

Preparing for Traceability

Roundtable Luncheon | Tuesday, June 3 | 12:00 – 1:15 PM

Panelists

- **Scott Mooney**, Vice President, Distribution Operations, McKesson Corporation
- **Brad Pine**, Senior Director, Compliance and Regulatory Affairs, Smith Drug Company
- **Heather Zenk**, Vice President, Secure Supply Chain, AmerisourceBergen Corporation

Moderator

- **Perry Fri**, Executive Vice President, Industry Relations, Membership and Education, HDMA

What is TI/TH/TS?

Transaction Information (TI):

Proprietary or established name or names of the product;
strength and dosage form of the product;
NDC number of the product;
container size;
number of containers;
lot number;
date of the transaction;
date of the shipment, if more than 24 hours after the date of the transaction;
business name and address of the person from whom and to whom ownership is being transferred.

Transaction History (TH): A statement (paper or electronic), including the TI for each prior transaction going back to the manufacturer of the product.

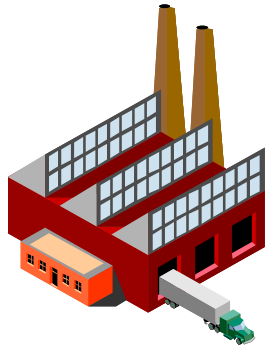
Transaction Statement (TS):

A statement, in paper or electronic form, that the--

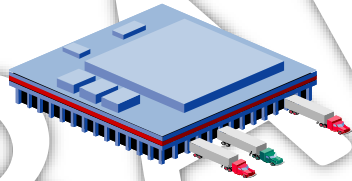
entity transferring ownership in a transaction is authorized as required under DSCSA;
received the product from a person that is authorized as required under DSCSA;
received transaction information and a transaction statement from the prior owner of the product, as required under the law;
did not knowingly ship a suspect or illegitimate product;
had systems and processes in place to comply with verification requirements under the law;
did not knowingly provide false transaction information; and
did not knowingly alter the TH

Direct Purchase to Dispenser

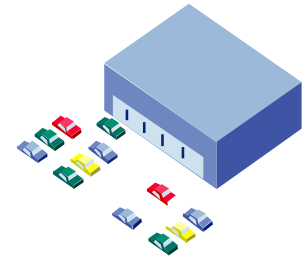
Manufacturer



Distributor
(Direct Purchaser)



Dispenser
(including Practitioner)



Product, Data,
Ownership

Product, Data,
Ownership

DRAFT


Direct Purchase Model

Transaction Information Sent	Manufacturer	Distributor
Proprietary or Established 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	✓ Manufacturer	✓ Distributor
Business Name / Address of Buyer	✓ Distributor	✓ Dispenser

Transaction History Sent*	Manufacturer	Distributor
Number of Containers		✓ Represented in Current TI
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

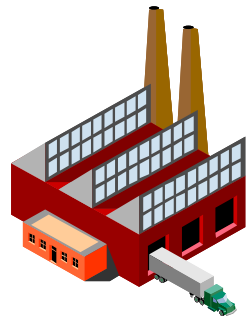
 * Proprietary/established name, strength/dosage form, NDC, and container size are static and appear in TH throughout the transmissions

Drop Shipment – Model 1 – Manufacturer to Dispenser

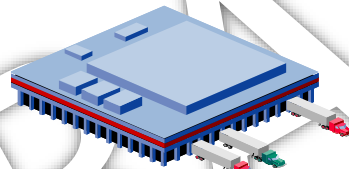
Manufacturer

Distributor

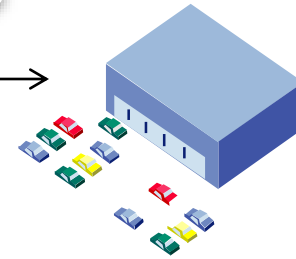
Dispenser
(including Practitioner)



Ownership



Ownership



Product, Data

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	✓	
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		
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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Panel Discussion

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Q & A



Additional Resources

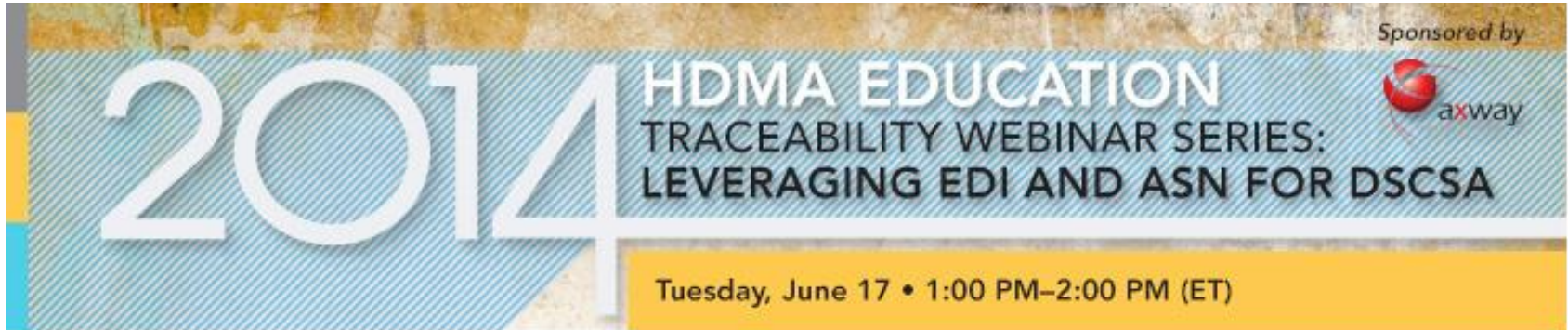
HDMA Resources

- Issue Overview:
http://www.healthcaredistribution.org/ir_issues/pedigree.asp
- Traceability Fact Sheet
http://hdmanet.org/press_room/pdf/HDMA-ToolKit-traceability.pdf

FDA Resources

- DSCSA Website
<http://www.fda.gov/drugs/drugsafety/drugintegrityandsupplychainsecurity/drugsupplychainsecurityact/ucm382022.htm>

Save the Dates . . .



- **Traceability Webinar Series**
 - *“Leveraging EDI and ASN for DSCSA”* on **June 17, 2014**
- **Traceability Seminar**
 - November 10-12, 2014 | Arlington, Virginia

<http://hdmanet.org/meetings/upcoming.asp>