (CPO) ships product to 3PL on April 3	CPO	MFG	CPO sends EPCIS Commissioning, Packing, Shipping events to MFG
2	Manufacturer (MFG) sends CPO-provided serialized data to 3PL on April 3	MFG	3PL	MFG sends CPO-provided a copy of EPCIS Commissioning, Packing, and Shipping events to 3PL
3	3PL receives shipment from CPO on April 4	3PL	MFG	3PL sends EPCIS Receiving and Unpacking event to MFG
4	3PL fulfills order and ships product to Wholesaler (W) on April 5	3PL	MFG	3PL sends EPCIS logistics Commissioning, Packing, and Shipping events, as applicable to MFG

Note: Dates are shown for illustrative purposes only.

Scenario 2.2.4.2.1 represents where the CMO manufactures and provides un-serialized Rx product for the CPO to complete the packaging with serialized labels, perform aggregation, and ship serialized commercial products to 3PL. Since the CMO is not involved in the serialization process, the CMO is not depicted in the physical and data flows.

2.2.4.2.2 Table of EPCIS messages exchanged by Sending and Receiving parties

The schedule below details the EPCIS Sending and Receiving parties with each of the XML examples for the bizSteps for each attribute.

Scenario: 4.2. Manufacturer utilizes Contract Packager and 3PL (Virtual MFG) – XML Examples									
Scenario Step	EPCIS Sending Party	EPCIS Receiving Party	relevant CoC EPCIS Events	readPoint	bizLocation	sourceOwningParty	sourceLocation	destOwningParty	destLocation
① Contract Packager (CPO) ships product to 3PL on April 3	CPO	MFG	Commissioning	CPO	CPO				
			Packing	CPO	CPO				
			Shipping	CPO	N/A (Omitted)	MFG	CPO	MFG	3PL
② Manufacturer (MFG) sends CPO-provided serialized data to 3PL on April 3	MFG	3PL	Commissioning	CPO	CPO				
			Packing	CPO	CPO				
			Shipping	CPO	N/A (Omitted)	MFG	CPO	MFG	3PL
③ 3PL receives shipment from CPO on April 4	3PL	MFG	Receiving	3PL	3PL	MFG	CPO	MFG	3PL
			Unpacking	3PL	3PL				
④ 3PL fulfills order and ships product to Wholesaler (W) on April 5	3PL	MFG	Commissioning (SSCCs)	3PL	3PL				
			Packing	3PL	3PL				
			Shipping	3PL	N/A (Omitted)	MFG	3PL	W	W

Note: Dates are shown for illustrative purposes only.

Grey fill indicates message is based on event data provided from dataflow 1.

2.2.4.2.3 XML examples of EPCIS messages exchanged between parties

- The XML examples can be accessed [here](#).

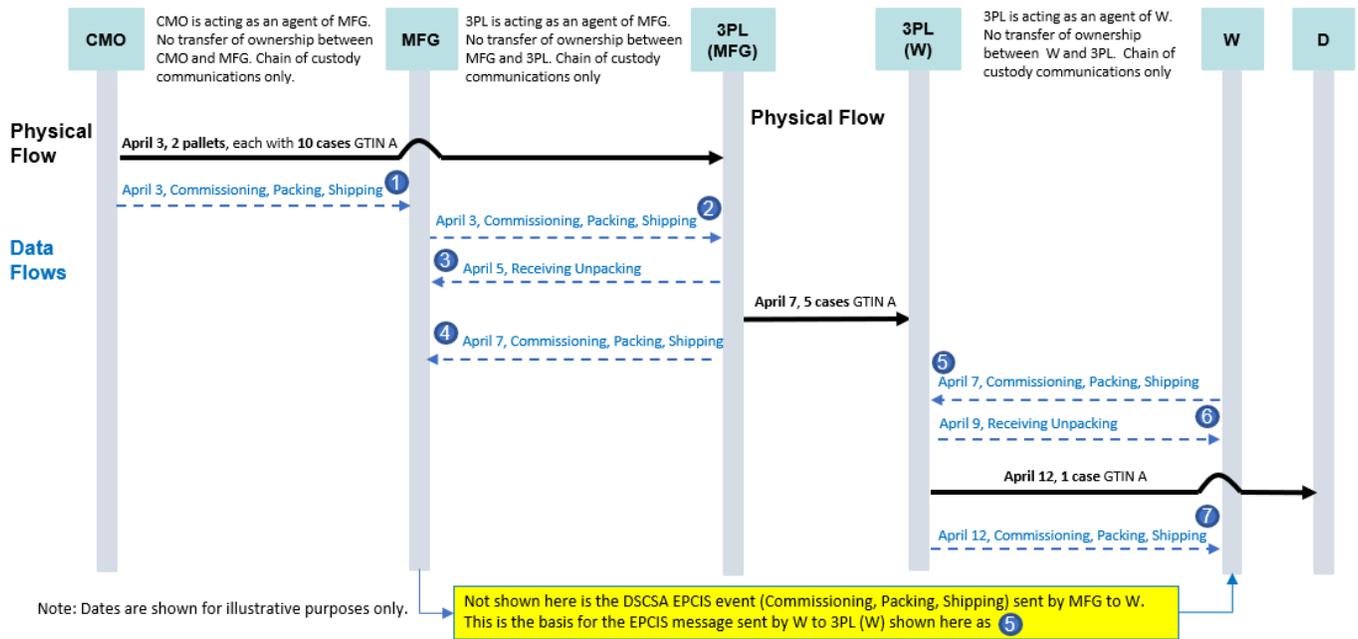
2.2.5 Manufacturer utilizes Contract Manufacturer and 3PL, and Wholesaler utilizes a 3PL

The scenario below details the physical flow of products with the Chain of Custody Business Processes plus the data flows of Electronic Exchange between the supply chain trading partners.

[CMO->3PL->MFG]->[3PL->W]->D

2.2.5.1 The Physical and Data Flow Diagram

In the diagram below, the physical and data flows between the CMO, Manufacturer, Third Party Logistics Provider on behalf of the Manufacturer, 3rd Party Logistics Provider on behalf of the Wholesaler, the Wholesaler, and the Dispenser are depicted in the seven steps.



	Chain of Custody Business Step	Message Sending Party	Message Receiving Party	Chain of Custody Electronic Exchange
1	Contract Manufacturer (CMO) ships product to 3PL (MFG) on April 3	CMO	MFG	CMO sends EPCIS Commissioning, Packing, Shipping data to MFG
2	Manufacturer (MFG) sends CMO-provided serialized data to 3PL (MFG) on April 3	MFG	3PL (MFG)	MFG sends CMO-provided EPCIS Commissioning, Packing, and Shipping data to 3PL (MFG)
3	3PL (MFG) receives shipment from CMO on April 5	3PL (MFG)	MFG	3PL (MFG) sends EPCIS Receiving and Unpacking data to MFG
4	3PL (MFG) fulfills order and ships product to 3PL (W) on April 7	3PL (MFG)	MFG	3PL (MFG) sends EPCIS logistics Commissioning, Packing, and Shipping events, as applicable to MFG
5	Wholesaler (W) sends MFG-provided serialized data to 3PL (W) on April 7	W	3PL (W)	W sends MFG-provided Commissioning, Packing, and Shipping events, as applicable to 3PL (W)
6	3PL (W) receives shipment from 3PL (MFG) on April 9	3PL (W)	W	3PL (W) sends EPCIS Receiving and Unpacking data to W
7	3PL (W) fulfills order and ships product to D on April 12	3PL (W)	W	3PL (W) sends EPCIS logistics Commissioning, Packing, and Shipping events, as applicable to W

2.2.5.2 Table of EPCIS messages exchanged by Sending and Receiving parties

The schedule below details the EPCIS Sending and Receiving parties with each of the XML examples for the bizSteps for each attribute.

Scenario: 5. Manufacturer utilizes Contract Manufacturer and 3PL, AND Wholesaler utilizes a 3PL – XML Examples									
Scenario Step	EPCIS Sending Party	EPCIS Receiving Party	relevant CoC EPCIS Events	readPoint	bizLocation	sourceOwningParty	sourceLocation	destOwningParty	destLocation
1	Contract Manufacturer (CMO) ships product to 3PL (MFG) on April 3	CMO	MFG	Commissioning	CMO	CMO			
				Packing	CMO	CMO			
				Shipping	CMO	N/A (Omitted)	MFG	CMO	MFG
2	Manufacturer (MFG) sends CMO-provided serialized data to 3PL (MFG) on April 3	MFG	3PL (MFG)	Commissioning	CMO	CMO			
				Packing	CMO	CMO			
				Shipping	CMO	N/A (Omitted)	MFG	CMO	MFG
3	3PL (MFG) receives shipment from CMO on April 5	3PL (MFG)	MFG	Receiving	3PL (MFG)	3PL (MFG)	MFG	CMO	MFG
				Unpacking	3PL (MFG)	3PL (MFG)			
4	3PL (MFG) fulfills order and ships product to 3PL (W) on April 7	3PL (MFG)	MFG	Commissioning (SSCCs)	3PL (MFG)	3PL (MFG)			
				Packing	3PL (MFG)	3PL (MFG)			
				Shipping	3PL (MFG)	N/A (Omitted)	MFG	3PL (MFG)	W
5	Wholesaler (W) sends MFG-provided serialized data to 3PL (W) on April 7	W	3PL (W)	Commissioning (SSCCs)	3PL (MFG)	3PL (MFG)			
				Packing	3PL (MFG)	3PL (MFG)			
				Shipping	3PL (MFG)	N/A (Omitted)	MFG	3PL (MFG)	W
6	3PL (W) receives shipment from 3PL (MFG) on April 9	3PL (W)	W	Receiving	3PL (W)	3PL (W)	MFG	3PL (MFG)	W
				Unpacking	3PL (W)	3PL (W)			
7	3PL (W) fulfills order and ships product to D on April 12	3PL (W)	W	Commissioning (SSCCs)	3PL (W)	3PL (W)			
				Packing	3PL (W)	3PL (W)			
				Shipping	3PL (W)	N/A (Omitted)	W	3PL (W)	D

Grey fill indicates message is based on event data provided from dataflows 1 & 4

2.2.5.3 XML examples of the EPCIS messages exchanged between parties.

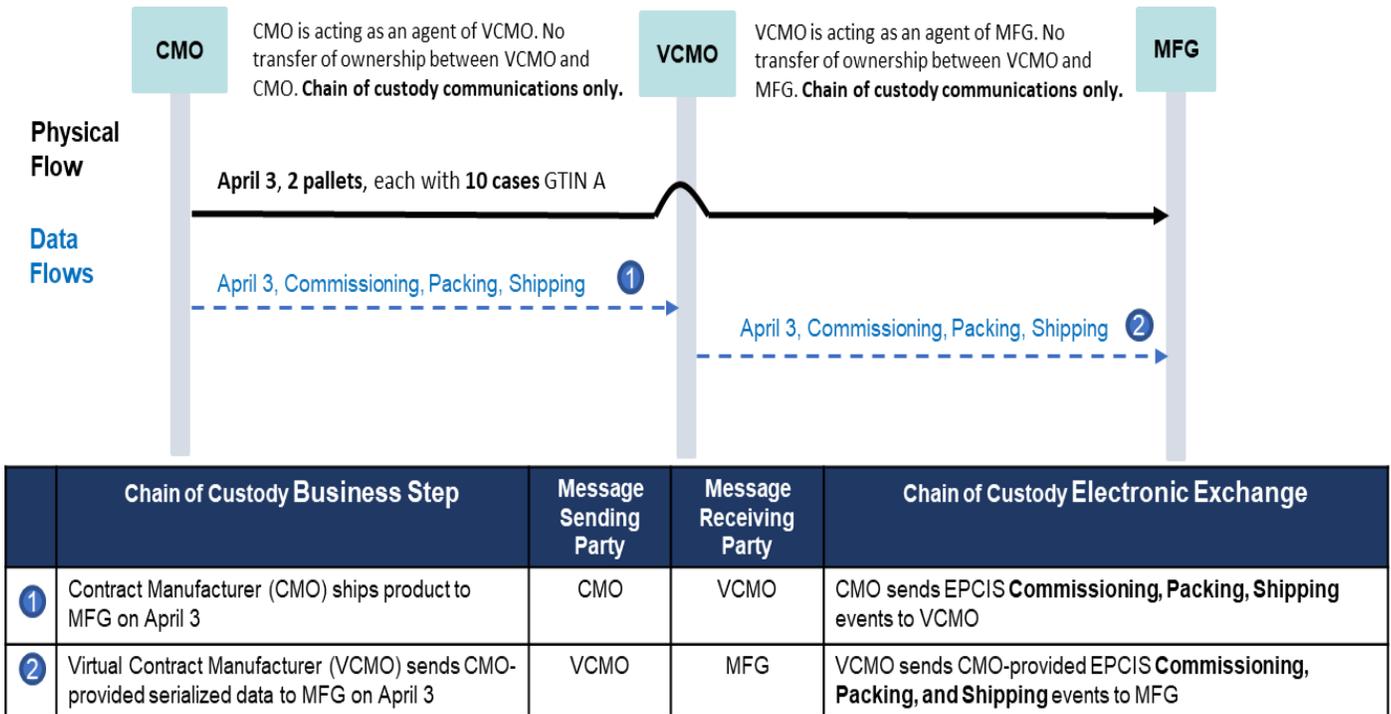
- The XML examples can be accessed [here](#).

2.2.6 Manufacturer utilizes Virtual Contract Manufacturer who outsources to another Contract Manufacturer (Virtual CMO scenario)

The scenario below details the physical flow of products with the Chain of Custody Business Processes plus the data flows of Electronic Exchange between the supply chain trading partners.
[CMO->CMO->MFG]

2.2.6.1 The Physical and Data Flow Diagram

In the diagram below, the physical and data flows between the CMO, a Virtual CMO and Manufacturer are depicted in the two steps.



Note: Dates are shown for illustrative purposes only.

2.2.6.2 Table of EPCIS messages exchanged by Sending and Receiving parties

The schedule below details the EPCIS Sending and Receiving parties with each of the XML examples for the bizSteps for each attribute.

Scenario: 6. Manufacturer utilizes Virtual Contract Manufacturer who outsources to another Contract Manufacturer (Virtual CMO scenario) – XML Example

Scenario Step	EPCIS Sending Party	EPCIS Receiving Party	relevant CoC EPCIS Events	readPoint	bizLocation	sourceOwningParty	sourceLocation	destOwningParty	destLocation
1 Contract Manufacturer (CMO) ships product to MFG on April 3	CMO	VCMO	Commissioning	CMO	CMO				
			Packing	CMO	CMO				
			Shipping	CMO	N/A (Omitted)	MFG	CMO	MFG	MFG
2 Virtual Contract Manufacturer (VCMO) sends CMO-provided serialized data to MFG on April 3	VCMO	MFG	Commissioning	CMO	CMO				
			Packing	CMO	CMO				
			Shipping	CMO	N/A (Omitted)	MFG	CMO	MFG	MFG

Note: Dates are shown for illustrative purposes only.

Grey fill indicates message is based on event data provided from dataflow 1

2.2.6.3 XML examples of the EPCIS messages exchanged between parties.

- The XML examples can be accessed [here](#).

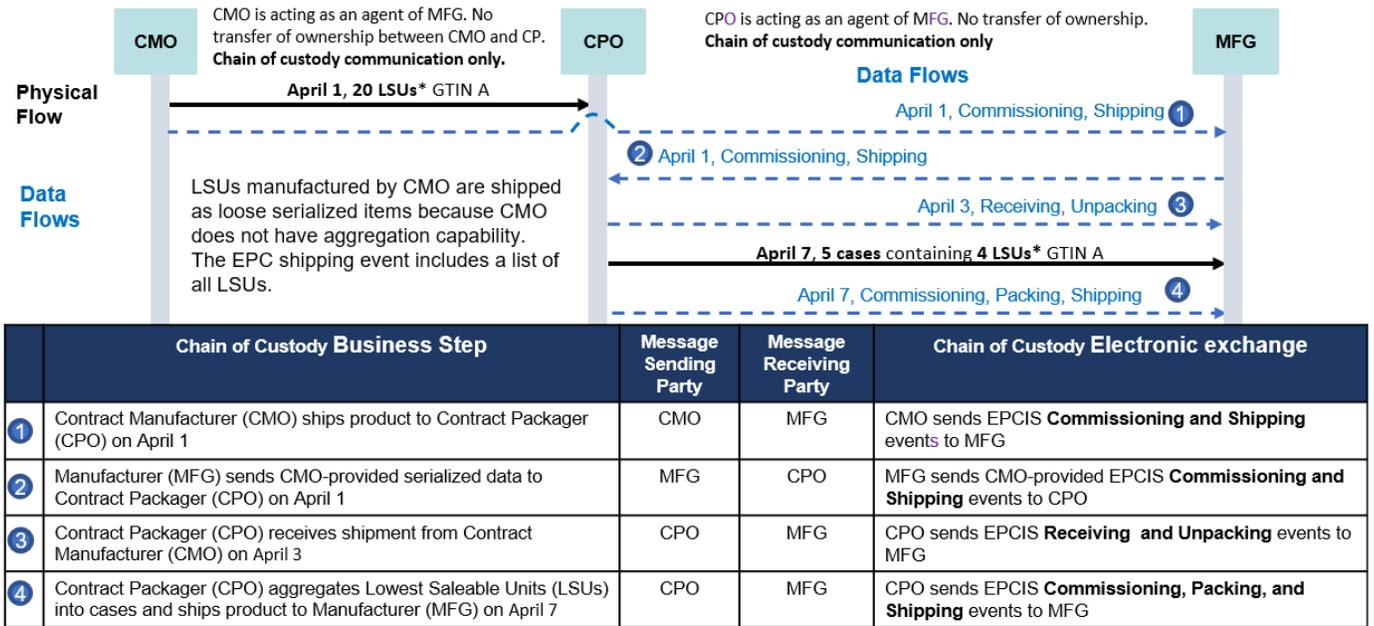
2.2.7 Manufacturer utilizes Contract Manufacturer for producing un-aggregated serialized products and utilizes Contract Packager for aggregation services

The scenario below details the physical flow of products with the Chain of Custody Business Processes plus the data flows of Electronic Exchange between the supply chain trading partners.

[CMO->CPO->MFG]

2.2.7.1 The Physical and Data Flow Diagram

In the diagram below, the physical and data flows between the CMO, a CPO and Manufacturer are depicted in the four steps.



* LSU – Lowest Saleable Unit Note: Dates are shown for illustrative purposes only.

2.2.7.2 Table of EPCIS messages exchanged by Sending and Receiving parties

The schedule below details the EPCIS Sending and Receiving parties with each of the XML examples for the bizSteps for each attribute.

Scenario: 7. Manufacturer utilizes Contract Manufacturer for producing un-aggregated serialized products and utilizes Contract Packager for aggregation services – XML Example										
Scenario Step	EPCIS Sending Party	EPCIS Receiving Party	relevant CoC EPCIS Events	readPoint	bizLocation	sourceOwningParty	sourceLocation	destOwningParty	destLocation	
1	Contract Manufacturer (CMO) ships product to Contract Packager (CPO) on April 1.	CMO	MFG	Commissioning	CMO	CMO				
				Shipping	CMO	N/A Omitted	MFG	CMO	MFG	CPO
2	Manufacturer (MFG) sends CMO-provided serialized data to Contract Packager (CPO) on April 1	MFG	CPO	Commissioning	CMO	CMO				
				Shipping	CMO	N/A Omitted	MFG	CMO	MFG	CPO
3	Contract Packager (CPO) receives shipment from Contract Manufacturer (CMO) on April 3	CPO	MFG	Receiving	CPO	CPO	MFG	CMO	MFG	
				Unpacking	CPO	CPO				
4	Contract Packager (CPO) aggregates Lowest Saleable Units (LSUs) into cases and ships product to Manufacturer (MFG) on April 7	CPO	MFG	Commissioning	CPO	CPO				
				Packing	CPO	CPO				
				Shipping	CPO	N/A Omitted	MFG	CPO	MFG	MFG

Note: Dates are shown for illustrative purposes only. Grey fill indicates message is based on event data provided from dataflow 1

2.2.7.3 XML examples of the EPCIS messages exchanged between parties.

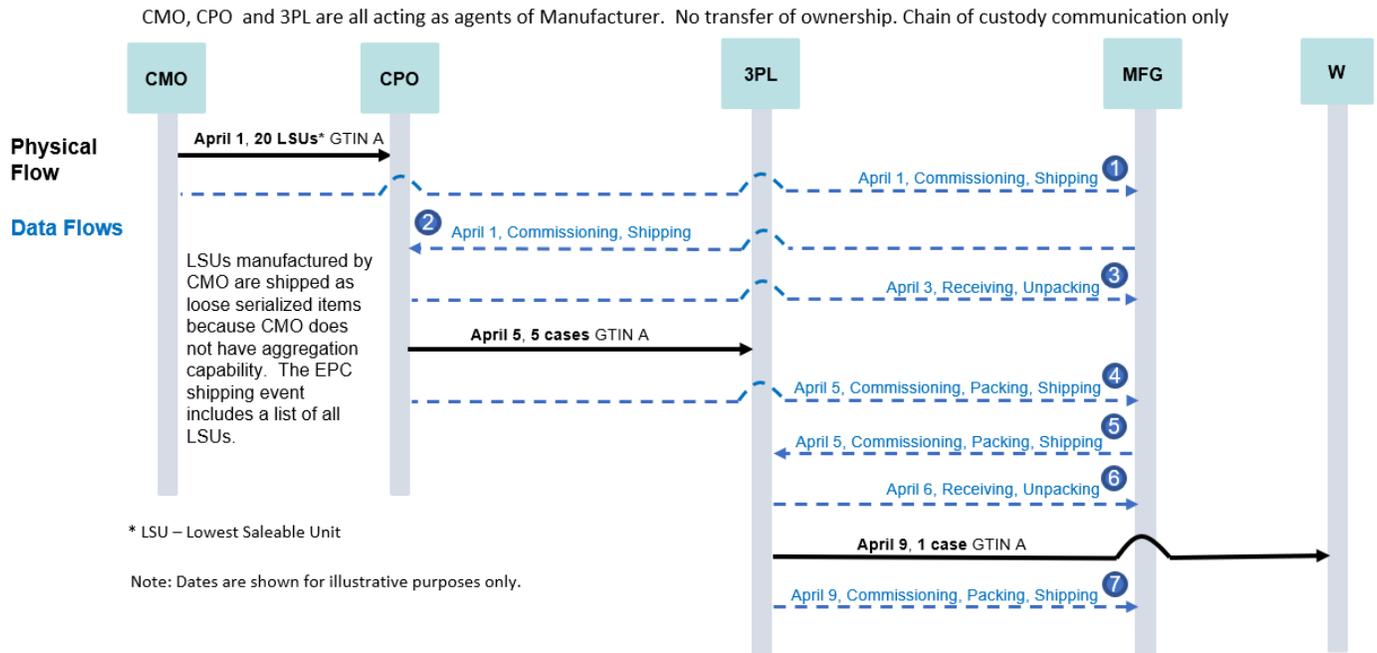
- The XML examples can be accessed [here](#).

2.2.8 Manufacturer utilizes Contract Manufacturer, Contract Packager and 3PL (Extended Virtual Manufacturer)

The scenario below details the physical flow of products with the Chain of Custody Business Processes plus the data flows of Electronic Exchange between the supply chain trading partners.
[CMO->CPO->3PL->MFG]->W

2.2.8.1 The Physical and Data Flow Diagram

In the diagram below the physical and data flows between the CMO, a CPO, Third Party Logistics Provider Manufacturer and Wholesaler are depicted in the seven steps.



	Chain of Custody Business Step	Message Sending Party	Message Receiving Party	Chain of Custody Electronic exchange
1	Contract Manufacturer (CMO) ships product to Contract Packager (CPO) on April 1.	CMO	MFG	CMO sends EPCIS Commissioning and Shipping events to MFG
2	Manufacturer (MFG) sends CMO-provided serialized data to Contract Packager (CPO) on April 1	MFG	CPO	MFG sends a CMO-provided EPCIS Commissioning and Shipping events to CPO
3	Contract Packager (CPO) receives shipment from Contract Manufacturer (CMO) on April 3	CPO	MFG	CPO sends EPCIS Receiving, Unpacking events to MFG
4	Contract Packager (CPO) aggregates Lowest Saleable Units (LSUs) into cases and ships product to 3PL on April 5	CPO	MFG	CPO sends EPCIS Commissioning, Packing, and Shipping events to MFG
5	Manufacturer (MFG) sends CPO-provided serialized data to 3PL on April 5	MFG	3PL	MFG sends CPO-provided EPCIS Commissioning, Packing, and Shipping events to 3PL
6	3PL receives shipment from CPO on April 6	3PL	MFG	3PL sends EPCIS Receiving, Unpacking events to MFG
7	3PL fulfills order and ships product to W on April 9	3PL	MFG	3PL sends EPCIS Commissioning, Packing, and Shipping events to MFG

* LSU – Lowest Saleable Unit

Note: Dates are shown for illustrative purposes only.

2.2.8.2 Table of EPCIS messages exchanged by Sending and Receiving parties

The schedule below details the EPCIS Sending and Receiving parties with each of the XML examples for the bizSteps for each attribute.

Scenario: 8. Manufacturer utilizes a Contract Manufacturer, Contract Packager, and 3PL – XML Example									
Scenario Step	EPCIS Sending Party	EPCIS Receiving Party	relevant CoC EPCIS Events	readPoint	bizLocation	sourceOwningParty	sourceLocation	destOwningParty	destLocation
1 CMO ships product to CPO on April 1.	CMO	MFG	Commissioning	CMO	CMO				
			Shipping	CMO	N/A Omitted	MFG	CMO	MFG	CPO
2 Manufacturer (MFG) sends CMO-provided serialized data to Contract Packager (CPO) on April 1	MFG	CPO	Commissioning	CMO	CMO				
			Shipping	CMO	N/A Omitted	MFG	CMO	MFG	CPO
3 CPO receives shipment from CMO on April 3	CPO	MFG	Receiving	CPO	CPO	MFG	CMO	MFG	CPO
4 CPO aggregates Lowest Saleable Units (LSUs) into cases and ships product to 3PL on April 5	CPO	MFG	Commissioning	CPO	CPO				
			Packing	CPO	CPO				
			Shipping	CPO	N/A Omitted	MFG	CPO	MFG	3PL
5 MFG sends CPO-provided serialized data to 3PL on April 5	MFG	3PL	Commissioning	CPO	CPO				
			Packing	CPO	CPO				
			Shipping	CPO	N/A Omitted	MFG	CPO	MFG	3PL
6 3PL receives shipment from CPO on April 6	3PL	MFG	Receiving	3PL	3PL	MFG	CPO	MFG	3PL
7 3PL fulfills order and ships product to W on April 9	3PL	MFG	Commissioning (SSCCs)	3PL	3PL				
			Packing	3PL	3PL				
			Shipping	3PL	N/A Omitted	MFG	3PL	W	W

* LSU – Lowest Saleable Unit Grey fill indicates message is based on event data provided from dataflows 1 & 4 Note: Dates are shown for illustrative purposes only.

2.2.8.3 XML examples of the EPCIS messages exchanged between parties.

- XML examples can be accessed [here](#).

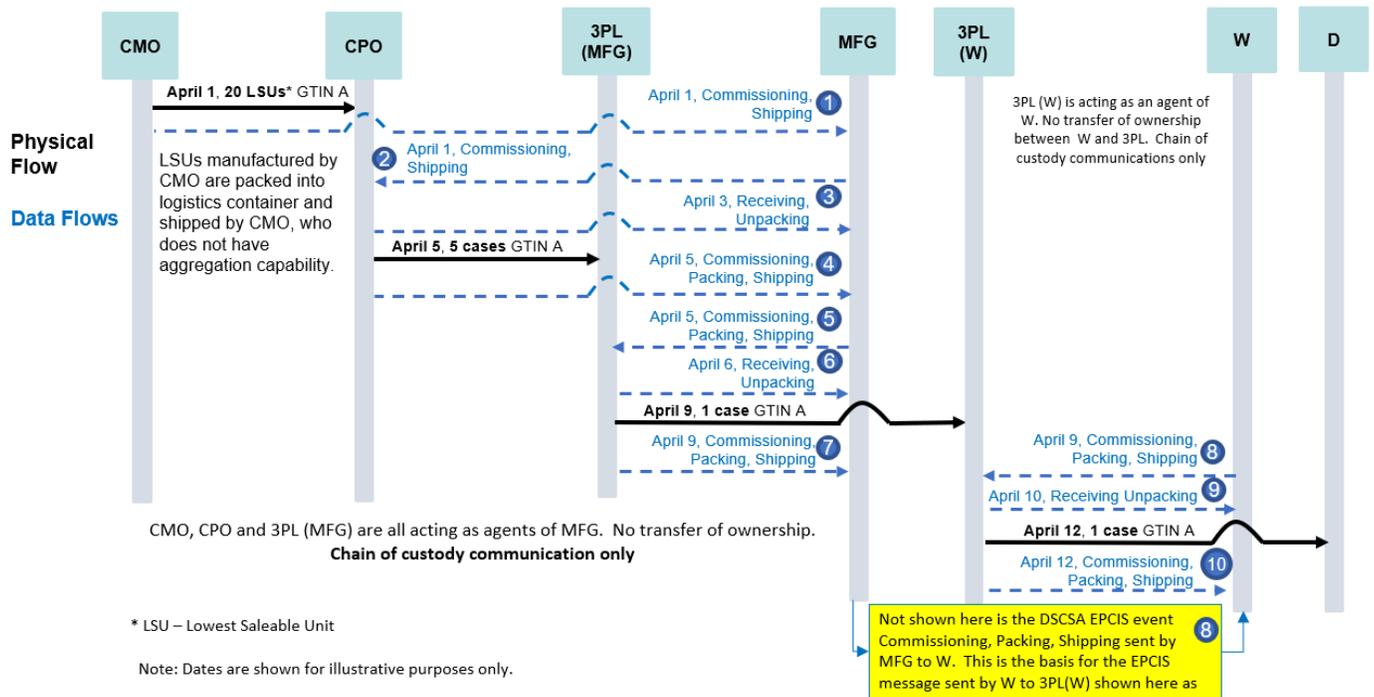
2.2.9 Manufacturer utilizes Contract Manufacturer, Contract Packager and 3PL and Wholesaler utilizes a 3PL

The scenario below details the physical flow of products with the Chain of Custody Business Processes plus the data flows of Electronic Exchange between the supply chain trading partners.

[CMO->CPO->3PL->MFG]->[3PL->W]->D

2.2.9.1 The Physical and Data Flow Diagram

In the diagram below the physical and data flows between the CMO, a CPO, Third Party Logistics Provider on behalf of the manufacturer, Manufacturer, Third Party Logistics Provider on behalf of the wholesaler, Wholesaler and Dispenser are depicted in the ten steps.



	Chain of Custody Business Step	Message Sending Party	Message Receiving Party	Chain of Custody Electronic exchange
1	Contract Manufacturer (CMO) ships product to Contract Packager (CPO) on April 1	CMO	MFG	CMO sends EPCIS Commissioning and Shipping events to MFG
2	Manufacturer (MFG) sends CMO-provided serialized data to Contract Packager (CPO) on April 1	MFG	CPO	MFG sends CMO-provided EPCIS Commissioning and Shipping events to CPO
3	Contract Packager (CPO) receives shipment from Contract Manufacturer (CMO) on April 3	CPO	MFG	CPO sends EPCIS Receiving and Unpacking events to MFG
4	Contract Packager (CPO) aggregates Lowest Saleable Units (LSUs) into cases and ships product to 3PL(MFG) on April 5	CPO	MFG	CPO sends EPCIS Commissioning, Packing, and Shipping events to MFG
5	Manufacturer (MFG) sends CPO-provided serialized data to 3PL(MFG) on April 5	MFG	3PL(MFG)	MFG sends CPO-provided EPCIS Commissioning, Packing, and Shipping events to 3PL(MFG)
6	3PL(MFG) receives shipment from CPO on April 6	3PL(MFG)	MFG	3PL(MFG) sends EPCIS Receiving and Unpacking events to MFG
7	3PL(MFG) fulfills order and ships product to 3PL (W) on April 9	3PL(MFG)	MFG	3PL(MFG) sends EPCIS logistics Commissioning, Packing, and Shipping events to MFG
8	Wholesaler (W) sends MFG-provided serialization data to 3PL(W) on April 9	W	3PL(W)	W sends MFG-provided EPCIS logistics Commissioning, Packing, and Shipping events to 3PL(W)
9	3PL(W) receives shipment from 3PL(MFG) on April 10	3PL(W)	W	3PL(W) sends EPCIS Receiving and Unpacking data to W
10	3PL(W) fulfills order and ships product to D on April 12	3PL(W)	W	3PL(W) sends EPCIS logistics Commissioning, Packing, and Shipping events, as applicable to W

* LSU – Lowest Saleable Unit

Note: Dates are shown for illustrative purposes only.

2.2.9.2 Table of EPCIS messages exchanged by Sending and Receiving parties

The schedule below details the EPCIS Sending and Receiving parties with each of the XML examples for the bizSteps for each attribute.

Scenario: 9. Manufacturer utilizes a Contract Manufacturer, Contract Packager, and 3PL and Wholesaler utilizes a 3PL – XML Example

Scenario Step	EPCIS Sending Party	EPCIS Receiving Party	relevant CoC EPCIS Events	readPoint	bizLocation	sourceOwningParty	sourceLocation	destOwningParty	destLocation
1 CMO ships product to CPO on April 1.	CMO	MFG	Commissioning	CMO	CMO				
			Shipping	CMO	N/A Omitted	MFG	CMO	MFG	CPO
2 MFG sends CMO-provided serialized data to Contract Packager (CPO) on April 1	MFG	CPO	Commissioning	CMO	CMO				
			Shipping	CMO	N/A Omitted	MFG	CMO	MFG	CPO
3 CPO receives shipment from CMO on April 3	CPO	MFG	Receiving	CPO	CPO	MFG	CMO	MFG	CPO
			Unpacking	CPO	CPO				
4 CPO aggregates Lowest Saleable Units (LSUs) into cases and ships product to 3PL(MFG) on April 5	CPO	MFG	Commissioning	CPO	CPO				
			Packing	CPO	CPO				
			Shipping	CPO	N/A Omitted	MFG	CPO	MFG	3PL(MFG)
5 MFG sends CPO-provided serialized data to 3PL(MFG) on April 5	MFG	3PL(MFG)	Commissioning	CPO	CPO				
			Packing	CPO	CPO				
			Shipping	CPO	N/A Omitted	MFG	CPO	MFG	3PL(MFG)
6 3PL(MFG) receives shipment from CPO on April 6	3PL(MFG)	MFG	Receiving	3PL(MFG)	3PL(MFG)	MFG	CPO	MFG	3PL(MFG)
			Unpacking	3PL(MFG)	3PL(MFG)				

* LSU – Lowest Saleable Unit Grey fill indicates message is based on event data provided from dataflows 1 & 4 Note: Dates are shown for illustrative purposes only.

Scenario: 9. Manufacturer utilizes a Contract Manufacturer, Contract Packager and 3PL, and Wholesaler utilizes a 3PL – XML Example

Scenario Step	EPCIS Sending Party	EPCIS Receiving Party	relevant CoC EPCIS Events	readPoint	bizLocation	sourceOwningParty	sourceLocation	destOwningParty	destLocation
7 3PL(MFG) fulfills order and ships product to 3PL(W) on April 9	3PL(MFG)	MFG	Commissioning (SSCCs)	3PL(MFG)	3PL(MFG)				
			Packing	3PL(MFG)	3PL(MFG)				
			Shipping	3PL(MFG)	N/A Omitted	MFG	3PL(MFG)	W	3PL(W)
8 Wholesaler (W) MFG-provided serialized data to 3PL(W) on April 9	W	3PL(W)	Commissioning (SSCCs)	3PL(MFG)	3PL(MFG)				
			Packing	3PL(MFG)	3PL(MFG)				
			Shipping	3PL(MFG)	N/A (Omitted)	MFG	3PL(MFG)	W	3PL(W)
9 3PL(W) receives shipment from 3PL(MFG) on April 10	3PL(W)	W	Receiving	3PL(W)	3PL(W)	MFG	3PL(MFG)	W	3PL(W)
			Unpacking	3PL(W)	3PL(W)				
10 3PL(W) fulfills order and ships product to D on April 12	3PL(W)	W	Commissioning (SSCCs)	3PL(W)	3PL(W)				
			Packing	3PL(W)	3PL(W)				
			Shipping	3PL(W)	N/A (Omitted)	W	3PL(W)	D	D

* LSU – Lowest Saleable Unit Grey fill indicates message is based on event data provided from dataflow 7 Note: Dates are shown for illustrative purposes only.

2.2.9.3 XML examples of the EPCIS messages exchanged between parties.

- The XML examples can be accessed [here](#).

2.2.10 Consignment held at Dispenser until Triggering Event.

The scenario below details the physical flow of products with the Chain of Custody Business Processes plus the data flows of Electronic Exchange between the supply chain trading partners.

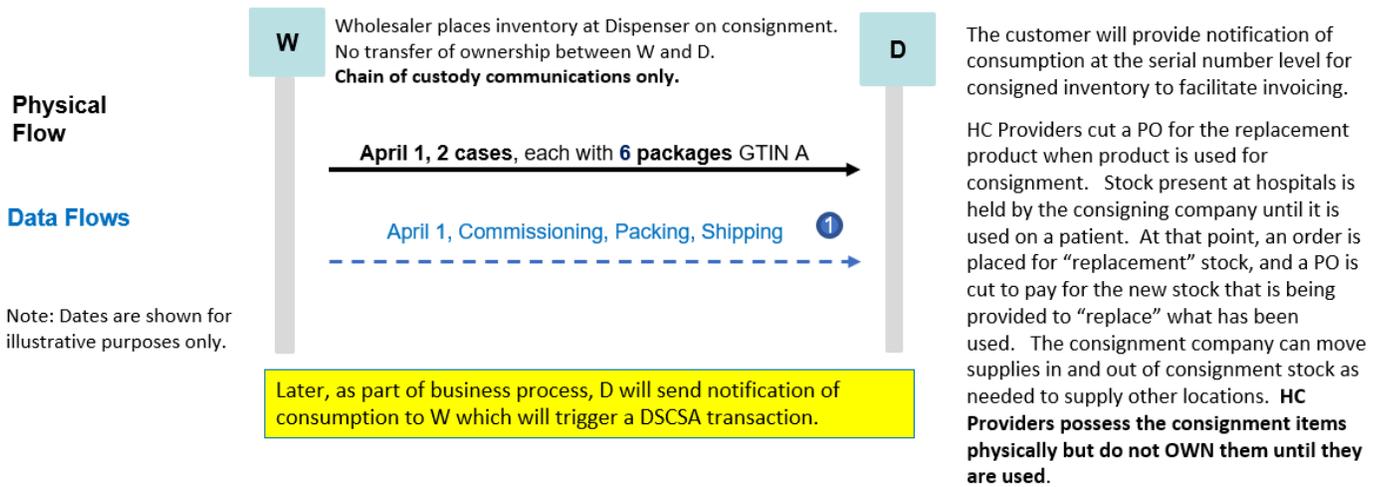
The schedule below details the EPCIS Sending and Receiving parties with each of the XML examples for the bizSteps for each attribute.

2.2.10.1 Scenario 10a

Sections 2.2.10.1.1-1.3: The TI/TS can be sent when a triggering business event occurs, such as consumption or dispensing, and would follow a standard transaction data flow. In this consignment scenario, (W->D), consumption triggered the Shipping event on the same day and time as the change of ownership, and the EPCs are detailed accordingly.

2.2.10.1.1 The Physical and Data Flow Diagram

In the diagram below the physical and data flow between the Wholesaler and Dispenser are depicted in one step.



	Chain of Custody Business Steps	Message Sending Party	Message Receiving Party	Chain of Custody Electronic Exchange
1	Wholesaler (W) ships product to Dispenser (D) on April 1 to hold on consignment	W	D	Wholesaler sends EPCIS MFG-provided Commissioning and Packing events, and Wholesaler generated logistics Commissioning, Packing and Shipping data

2.2.10.1.2 Table of EPCIS messages exchanged by Sending and Receiving parties

Scenario 10a: Consignment held at Dispenser until consumption - XML Examples									
Scenario Step	EPCIS Sending Party	EPCIS Receiving Party	relevant CoC EPCIS Events	readPoint	bizLocation	sourceOwningParty	sourceLocation	destOwningParty	destLocation
1 Wholesaler (W) ships product to Dispenser (D) on April 1 to hold on consignment	W	D	Commissioning	M	M				
			Packing	M	M				
			Commissioning (SSCCs)	W	W				
			Packing into logistics container	w	w				
			Shipping	W	N/A (Omitted)	W	W	W	D

Note: Dates are shown for illustrative purposes only.

2.2.10.1.3 XML example of the EPCIS messages exchanged between parties.

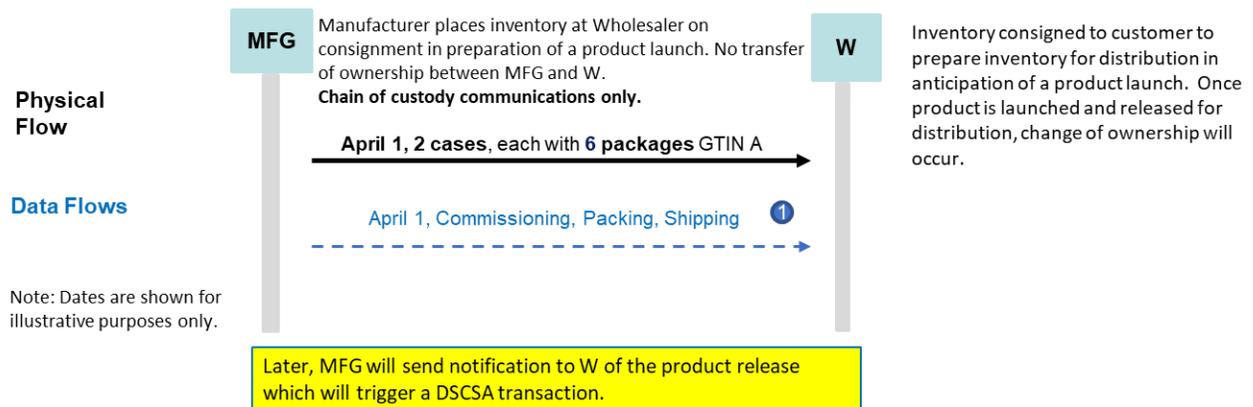
- The XML example can be accessed [here](#).

2.2.10.2 Scenario 10b

Sections 2.2.10.2.1-2.3: The TI/TS can be sent when a triggering business event occurs and would follow a standard transaction data flow. In this consignment scenario, (MFG->W), the Change of Custody *Shipping* event captures the manufacturer’s product launch activities to seed the distribution channel with product. The manufacturer will send notification to the Wholesaler of the product release and subsequently send TI/TS for the product.

2.2.10.2.1 The Physical and Data Flow Diagram

In the diagram below the physical and data flow between the Manufacturer and Wholesaler are depicted in one step.



	Chain of Custody Business Steps	Message Sending Party	Message Receiving Party	Chain of Custody Electronic Exchange
1	Manufacturer (MFG) ships product to Wholesaler (W) on April 1 to hold on consignment	MFG	W	Manufacturer sends EPCIS Commissioning, Packing, and Shipping data

2.2.10.2.2 Table of EPCIS messages exchanged by Sending and Receiving parties

Scenario 10b: Consignment held at Wholesaler until product launch - XML Examples									
Scenario Step	EPCIS Sending Party	EPCIS Receiving Party	relevant CoC EPCIS Events	readPoint	bizLocation	sourceOwningParty	sourceLocation	destOwningParty	destLocation
1 Manufacturer (MFG) ships product to Wholesaler (W) on April 1 to hold on consignment	MFG	W	Commissioning	MFG	MFG				
			Packing	MFG	MFG				
			Shipping	MFG	N/A (Omitted)	MFG	MFG	MFG	W

Note: Dates are shown for illustrative purposes only.

2.2.10.2.3 XML example of the EPCIS messages exchanged between parties.

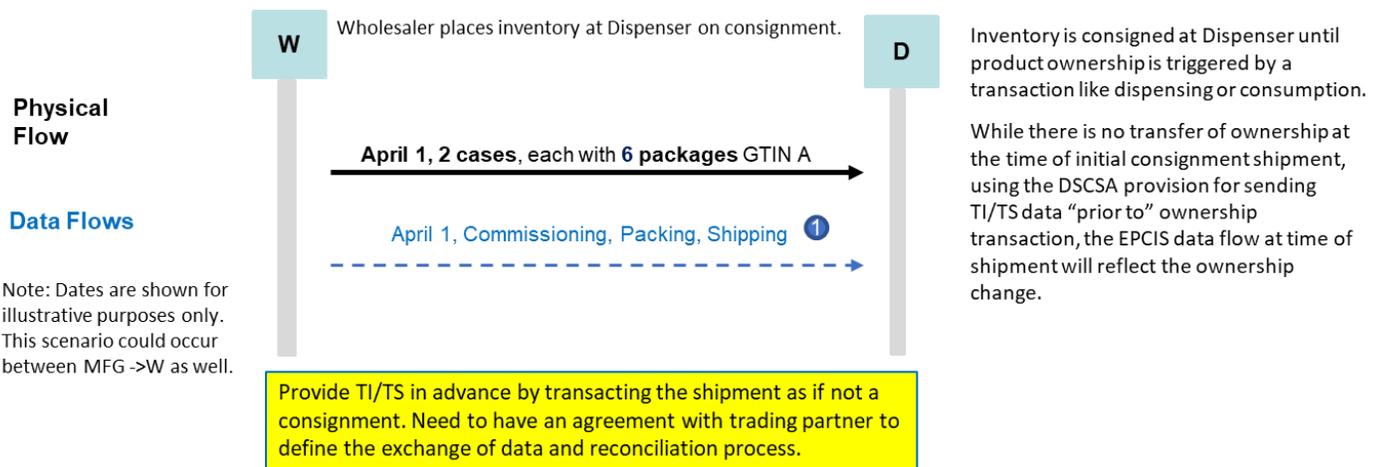
- The XML example can be accessed [here](#).

2.2.10.3 Scenario 10c

Sections 2.2.10.3.1-3.3: Alternatively, scenario 10c below, illustrates how the TI/TS can be sent during a change of possession as opposed to a change of ownership using the DSCSA provision for sending TI/TS data “prior to”¹ ownership transaction . EPCIS is provided at the change of possession and not resent at the change of ownership. This specific example has no triggering business event.

2.2.10.3.1 The Physical and Data Flow Diagram

In the diagram below the physical and data flow between the Wholesaler and Dispenser are depicted in one step.



Chain of Custody Business Steps	Message Sending Party	Message Receiving Party	Chain of Custody Electronic Exchange
① Wholesaler (W) ships product to Dispenser (D) on April 1 under consignment.	W	D	Wholesaler sends EPCIS Commissioning, Packing, and Shipping data to D. Note: Since TI/TS is provided in advance by transacting the shipment as if not a consignment , the Shipping eventTime reflects the actual consignment shipment date instead of ownership change date.

¹ DSCSA (Title II, Section 582 (9)(b)(1)(A)(i); (c)(1)(A)(i); (d)(1)(A)(i))

2.2.10.3.2 Table of EPCIS messages exchanged by Sending and Receiving parties

Scenario 10c: Consignment held at Dispenser until consumption but TI/TS sent in advance - XML Examples									
Scenario Step	EPCIS Sending Party	EPCIS Receiving Party	relevant CoC EPCIS Events	readPoint	bizLocation	sourceOwningParty	sourceLocation	destOwningParty	destLocation
① Wholesaler (W) ships product to Dispenser (D) on April 1 to hold on consignment	W	D	Commissioning	MFG	MFG				
			Packing	MFG	MFG				
			Commissioning (SSCCs)	W	W				
			Packing into logistics container	W	W				
			Shipping	W	N/A (Omitted)	W	W	D*	D

*Data is sent in anticipation of the change of ownership without anticipated event time. This scenario does not treat the transaction as consignment as the change of ownership transaction information and statement is provided at the change of possession.

Note: Dates are shown for illustrative purposes only

2.2.10.3.3 XML example of the EPCIS messages exchanged between parties.

- The XML example can be accessed [here](#).

2.2.11 340B Dispensing Entity utilizes Contract Pharmacy (with Patient)

340B Contract Pharmacy program is The Public Health Services 340B drug discount Program (the “340B Program”) was passed by Congress in 1992 and requires drug manufacturers to provide outpatient drugs to eligible health care organizations at significantly reduced prices. The intent of the 340B program is to reduce outpatient drug costs for health care providers that serve high volumes of poor, uninsured, and underinsured patients, so these providers can better serve them. Over time, Congress has expanded the numbers and types of institutions that can access 340B program prices to include children’s hospitals, rural referral centers, critical access hospitals and certain cancer hospitals in addition to the original 13 categories of safety-net providers who could participate in this program. Today, there are approximately 17,000 health care facilities eligible to participate in the 340B program, enabling them to stretch scarce resources, reach more eligible patients, and provide more comprehensive services.

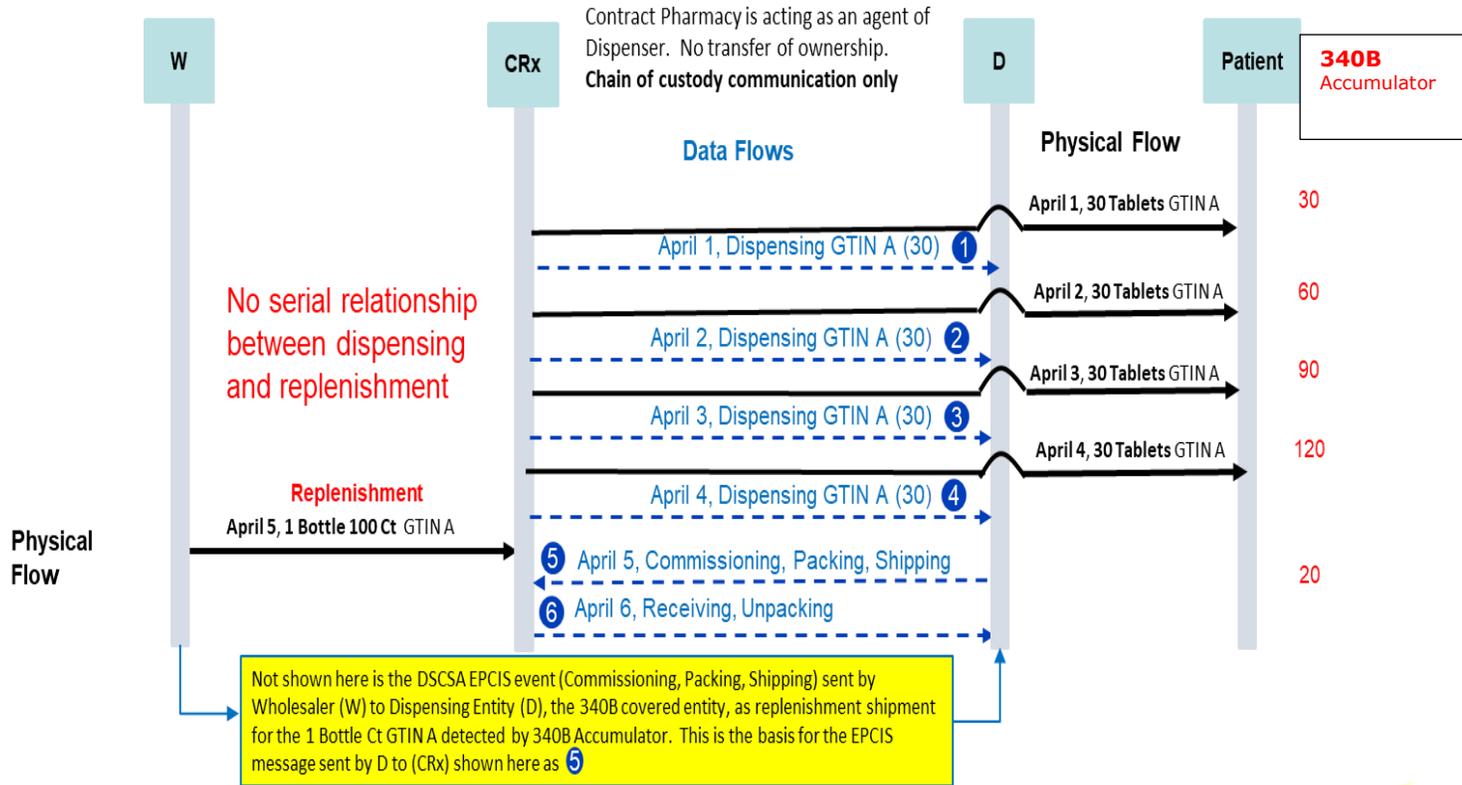
While the 340B program accommodates many dispensing arrangements for program participants, retail pharmacies became eligible to serve Covered Entities as contract pharmacies in 1996. The ability for retail pharmacies to be involved in the 340B program was expanded further in 2010 when Covered Entities were granted the ability to establish agreements with multiple pharmacies to meet their 340B dispensing requirements. Over time as safety-net participation in the 340B Program has increased and as greater numbers of retail pharmacies have entered into agreements with Covered Entities to become contracted 340B pharmacies, safety-net facilities have been able to offer their eligible patients a greater number of locations to receive their medications, while expanding on the services they provide for our neediest citizens².

The scenario below details the physical flow of products with the Chain of Custody Business Processes plus the data flows of Electronic Exchange between the supply chain trading partners. The flow is that the contract pharmacy orders the item for replenishment based on whatever process they use. It goes to the 340B Accumulator and see if there are full packages available. If so, it orders as many of the full packages as it can at the 340B price, and that is billed to the covered entity. If none or not enough in the accumulator it orders the rest on the pharmacies normal account.

² 340B Contract Pharmacy Services Best Practice Guide V.09062013 National Community Pharmacists Association

2.2.11.1 The Physical and Data Flow Diagram

In the diagram below the physical and data flow between the Wholesaler, Contract Pharmacy, Dispenser and Patient are depicted in six steps.



Note: Dates are shown for illustrative purposes only.

	Chain of Custody Business Step	Message Sending Party	Message Receiving Party	Chain of Custody Electronic Exchange
1	Contract Pharmacy (CRx) dispenses 30 tablets of GTIN A from stock to Patient(s) on April 1	CRx	D	CRx sends EPCIS Dispensing event to D
2	Contract Pharmacy (CRx) dispenses 30 tablets of GTIN A from stock to Patient(s) on April 2	CRx	D	CRx sends EPCIS Dispensing event to D
3	Contract Pharmacy (CRx) dispenses 30 tablets of GTIN A from stock to Patient(s) on April 3	CRx	D	CRx sends EPCIS Dispensing event to D
4	Contract Pharmacy (CRx) dispenses 30 tablets of GTIN A from stock to Patient(s) on April 4	CRx	D	CRx sends EPCIS Dispensing event to D
5	Dispenser (D) sends Wholesaler-provided serialized data to Contract Pharmacy (CRx) on April 5	D	CRx	D sends wholesaler-provided-EPCIS Commissioning, Packing and Shipping events to CRx as provided by Wholesaler (W) in DSCSA messages.
6	Contract Pharmacy (CRx) receives shipment from Wholesaler (W) on April 6	CRx	D	CRx sends EPCIS Receiving, Unpacking events to D

Capturing dispensing event is out of scope for this implementation guideline and will be managed by another system.

Note: Dates are shown for illustrative purposes only.

For consideration in future discussions on capturing dispensing event: Upon receipt of serialized products, CRx consolidates the contents of the serialized bottle of GTIN A into a single container from

which the tablets are dispensed. Visibility capture and tracking is reduced from instance level to class level identifier. Consider transformation event to transform sGTIN to GTIN. This impacts partial dispensing and potentially shipping and receiving.

2.2.11.2 Table of EPCIS messages exchanged by Sending and Receiving parties

The schedule below details the EPCIS Sending and Receiving parties with each of the XML examples for the bizSteps for each attribute.

Scenario: 11. 340B Dispensing Entity utilizes Contract Pharmacy – XML Examples									
Scenario Step	EPCIS Sending Party	EPCIS Receiving Party	relevant CoC EPCIS Events	readPoint	bizLocation	sourceOwningParty	sourceLocation	destOwningParty	destLocation
1 Contract Pharmacy (CRx) dispenses 30 tablets of GTIN A from stock to Patient(s) on April 1	CRx	D	Dispensing	CRx	N/A (omitted)				
2 Contract Pharmacy (CRx) dispenses 30 tablets of GTIN A from stock to Patient(s) on April 2	CRx	D	Dispensing	CRx	N/A (omitted)				
3 Contract Pharmacy (CRx) dispenses 30 tablets of GTIN A from stock to Patient(s) on April 3	CRx	D	Dispensing	CRx	N/A (omitted)				
4 Contract Pharmacy (CRx) dispenses 30 tablets of GTIN A from stock to Patient(s) on April 4	CRx	D	Dispensing	CRx	N/A (omitted)				
5 Dispenser (D) sends Wholesaler-provided serialized data to Contract Pharmacy (CRx) on April 5	D	CRx	Commissioning	W	W				
			Packing	W	W				
			Shipping	W	N/A (omitted)	W	W	D	CRx
6 Contract Pharmacy (CRx) receives shipment from Wholesaler (W) on April 6	CRx	D	Receiving	CRx	CRx	W	W	D	CRx
			Unpacking	CRx	CRx				

Capturing dispensing event is out of scope for this implementation guideline.

Note: Dates are shown for illustrative purposes only.

For consideration in future discussions on capturing dispensing event: Upon receipt of serialized products, CRx consolidates the contents of the serialized bottle of GTIN A into a single container from which the tablets are dispensed. Visibility capture and tracking is reduced from instance level to class level identifier. Consider transformation event to transform sGTIN to GTIN. Impacts partial dispensing and potentially shipping and receiving.

2.2.11.3 XML examples of the EPCIS messages exchanged between parties.

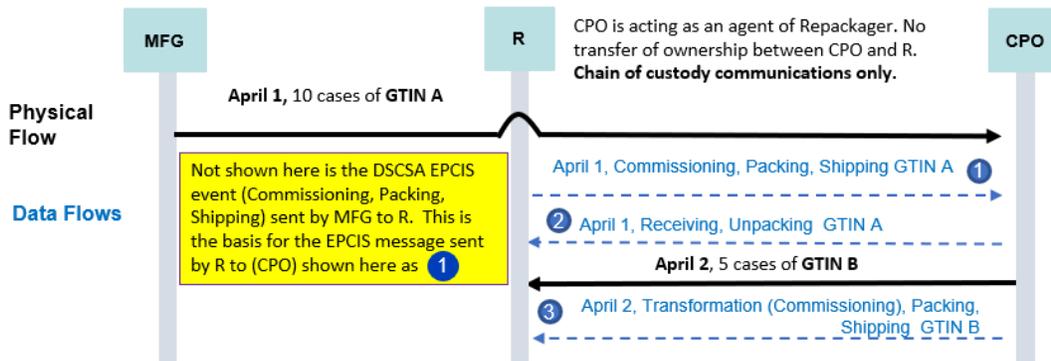
- The XML examples can be accessed [here](#).

2.2.12 Repackager utilizes Contract Packager (Virtual Repackager)

The scenario below details the physical flow of products with the Chain of Custody Business Processes plus the data flows of Electronic Exchange between the supply chain trading partners. MFG->[Repackager->CPO]->W

2.2.12.1 The Physical and Data Flow Diagram

In the diagram below the physical and data flow between the Manufacturer, Repackager, and CPO are depicted in three steps.



	Chain of Custody Business Steps	Message Sending Party	Message Receiving Party	Chain of Custody Electronic Exchange
1	Manufacturer (MFG) ships product (GTIN A) to Contract Packager (CPO) on April 1	R	CPO	R sends MFG-provided EPCIS Commissioning, Packing, and Shipping data to CPO as informed by DSCSA transaction.
2	CPO receives shipment of GTIN A from MFG on April 1	CPO	R	CPO sends EPCIS Receiving and Unpacking data to R
3	CPO repackages product, transforming into new product (GTIN B), and fulfills order and ships GTIN B to Repackager (R) on April 2	CPO	R	CPO sends EPCIS Transformation (Commissioning), Packing, and Shipping data, as applicable, to R

Note: Dates are shown for illustrative purposes only.

2.2.12.2 Table of EPCIS messages exchanged by Sending and Receiving parties

The schedule below details the EPCIS Sending and Receiving parties with each of the XML examples for the bizSteps for each attribute.

Scenario: 12. Repackager utilizes Contract Packager (Virtual Repackager) – XML Examples									
Scenario Step	EPCIS Sending Party	EPCIS Receiving Party	relevant CoC EPCIS Events	readPoint	bizLocation	sourceOwningParty	sourceLocation	destOwningParty	destLocation
1 Manufacturer (M) ships product (GTIN A) to Contract Packager (CPO) on April 1	R	CPO	Commissioning	MFG	MFG				
			Packing	MFG	MFG				
			Shipping	MFG	N/A (Omitted)	MFG	MFG	R	CPO
2 CPO receives shipment of GTIN A from M on April 1	CPO	R	Receiving	CPO	CPO	MFG	MFG	R	CPO
			Unpacking	CPO	CPO				
3 CPO repackages product, transforming into new product (GTIN B), and ships to Repackager (R) on April 2	CPO	R	Transformation (Commissioning)	CPO	CPO				
			Packing	CPO	CPO				
			Shipping	CPO	N/A (Omitted)	R	CPO	R	R

Note: Dates are shown for illustrative purposes only.

Grey fill indicates message is based on MFG-provided event data sent to R as part of DSCSA transaction.

2.2.12.3 XML examples of the EPCIS messages exchanged between parties.

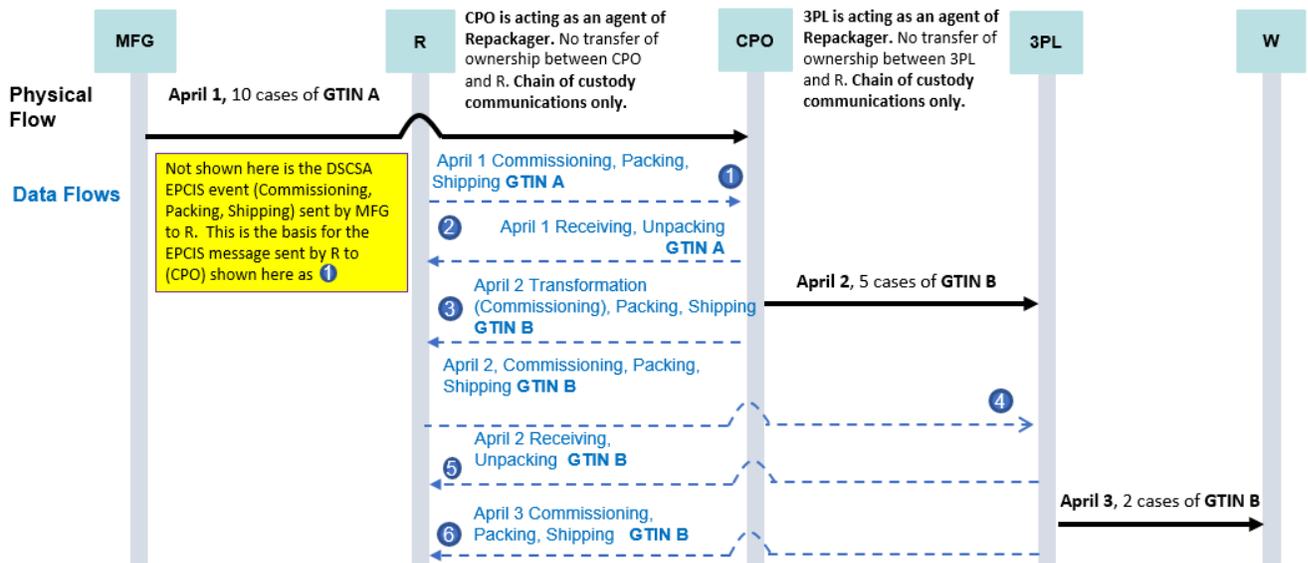
- The XML examples can be accessed [here](#).

2.2.13 Repackager utilizes Contract Packager and 3PL

The scenario below details the physical flow of products with the Chain of Custody Business Processes plus the data flows of Electronic Exchange between the supply chain trading partners.
MFG->[Repackager->CPO->3PL]->W

2.2.13.1 The Physical and Data Flow Diagram

In the diagram below the physical and data flow between the Manufacturer, Repackager, CPO, Third Party Logistics Provider and wholesaler are depicted in six steps.



Note: Dates are shown for illustrative purposes only.

	Chain of Custody Business Steps	Message Sending Party	Message Receiving Party	Chain of Custody Electronic Exchange
1	Manufacturer (M) ships product (GTIN A) to Contract Packager (CPO) on April 1	R	CPO	R sends MFG-provided EPCIS Commissioning, Packing, and Shipping data to CPO as informed by DSCSA transaction.
2	CPO receives shipment of GTIN A from M on April 1	CPO	R	CPO sends EPCIS Receiving and Unpacking data to R
3	CPO repackages product, transforming into new product (GTIN B), and ships to 3PL on April 2	CPO	R	CPO sends EPCIS Transformation (Commissioning), Packing, and Shipping data, as applicable, to R
4	R sends CPO-provided serialized data for GTIN B to 3PL on April 2	R	3PL	R sends CPO-provided EPCIS Commissioning, Packing, and Shipping data, as applicable, to 3PL
5	3PL receives shipment (GTIN B) from CPO on April 2	3PL	R	3PL sends EPCIS Receiving and Unpacking data to R
6	3PL fulfills order and ships product (GTIN B) to Wholesaler (W) on April 3	3PL	R	3PL sends EPCIS logistics Commissioning, Packing, and Shipping data to R

2.2.13.2 Table of EPCIS messages exchanged by Sending and Receiving parties

The schedule below details the EPCIS Sending and Receiving parties with each of the XML examples for the bizSteps for each attribute.

Scenario: 13. Repackager utilizes Contract Packager and 3PL – XML Examples									
Scenario Step	EPCIS Sending Party	EPCIS Receiving Party	relevant CoC EPCIS Events	readPoint	bizLocation	sourceOwningParty	sourceLocation	destOwningParty	destLocation
1	R	CPO	Commissioning	MFG	MFG				
			Packing	MFG	MFG				
			Shipping	MFG	N/A (Omitted)	MFG	MFG	R	CPO
2	CPO	R	Receiving	CPO	CPO	MFG	MFG	R	CPO
			Unpacking	CPO	CPO				
3	CPO	R	Transformation (Commissioning)	CPO	CPO				
			Packing	CPO	CPO				
			Shipping	CPO	N/A (Omitted)	R	CPO	R	3PL
4	R	3PL	Commissioning	CPO	CPO				
			Packing	CPO	CPO				
			Shipping	CPO	N/A (Omitted)	R	CPO	R	3PL

Scenario: 13. Repackager utilizes Contract Packager and 3PL – XML Examples									
Scenario Step	EPCIS Sending Party	EPCIS Receiving Party	relevant CoC EPCIS Events	readPoint	bizLocation	sourceOwningParty	sourceLocation	destOwningParty	destLocation
5 3PL receives shipment (GTIN B) from CPO on April 2	3PL	R	Receiving	3PL	3PL	R	CPO	R	3PL
			Unpacking	3PL	3PL				
6 3PL fulfills order and ships product (GTIN B) to Wholesaler (W) on April 3	3PL	R	Commissioning SSCCs	3PL	3PL				
			Packing	3PL	3PL				
			Shipping	3PL	N/A (Omitted)	R	3PL	W	W

Note: Dates are shown for illustrative purposes only.
 Grey fill indicates message is based on event data provided from dataflow 3

An EPCIS event previously generated and shared with a trading partner is later discovered to be incorrect. In such scenarios, the preferred approach is to create a new EPCIS event that reverses the earlier, incorrect event.

2.2.13.3 XML examples of the EPCIS messages exchanged between parties.

- The XML examples can be accessed [here](#).

2.3 Chain of Custody Reverse Logistics Supply Chain Choreographies

These two reverse logistics scenarios focus on the physical flow of products with the Chain of Custody Business Processes plus the data flows of Electronic Exchange between the supply chain trading partners.

The XML examples for reverse logistics scenarios can be accessed [here](#).

2.3.1 Collection of Returned Products

Reverse Logistics Providers (RLPs) are contracted by Manufacturer to collect returned products from Dispensers and Wholesalers. RLPs are agents of both Wholesalers and Manufacturers. Only non-sellable returns are expected to be returned to RLPs.

RLP services include:

- Processing return products for credit;
- Sending products to destruction facilities for destruction;
- Perform recording keeping

For consistency, we will illustrate how EPCIS can be utilized by Dispensers and Wholesalers to capture the product return with an EPCIS shipping event (disposition = returned).

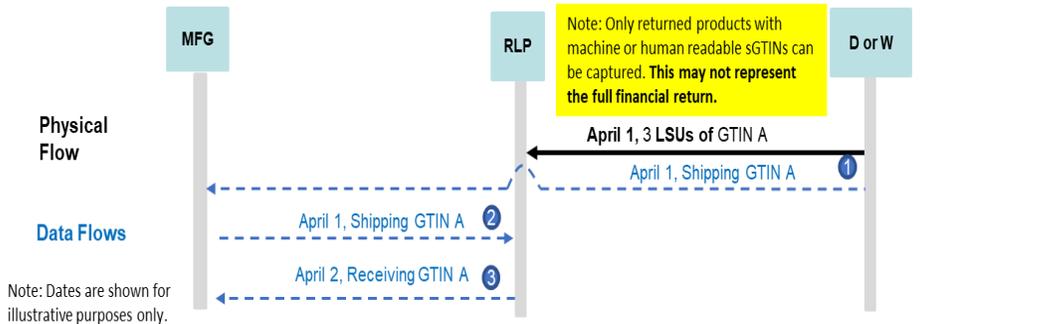
Regardless of whether an incoming shipping event accompanies the physical returned product, RLPs record the receiving event and send it to Manufacturer.

2.3.1.1 Collection of Returned Products – received & assess in 1 Step

Scenario 1 is separated into two categories as a single event and a two-step process. Scenario 1a is the Reverse Logistics Provider receiving and access the status of the products in a single step. The Reverse Logistics Provider is receiving at the logistics unit level and inferring the status of the contents based on the RMA indicating that the products being returned are damaged.

2.3.1.1.1 The Physical and Data Flow Diagram

In the diagram below the physical and data flow between the Manufacturer, Reverse Logistics Provider and Dispenser or Wholesaler are depicted in three steps.



	Chain of Custody Business Steps	Message Sending Party	Message Receiving Party	Chain of Custody Electronic Exchange
1	Dispenser (D) or Wholesaler (W) ships returned products to Reverse Logistics Provider (RLP) on April 1	D or W	MFG	Dispenser (D) or Wholesaler (W) optionally sends Shipping data.
2	When Dispenser (D) or Wholesaler (W) sends returned shipping data to Manufacturers, the Manufacturer (MFG) sends dispenser or wholesaler-provided shipping data to RLP	MFG	RLP	The Manufacturer (MFG) conditionally sends dispenser or wholesaler-provided shipping data to RLP
3	RLP receives returned product on April 2. Since the incoming returned shipment pertain to multiple manufacturers, RLP will receive product per manufacturer. As part of this receipt process, they assess the state of the product (whether it's damaged, expired, recalled, non_sellable_other)	RLP	MFG	Grouping the returned products per manufacturer, RLP must send the EPCIS Receiving data with the disposition reflecting the RLP's assessment of the returned product at time of receipt. Consequently, the single shipment from D or W will result in 1 or more receiving events depending on the number of distinct manufacturers.

2.3.1.1.2 Table of EPCIS messages exchanged by Sending and Receiving parties

The schedule below details the EPCIS Sending and Receiving parties with each of the XML examples for the bizSteps for each attribute.

1a. Collection of Returned Products – receive & assess in 1 step

Scenario 1a: Collection of Returned Products – receive & assess in 1 step									
Scenario Step	EPCIS Sending Party	EPCIS Receiving Party	relevant CoC EPCIS Events	action	disposition	readPoint	bizLocation	sourceLocation	destLocation
1 Dispenser (D) or Wholesaler (W) ships returned products to Reverse Logistics Provider (RLP) on April 1. D or W optionally sends Shipping data to MFG.	D or W	MFG	Shipping	OBSERVE	in_transit	D or W	N/A (Omitted)	D or W	RLP
2 Manufacturer (MFG) conditionally sends dispenser or wholesaler-provided shipping data to RLP	MFG	RLP	Shipping	OBSERVE	in_transit	D or W	N/A (Omitted)	D or W	RLP
3 RLP receives returned product on April 2. Since the incoming returned shipment pertain to multiple manufacturers, RLP must receive product per manufacturer. As part of this receipt process, they assess the state of the product (whether it's damaged, expired, recalled, non_sellable_other)	RLP	MFG	Receiving	OBSERVE	damaged, expired, recalled or non_sellable_other	RLP	RLP	D or W	RLP

Note: Dates are shown for illustrative purposes only.

Grey fill indicates message is based on event data provided from dataflow 1.

Note: Only returned products with machine or human readable sGTINs can be captured. This may not represent the full financial return. Since returned products are exempted from DSCSA transfer of ownership requirements, we will track the return product movements as chain of custody events and therefore exclude sourceOwningParty and destOwningParty in the EPCIS messages.

2.3.1.1.3 XML examples of the EPCIS messages exchanged between parties.

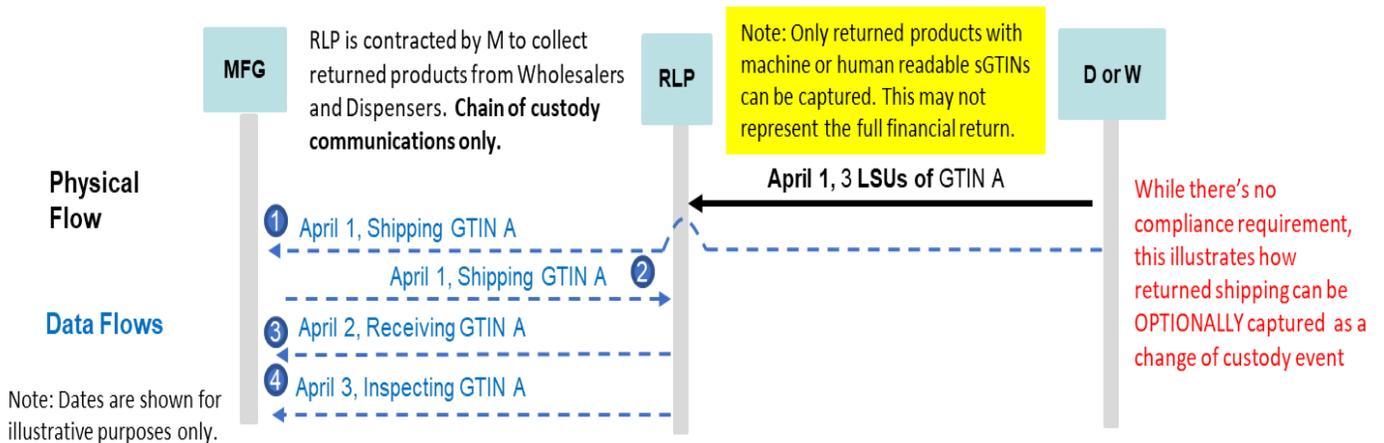
- The XML examples can be accessed [here](#).

2.3.1.2 Collection of Returned Products – Received & Assess in 2 Steps

In this scenario the RLP receives the return first, and then assesses the status of the product in a second step.

2.3.1.2.1 The Physical and Data Flow Diagram

In the diagram below the physical and data flow between the Manufacturer, Reverse Logistics Provider and Dispenser or Wholesaler are depicted in four steps.



	Chain of Custody Business Steps	Message Sending Party	Message Receiving Party	Chain of Custody Electronic Exchange
1	Dispenser (D) or Wholesaler (W) ships returned products to Reverse Logistics Provider (RLP) on April 1	D or W	MFG	Dispenser (D) or Wholesaler (W) optionally sends Shipping data
2	When Dispenser (D) or Wholesaler (W) sends returned shipping data to Manufacturers, the Manufacturer (MFG) sends dispenser or wholesaler-provided shipping data to RLP	MFG	RLP	Manufacturer (MFG) conditionally sends dispenser or wholesaler-provided shipping data to RLP
3	RLP receives returned product on April 2. Since the incoming returned shipment pertain to multiple manufacturers, RLP will receive product per manufacturer.	RLP	MFG	Grouping the returned products per manufacturer, RLP must send EPCIS Receiving data . Consequently, the single shipment from D or W will result in 1 or more receiving event depending on the number of distinct manufacturers.
4	RLP inspects the state of the product to assess whether it's damaged, expired, recalled, non_sellable_other	RLP	MFG	RLP must send EPCIS Inspecting data with the disposition reflecting the RLP's assessment of the returned product

2.3.1.2.2 Table of EPCIS messages exchanged by Sending and Receiving parties

The schedule below details the EPCIS Sending and Receiving parties with each of the XML examples for the bizSteps for each attribute.

Scenario 1b: Collection of Returned Products – receive and assess in 2 steps									
Scenario Step	EPCIS Sending Party	EPCIS Receiving Party	relevant CoC EPCIS Events	action	disposition	readPoint	bizLocation	sourceLocation	destLocation
1 Dispenser (D) or Wholesaler (W) ships returned products to Reverse Logistics Provider (RLP) on April 1. D or W optionally sends Shipping data to MFG.	D or W	MFG	Shipping	OBSERVE	in_transit	D or W	N/A (Omitted)	D or W	RLP
2 Manufacturer (MFG) conditionally sends dispenser or wholesaler-provided shipping data to RLP	MFG	RLP	Shipping	OBSERVE	in_transit	D or W	N/A (Omitted)	D or W	RLP
3 RLP receives returned product on April 2. Since the incoming returned shipment pertain to multiple manufacturers, RLP must receive product per manufacturer.	RLP	MFG	Receiving	OBSERVE	In_progress	RLP	RLP	D or W	RLP
4 RLP must inspect the state of the product to assess whether it's damaged, expired, recalled, non_sellable_other	RLP	MFG	Inspecting	OBSERVE	damaged, expired, recalled or non_sellable_other	RLP	RLP	N/A	N/A

Grey fill indicates message is based on event data provided from dataflow 1.

Note: Dates are shown for illustrative purposes only.

Note: Only returned products with machine or human readable sGTINs can be captured. This may not represent the full financial return. Since returned products are exempted from DSCSA transfer of ownership requirements, we will track the return product movements as chain of custody events and therefore exclude sourceOwningParty and destOwningParty in the EPCIS messages.

2.3.1.2.3 XML examples of the EPCIS messages exchanged between parties.

- The XML examples can be accessed [here](#).

2.3.2 Destruction of Returned Products

Destruction Facilities are contracted by Manufacturer to physically destroy and dispose products. The Manufacturer is ultimately responsible for the destruction and disposal of their products while they are outsourcing these services to a destruction facility. The Manufacturer can monitor and communicate directly with Destruction Facilities to track when the physical destruction has occurred and complete documentation.

Alternatively, the Manufacturer can outsource the coordination of destruction activities with RLPs. Consequently, Manufacturer delegates RLP to:

- Identify products for destruction,
- Ship products to Destruction Facility and
- Record the destruction.

RLP captures and sends Shipping event as returned products are sent to the destruction facility. Upon notification of destruction, RLP captures and sends the destruction facility-provided Destroying event: Destruction facility has the capability to perform data exchanges. This also covers the situation wherein an RLP is delegated as destruction facility.

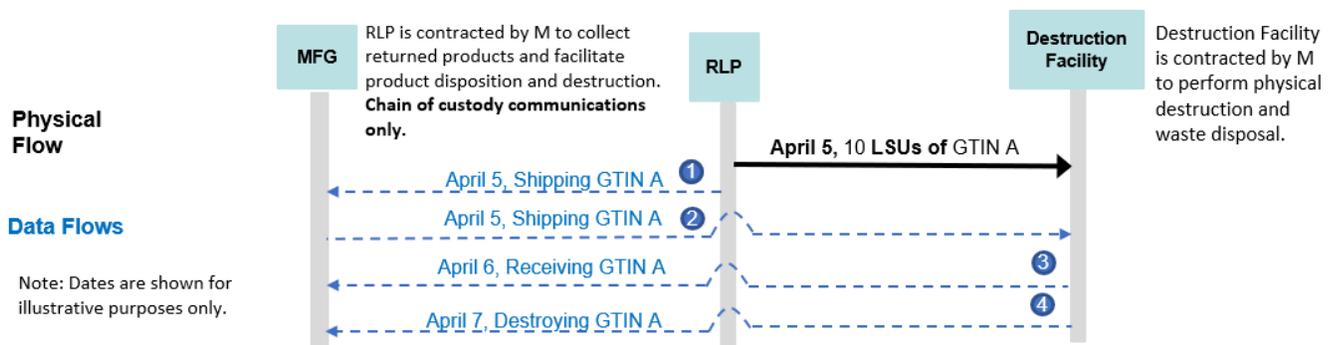
These two Returned Goods logistics scenarios, focus on the physical flow of products destroyed with the Chain of Custody Business Processes plus the data flows of Electronic Exchange between the supply chain trading partners.

- The XML examples can be accessed [here](#).

2.3.2.1 Destruction of Returned Products – wherein the Destruction facility has capability to perform data exchanges.

2.3.2.1.1 The Physical and Data Flow Diagram

In the diagram below, the physical and data flow between the Manufacturer, Reverse Logistics Provider, and Destruction Facility are depicted in four steps.



Note: Only returned products with machine or human readable sGTINs can be captured. This may not represent the full financial return.

	Chain of Custody Business Steps	Message Sending Party	Message Receiving Party	Chain of Custody Electronic Exchange
1	RLP ships returned products to Destruction Facility designated by MFG as destruction agent	RLP	MFG	RLP sends EPCIS Shipping data to MFG
2	MFG sends RLP-provided Shipping data to Destruction Facility	MFG	Destruction Facility	MFG sends RLP-provided Shipping data
3	Destruction Facility receives products for destruction	Destruction Facility	MFG	Destruction Facility sends EPCIS Receiving data
4	Destruction Facility performs physical destruction	Destruction Facility	MFG	Destruction Facility sends EPCIS destroying data

Although the product returned for destruction is an unsaleable product and beyond the scope of the DSCSA track and trace requirements, many manufacturers are interested in gathering decommissioning information from the reverse logistic providers as they process the unsaleable returns.



Recommend:

1. Decommission until at or right before the product is destroyed.

- Decommissioning is the end-of-life event for the EPC identifier. Unlike the destroying business process, the item may still physically exist after decommissioning even though it no longer carries serialized identification.
- 2. The Reverse Logistic Provider should report the Decommissioning event to the manufacturer who can update their repository to show that serial is no longer valid should anyone else inquire about the serial using verification.
 - The Decommissioning event should be populated as described in Implementation Guideline (See Section link)

2.3.2.1.2 Table of EPCIS messages exchanged by Sending and Receiving parties

The schedule below details the EPCIS Sending and Receiving parties with each of the XML examples for the bizSteps for each attribute.

Scenario: Destruction of Returned Products – wherein the Destruction Facility has capability to perform data exchanges									
Scenario Step	EPCIS Sending Party	EPCIS Receiving Party	relevant CoC EPCIS Events	action	disposition	readPoint	bizLocation	sourceLocation	destLocation
1 RLP ships returned products to Destruction Facility designated by MFG as destruction agent	RLP	MFG	Shipping	OBSERVE	In_transit	RLP	N/A (Omitted)	RLP	Destruction Facility
2 MFG sends RLP- provided Shipping data to Destruction Facility	MFG	Destruction Facility	Shipping	OBSERVE	In_transit	RLP	N/A (Omitted)	RLP	Destruction Facility
3 Destruction Facility receives products for destruction	Destruction Facility	MFG	Receiving	OBSERVE	in_progress	Destruction Facility	Destruction Facility	RLP	Destruction Facility
4 Destruction Facility performs physical destruction	Destruction Facility	MFG	Destroying	DELETE	destroyed	Destruction Facility	N/A	N/A	N/A

Note: Since returned products are exempted from DSCSA transfer of ownership requirements, we will track the return product movements as chain of custody events and therefore exclude sourceOwningParty and destOwningParty in the EPCIS messages.

Note: Only returned products with machine or human readable sGTINs can be captured. This may not represent the full financial return.

Grey fill indicates message is based on event data provided from dataflow 1.

Note: Dates are shown for illustrative purposes only.

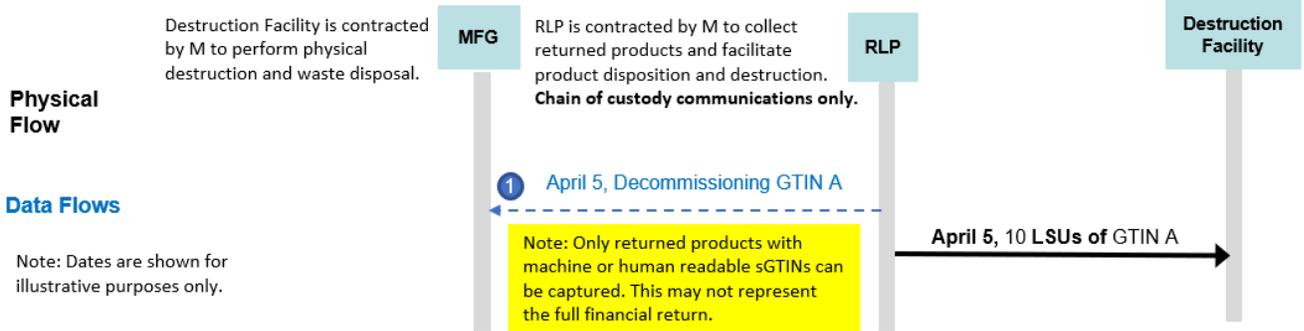
2.3.2.1.3 XML examples of the EPCIS messages exchanged between parties.

- The XML examples can be accessed [here](#).

2.3.2.2 Destruction of Returned Products – wherein the Destruction facility ONLY performs destruction.

2.3.2.2.1 The Physical and Data Flow Diagram

In the diagram below the physical and data flow between the Manufacturer, Reverse Logistics Provider and Destruction Facility are depicted in one step.



	Chain of Custody Business Steps	Message Sending Party	Message Receiving Party	Chain of Custody Electronic Exchange
1	RPL decommissions returned products BEFORE physically shipping them to the destruction facility	RPL	MFG	RPL sends EPCIS Decommissioning data

2.3.2.2.2 Table of EPCIS messages exchanged by Sending and Receiving parties

The schedule below details the EPCIS Sending and Receiving parties with each of the XML examples for the bizSteps for each attribute.

Scenario: Destruction of Returned Products – wherein the Destruction facility ONLY performs physical destruction									
Scenario Step	EPCIS Sending Party	EPCIS Receiving Party	relevant CoC EPCIS Events	action	disposition	readPoint	bizLocation	sourceLocation	destLocation
1 RPL decommissions returned products BEFORE physically shipping them to the destruction facility	RPL	MFG	Decommissioning	DELETE	inactive	RPL	N/A (Omitted)	N/A	N/A

Note: Only returned products with machine or human readable sGTINs can be captured. This may not represent the full financial return.

2.3.2.2.3 XML examples of the EPCIS messages exchanged between parties.

- The XML examples can be accessed [here](#).

Appendix A: GS1 Standards

From an information management point of view, supply chain applications like item level traceability require all parties to systematically associate the physical flow of products with the flow of information about them. This is best attained by deploying a common business language within the framework of a comprehensive standards system. The GS1 System is such a system, providing a comprehensive platform for companies to identify products and other business entities, capture supply chain data, and share data with trading partners.

The GS1 System encompasses identification standards, data standards, automatic identification data capture (AIDC) standards, and data communication standards. Table 16 below summarizes some of the GS1 Standards that support item level traceability.

Table Error! No text of specified style in document. -1 Overview of GS1 Standards to Support Traceability

GS1 Standards Supporting Item Level Traceability			
Identification Standards	Trade Items	Global Trade Item Number (GTIN)	
	Locations & Trading Partners	Global Location Number (GLN)	
	Logistics Units	Serial Shipping Container Code (SSCC)	
AIDC Standards	GS1 BarCodes	GS1-128 GS1 DataMatrix RSS EAN/UPC ITF-14 Composite Component	
Data Standards	Master Data: Global Data Dictionary Item Business Messaging Standard Party Business Messaging Standard	Transactional Data: eCom/EDI	Event Data: EPCIS Schema EPCIS Core Business Vocabulary
Sharing & Communication Standards	Master Data: GDSN Data Hub Location EPCIS Master Data	Transactional Data: AS2	Event Data: EPCIS Capture EPCIS Query Discovery Services

Appendix B: XML Examples for Choreographed Supply Chain Scenarios

Scenario	XML Example
Sample XML for Exchange 1 between Manufacturer and 3PL	Scenario-2.2.1.3.1 MFG utilizes 3PL[MFGto3PL] Exchange1.xml
Sample XML for Exchange 2 between 3PL and Manufacturer	Scenario-2.2.1.3.2 MFG utilizes 3PL[3PLtoMFG] Exchange2.xml
Sample XML for Exchange 3 between 3PL and Manufacturer	Scenario-2.2.1.3.3 MFG utilizes 3PL[3PLtoMFG] Exchange3.xml
Sample XML for Exchange 1 between Wholesaler and 3PL to Wholesaler	Scenario-2.2.2.3.1 WHLS utilizes 3PL[WHLSto3PL] Exchange1.xml
Sample XML for Exchange 1 between Wholesaler and 3PL to Wholesaler	Scenario-2.2.2.3.2 WHLS utilizes 3PL[3PLtoWHLS] Exchange2.xml
Sample XML for Exchange 1 between Wholesaler and 3PL to Wholesaler	Scenario-2.2.2.3.3 WHLS utilizes 3PL[3PLtoWHLS] Exchange3.xml
Sample XML for Exchange 1 between Wholesaler and 3PL to Wholesaler	Scenario-2.2.3.3.1 MFG utilizes CMO[CMOtoMFG] Exchange1.xml
Sample XML for Exchange 1 between CMO and Manufacturer	Scenario-2.2.4.1.3.1 MFG utilizes CMO 3PL[CMOtoMFG] Exchange1.xml
Sample XML for Exchange 2 between Manufacturer and 3PL	Scenario-2.2.4.1.3.2 MFG utilizes CMO 3PL[MFGto3PL] Exchange2.xml
Sample XML for Exchange 3 between 3PL and Manufacturer	Scenario-2.2.4.1.3.3 MFG utilizes CMO 3PL[3PLtoMFG] Exchange3.xml
Sample XML for Exchange 4 between 3PL and Manufacturer	Scenario-2.2.4.1.3.4 MFG utilizes CMO 3PL[3PLtoMFG] Exchange4.xml
Sample XML for Exchange 1 between CMO and Manufacturer	Scenario-2.2.4.2.3.1 MFG utilizes CMO 3PL[CMOtoMFG] Exchange1.xml
Sample XML for Exchange 2 between Manufacturer and 3PL	Scenario-2.2.4.2.3.2 MFG utilizes CMO 3PL[MFGto3PL] Exchange2.xml
Sample XML for Exchange 3 between 3PL and Manufacturer	Scenario-2.2.4.2.3.3 MFG utilizes CMO 3PL[3PLtoMFG] Exchange3.xml
Sample XML for Exchange 4 between 3PL and Manufacturer	Scenario-2.2.4.2.3.4 MFG utilizes CMO 3PL[3PLtoMFG] Exchange4.xml
Sample XML Exchange 1 between CMO and Manufacturer	Scenario-2.2.5.3.1 MFG utilizes CMO 3PL WHLS utilizes 3PL[CMOtoMFG] Exchange1.xml
Sample XML Exchange 2 between Manufacturer and Manufacturer's 3PL	Scenario-2.2.5.3.2 MFG utilizes CMO 3PL WHLS utilizes 3PL[MFGto3PL] Exchange2.xml
Sample XML Exchange 3 between Manufacturer's 3PL and Manufacturer	Scenario-2.2.5.3.3 MFG utilizes CMO 3PL WHLS utilizes 3PL[3PLtoMFG] Exchange3.xml

Scenario	XML Example
Sample XML Exchange 4 between Manufacturer's 3PL and Manufacturer	<u>Scenario-2.2.5.3.4</u> <u>MFG utilizes CMO 3PL WHLS utilizes 3PL[3PLtoMFG] Exchange4.xml</u>
Sample XML Exchange 5 between Wholesaler and Wholesaler's 3PL	<u>Scenario-2.2.5.3.5</u> <u>MFG utilizes CMO 3PL WHLS utilizes 3PL[WHLS to 3PL] Exchange5.xml</u>
Sample XML Exchange 6 between Wholesaler's 3PL and Wholesaler	<u>Scenario-2.2.5.3.6</u> <u>MFG utilizes CMO 3PL WHLS utilizes 3PL[3PLtoWHLS] Exchange6.xml</u>
Sample XML Exchange 6 between Wholesaler's 3PL and Wholesaler	<u>Scenario-2.2.5.3.7</u> <u>MFG utilizes CMO 3PL WHLS utilizes 3PL[3PLtoWHLS] Exchange7.xml</u>
Sample XML Exchange 1 between CMO and Virtual Contract Manufacturer	<u>Scenario-2.2.6.3.1</u> <u>MFG utilizes VCMO outsourceto CMO[CMOtoVCMO] Exchange1.xml</u>
Sample XML Exchange 2 between Virtual Contract Manufacturer and Manufacturer	<u>Scenario-2.2.6.3.2</u> <u>MFG utilizes VCMO outsourceto CMO[VCMOtoMFG] Exchange2.xml</u>
Sample XML Exchange 1 between CMO and Manufacturer	<u>Scenario-2.2.7.3.1</u> <u>MFG utilizes CMO serial CPO agg[CMOtoMFG] Exchange1.xml</u>
Sample XML Exchange 2 between Manufacturer and CPO	<u>Scenario-2.2.7.3.2</u> <u>MFG utilizes CMO serial CPO agg[MFGtoCPO] Exchange2.xml</u>
Sample XML Exchange 3 between CPO and Manufacturer	<u>Scenario-2.2.7.3.3</u> <u>MFG utilizes CMO serial CPO agg[CPOtoMFG] Exchange3.xml</u>
Sample XML Exchange 2 between CPO and Manufacturer	<u>Scenario-2.2.7.3.4</u> <u>MFG utilizes CMO serial CPO agg[CPOtoMFG] Exchange4.xml</u>
Sample XML Exchange 1 between CMO and Manufacturer	<u>Scenario-2.2.8.3.1</u> <u>MFG utilizes CMO serial CPO agg 3PL[CMOtoMFG] Exchange1.xml</u>
Sample XML Exchange 2 between Manufacturer and CPO	<u>Scenario-2.2.8.3.2</u> <u>MFG utilizes CMO serial CPO agg 3PL[MFGtoCPO] Exchange2.xml</u>
Sample XML Exchange 3 between CPO and Manufacturer	<u>Scenario-2.2.8.3.3</u> <u>MFG utilizes CMO serial CPO agg 3PL[CPOtoMFG] Exchange3.xml</u>
Sample XML Exchange 2 between CPO and Manufacturer	<u>Scenario-2.2.8.3.4</u> <u>MFG utilizes CMO serial CPO agg 3PL[CPOtoMFG] Exchange4.xml</u>
Sample XML Exchange 2 between Manufacturer and 3PL	<u>Scenario-2.2.8.3.5</u> <u>MFG utilizes CMO serial CPO agg 3PL[MFGto3PL] Exchange5.xml</u>
Sample XML Exchange 2 between 3PL and Manufacturer	<u>Scenario-2.2.8.3.6</u> <u>MFG utilizes CMO serial CPO agg 3PL[3PLtoMFG] Exchange6.xml</u>

Scenario	XML Example
Sample XML Exchange 2 between 3PL and Manufacturer	<u>Scenario-2.2.8.3.7</u> <u>MFG utilizes CMO serial CPO agg 3PL[3PLtoMFG] Exchange7.xml</u>
Sample XML Exchange 1 between CMO and Manufacturer	<u>Scenario-2.2.9.3.1</u> <u>MFG utilizes CMO serial CPO agg 3PL W uses 3PL[CMOtoMFG] Exchange1.xml</u>
Sample XML Exchange 2 between Manufacturer and CPO	<u>Scenario-2.2.9.3.2</u> <u>MFG utilizes CMO serial CPO agg 3PL W uses 3PL[MFGtoCPO] Exchange2.xml</u>
Sample XML Exchange 3 between CPO and Manufacturer	<u>Scenario-2.2.9.3.3</u> <u>MFG utilizes CMO serial CPO agg 3PL W uses 3PL[CPOtoMFG] Exchange3.xml</u>
Sample XML Exchange 2 between CPO and Manufacturer	<u>Scenario-2.2.9.3.4</u> <u>MFG utilizes CMO serial CPO agg 3PL W uses 3PL[CPOtoMFG] Exchange4.xml</u>
Sample XML Exchange 2 between Manufacturer and 3PL	<u>Scenario-2.2.9.3.5</u> <u>MFG utilizes CMO serial CPO agg 3PL W uses 3PL[MFGto3PL] Exchange5.xml</u>
Sample XML Exchange 2 between 3PL and Manufacturer	<u>Scenario-2.2.9.3.6</u> <u>MFG utilizes CMO serial CPO agg 3PL W uses 3PL[3PLtoMFG] Exchange6.xml</u>
Sample XML Exchange 2 between 3PL and Manufacturer	<u>Scenario-2.2.9.3.7</u> <u>MFG utilizes CMO serial CPO agg 3PL W uses 3PL[3PLtoMFG] Exchange7.xml</u>
Sample XML Exchange 2 between 3PL and Manufacturer	<u>Scenario-2.2.9.3.8</u> <u>MFG utilizes CMO serial CPO agg 3PL W uses 3PL[Wto3PL W] Exchange8.xml</u>
Sample XML Exchange 2 between 3PL and Manufacturer	<u>Scenario-2.2.9.3.9</u> <u>MFG utilizes CMO serial CPO agg 3PL W uses 3PL[3PL Wto W] Exchange9.xml</u>
Sample XML Exchange 2 between 3PL and Manufacturer	<u>Scenario-2.2.9.3.10</u> <u>MFG utilizes CMO serial CPO agg 3PL W uses 3PL[3PL Wto W] Exchange10.xml</u>
Sample XML Exchange 1 between Wholesaler and Dispenser for Consignment	<u>Scenario-2.2.10.1.3 W consignment D[WtoD] Exchange1.xml</u>
Sample XML Exchange 1 between Manufacturer and Wholesaler	<u>Scenario-2.2.10.2.3 MFG consignment W[MFGtoW] Exchange1.xml</u>
Sample XML Exchange 2 between Wholesaler and Dispenser for Consignment	<u>Scenario-2.2.10.3.3 W consignment D[WtoD] Exchange2.xml</u>
Sample XML Exchange 1 between Dispenser and Contract Pharmacy	<u>Scenario-2.2.11.3.1 340B Dispenser utilizes CRx[DtoCRx] Exchange1.xml</u>
Sample XML Exchange 2 between Contract Pharmacy and Dispenser	<u>Scenario-2.2.11.3.2 340B Dispenser utilizes CRx[CRxtoD] Exchange2.xml</u>
Sample XML Exchange 1 between Repackager and CPO	<u>Scenario-2.2.12.3.1 Repkg utilizes CPO[RtoCPO] Exchange1.xml</u>

Scenario	XML Example
Sample XML Exchange 2 between CPO and Repackager	Scenario-2.2.12.3.2 Repkg utilizes CPO[CPOtoR] Exchange2.xml
Sample XML Exchange 3 between CPO and Repackager	Scenario-2.2.12.3.3 Repkg utilizes CPO[CPOtoR] Exchange3.xml
Sample XML Exchange 1 between Repackager and CPO	Scenario-2.2.13.3.1 Repkg utilizes CPO 3PL[RtoCPO] Exchange1.xml
Sample XML Exchange 2 between CPO and Repackager	Scenario-2.2.13.3.2 Repkg utilizes CPO 3PL[CPOtoR] Exchange2.xml
Sample XML Exchange 3 between CPO and Repackager	Scenario-2.2.13.3.3 Repkg utilizes CPO 3PL[CPOtoR] Exchange3.xml
Sample XML Exchange 4 between Repackager and 3PL	Scenario-2.2.13.3.4 Repkg utilizes CPO 3PL[Rto3PL] Exchange4.xml
Sample XML Exchange 5 between 3PL and Repackager	Scenario-2.2.13.3.5 Repkg utilizes CPO 3PL[3PLtoR] Exchange5.xml
Sample XML Exchange 6 between 3PL and Repackager	Scenario-2.2.13.3.6 Repkg utilizes CPO 3PL[3PLtoR] Exchange6.xml
Sample XML Exchange 1 between Dispenser and Manufacturer	Scenario-2.3.1.1.3.1 Reverse-CollectionRetProd[DtoMFG] Exchange1.xml
Sample XML Exchange 2 between Manufacturer and RLP	Scenario-2.3.1.1.3.2 Reverse-CollectionRetProd[MFGtoRLP] Exchange2.xml
Sample XML Exchange 3 between RLP and Manufacturer	Scenario-2.3.1.1.3.3 Reverse-CollectionRetProd[RLPtoMFG] Exchange3
Sample XML Exchange 1 between Dispenser and Manufacturer	Scenario-2.3.1.2.3.1 Reverse-CollectionRetProd[DtoMFG] Exchange1.xml
Sample XML Exchange 2 between Manufacturer and RLP	Scenario-2.3.1.2.3.2 Reverse-CollectionRetProd[MFGtoRLP] Exchange2.xml
Sample XML Exchange 3 between RLP and Manufacturer	Scenario-2.3.1.2.3.3 Reverse-CollectionRetProd[RLPtoMFG] Exchange3.xml
Sample XML Exchange 4 between RLP and Manufacturer	Scenario-2.3.1.2.3.4 Reverse-CollectionRetProd[RLPtoMFG] Exchange4.xml
Sample XML Exchange 1 between RLP and Manufacturer	Scenario-2.3.2.1.3.1 Reverse-DestructionOfRetProducts[RLPtoMFG] Exchange1.xml
Sample XML Exchange 2 between Manufacturer and Destruction Facility	Scenario-2.3.2.1.3.2 Reverse-DestructionOfRetProducts[MFGtoDF] Exchange2.xml
Sample XML Exchange 3 between Destruction Facility and Manufacturer	Scenario-2.3.2.1.3.3 Reverse-DestructionOfRetProducts[DFtoMFG] Exchange3.xml
Sample XML Exchange 4 between Destruction Facility and Manufacturer	Scenario-2.3.2.1.3.4 Reverse-DestructionOfRetProducts[DFtoMFG] Exchange4.xml
Sample XML Exchange 1 between RLP and Manufacturer	Scenario-2.3.2.2.3.1 Reverse-DestructionOfRetProducts[DFtoMFG] Exchange1.xml

Appendix C: Acronyms

AI	Application Identifier
CBV	Core Business Vocabulary
XML	eXtensible Markup Language
GDSN	Global Data Synchronization Network
URI	Uniform Resource Identifier
URN	Uniform Resource Name

Appendix D: Glossary

Glossary for Extended Definitions

Repackager

FDA regards Repackaging as the act of taking a finished drug product from the container in which it was distributed by the original manufacturer and placing it into a different container without further manipulation of the drug³.

Repackaging also includes the act of placing the contents of multiple containers (e.g., vials) of the same finished drug product into one container, as long as the container does not include other ingredients. If a drug is manipulated in any other way, including if the drug is reconstituted, diluted, mixed, or combined with another ingredient, that act is not considered repackaging⁴.

Repackager term `repackager' means a person who owns or operates an establishment that repacks and relabels a product or package for-- further sale; or distribution without a further transaction⁵.

Repackaging is performed by a range of entities, including pharmacies and other facilities that specialize in repackaging drug products. The FDA is aware that repackaging is done for a variety of reasons including: to meet the needs of specific groups of patients (e.g., pediatric patients or patients receiving drugs for ophthalmic use) who require smaller doses of approved sterile drug products that may not be available commercially; to reduce medication errors associated with drawing up a dose from a vial at the point of patient care; to reduce the availability of drug products that could be abused when controlled substances are left over in a vial after a dose is drawn out; to provide a particular sized container to fit into a particular device to administer the drug (such as a particular pain medication pump); for convenience for the practitioner administering an injection to a patient; to reduce waste and conserve drug supplies; and in some cases to reduce cost. Some repackagers repackage both sterile and non-sterile drug products. Examples of repackaging include tablets and capsules that are repackaged from large containers into smaller containers or blister packs, and creams and lotions are sometimes purchased in bulk and repackaged into smaller tubes or containers.

Term	Acronym	Definition
Government Definitions:		
U.S. Food and Drug Administration	U.S. FDA	The Food and Drug Administration is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation.
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 ⁶ .
National Drug Code	NDC	The National Drug Code is a 10-digit identification number established by the U.S. Food and Drug Administration (U.S. FDA) to identify drugs in accordance with Section 510 of the Federal Food, Drug and Cosmetic Act (Act), 21 U.S.C. §360.
Standardized Numerical Identification	SNI	SNI is the U.S. FDA's term for the unique identification mandated by the DSCSA.

³ For example, if tablets are removed from a blister pack and placed into a different container, that would be repackaging. However, if the blister packs containing tablets are placed into a different container for later use (without opening the individual blister packs), that would not be repackaging.

⁴ This guidance does not apply to the compounding of drug products. Compounding is addressed in other guidance documents. See, for example, the guidance's Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act and For Entities Considering Whether to Register as Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act.

⁵ Drug Supply Chain Security Act SEC. 581. DEFINITIONS `` (16) Repackager

⁶ Source: <https://www.fda.gov/drugs/drug-supply-chain-integrity/drug-supply-chain-security-act-dscsa>

Drug Enforcement Administration	DEA	The DEA was established in 1973 as the federal organization in charge of enforcing the controlled substances laws of the United States. [Source: https://www.dea.gov/who-we-are]
Trading Partner Definitions:		
340B Program		The Public Health Services 340B drug discount Program (the “340B Program”) was passed by Congress in 1992 and requires drug manufacturers to provide outpatient drugs to eligible healthcare organizations, ‘Covered Entities’, at significantly reduced prices. These medications need only to be provided to the Covered Entities “own patients.” A 340B Contract Pharmacy is a contracted agent of the 340B Covered Entity where the covered entity is eligible for participation in the 340B program. The 340B Contract Pharmacy is not a direct participant in the 340B program and acts only as an agent and dispenses 340B priced medications to patients who are part of the covered entity. While the 340B program accommodates many dispensing arrangements for program participants, retail pharmacies became eligible to serve Covered Entities as contract pharmacies in 1996. The ability for retail pharmacies to be involved in the 340B program was expanded further in 2010 when Covered Entities were granted the ability to establish agreements with multiple pharmacies to meet their 340B dispensing requirements ⁷ .
Co-License Partner	CLP	For purposes of the DSCSA, FDA interprets the term co-licensed partner of a manufacturer, referenced in section 581(10)(B) of the FD&C Act, to mean one of two or more entities that have entered into a written agreement for the right to engage in the marketing of a prescription drug. While the term co-licensed partner is not defined in the FD&C Act, the Agency believes this interpretation is in alignment with industry practice and existing state laws ⁸ .
Consignment		When the product is shipped to and possessed by the consignee, but the consignee does not take ownership of that product until the consignee uses the product. Consignment product is typically considered the property of the consigning supplier (typically the manufacturer, repackager, or wholesaler) until the product is used by the consignee (typically the dispenser) ⁹ .
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 ¹⁰ .
Contract Packaging Organizations	CPO	Providers specializing in packaging, labeling, and potentially distribution on the behalf of manufacturers, repackagers, and wholesalers without transfer of ownership, just physical possession to perform services.
Direct Purchase		When product(s) are purchased directly from the manufacturer, exclusive distributor of the manufacturer, or a repackager who purchased directly unless noted as being indirectly sourced ¹¹ .
Dispenser	D	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

⁷ Source: GS1 US Addendum: Diagrams and XML Examples for Chain of Custody of Supply Chain Choreographies

⁸ Source: U.S. FDA, “Identifying Trading Partners Under the Drug Supply Chain Security Act, Guidance for Industry, July 2022

⁹ Source: Partnership for DSCSA Governance (PDG) Foundational Blueprint for 2023 Interoperability, Chapter 3: DSCSA TI/TS Exchange Functional Design, Version 1.0, February 2, 2023

¹⁰ Source: http://pdsaonline.org/wp-content/uploads/2015/06/PDSA-Letter_DSCSA-QA_May-2014.pdf

¹¹ Source: GS1 US Applying GS1 System of Standards for DSCSA and Serialized Interoperable Traceability R1.3

		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).
Drop Shipment		When products are being shipped directly by the seller to the buyer's customer while the transfer of ownership transaction is between the seller and the buyer. For example, a manufacturer sells the product to the wholesaler and the manufacturer is drop shipping the product to the dispenser who is the wholesaler's customer ¹² .
Exclusive Distributor		The term `exclusive distributor' means the wholesale distributor that directly purchased the product from the manufacturer and is the sole distributor of that manufacturer's product to a subsequent repackager, wholesale distributor, or dispenser ¹³ .
Indirect purchase		When product(s) are not purchased directly from the manufacturer, exclusive distributor of the manufacturer, or a repackager who purchased directly unless noted as being indirectly sourced.
Manufacturer	MFG	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).
Primary Wholesale Distributor		Wholesale distributor that purchased product directly from the manufacturer.
Repackager	R	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."
Reverse Logistics Providers	RLP	Contracted by Manufacturers to collect returned products from Dispensers and Wholesalers. RLPs are agents of both Wholesalers and Manufacturers. Only non-sellable returns are expected to be returned to RLPs. RLP services include processing returned products for credit; sending products to destruction facilities for destruction; and performing recordkeeping ¹⁴ .
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.
Virtual Manufacturer	VM	An entity that engages in the manufacture of a prescription drug for which it: holds the NDA or ANDA; contracts with a contract manufacturing organization for the physical manufacture of the drug product; is not involved in the physical manufacture of the drug product; and at no time takes physical possession of, or stores, the drug product for wholesale distribution ¹⁵ .

¹² Source: GS1 US Applying GS1 System of Standards for DSCSA and Serialized Interoperable Traceability R1.3

¹³ Source: <https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/title-ii-drug-quality-and-security-act>

¹⁴ Source: GS1 US, Addendum: Diagrams and XML Examples for Chain of Custody of Supply Chain Choreographies

¹⁵ Source: <https://www.ncbold.com/license/30814>

Wholesaler/Wholesale Distributor	W	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]).”
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.
S 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.
Radio-Frequency Identification	RAIN RFID	The RAIN RFID alliance is a global alliance promoting the universal adoption of passive UHF RFID (called RAIN RFID). GS1 refers to “RAIN RFID” tags in this document whenever making reference to passive UHF RFID tags. NOTE: Within the UHF RFID technology space, GS1 only endorses RAIN RFID implementations that are encoded per GS1’s EPC standards(which are a subset of all RAIN RFID implementations).
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 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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GS1 US Corporate Headquarters

Princeton South Corporate Center, 300 Charles Ewing Boulevard
Ewing, NJ 08628 USA

T +1 609.620.0200 | **E** info@gs1us.org

www.gs1us.org

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