The Global Language of Business

Healthcare

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

Release 1.0, March 31, 2021

Table of Contents

About GS1

GS1® is a neutral, not-for-profit, global organization that develops and maintains the most widely-used supply chain standards system in the world. GS1 Standards improve the efficiency, safety, and visibility of supply chains across multiple sectors. With local Member Organizations in over 110 countries, GS1 engages with communities of trading partners, industry organizations, governments, and technology providers to understand and respond to their business needs through the adoption and implementation of global standards. GS1 is driven by over a million user companies, which execute more than six billion transactions daily in 150 countries using GS1 Standards.

About GS1 US

GS1 US®, a member of GS1 global, is a not-for-profit information standards organization that facilitates industry collaboration to improve supply chain visibility and efficiency through the use of GS1 Standards, the most widely used supply chain standards system in the world. Nearly 300,000 businesses in 25 industries rely on GS1 US for trading-partner collaboration that optimizes their supply chains, drives cost performance and revenue growth while also enabling regulatory compliance. They achieve these benefits through solutions based on GS1 global unique numbering and identification systems, barcodes, Electronic Product Code-based RFID, data synchronization, and electronic information exchange. GS1 US also manages the United Nations Standard Products and Services Code® (UNSPSC®).

About GS1 Healthcare

GS1 Healthcare is a global, voluntary healthcare user group developing global standards for the healthcare supply chain and advancing global harmonization. GS1 Healthcare consists of participants from all stakeholders of the healthcare supply chain: manufacturers, wholesalers, and distributors, as well as hospitals and pharmacy retailers. GS1 Healthcare also maintains close contacts with regulatory agencies and trade organizations worldwide. GS1 Healthcare drives the development of GS1 Standards and solutions to meet the needs of the global healthcare industry, and promotes the effective utilization and implementation of global standards in the healthcare industry through local support initiatives like GS1 Healthcare US® in the United States.

About GS1 Healthcare US

GS1 Healthcare US is an industry group that focuses on driving the adoption and implementation of GS1 Standards in the healthcare industry in the United States to improve patient safety and supply chain efficiency. GS1 Healthcare US brings together members from all segments of the healthcare industry to address the supply chain issues that most impact healthcare in the United States. Facilitated by GS1 US, GS1 Healthcare US is one of over 30 local GS1 Healthcare user groups around the world that supports the adoption and implementation of global standards developed by GS1.

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.

These links will also be available at *www.gs1us.org/chain-of-custody*

- *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 1.13), 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 *R1.2 Implementation Guideline*.

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*.

- 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
- Sample XML Exchange 4 between Manufacturer's 3PL and Manufacturer
  Scenario-2.2.5.3.4 MFG_utilizes_CMO_3PL_WHLS_utilizes_3PL[3PLtoMFG] Exchange4.xml
- Sample XML Exchange 5 between Wholesaler and Wholesaler's 3PL
  Scenario-2.2.5.3.5 MFG_utilizes_CMO_3PL_WHLS_utilizes_3PL[WHLSto3PL] Exchange5.xml
- Sample XML Exchange 6 between Wholesaler's 3PL and Wholesaler
  Scenario-2.2.5.3.6 MFG_utilizes_CMO_3PL_WHLS_utilizes_3PL[3PLtoWHLS] Exchange6.xml
- Sample XML Exchange 6 between Wholesaler's 3PL and Wholesaler
  Scenario-2.2.5.3.7 MFG_utilizes_CMO_3PL_WHLS_utilizes_3PL[3PLtoWHLS] Exchange7.xml
- Sample XML Exchange 1 between CMO and Virtual Contract Manufacturer
  Scenario-2.2.6.3.1 MFG_utilizes_VCMO_outsourceto_CMO[CMOtoVCMO] Exchange1.xml
- Sample XML Exchange 2 between Virtual Contract Manufacturer and Manufacturer
  Scenario-2.2.6.3.2 MFG_utilizes_VCMO_outsourceto_CMO[VCMOtoMFG] Exchange2.xml
- Sample XML Exchange 1 between CMO and Manufacturer
  Scenario-2.2.7.3.1 MFG_utilizes_CMO_serial_CPO_agg[CMOtoMFG] Exchange1.xml
- Sample XML Exchange 2 between Manufacturer and CPO

Scenario-2.2.7.3.2 MFG_utilizes_CMO_serial_CPO_agg[MFGtoCPO] Exchange2.xml

- Sample XML Exchange 3 between CPO and Manufacturer

  Scenario-2.2.7.3.3 MFG_utilizes_CMO_serial_CPO_agg[CPOtoMFG] Exchange3.xml

- Sample XML Exchange 2 between CPO and Manufacturer

  Scenario-2.2.7.3.4 MFG_utilizes_CMO_serial_CPO_agg[CPOtoMFG] Exchange4.xml

- Sample XML Exchange 1 between CMO and Manufacturer

  Scenario-2.2.8.3.1 MFG_utilizes_CMO_serial_CPO_agg_3PL[CMOtoMFG] Exchange1.xml

- Sample XML Exchange 2 between Manufacturer and CPO

  Scenario-2.2.8.3.2 MFG_utilizes_CMO_serial_CPO_agg_3PL[MFGtoCPO] Exchange2.xml

- Sample XML Exchange 3 between CPO and Manufacturer

  Scenario-2.2.8.3.3 MFG_utilizes_CMO_serial_CPO_agg_3PL[CPOtoMFG] Exchange3.xml

- Sample XML Exchange 2 between CPO and Manufacturer

  Scenario-2.2.8.3.4 MFG_utilizes_CMO_serial_CPO_agg_3PL[CPOtoMFG] Exchange4.xml

- Sample XML Exchange 2 between Manufacturer and 3PL

  Scenario-2.2.8.3.5 MFG_utilizes_CMO_serial_CPO_agg_3PL[MFGto3PL] Exchange5.xml

- Sample XML Exchange 2 between 3PL and Manufacturer

  Scenario-2.2.8.3.6 MFG_utilizes_CMO_serial_CPO_agg_3PL[3PLtoMFG] Exchange6.xml

- Sample XML Exchange 2 between 3PL and Manufacturer

  Scenario-2.2.8.3.7 MFG_utilizes_CMO_serial_CPO_agg_3PL[3PLtoMFG] Exchange7.xml

- Sample XML Exchange 1 between CMO and Manufacturer

  Scenario-2.2.9.3.1 MFG_utilizes_CMO_serial_CPO_agg_3PL_W_uses_3PL[CMOtoMFG] Exchange1.xml

- Sample XML Exchange 2 between Manufacturer and CPO

  Scenario-2.2.9.3.2 MFG_utilizes_CMO_serial_CPO_agg_3PL_W_uses_3PL[MFGtoCPO] Exchange2.xml

- Sample XML Exchange 3 between CPO and Manufacturer

  Scenario-2.2.9.3.3 MFG_utilizes_CMO_serial_CPO_agg_3PL_W_uses_3PL[CPOtoMFG] Exchange3.xml

- Sample XML Exchange 2 between CPO and Manufacturer

  Scenario-2.2.9.3.4 MFG_utilizes_CMO_serial_CPO_agg_3PL_W_uses_3PL[CPOtoMFG] Exchange4.xml

- Sample XML Exchange 2 between Manufacturer and 3PL

  Scenario-2.2.9.3.5 MFG_utilizes_CMO_serial_CPO_agg_3PL_W_uses_3PL[MFGto3PL] Exchange5.xml

- Sample XML Exchange 2 between 3PL and Manufacturer

  Scenario-2.2.9.3.6 MFG_utilizes_CMO_serial_CPO_agg_3PL_W_uses_3PL[3PLtoMFG] Exchange6.xml

- Sample XML Exchange 2 between 3PL and Manufacturer

  Scenario-2.2.9.3.7 MFG_utilizes_CMO_serial_CPO_agg_3PL_W_uses_3PL[3PLtoMFG] Exchange7.xml

- Sample XML Exchange 2 between 3PL and Manufacturer

  Scenario-2.2.9.3.8 MFG_utilizes_CMO_serial_CPO_agg_3PL_W_uses_3PL[Wto3PL_W] Exchange8.xml

- Sample XML Exchange 2 between 3PL and Manufacturer

  Scenario-2.2.9.3.9 MFG_utilizes_CMO_serial_CPO_agg_3PL_W_uses_3PL[3PL_WtoW] Exchange9.xml

- Sample XML Exchange 2 between 3PL and Manufacturer

  Scenario-2.2.9.3.10 MFG_utilizes_CMO_serial_CPO_agg_3PL_W_uses_3PL[3PL_WtoW] Exchange10.xml

- Sample XML Exchange 1 between Wholesaler and Dispenser

  Scenario-2.2.10.3.1 WHLS_consignment_D[WHLStoD] Exchange1.xml

- Sample XML Exchange 1 between Dispenser and Contract Pharmacy

  Scenario-2.2.11.3.1 340B_Dispenser_utilizes_CRx[DtoCRx] Exchange1.xml

- Sample XML Exchange 2 between Contract Pharmacy and Dispenser

  Scenario-2.2.11.3.2 340B_Dispenser_utilizes_CRx[CRxtoD] Exchange2.xml

- Sample XML Exchange 1 between Repackager and CPO

  Scenario-2.2.12.3.1 Repkg_utilizes_CPO[RtoCPO] Exchange1.xml

- 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

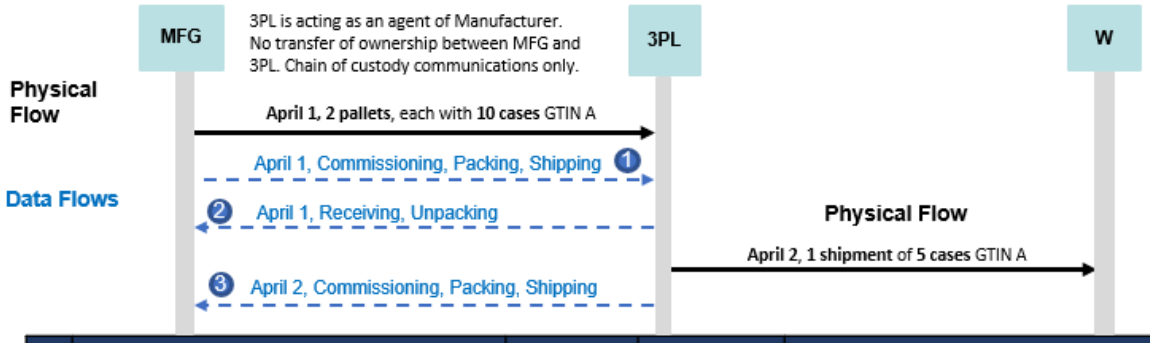
  Scenario-2.2.13.3.6 Repkg_utilizes_CPO_3PL[3PLtoR] Exchange6.xml

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.

- 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

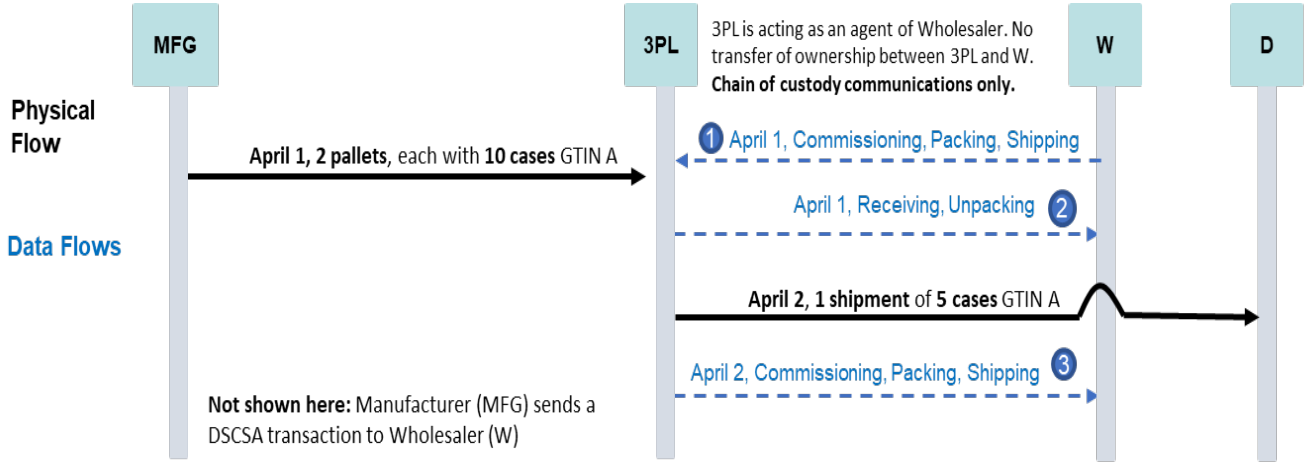
  Scenario-2.2.1.3.3 MFG_utilizes_3PL[3PLtoMFG] Exchange3.xml

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.

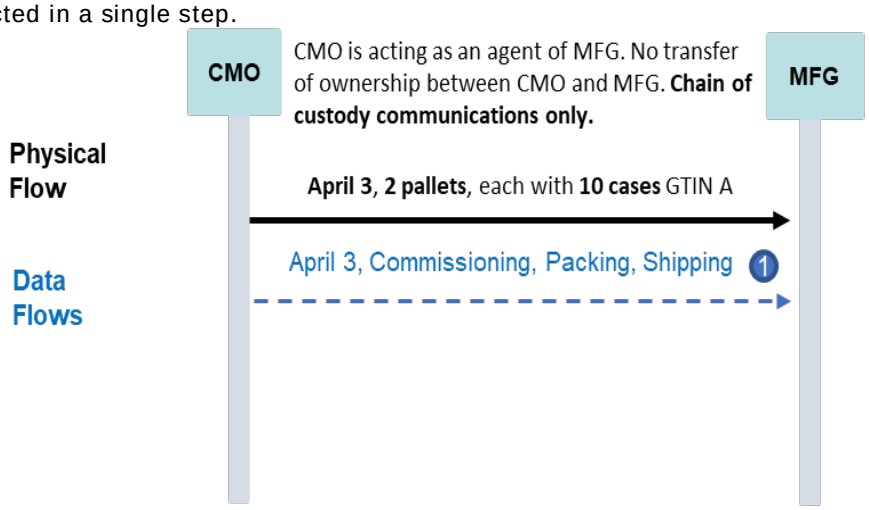
- Sample XML for Exchange 1 between Wholesaler and 3PL to Wholesaler
  Scenario-2.2.2.3.1 WHLS_utilizes_3PL[WHLSto3PL] Exchange1.xml
- Sample XML for Exchange 1 between Wholesaler and 3PL to Wholesaler
  Scenario-2.2.2.3.2 WHLS_utilizes_3PL[3PLtoWHLS] Exchange2.xml
- Sample XML for Exchange 1 between Wholesaler and 3PL to Wholesaler
  Scenario-2.2.2.3.3 WHLS_utilizes_3PL[3PLtoWHLS] Exchange3.xml

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 examples of the EPCIS messages exchanged between parties.

- Sample XML for Exchange 1 between Wholesaler and 3PL to Wholesaler

  Scenario-2.2.3.3.1 MFG_utilizes_CMO[CMOtoMFG] Exchange1.xml

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

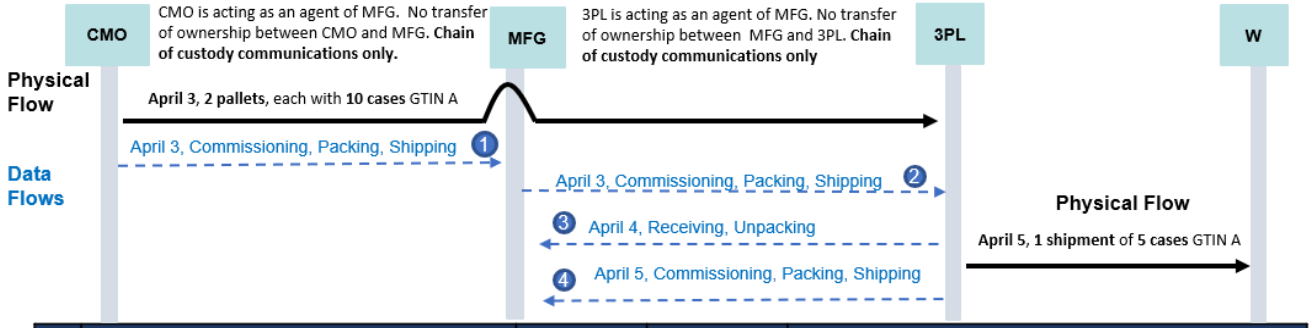
The scenario below details the physical flow of products with the Chain of Custody Business Processes plus the data flows of Electronic Exchange between the supply chain trading partners.

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	Contract manufacturer (CMO) ships product to 3PL on April 3	CMO	MFG	Commissioning	CMO	CMO				
				Packing	CMO	CMO				
				Shipping	CMO	N/A (Omitted)	MFG	CMO	MFG	3PL
2	Manufacturer (MFG) sends CMO-provided serialized data to 3PL on April 3	MFG	3PL	Commissioning	CMO	CMO				
				Packing	CMO	CMO				
				Shipping	CMO	N/A (Omitted)	MFG	CMO	MFG	3PL
3	3PL receives shipment from CMO on April 4	3PL	MFG	Receiving	3PL	3PL	MFG	CMO	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.

2.2.4.1.3 XML examples of the EPCIS messages exchanged between parties.

- 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

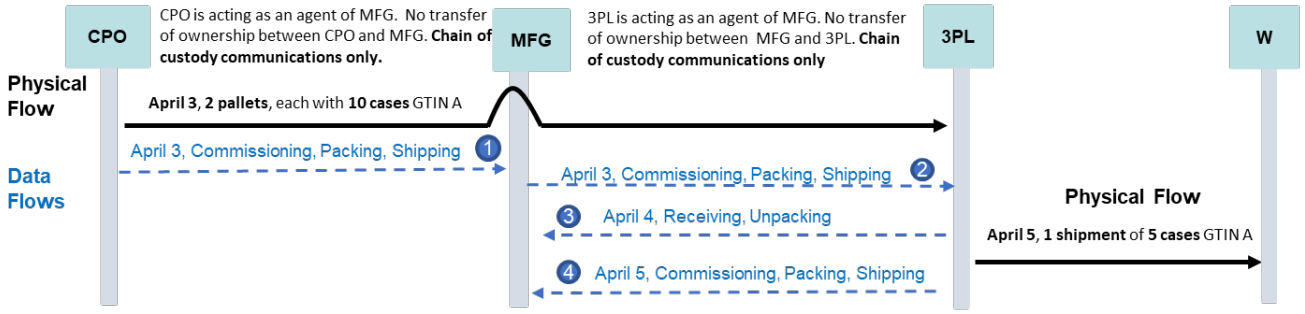
  Scenario-2.2.4.1.3.4 MFG_utilizes_CMO_3PL[3PLtoMFG] Exchange4.xml

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

- Sample XML for Exchange 1 between CPO and Manufacturer

  Scenario-2.2.4.2.3.1 MFG_utilizes_CPO_3PL[CPOtoMFG] Exchange1.xml

- Sample XML for Exchange 2 between Manufacturer and 3PL

  Scenario-2.2.4.2.3.2 MFG_utilizes_CPO_3PL[MFGto3PL] Exchange2.xml

- Sample XML for Exchange 3 between 3PL and Manufacturer

  Scenario-2.2.4.2.3.3 MFG_utilizes_CPO_3PL[3PLtoMFG] Exchange3.xml

- Sample XML for Exchange 4 between 3PL and Manufacturer

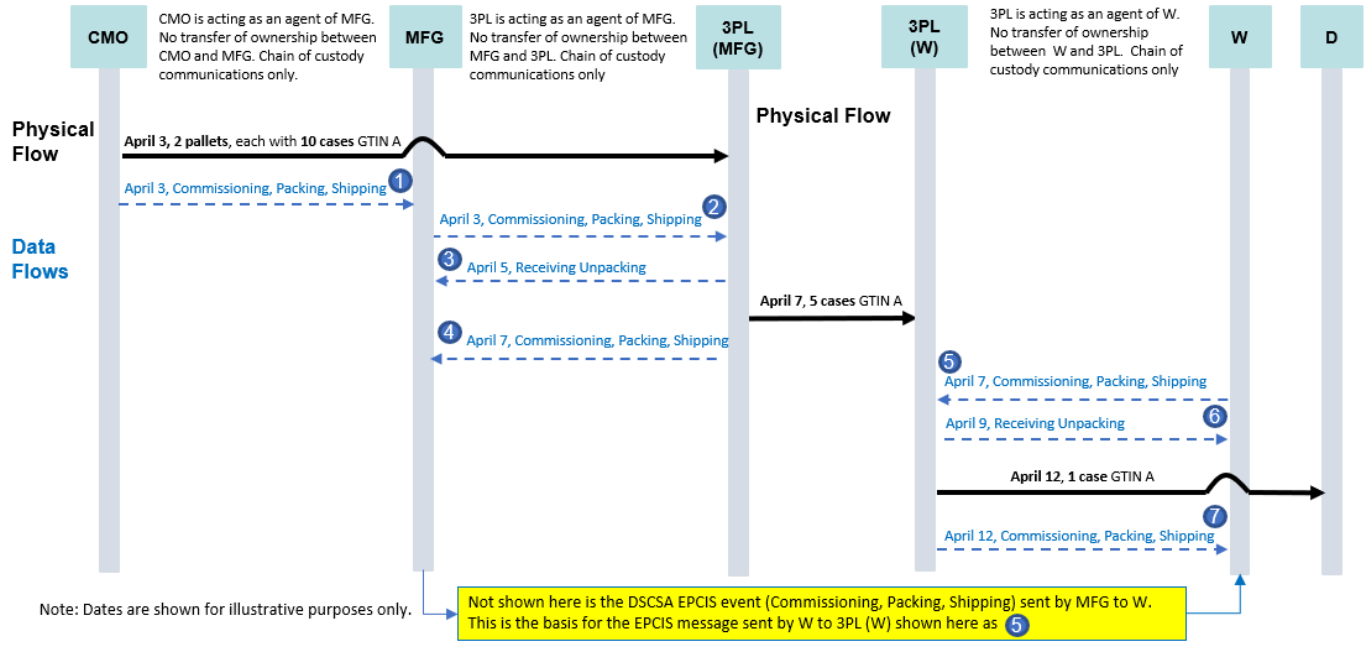
  Scenario-2.2.4.2.3.4 MFG_utilizes_CPO_3PL[3PLtoMFG] Exchange4.xml

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	3PL (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	3PL (MFG)
3	3PL (MFG) receives shipment from CMO on April 5	3PL (MFG)	MFG	Receiving	3PL (MFG)	3PL (MFG)	MFG	CMO	MFG	3PL (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	3PL (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	3PL (W)
6	3PL (W) receives shipment from 3PL (MFG) on April 9	3PL (W)	W	Receiving	3PL (W)	3PL (W)	MFG	3PL (MFG)	W	3PL (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	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.

- 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

- Sample XML Exchange 4 between Manufacturer's 3PL and Manufacturer

  Scenario-2.2.5.3.4 MFG_utilizes_CMO_3PL_WHLS_utilizes_3PL[3PLtoMFG] Exchange4.xml

- Sample XML Exchange 5 between Wholesaler and Wholesaler's 3PL

  Scenario-2.2.5.3.5 MFG_utilizes_CMO_3PL_WHLS_utilizes_3PL[WHLSto3PL] Exchange5.xml

- Sample XML Exchange 6 between Wholesaler's 3PL and Wholesaler

  Scenario-2.2.5.3.6 MFG_utilizes_CMO_3PL_WHLS_utilizes_3PL[3PLtoWHLS] Exchange6.xml

- Sample XML Exchange 6 between Wholesaler's 3PL and Wholesaler

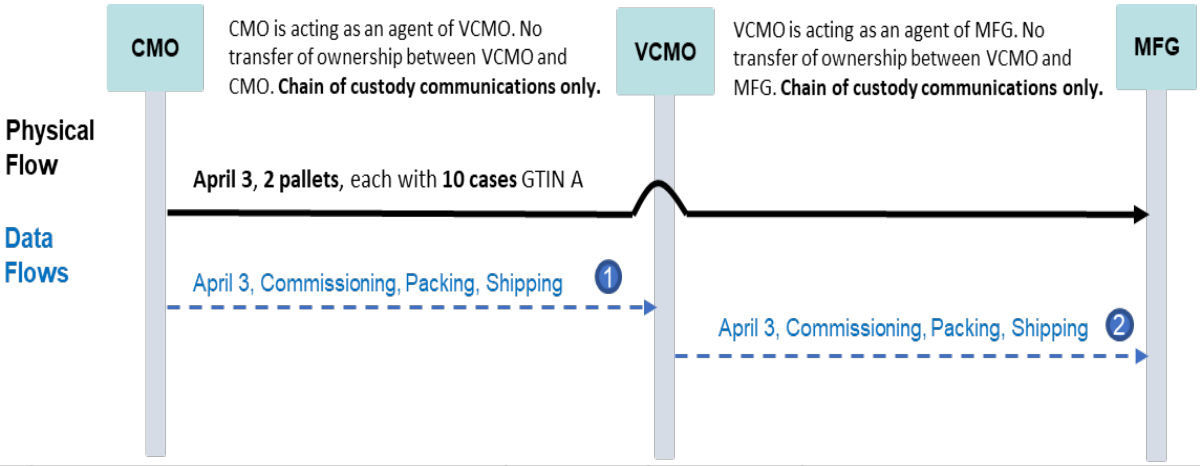
  Scenario-2.2.5.3.7 MFG_utilizes_CMO_3PL_WHLS_utilizes_3PL[3PLtoWHLS] Exchange7.xml

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.



	Chain of Custody Business Step	Message Sending Party	Message Receiving Party	Chain of Custody Electronic Exchange
1	Contract Manufacturer (CMO) ships product to MFG on April 3	CMO	VCMO	CMO sends EPCIS **Commissioning, Packing, Shipping** events to VCMO
2	Virtual Contract Manufacturer (VCMO) sends CMO-provided serialized data to MFG on April 3	VCMO	MFG	VCMO sends CMO-provided EPCIS **Commissioning, Packing, and Shipping** events to MFG

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.

- Sample XML Exchange 1 between CMO and Virtual Contract Manufacturer

  Scenario-2.2.6.3.1 MFG_utilizes_VCMO_outsourceto_CMO[CMOtoVCMO] Exchange1.xml
- Sample XML Exchange 2 between Virtual Contract Manufacturer and Manufacturer

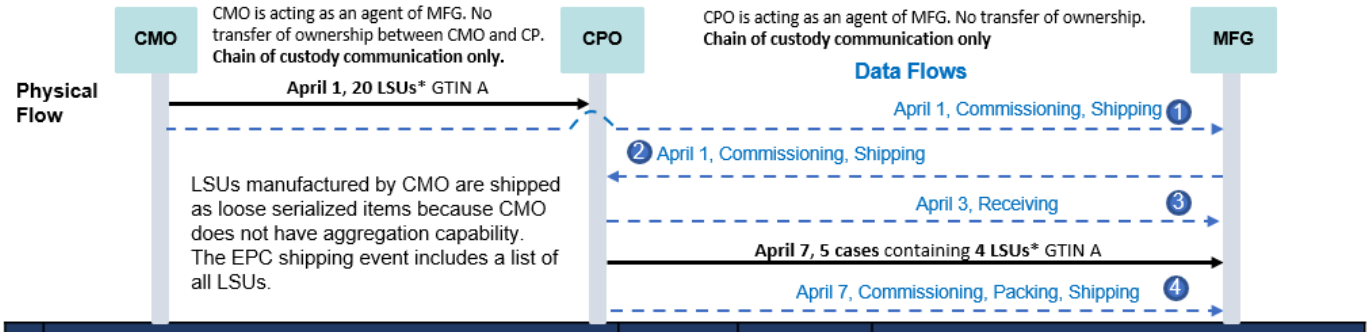
  Scenario-2.2.6.3.2 MFG_utilizes_VCMO_outsourceto_CMO[VCMOtoMFG] Exchange2.xml

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.



	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** event to MFG
4	Contract Packager (CPO) aggregates Lowest Saleable Units (LSUs) into cases and ships product to Manufacturer (MFG) on April 7	CPO	MFG	CPO sends EPCIS **Commissioning, Packing, and Shipping** events to MFG

* 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	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.

- Sample XML Exchange 1 between CMO and Manufacturer

  Scenario-2.2.7.3.1 MFG_utilizes_CMO_serial_CPO_agg[CMOtoMFG] Exchange1.xml

- Sample XML Exchange 2 between Manufacturer and CPO

  Scenario-2.2.7.3.2 MFG_utilizes_CMO_serial_CPO_agg[MFGtoCPO] Exchange2.xml

- Sample XML Exchange 3 between CPO and Manufacturer

  Scenario-2.2.7.3.3 MFG_utilizes_CMO_serial_CPO_agg[CPOtoMFG] Exchange3.xml

- Sample XML Exchange 2 between CPO and Manufacturer

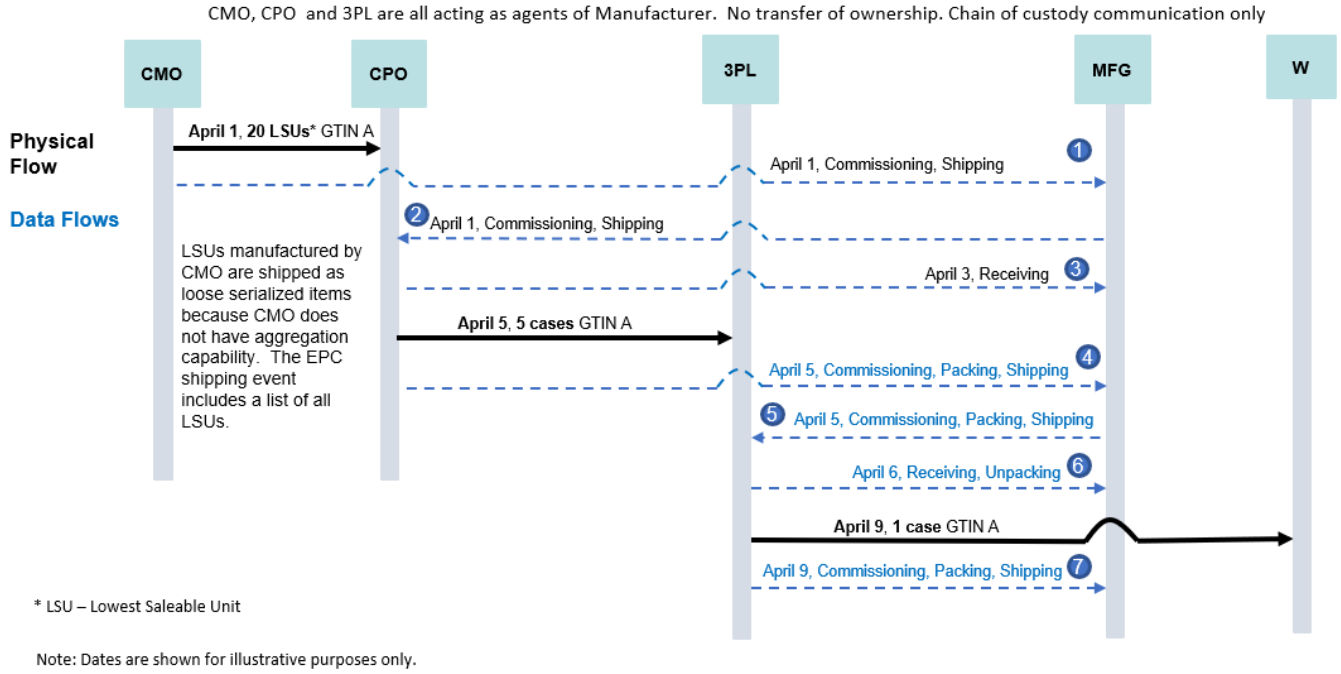
  Scenario-2.2.7.3.4 MFG_utilizes_CMO_serial_CPO_agg[CPOtoMFG] Exchange4.xml

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** event 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** event 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 Note: Dates are shown for illustrative purposes only.

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

2.2.8.3 XML examples of the EPCIS messages exchanged between parties.

- Sample XML Exchange 1 between CMO and Manufacturer

  Scenario-2.2.8.3.1 MFG_utilizes_CMO_serial_CPO_agg_3PL[CMOtoMFG] Exchange1.xml

- Sample XML Exchange 2 between Manufacturer and CPO

  Scenario-2.2.8.3.2 MFG_utilizes_CMO_serial_CPO_agg_3PL[MFGtoCPO] Exchange2.xml

- Sample XML Exchange 3 between CPO and Manufacturer

  Scenario-2.2.8.3.3 MFG_utilizes_CMO_serial_CPO_agg_3PL[CPOtoMFG] Exchange3.xml

- Sample XML Exchange 2 between CPO and Manufacturer

  Scenario-2.2.8.3.4 MFG_utilizes_CMO_serial_CPO_agg_3PL[CPOtoMFG] Exchange4.xml

- Sample XML Exchange 2 between Manufacturer and 3PL

  Scenario-2.2.8.3.5 MFG_utilizes_CMO_serial_CPO_agg_3PL[MFGto3PL] Exchange5.xml

- Sample XML Exchange 2 between 3PL and Manufacturer

  Scenario-2.2.8.3.6 MFG_utilizes_CMO_serial_CPO_agg_3PL[3PLtoMFG] Exchange6.xml

- Sample XML Exchange 2 between 3PL and Manufacturer

  Scenario-2.2.8.3.7 MFG_utilizes_CMO_serial_CPO_agg_3PL[3PLtoMFG] Exchange7.xml

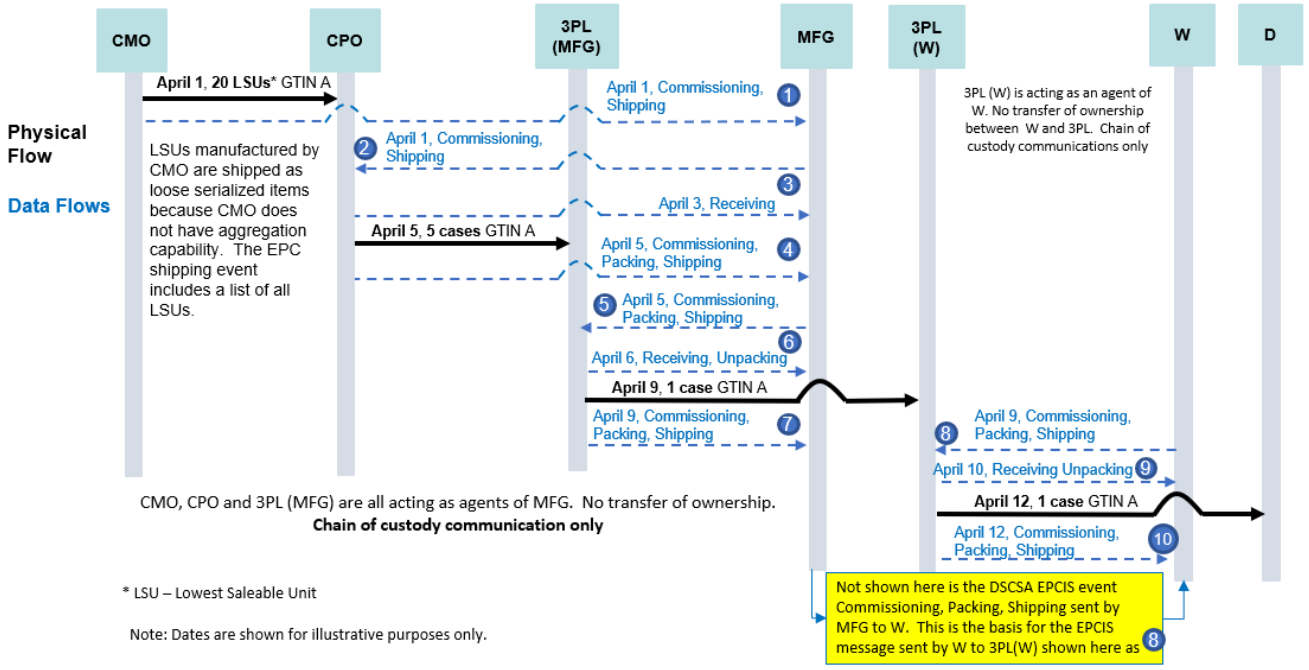
2.2.9 Manufacturer utilizes Contract Manufacturer, Contract Packager and 3PL and Wholesaler utilizes a 3PL

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** event 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** event 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
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)

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

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

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

Note: Dates are shown for illustrative purposes only.

Grey fill indicates message is based on event data provided from dataflow 7

2.2.9.3 XML examples of the EPCIS messages exchanged between parties.

- Sample XML Exchange 1 between CMO and Manufacturer

  Scenario-2.2.9.3.1 MFG_utilizes_CMO_serial_CPO_agg_3PL_W_uses_3PL[CMOtoMFG] Exchange1.xml

- Sample XML Exchange 2 between Manufacturer and CPO

  Scenario-2.2.9.3.2 MFG_utilizes_CMO_serial_CPO_agg_3PL_W_uses_3PL[MFGtoCPO] Exchange2.xml

- Sample XML Exchange 3 between CPO and Manufacturer

  Scenario-2.2.9.3.3 MFG_utilizes_CMO_serial_CPO_agg_3PL_W_uses_3PL[CPOtoMFG] Exchange3.xml

- Sample XML Exchange 2 between CPO and Manufacturer

  Scenario-2.2.9.3.4 MFG_utilizes_CMO_serial_CPO_agg_3PL_W_uses_3PL[CPOtoMFG] Exchange4.xml

- Sample XML Exchange 2 between Manufacturer and 3PL

  Scenario-2.2.9.3.5 MFG_utilizes_CMO_serial_CPO_agg_3PL_W_uses_3PL[MFGto3PL] Exchange5.xml

- Sample XML Exchange 2 between 3PL and Manufacturer

  Scenario-2.2.9.3.6 MFG_utilizes_CMO_serial_CPO_agg_3PL_W_uses_3PL[3PLtoMFG] Exchange6.xml

- Sample XML Exchange 2 between 3PL and Manufacturer

  Scenario-2.2.9.3.7 MFG_utilizes_CMO_serial_CPO_agg_3PL_W_uses_3PL[3PLtoMFG] Exchange7.xml

- Sample XML Exchange 2 between 3PL and Manufacturer

  Scenario-2.2.9.3.8 MFG_utilizes_CMO_serial_CPO_agg_3PL_W_uses_3PL[Wto3PL_W] Exchange8.xml

- Sample XML Exchange 2 between 3PL and Manufacturer

  Scenario-2.2.9.3.9 MFG_utilizes_CMO_serial_CPO_agg_3PL_W_uses_3PL[3PL_WtoW] Exchange9.xml

- Sample XML Exchange 2 between 3PL and Manufacturer

  Scenario-2.2.9.3.10 MFG_utilizes_CMO_serial_CPO_agg_3PL_W_uses_3PL[3PL_WtoW] Exchange10.xml

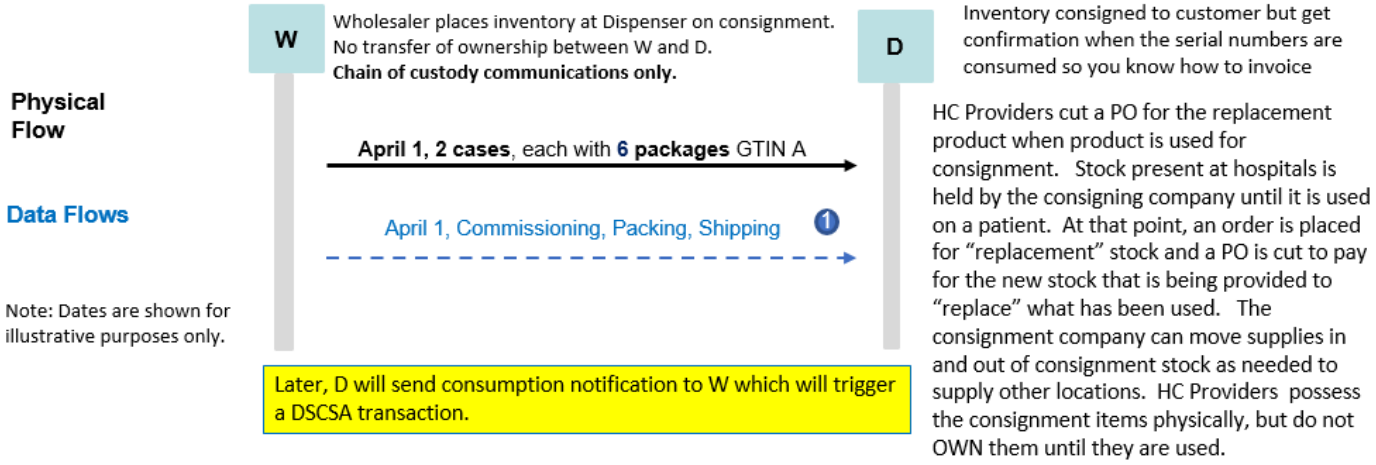
2.2.10 Consignment held at Dispenser until consumption.

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. W->D

2.2.10.1 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 **Commissioning, Packing, and Shipping** data

2.2.10.2 Table of EPCIS messages exchanged by Sending and Receiving parties

Scenario: 10. 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

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

Note: Dates are shown for illustrative purposes only

2.2.10.3 XML examples of the EPCIS messages exchanged between parties.

- Sample XML Exchange 1 between Wholesaler and Dispenser

  Scenario-2.2.10.3.1 WHLS_consignment_D[WHLStoD] Exchange1.xml

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.

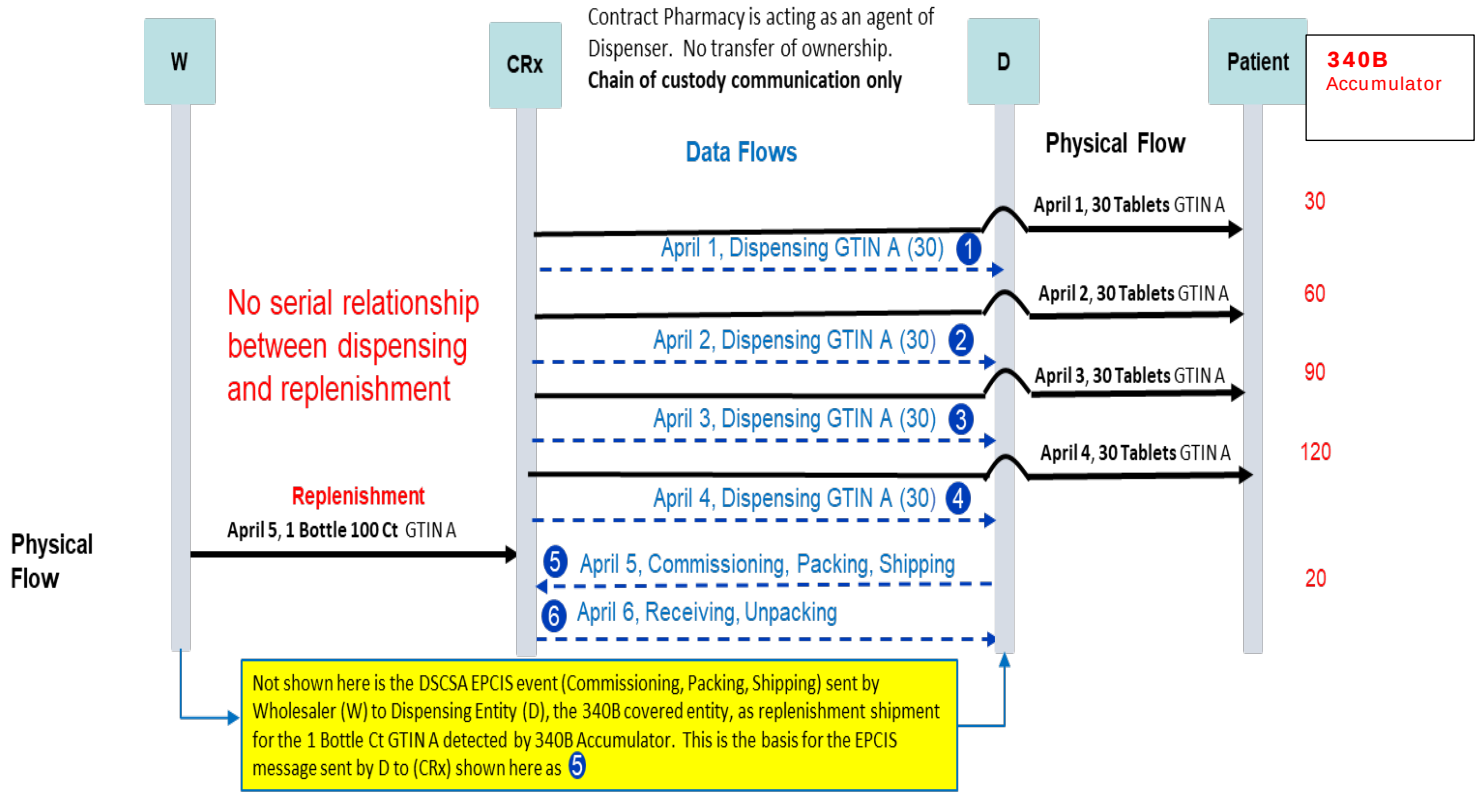
While the 340B program accommodates many dispensing arrangements for program participants, retail pharmacies became eligible to serve Covered Entities as contract pharmacies in 1996. The ability for retail pharmacies to be involved in the 340B program was expanded further in 2010 when Covered Entities 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 citizens[1].

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.

[1] 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.

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

	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

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.

- Sample XML Exchange 1 between Dispenser and Contract Pharmacy

  Scenario-2.2.11.3.1 340B_Dispenser_utilizes_CRx[DtoCRx] Exchange1.xml

- Sample XML Exchange 2 between Contract Pharmacy and Dispenser

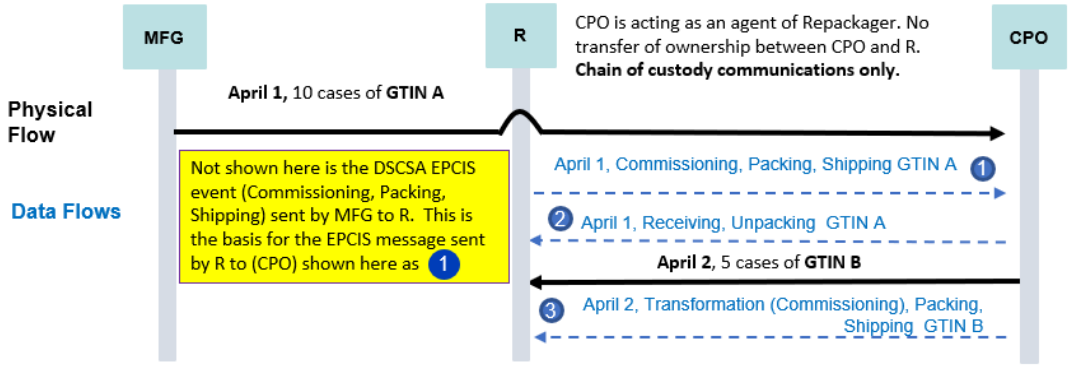
  Scenario-2.2.11.3.2 340B_Dispenser_utilizes_CRx[CRxtoD] Exchange2.xml

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.

- Sample XML Exchange 1 between Repackager and CPO

  Scenario-2.2.12.3.1 Repkg_utilizes_CPO[RtoCPO] Exchange1.xml

- 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

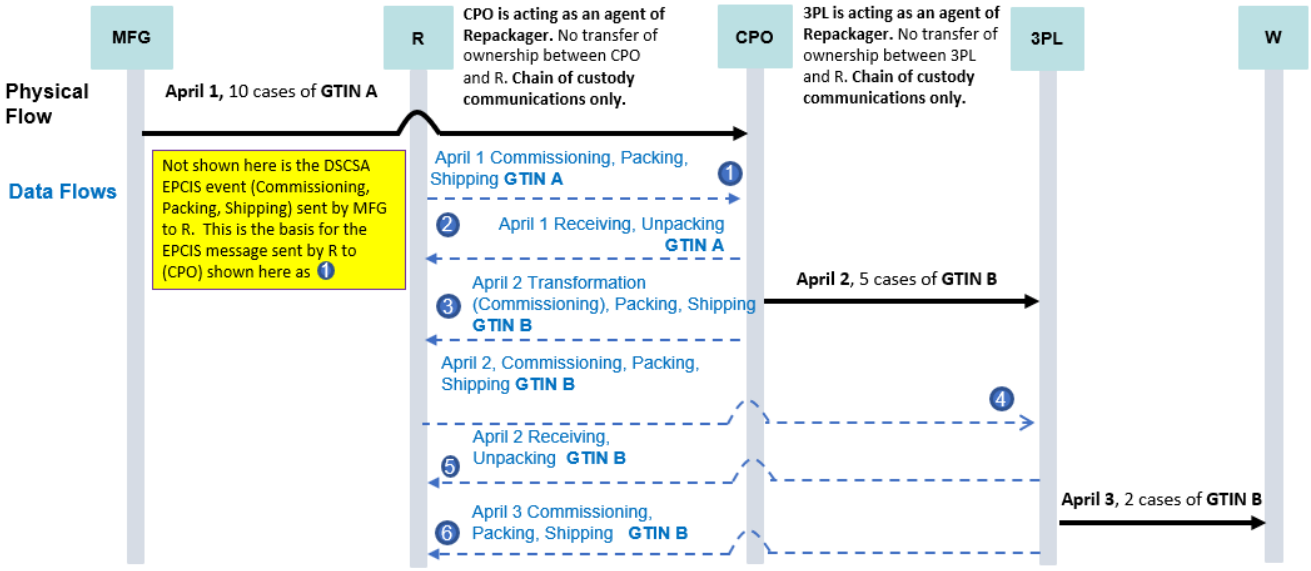
  Scenario-2.2.12.3.3 Repkg_utilizes_CPO[CPOtoR] Exchange3.xml

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	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 3PL on April 2	CPO	R	Transformation (Commissioning)	CPO	CPO				
				Packing	CPO	CPO				
				Shipping	CPO	N/A (Omitted)	R	CPO	R	3PL
4	R sends CPO-provided serialized data for **GTIN B** to 3PL on April 2	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. For example:

2.2.13.3 XML examples of the EPCIS messages exchanged between parties.

- 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

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 to Manufacturer.

- 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

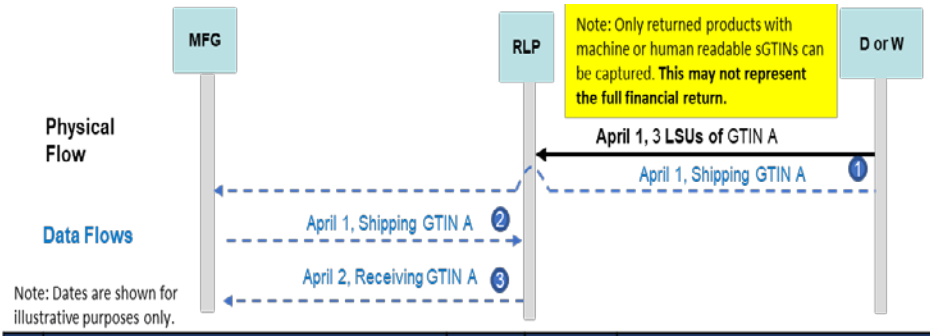
  Scenario-2.3.1.2.3.4 Reverse-CollectionRetProd[RLPtoMFG] Exchange4.xml

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.

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.

- 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

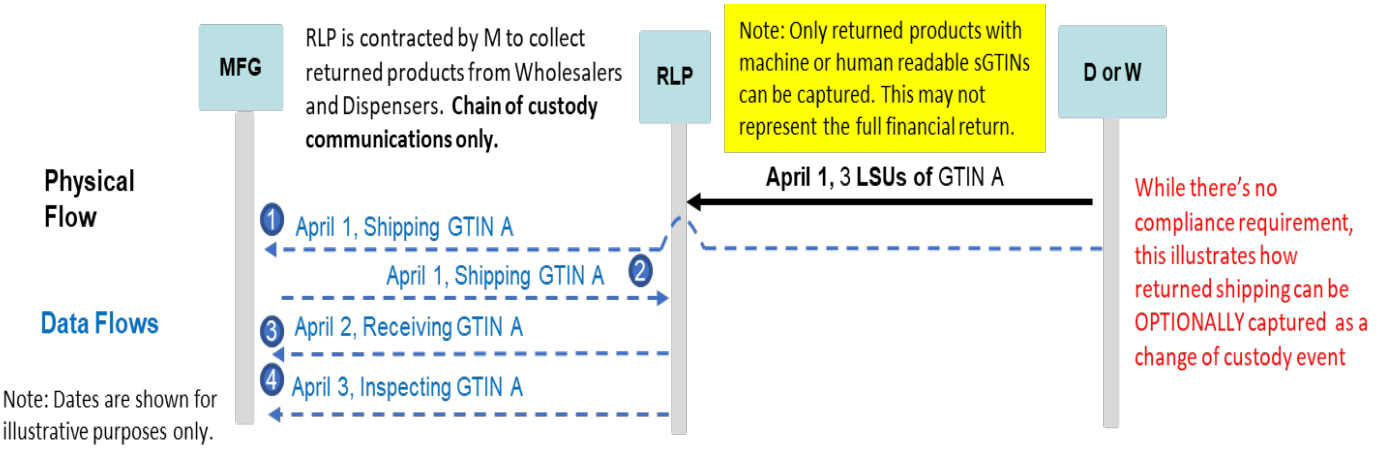
  Scenario-2.3.1.1.3.3 Reverse-CollectionRetProd[RLPtoMFG] Exchange3

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.

- 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

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 destructed with the Chain of Custody Business Processes plus the data flows of Electronic Exchange between the supply chain trading partners.

- 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

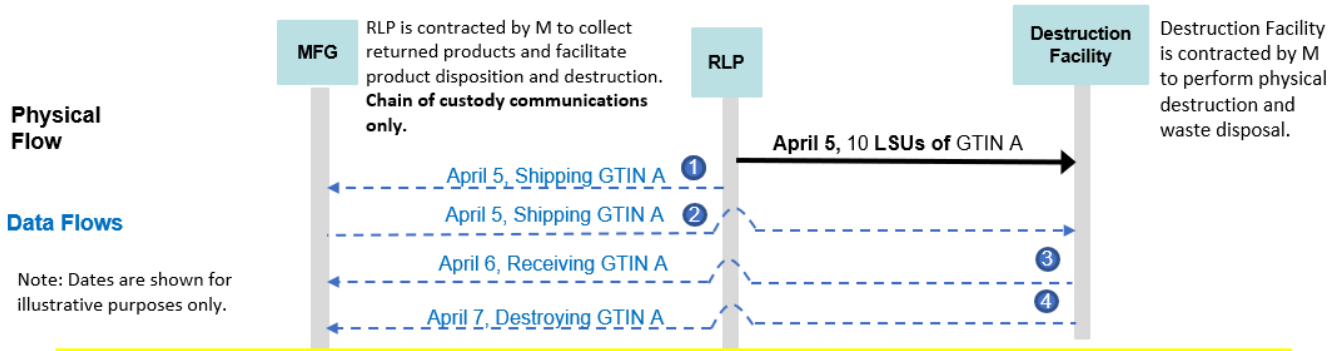
- Sample XML Exchange 1 between RLP and Manufacturer

  Scenario-2.3.2.2.3.1 Reverse-DestructionOfRetProducts[DFtoMFG] Exchange1.xml

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

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.

- 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

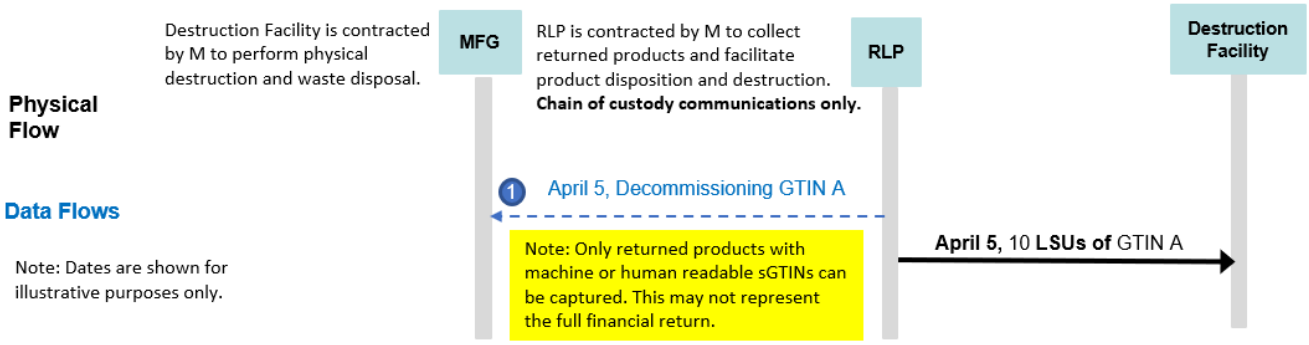
- Sample XML Exchange 4 between Destruction Facility and Manufacturer

  Scenario-2.3.2.1.3.4 Reverse-DestructionOfRetProducts[DFtoMFG] Exchange4.xml

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	RLP decommissions returned products **BEFORE** physically shipping them to the destruction facility	RLP	MFG	RLP 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	RLP decommissions returned products **BEFORE** physically shipping them to the destruction facility	RLP	MFG	Decommissioning	DELETE	inactive	RLP	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.

- Sample XML Exchange 1 between RLP and Manufacturer

  Scenario-2.3.2.2.3.1 Reverse-DestructionOfRetProducts[DFtoMFG] Exchange1.xml

A Appendix: 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 A-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

B Appendix: Acronyms

AI	Application Identifier
CBV	Core Business Vocabulary
EPC/RIFD	Electronic Product Code / Radio Frequency Identification
EPCIS	Electronic Product Code Information Services
XML	eXtensible Markup Language
GDSN	Global Data Synchronization Network
GLN	Global Location Number
GTIN	Global Trade Item Number
NDC	National Drug Code
RFID	Radio Frequency Identification
SSCC	Serial Shipping Container Code
SGLN	Serialized Global Location Number (GLN)
SGTIN	Serialized Global Trade Item Number (GTIN)
U.P.C.	Universal Product Code (U.P.C.)
URI	Uniform Resource Identifier
URN	Uniform Resource Name

C 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 drug[2].

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 repackaging[3].

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 transaction[4].

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.

340B Contract Pharmacy

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. 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 an agent of the 340B Covered Entity and not a direct participant in the 340B program.

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

[2] 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.

[3] 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.

[4] Drug Supply Chain Security Act SEC. 581. DEFINITIONS ``(16) Repackager

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 citizens[5].

[5] 340B Contract Pharmacy Services Best Practice Guide V.09062013 National Community Pharmacists Association

Proprietary Statement

This document contains proprietary information of GS1 US. Such proprietary information may not be changed for use with any other parties for any other purpose without the expressed written permission of GS1 US.

Improvements

Improvement and changes are periodically made to publications by GS1 US. All material is subject to change without notice. Please refer to GS1 US website for the most current publication available. Although GS1 publications may, where appropriate, consider or address applicable statutory and regulatory requirements, such requirements are subject to change by implementing government agencies, and GS1 cannot guarantee that its publications will reflect all current statutory and regulatory requirements.

Disclaimer

Except as may be otherwise indicated in specific documents within this publication, you are authorized to view documents within this publication, subject to the following:

1. You agree to retain all copyright and other proprietary notices on every copy you make.
2. Some documents may contain other proprietary notices and copyright information relating to that document. You agree that GS1 US has not conferred by implication, estoppels or otherwise any license or right under any patent, trademark, or copyright (except as expressly provided above) of GS1 US or of any third party.

THIS PUBLICATION IS PROVIDED "AS IS" WITHOUT WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, THE IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR NON-INFRINGEMENT. You are solely responsible for determining the appropriateness of using this publication and assume any risks associated with your use thereof, and GS1 US does not represent or warrant that the guidelines in this publication are appropriate for your particular company or your particular applications, products, or processes. Any GS1 US publication may include technical inaccuracies or typographical errors. GS1 US assumes no responsibility for and disclaims all liability for any errors or omissions in this publication or in other documents which are referred to within or linked to this publication. Some jurisdictions do not allow the exclusion of implied warranties, so the above exclusion may not apply to you.

Several products and company names mentioned herein may be trademarks and/or registered trademarks of their respective companies. GS1 US does not, by promulgating this document on behalf of the parties involved in the creation of this document, represent that any methods, products, and/or systems discussed or recommended in the document do not violate the intellectual property rights of any third party. GS1 US has not performed a search to determine what intellectual property may be infringed by an implementation of any strategies or suggestions included in this document. GS1 US hereby disclaims any liability for any party's infringement of intellectual property rights that arise as a result of any implementation of strategies or suggestions included in this document.

This publication may be distributed internationally and may contain references to GS1 US products, programs and services that have not been announced in your country. These references do not imply that GS1 US intends to announce such products, programs, or services in your country.

Limitation of Liability; No Liability for Consequential Damage

In no event shall GS1 US or anyone else involved in the creation, production, or delivery of the accompanying documentation be liable for any direct, indirect, special, incidental, or consequential damages of any character whatsoever (including, without limitation, damages for loss of business profits, business interruption, loss of business information, loss of goodwill, work stoppage, or other loss of any kind) arising out of the use of or the results of use of or inability to use such documentation, even if GS1 US has been advised of the possibility of such damages.

IAPMO

In this publication, the letters "U.P.C." are used solely as an abbreviation for the "Universal Product Code" which is a product identification system. They do not refer to the UPC, which is a federally registered certification mark of the International Association of Plumbing and Mechanical Officials (IAPMO) to certify compliance with a Uniform Plumbing Code as authorized by IAPMO.

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

Connect With Us