

2014

HDMA DISTRIBUTION MANAGEMENT CONFERENCE AND TECHNOLOGY EXPO

Co-hosted with IFPW (International Federation of Pharmaceutical Wholesalers)
Supported by CAPDM (Canadian Association for Pharmacy Distribution Management)

Distributor Traceability Updates

Chris Anderson – Cardinal Health

Julie Kuhn – H. D. Smith

Scott Mooney - McKesson

Heather Zenk – AmerisourceBergen

Agenda

- Industry approach
- Suspect and illegitimate products
- Transaction data flow / traceability
- EDI

Standard Approach to Implementation

- Many teams actively working on alignment of year-end requirements
 - HDMA
 - Suspect and Illegitimate Product
 - Traceability
 - EDI
 - Pharmaceutical Distribution Security Alliance (PDSA)
 - Forum to discuss
 - Industry-wide approach to implementation issue by issue
 - Interpretation of law with many stakeholder perspectives
 - Continued discussion with key Hill staff as needed

Sunday, March 9–Wednesday, March 12, 2014 | JW Marriott Desert Springs, Palm Desert, Calif.

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Group Challenge Chris Anderson

jeopardylabs.com/play/traceability

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Suspect Product

Julie Kuhn

Definition

- The term ‘suspect product’ means a product for which there is reason to believe that such product—
 - (A) is potentially counterfeit, diverted, or stolen;
 - (B) is potentially intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;
 - (C) is potentially the subject of a fraudulent transaction; or
 - (D) appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans.

Suspect Products

- Suspect product actions
 - Quarantine
 - Investigation
- FDA Guidance document
 - Publish by end of May 2014
 - No docket request to-date

Suspect Products

- HDMA letter
 - Proactive information to FDA in advance of formal request
 - Member input informed letter content
- HDMA comments:
 - Wholesale distributors receive, handle, store, and distribute products in final packaging daily
 - Limited role in identifying suspect and illegitimate product
 - Leverage processes already in place
 - Recognize the variability among supply chain partners

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Product Flows

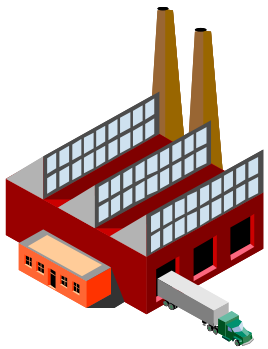
Heather Zenk

Direct Purchase

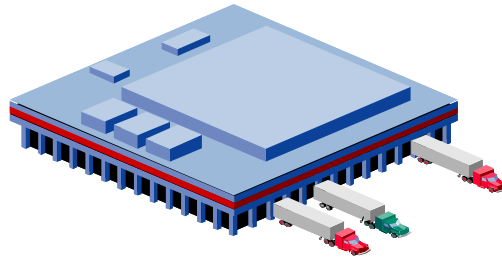
Manufacturer

Distributor

Dispenser



Product, Data,
Ownership



Product, Data,
Ownership



Direct Purchase

Transaction Information Sent

	Manufacturer	Distributor
Proprietary Name	✓	✓
Strength / Dosage Form	✓	✓
National Drug Code	✓	✓
Container Size	✓	✓
Number of Containers	✓	✓
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	✓	✓
Business Name / Address of Buyer	✓	✓

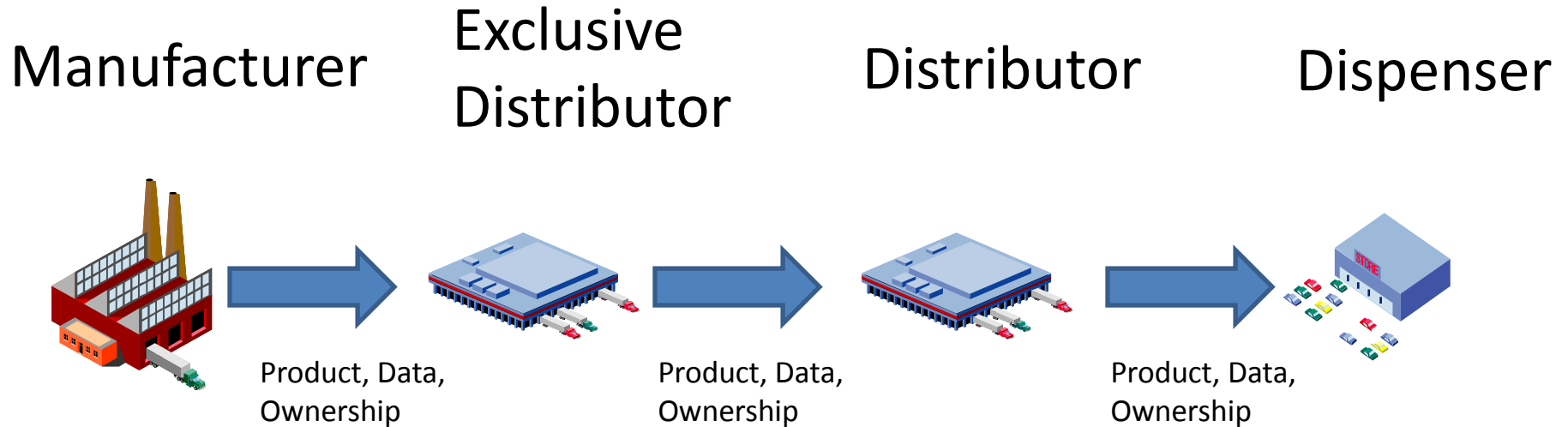
Transaction History Sent

Number of Containers		Represented in TI
Lot Number		Not Required
Transaction Date		Not Required
Date of Shipment		Not Required
Business Name / Address of Seller		✓
Business Name / Address of Buyer		Represented in TI

Transaction Statement Sent

	✓	✓
Data Format	Single Document; Electronic 11/27/17	Single Document

Direct Purchase – Excl. Distributor



Direct Purchase- Exclusive Distributor

Transaction Information Sent	Manufacturer	Exclusive Distributor	Distributor 2
Proprietary Name	✓	✓	✓
Strength / Dosage Form	✓	✓	✓
National Drug Code	✓	✓	✓
Container Size	✓	✓	✓
Number of Containers	✓	✓	✓
Lot Number	✓	Not Required	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	✓	✓ Exclusive Distributor	✓ Distributor 2
Business Name / Address of Buyer	✓	✓ Distributor 2	✓ Dispenser

Transaction History Sent

Number of Containers		Represented in TI	Represented in TI
Lot Number		Not Required	Not Required
Transaction Date		Not Required	Not Required
Date of Shipment		Not Required	Not Required
Business Name / Address of Seller		✓ Manufacturer	✓ Exclusive Distributor
Business Name / Address of Buyer		Represented in TI	Represented in TI

Transaction Statement Sent

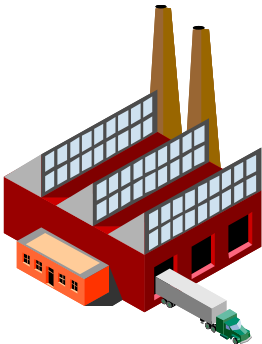
	✓	✓	✓
Data Format	Single Document; Electronic 11/27/17	Multiple Documents Allowed	Single Document

Drop Shipment

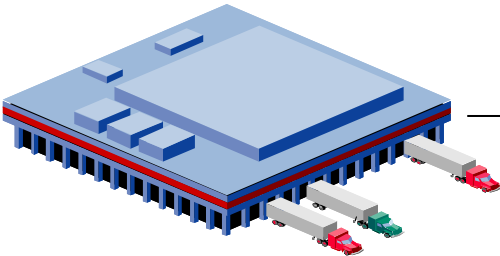
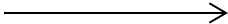
Manufacturer

Distributor

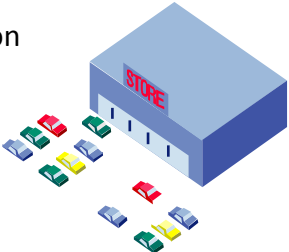
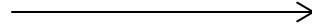
Dispenser



Data not defined in H.R. 3204



Financial Transaction



Drop Shipment

Transaction Information Sent

	Manufacturer	Dispenser
Proprietary Name	✓	
Strength / Dosage Form	✓	
National Drug Code	✓	
Container Size	✓	
Number of Containers	✓	
Lot Number	✓	
Transaction Date	✓	
Date of Shipment	✓	
Business Name / Address of Seller	✓	
Business Name / Address of Buyer	✓ (Distributor Info)	

Transaction History Sent

Number of Containers	✓	
Lot Number	✓	
Transaction Date	✓	
Date of Shipment	✓	
Business Name / Address of Seller	✓	
Business Name / Address of Buyer	✓	

Transaction Statement Sent

	✓	✓
Data Format	Single Document	

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EDI

Scott Mooney

Information Required

- Transaction Information
 - Name of Product
 - Strength and dosage form
 - NDC
 - Container size and number of containers
 - Lot number
 - Date of Transaction (and ship date if different more than 24 hours)
 - Party ownership is transferring from
 - Party ownership is transferring to (Bill To)
- Transaction History
 - Previous Transaction Information
- Transaction Statement
 - Attestation required under law

Existing Data Formats










- Electronic Potentials
 - EDI
 - ASN (856)
 - Invoice (810)
 - Other EDI formats, ie; Chargebacks, Contracts, etc
 - GS1
 - EPCIS
- Paper

EDI ASN (856)

- Higher current adoption rate than other electronic formats
- Connectivity between vendors and distributors already exists
- Some connectivity between distributors and pharmacy already exists
- Fastest “standardized” approach to adapt before 1-1-15

EDI ASN (856) Status

- Transaction Information

- Name of Product 
- Strength and dosage form 
- NDC 
- Container size  and number of containers 
- Lot number 
- Date of Transaction (and ship date if different more than 24 hours) 
- Party ownership is transferring from 
- Party ownership is transferring to (Bill To) 

- Transaction History

- Previous Transaction Information 

Layering multiple levels needs attention

- Transaction Statement

- Attestation required under law 

Looking at single statement in YNQ field

EDI ASN (856) Status

- Could be used for inbound transactions to the distributors
- Could be used for outbound from distributors to customers who can use ASN
- Likely from distributor to pharmacy that multiple methodologies may be used to communicate TI, TH & TS

Session Wrap-up

❖ *Speakers Engage!*

- New to the Expo Hall this year
- Located in the RIGHT back corner
- Let's continue the conversation

❖ Session Evaluation

- Two easy ways!
 - Mobile App (dmc.hdma.net)
 - HDMA website