

SUPPLY CHAIN PRODUCT TRANSACTION SCENARIOS: DRUG SUPPLY CHAIN SECURITY ACT IMPLEMENTATION



**PREPARED BY
THE HEALTHCARE DISTRIBUTION MANAGEMENT ASSOCIATION (HDMA)**

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SUPPLY CHAIN PRODUCT TRANSACTION SCENARIOS: DRUG SUPPLY CHAIN SECURITY ACT IMPLEMENTATION

INTRODUCTION

This document, *Supply Chain Product Transaction Scenarios: Drug Supply Chain Security Act Implementation* has been prepared by the Healthcare Distribution Management Association (HDMA) in consultation with its Traceability Implementation Work Group (Work Group). This document represents HDMA's interpretation of how physical product, product ownership and data move between trading partners under numerous product transaction scenarios and the requirements for trading partners to pass Transaction Information (TI), Transaction History (TH) and the Transaction Statement (TS) under the Drug Supply Chain Security Act (DSCSA).

For each product transaction scenario, a matrix describes the elements of TI, TH and TS that must be sent by the trading partner identified in the column heading. A checkmark indicates that that element of TI, TH or TS must be sent to the next entity in the product transaction. Where applicable, unique and special DSCSA requirements are noted next to the checkmark.

The graphic depictions that follow a matrix are a visual guide demonstrating the flow and transfer of physical product, product ownership and data among trading partners. Because TI, TH and TS requirements change depending upon whether an entity is a direct purchaser, i.e., an entity that purchases product from a manufacturer, exclusive distributor, or direct purchase repackager, parentheses indicate whether an entity in the mapped transaction is or is not a direct purchaser as that term is used in the DSCSA.

The matrices and corresponding graphic depictions must be used in conjunction with one another for a full picture of the transaction scenarios and the related DSCSA requirements.

Since the original release of Version 1.0 of these *Transaction Scenarios* in July, 2014, supply chain users applying them to their systems have suggested certain editorial revisions to more clearly describe the DSCSA's data requirements. This revision, *Version 1.1 - December 2014*, is intended to provide such clarifications.

The changes made in creating this Version 1.1 are editorial in scope and merely intended to clarify the data elements recommended for transmission. The suggested DSCSA interpretations have not been altered. The only changes made are in the data descriptions.

These materials are not legal advice and are based on evolving requirements. As such, they may change as the Food and Drug Administration (FDA) issues guidance and regulations implementing the DSCSA. Each company must make its own business decisions about passing and accepting TI, TH and TS among its trading partners. Please consult your legal counsel and your trading partners for further implementation guidance.

SUPPLY CHAIN PRODUCT TRANSACTION SCENARIOS: DRUG SUPPLY CHAIN SECURITY ACT IMPLEMENTATION

PRODUCT TRACING – PHASE 1

Transaction Information (TI) – includes:

- + Name of the product
- + Strength and dosage form
- + NDC
- + Container size
- + Number of containers
- + Lot number
- + Transaction date/shipment date*
- + Name and address of the seller
- + Name and address of the purchaser

Transaction History (TH) – A paper or electronic statement that includes the transaction information for each prior transaction back to the manufacturer.

Transaction Statement (TS) – A paper or electronic attestation by the entity transferring ownership of the product that it:

- + Is authorized under the Act
- + Received the product from an authorized party
- + Received TI and TS from the previous seller
- + Did not knowingly ship suspect or illegitimate product
- + Has systems and processes to perform verification
- + Did not knowingly provide false transaction information and did not knowingly alter the transaction history

* Needed if shipment date is more than 24 hours after date of the transaction

DIRECT PURCHASE MODEL

Transaction Information Sent	Manufacturer	Distributor
Proprietary or Established Name	✓	✓
Strength/Dosage Form	✓	✓
National Drug Code	✓	✓
Container Size	✓	✓
Number of Containers (units shipped)	✓	✓
Lot Number	✓	Not Required
Transaction Date	✓	✓
Date of Shipment	✓ (If >24 hr From Transaction Date)	✓ (If >24 hr From Transaction Date)
Business Name/Address of Seller	✓ Manufacturer	✓ Distributor
Business Name/Address of Buyer	✓ Distributor	✓ Dispenser

Transaction History Sent*	Manufacturer	Distributor
Number of Containers (units shipped)		✓ Represented in Current TI (units shipped)
Lot Number		Not Required
Transaction Date		Not Required
Date of Shipment		Not Required
Business Name/Address of Seller		✓ Manufacturer
Business Name/Address of Buyer		✓ Represented in Current TI

Transaction Statement Sent	Manufacturer	Distributor
✓ = Yes	✓	✓ Must include direct purchase statement

Data Format	Manufacturer	Distributor
	Single Document; Electronic Required 11/27/17	Single Document if to Dispenser

* Proprietary/established name, strength/dosage form, NDC and container size are static and appear in TI

DIRECT PURCHASE TO DISPENSER



KEY



PRODUCT



DATA



OWNERSHIP

DIRECT PURCHASE TO 340B



** There may be additional changes in ownership and/or product flow with purchases by a health system in a 340B transaction.*

KEY



PRODUCT

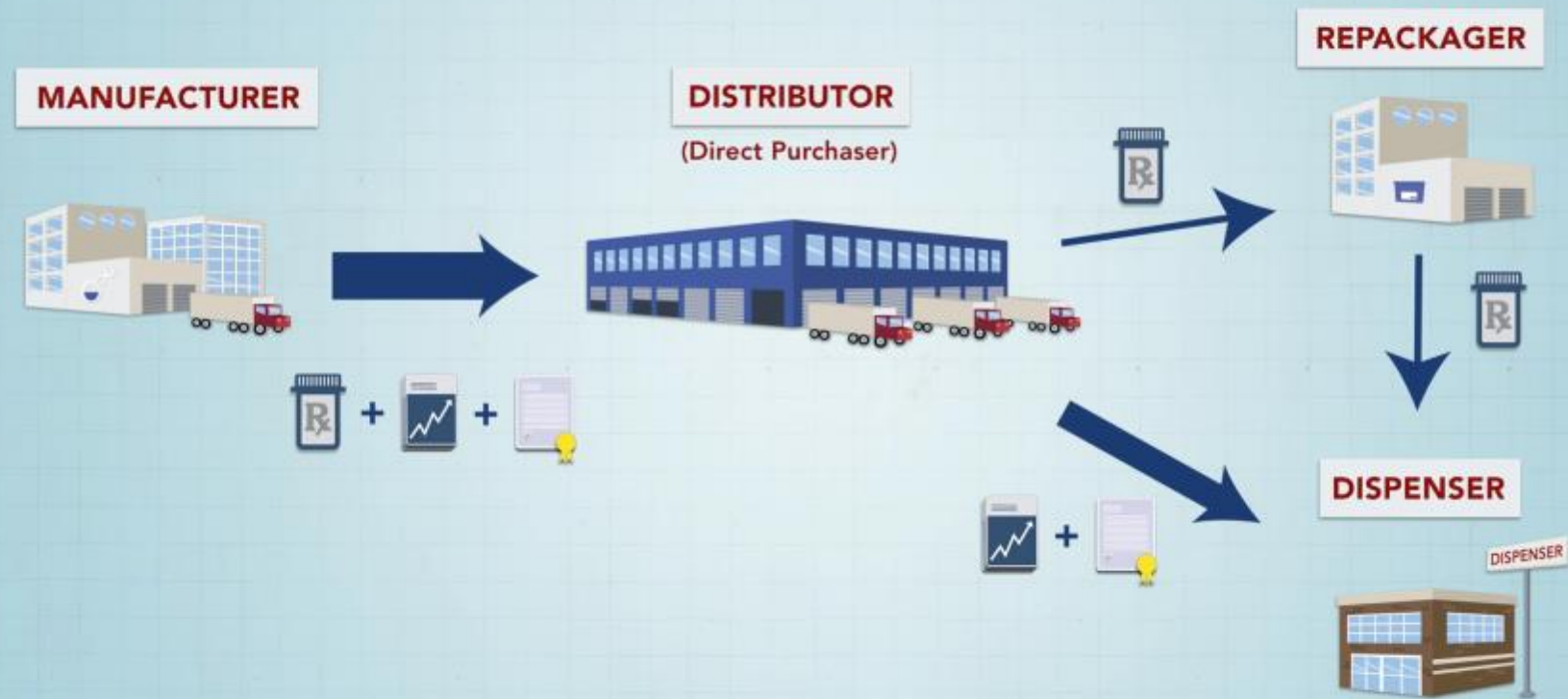


DATA



OWNERSHIP

DIRECT PURCHASE TO DISPENSER'S REPACKAGER



KEY



PRODUCT



DATA



OWNERSHIP

DIRECT PURCHASE THROUGH MANUFACTURER'S 3PL



KEY

- PRODUCT
- DATA
- OWNERSHIP

DISTRIBUTOR AS 3PL FOR DISPENSER

Transaction Information Sent	Manufacturer	Dispenser
Proprietary or Established Name	✓	
Strength/Dosage Form	✓	
National Drug Code	✓	
Container Size	✓	
Number of Containers (units shipped)	✓	
Lot Number	✓	
Transaction Date	✓	
Date of Shipment	✓ (If >24 hr From Transaction Date)	
Business Name/Address of Seller	✓ Manufacturer	
Business Name/Address of Buyer	✓ Dispenser	

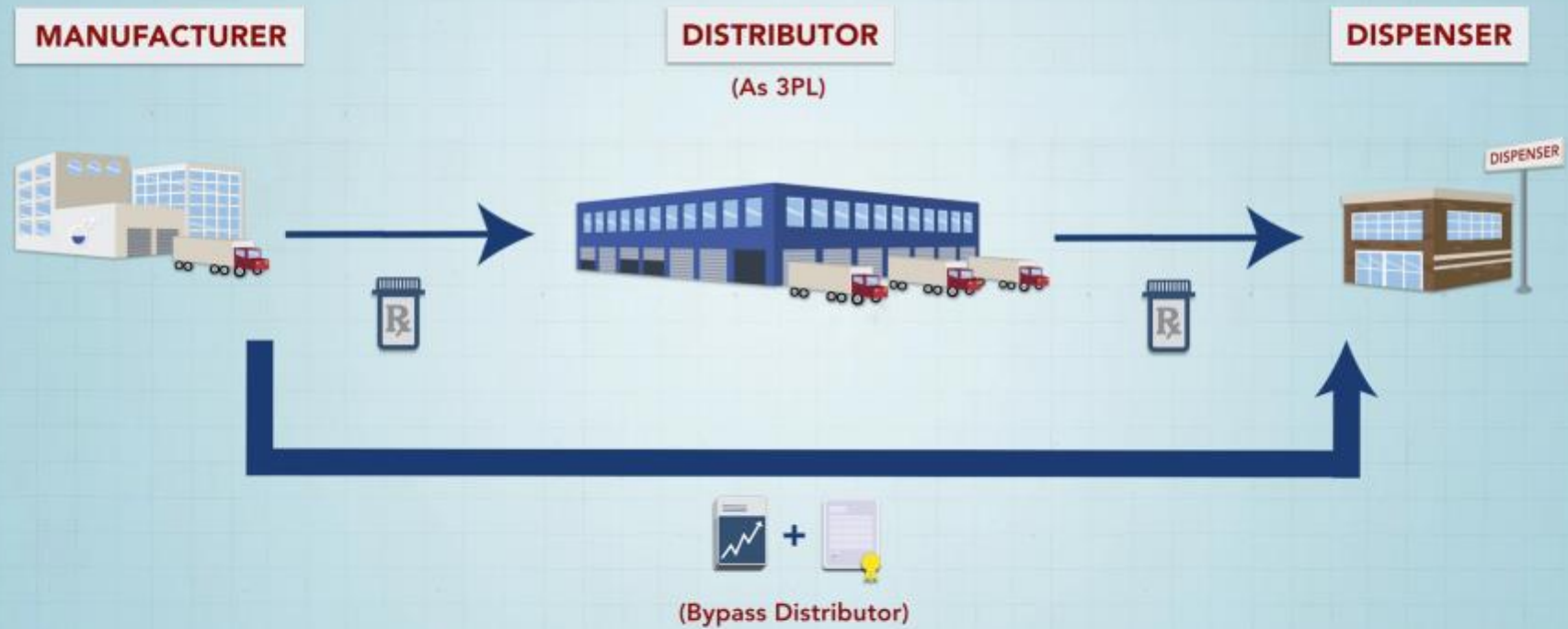
Transaction History Sent*	Manufacturer	Dispenser
Number of Containers (units shipped)		
Lot Number		
Transaction Date		
Date of Shipment		
Business Name/Address of Seller		
Business Name/Address of Buyer		

Transaction Statement Sent	Manufacturer	Dispenser
✓ = Yes	✓	

Data Format	Single Document; Electronic Required 11/27/17	
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* Proprietary/established name, strength/dosage form, NDC and container size are static and appear in TI

DISTRIBUTOR AS 3PL FOR DISPENSER



KEY					
	PRODUCT		DATA		OWNERSHIP

EXCLUSIVE DISTRIBUTOR – MODEL 1

Transaction Information Sent	Manufacturer	Exclusive Distributor	Distributor X
Proprietary or Established Name	✓	✓	✓
Strength/Dosage Form	✓	✓	✓
National Drug Code	✓	✓	✓
Container Size	✓	✓	✓
Number of Containers (units shipped)	✓	✓	✓
Lot Number	✓	✓	Not Required
Transaction Date	✓	✓	✓
Date of Shipment	✓ (If >24 hr From Transaction Date)	✓ (If >24 hr From Transaction Date)	✓ (If >24 hr From Transaction Date)
Business Name/Address of Seller	✓ Manufacturer	✓ Exclusive Distributor	✓ Distributor X
Business Name/Address of Buyer	✓ Exclusive Distributor	✓ Distributor X	✓ Dispenser

Transaction History Sent*	Manufacturer	Exclusive Distributor	Distributor X
Number of Containers (units shipped)			✓ Represented in Current TI (units shipped)
Lot Number			Not Required
Transaction Date			Not Required
Date of Shipment			Not Required
Business Name/Address of Seller			✓ Exclusive Distributor
Business Name/Address of Buyer			✓ Represented in Current TI

Transaction Statement Sent	Manufacturer	Exclusive Distributor	Distributor X
✓ = Yes	✓	✓	✓ Must include direct purchase statement

Data Format	Single Document; Electronic Required 11/27/17	Single Document; Electronic Required 11/27/17	Single Document if to Dispenser
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* Proprietary/established name, strength/dosage form, NDC and container size are static and appear in TI

EXCLUSIVE DISTRIBUTOR – MODEL 1



KEY



PRODUCT



DATA



OWNERSHIP

EXCLUSIVE DISTRIBUTOR – MODEL 2

Transaction Information Sent	Manufacturer	Exclusive Distributor	Distributor X	Distributor Y
Proprietary or Established Name	✓	✓	✓	✓
Strength/Dosage Form	✓	✓	✓	✓
National Drug Code	✓	✓	✓	✓
Container Size	✓	✓	✓	✓
Number of Containers (units shipped)	✓	✓	✓	✓
Lot Number	✓	✓	Not Required	✓
Transaction Date	✓	✓	✓	✓
Date of Shipment	✓ (If >24 hr From Transaction Date)	✓ (If >24 hr From Transaction Date)	✓ (If >24 hr From Transaction Date)	✓ (If >24 hr From Transaction Date)
Business Name/Address of Seller	✓ Manufacturer	✓ Exclusive Distributor	✓ Distributor X	✓ Distributor Y
Business Name/Address of Buyer	✓ Exclusive Distributor	✓ Distributor X	✓ Distributor Y	✓ Dispenser

Transaction History Sent*	Manufacturer	Exclusive Distributor	Distributor X	Distributor Y
Number of Containers (units shipped)			✓ Represented in Current TI (units shipped)	✓ Represented in Current TI (units shipped)
Lot Number			Not Required	✓ Represented in Current TI
Transaction Date			Not Required	✓ Distributor X
Date of Shipment			Not Required	✓ Distributor X (If included from Distributor X)
Business Name/Address of Seller			✓ Exclusive Distributor	✓ Distributor X
Business Name/Address of Buyer			✓ Represented in Current TI	✓ Represented in Current TI

Transaction Statement Sent	Manufacturer	Exclusive Distributor	Distributor X	Distributor Y
✓ = Yes	✓	✓	✓ Must include direct purchase statement	✓ Must also inform customer that Distributor Y received a direct purchase statement

Data Format	Single Document; Electronic Required 11/27/17	Single Document; Electronic Required 11/27/17	Multiple Documents Allowed	Multiple Documents Allowed
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* Proprietary/established name, strength/dosage form, NDC and container size are static and appear in TI

EXCLUSIVE DISTRIBUTOR – MODEL 2



KEY



PRODUCT



DATA



OWNERSHIP

MULTIPLE DISTRIBUTORS

Transaction Information Sent	Manufacturer	Distributor X	Distributor Y
Proprietary or Established Name	✓	✓	✓
Strength/Dosage Form	✓	✓	✓
National Drug Code	✓	✓	✓
Container Size	✓	✓	✓
Number of Containers (units shipped)	✓	✓	✓
Lot Number	✓	Not Required	✓
Transaction Date	✓	✓	✓
Date of Shipment	✓ (If >24 hr From Transaction Date)	✓ (If >24 hr From Transaction Date)	✓ (If >24 hr From Transaction Date)
Business Name/Address of Seller	✓ Manufacturer	✓ Distributor X	✓ Distributor Y
Business Name/Address of Buyer	✓ Distributor X	✓ Distributor Y	✓ Dispenser

Transaction History Sent*	Manufacturer	Distributor X	Distributor Y
Number of Containers (units shipped)		✓ Represented in Current TI (units shipped)	✓ Represented in Current TI (units shipped)
Lot Number		Not Required	✓ Represented in Current TI
Transaction Date		Not Required	✓ Distributor X
Date of Shipment		Not Required	✓ Distributor X (If included from Distributor X)
Business Name/Address of Seller		✓ Manufacturer	✓ Distributor X
Business Name/Address of Buyer		✓ Represented in Current TI	✓ Represented in Current TI

Transaction Statement Sent	Manufacturer	Distributor X	Distributor Y
✓ = Yes	✓	✓ Must include direct purchase statement	✓ Must also inform customer that Distributor Y received a direct purchase statement

Data Format	Manufacturer	Distributor X	Distributor Y
	Single Document; Electronic Required 11/27/17	Multiple Documents Allowed	Multiple Documents Allowed

* Proprietary/established name, strength/dosage form, NDC and container size are static and appear in TI

MULTIPLE DISTRIBUTORS



KEY

-  PRODUCT
-  DATA
-  OWNERSHIP

REPACKAGER – MODEL 1

Transaction Information Sent	Manufacturer	Repackager	Distributor
Proprietary or Established Name	✓	✓	✓
Strength/Dosage Form	✓	✓	✓
National Drug Code	✓	✓ NDC of Repackaged Product	✓ NDC of Repackaged Product
Container Size	✓	✓ Container Size of Repackaged Product	✓ Container Size of Repackaged Product
Number of Containers (units shipped)	✓	✓	✓
Lot Number	✓	✓ Repackager's Lot Number	Not Required
Transaction Date	✓	✓	✓
Date of Shipment	✓ (If >24 hr From Transaction Date)	✓ (If >24 hr From Transaction Date)	✓ (If >24 hr From Transaction Date)
Business Name/Address of Seller	✓ Manufacturer	✓ Repackager	✓ Distributor
Business Name/Address of Buyer	✓ Repackager	✓ Distributor	✓ Dispenser

Transaction History Sent*	Manufacturer	Repackager	Distributor
National Drug Code			✓ Represented in Current TI
Container Size			✓ Represented in Current TI
Number of Containers (units shipped)			✓ Represented in Current TI (units shipped)
Lot Number			Not Required
Transaction Date			Not Required
Date of Shipment			Not Required
Business Name/Address of Seller			✓ Repackager
Business Name/Address of Buyer			✓ Represented in Current TI

Transaction Statement Sent	Manufacturer	Repackager	Distributor
✓ = Yes	✓	✓	✓ Must include direct purchase statement

Data Format	Manufacturer	Repackager	Distributor
	Single Document; Electronic Required 11/27/17	Single Document; Electronic Required 11/27/17	Single Document if to Dispenser

* Proprietary/established name and strength/dosage form are static and appear in TI

REPACKAGER – MODEL 1

MANUFACTURER

REPACKAGER

DISTRIBUTOR X

(Direct Purchaser)

DISPENSER

(Including Practitioner)



KEY



PRODUCT



DATA



OWNERSHIP

REPACKAGER – MODEL 2

Transaction Information Sent	Manufacturer	Distributor X	Repackager	Distributor Y
Proprietary or Established Name	✓	✓	✓	✓
Strength/Dosage Form	✓	✓	✓	✓
National Drug Code	✓	✓	✓ NDC of Repackaged Product	✓ NDC of Repackaged Product
Container Size	✓	✓	✓ Container Size of Repackaged Product	✓ Container Size of Repackaged Product
Number of Containers (units shipped)	✓	✓	✓	✓
Lot Number	✓	Not Required	✓ Lot# of Repackaged Product	✓ Lot# of Repackaged Product
Transaction Date	✓	✓	✓	✓
Date of Shipment	✓ (If >24 hr From Transaction Date)	✓ (If >24 hr From Transaction Date)	✓ (If >24 hr From Transaction Date)	✓ (If >24 hr From Transaction Date)
Business Name/Address of Seller	✓ Manufacturer	✓ Distributor X	✓ Repackager	✓ Distributor Y
Business Name/Address of Buyer	✓ Distributor X	✓ Repackager	✓ Distributor Y	✓ Dispenser

Transaction History Sent*	Manufacturer	Distributor X	Repackager	Distributor Y
National Drug Code		✓ Represented in Current TI	✓ Manufacturer-assigned NDC number	✓ Manufacturer <u>and</u> Repackager assigned NDC(s)
Container Size		✓ Represented in Current TI	✓ Manufacturer's Container Size	✓ Manufacturer's & Repackager's Container Size
Number of Containers (units shipped)		✓ Represented in Current TI (units shipped)	✓ Represented in Current TI (units shipped)	✓ Represented in Current TI (units shipped)
Lot Number		Not Required	✓ Manufacturer-assigned lot number	✓ Manufacturer <u>and</u> Repackager assigned lot number(s)
Transaction Date		Not Required	✓ (of all prior transactions!)	✓ (of all prior transactions!)
Date of Shipment		Not Required	✓ if > 24 hrs from transaction date (all prior transactions!)	✓ if > 24 hrs from transaction date (all prior transactions!)
Business Name/Address of Seller		✓ Manufacturer	✓ Both Manufacturer <u>and</u> Distributor X	✓ Of Manufacturer, Distributor X <u>and</u> Repackager
Business Name/Address of Buyer		✓ Represented in Current TI	✓ Distributor X	✓ Distributor X and Repackager

Transaction Statement Sent	Manufacturer	Distributor X	Repackager	Distributor Y
✓ = Yes	✓	✓ Must include direct purchase statement	✓	✓

Data Format	Single Document; Electronic Required 11/27/17	Multiple Documents Allowed	Multiple Documents Allowed	Multiple Documents Allowed
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* Proprietary/established name and strength/dosage form are static and appear in TI

REPACKAGER – MODEL 2

MANUFACTURER

DISTRIBUTOR X

(Direct Purchaser)

REPACKAGER

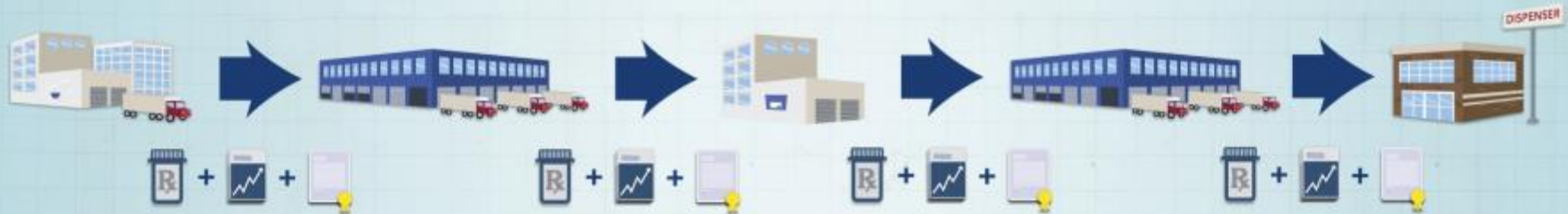
(Not Direct Purchaser)

DISTRIBUTOR Y

(Not Direct Purchaser)

DISPENSER

(Including Practitioner)



KEY



PRODUCT



DATA



OWNERSHIP

DROP SHIPMENT – MODEL 1 MANUFACTURER TO DISPENSER

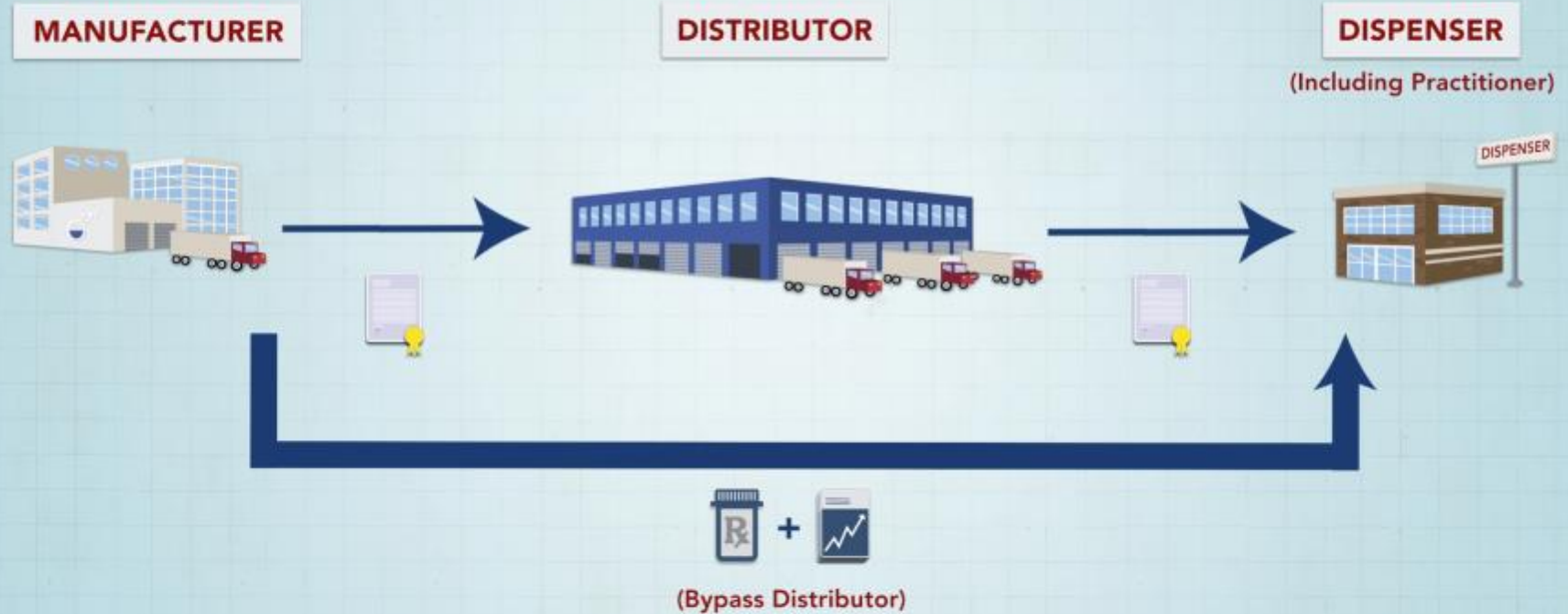
Transaction Information Sent	Manufacturer	Dispenser
Proprietary or Established Name	✓	
Strength/Dosage Form	✓	
National Drug Code	✓	
Container Size	✓	
Number of Containers (units shipped)	✓	
Lot Number	✓	
Transaction Date	✓	
Date of Shipment	✓ (If >24 hr From Transaction Date)	
Business Name/Address of Seller	✓ Manufacturer	
Business Name/Address of Buyer	✓ Dispenser and Distributor	

Transaction History Sent*	Manufacturer	Dispenser
Number of Containers (units shipped)		
Lot Number		
Transaction Date		
Date of Shipment		
Business Name/Address of Seller		
Business Name/Address of Buyer		

Transaction Statement Sent	Manufacturer	Dispenser
✓ = Yes	✓	
Data Format	Single Document; Electronic Required 11/27/17 (except if to practitioner)	

* Proprietary/established name, strength/dosage form, NDC and container size are static and appear in TI

DROP SHIPMENT – MODEL 1 MANUFACTURER TO DISPENSER



DROP SHIPMENT – MODEL 2 REPACKAGER TO DISPENSER

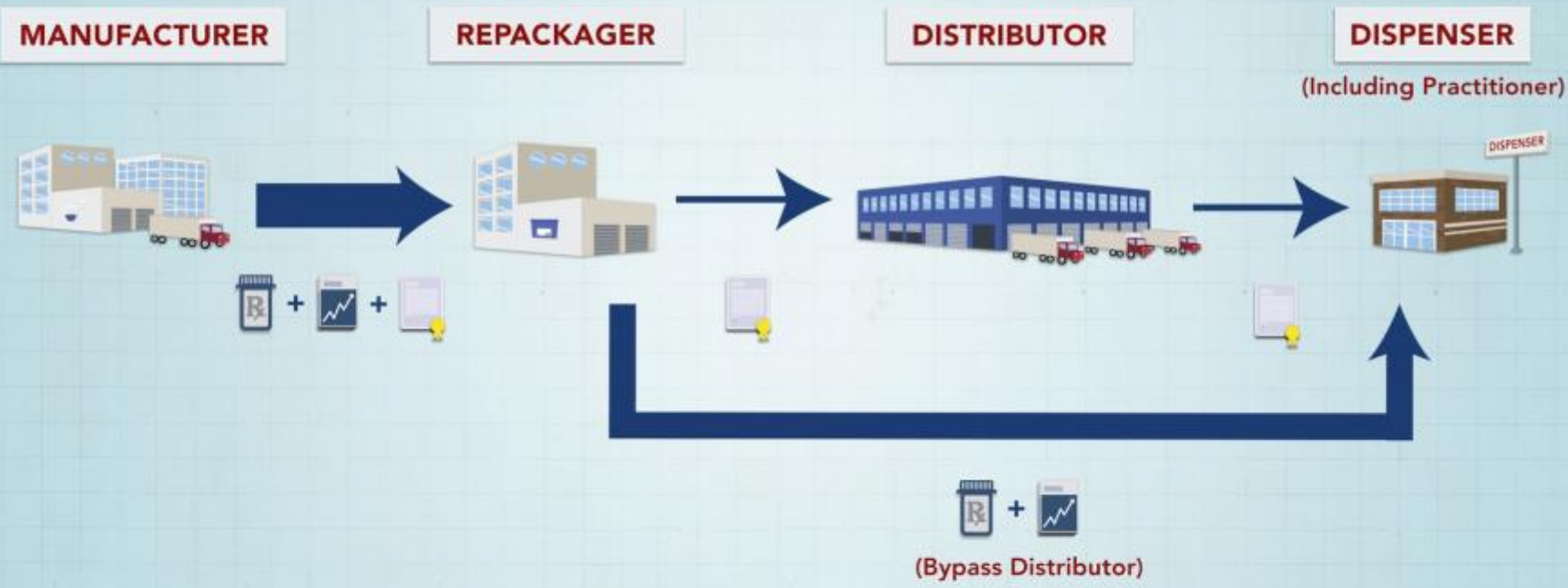
Transaction Information Sent	Manufacturer	Repackager	Dispenser
Proprietary or Established Name	✓	✓	
Strength/Dosage Form	✓	✓	
National Drug Code	✓	✓ NDC of Repackaged Product	
Container Size	✓	✓ Container Size of Repackaged Product	
Number of Containers (units shipped)	✓	✓	
Lot Number	✓	✓ Lot # of Repackaged Product	
Transaction Date	✓	✓	
Date of Shipment	✓ (If >24 hr From Transaction Date)	✓	
Business Name/Address of Seller	✓ Manufacturer	✓ Repackager	
Business Name/Address of Buyer	✓ Repackager	✓ Dispenser and Distributor	

Transaction History Sent*	Manufacturer	Repackager	Dispenser
National Drug Code			
Container Size			
Number of Containers (units shipped)			
Lot Number			
Transaction Date			
Date of Shipment			
Business Name/Address of Seller			
Business Name/Address of Buyer			

Transaction Statement Sent	Manufacturer	Repackager	Dispenser
✓ = Yes	✓	✓	
Data Format	Single Document; Electronic Required 11/27/17	Multiple Documents Allowed	

* Proprietary/established name and strength/dosage form are static and appear in TI

DROP SHIPMENT – MODEL 2 REPACKAGER TO DISPENSER



KEY

- PRODUCT
- DATA
- OWNERSHIP

DROP SHIPMENT – MODEL 3 DISTRIBUTOR TO DISPENSER

Transaction Information Sent	Manufacturer	Distributor X	Distributor Y	Dispenser
Proprietary or Established Name	✓	✓		
Strength/Dosage Form	✓	✓		
National Drug Code	✓	✓		
Container Size	✓	✓		
Number of Containers (units shipped)	✓	✓		
Lot Number	✓	Not Required		
Transaction Date	✓	✓		
Date of Shipment	✓ (If >24 hr From Transaction Date)	✓ (If >24 hr From Transaction Date)		
Business Name/Address of Seller	✓ Manufacturer	✓ Distributor X		
Business Name/Address of Buyer	✓ Distributor X	✓ Dispenser and Distributor Y		

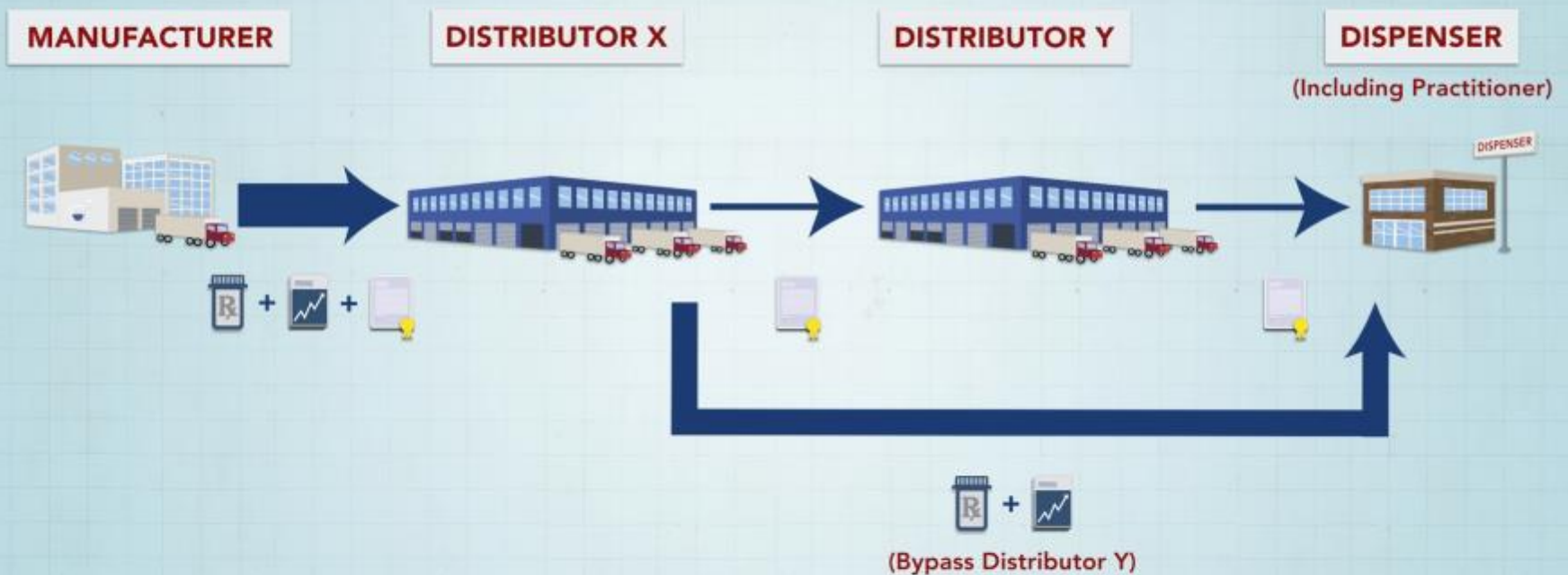
Transaction History Sent*	Manufacturer	Distributor X	Distributor Y	Dispenser
Number of Containers (units shipped)		✓ Represented in Current TI (units shipped)		
Lot Number		Not Required		
Transaction Date		Not Required		
Date of Shipment		Not Required		
Business Name/Address of Seller		✓ Manufacturer		
Business Name/Address of Buyer		✓ Represented in Current TI		

Transaction Statement Sent	Manufacturer	Distributor X	Distributor Y	Dispenser
✓ = Yes	✓	✓ Must include direct purchase statement		

Data Format	Single Document; Electronic Required 11/27/17	✓ Single Document		
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* Proprietary/established name, strength/dosage form, NDC and container size are static and appear in TI

DROP SHIPMENT – MODEL 3 DISTRIBUTOR TO DISPENSER



KEY



PRODUCT



DATA



OWNERSHIP

HEALTHCARE DISTRIBUTION MANAGEMENT ASSOCIATION

www.HealthcareDistribution.org

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CHDMA