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Drug Supply Chain Security Act: Overview and Impact on the Dispenser

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Trials and Tribulations of the Pharmacy Supply Chain

- Diversion
- Drug Shortages
- Recalls
- Grey market activities
- Illegitimate/counterfeit products...etc.



Counterfeit Medications in North Carolina

Nov 2012: "Distributor of counterfeit pharmaceuticals sentenced to 10 months in prison"

Feb 2013: "Wilson, N.C. Man Sentenced To Two Years In Prison For Distributing Counterfeit Viagra And Cialis In Charlotte"

August 4, 2015: "North Carolina Man Indicted for Receiving and Selling Misbranded Silicone for Buttocks Injections"

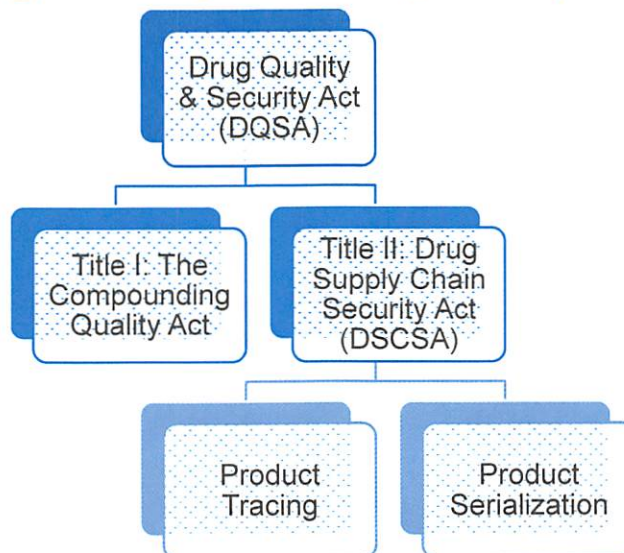


Once mixed in with your inventory, would you be able to pull these immediately if asked and trace back exactly where it came from?

Objectives

- Describe the Drug Supply Chain Security Act
- Discuss the timeline and implementation plan for the law
- Develop a plan for compliance from the perspective of the dispenser

Drug Quality Security Act (DQSA)



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Drug Supply Chain Security Act (DSCSA)




- Enacted November 2013 as part of the Drug Quality and Safety Act of 2013 (DQSA)
 - Establishes a national system for tracing pharmaceutical products through the supply chain
 - Sets national licensing standards for wholesale distributors and third-party logistics providers, and
 - Preempts existing state pedigree requirements

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Goals of the DSCSA

- Enable verification of the legitimacy of the drug product identifier down to the package level
- Enhance detection and notification of illegitimate products in the drug supply chain
- Facilitate more efficient recalls of drug products

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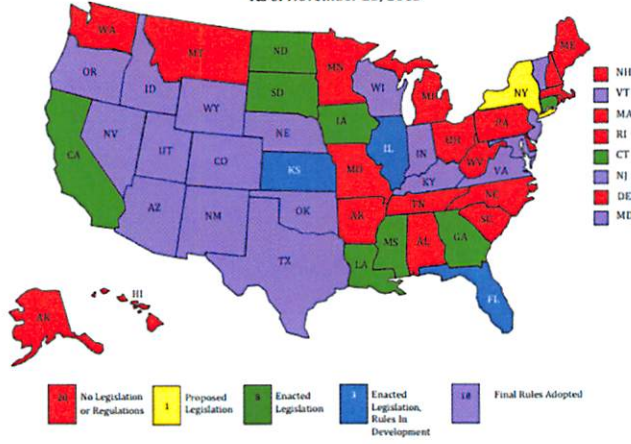
Reasons for Action

- Replace a 50-state patchwork of pedigree requirements with one federal traceability solution
- Industry stakeholders generally united with goals but unsure how to get there
- Transform how supply chain operates to the benefits of healthcare providers, pharmacists, and their patients

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State Regulations

2013 HDMA Map of State Pedigree Legislation/Regulations
As of November 25, 2013



Legend:

- No Legislation or Regulations
- Proposed Legislation
- Enacted Legislation
- Enacted Legislation, Rules in Development
- Final Rules Adopted


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One Federal Solution



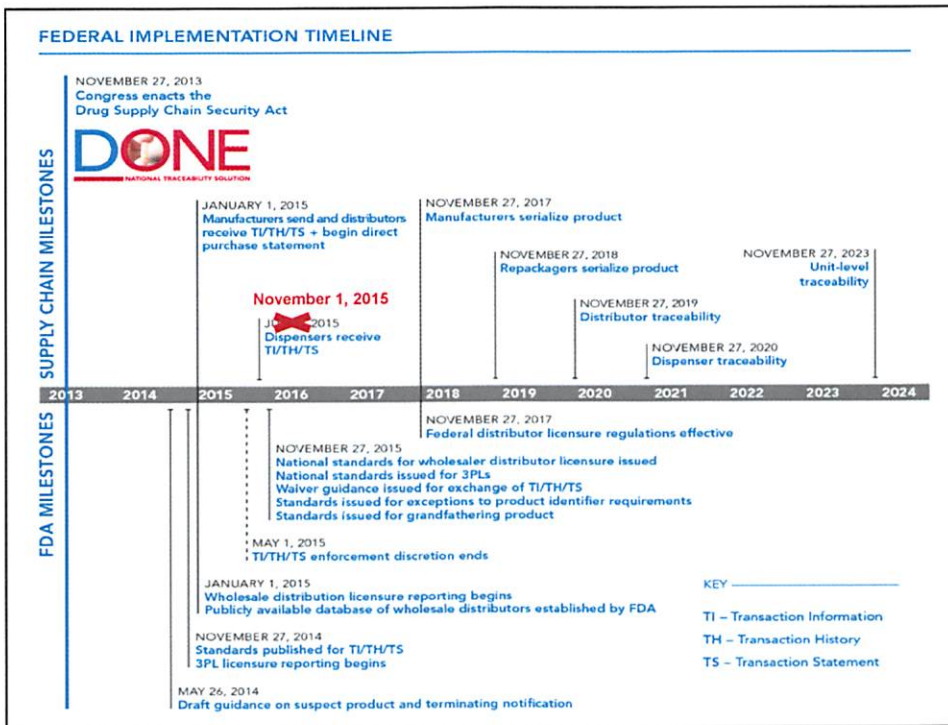
DONE
NATIONAL TRACEABILITY SOLUTION

We applaud Congress for establishing a national solution to ensure a safer and more secure pharmaceutical supply chain. #1RxSolution

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Intent of DSCSA

- A single, federal framework to trace prescription medications through the supply chain to provide regulatory clarity and consistency
- Eliminate the effects of competing state requirements and facilitate efficient interstate commerce
- Help to prevent counterfeits from entering and discouraging “gray market” activities in the supply chain



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FDA Delays Enforcement

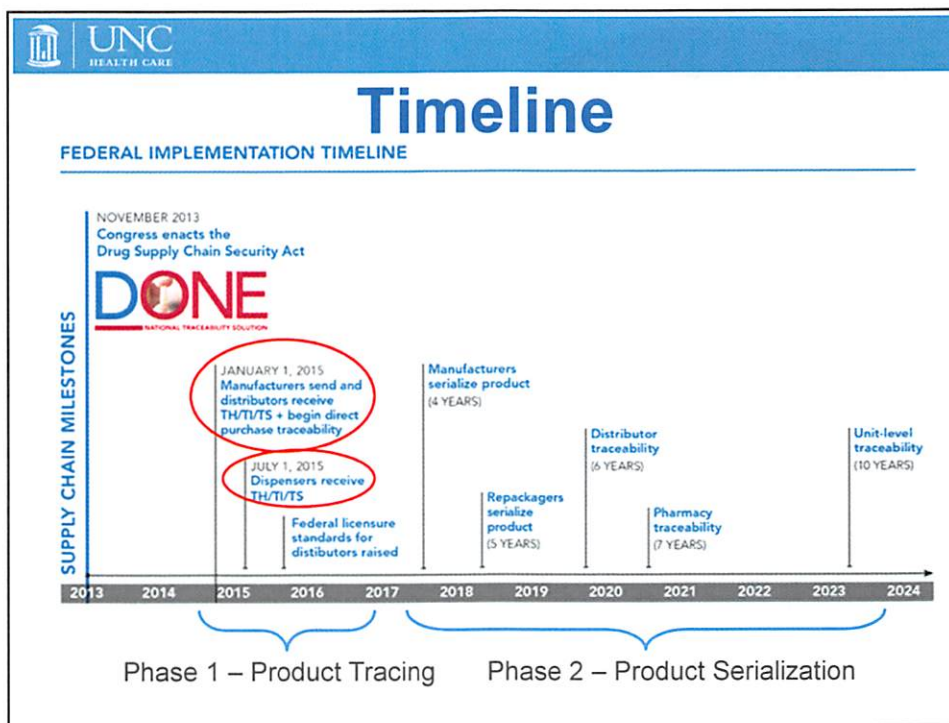
June 30, 2015


With One Day Remaining Before July 1 Compliance Date, FDA Exercises Enforcement Discretion of DSCSA's Product-Tracing Requirements for Dispensers

Excerpt from DSCSA Implementation: Product Tracing Requirements for Dispensers Compliance Policy:

FDA does not intend to take action against dispensers who, prior to November 1, 2015, (1) accept ownership of product without receiving product tracing information, prior to or at the time of a transaction, ... or (2) do not capture and maintain the product tracing information

Section of DSCSA	Deliverable Type	Deliverable Description	Estimated Target Date
202	FR Notice	Issue notice of public docket to collect stakeholder comments on standards for interoperable exchange of transaction information/history/statement in paper or electronic format	2/20/2014
203	Guidance	Publish guidance on identification of suspect product and termination of notifications of illegitimate product for finished human prescription drugs	5/27/2014
202	Guidance	Publish draft guidance establishing standards for interoperable exchange of transaction information/history/statement in paper or electronic format	11/27/2014
205	Database	Establish a system for third-party logistic provider reporting to FDA	11/27/2014
204	Database	Establish a system for wholesale drug distributor reporting to FDA and public database with licensing information	1/1/2015
202	Guidance	Publish guidance on processes for waivers, exceptions, exemptions	11/27/2015
202	Guidance	Publish final guidance on grandfathering product	11/27/2015
204	Regulation	Develop regulations establishing standards for licensing of wholesale drug distributors	11/27/2015
205	Regulation	Develop regulations establishing standards for licensing of third-party logistic providers	11/27/2015
203	Regulation	Develop regulations establishing enhanced drug distribution security system for interoperable electronic tracing of product at the package level	11/27/2021
203	Guidance	Publish final guidance on system attributes necessary to enable secure tracing at the package level	11/27/2022
203	Guidance	Publish final guidance on standards for interoperable data exchange to enhance secure tracing of product at the package level	11/27/2022
203	Assessment	Conduct and compete a technology and software assessment on feasibility of small dispensers to conduct drug tracing at the package level	TBD
203	Public Meeting	Conduct at least 5 public meetings	TBD
203	Pilot Project	Establish 1 or more pilot projects in coordination with stakeholders to explore and evaluate methods to enhance the safety and security of supply chain	TBD




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Title II States:

- Beginning 01/01/2015, manufacturers, wholesaler drug distributors, repackagers, and dispensers must provide:
 1. History
 2. Information
 3. Statement

} Keep for 6 years in paper or electronic format

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Transaction Data

Transaction Information (TI)
Name, strength, dosage, NDC, container size, transaction date, shipment date, name & address of previous owner

Transaction History (TH)

Paper or electronic statement including information for each prior transaction of the drug, tracing back to manufacturer

Transaction Statement (TS)

Paper or electronic attestation by the entity transferring ownership of the product that the product is authorized under DQSA



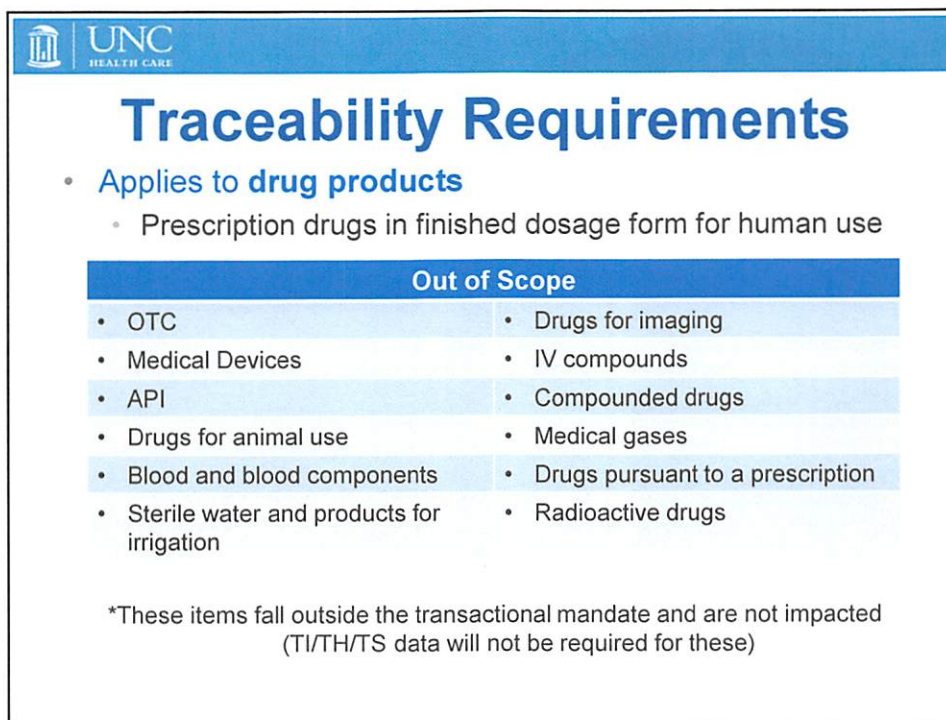
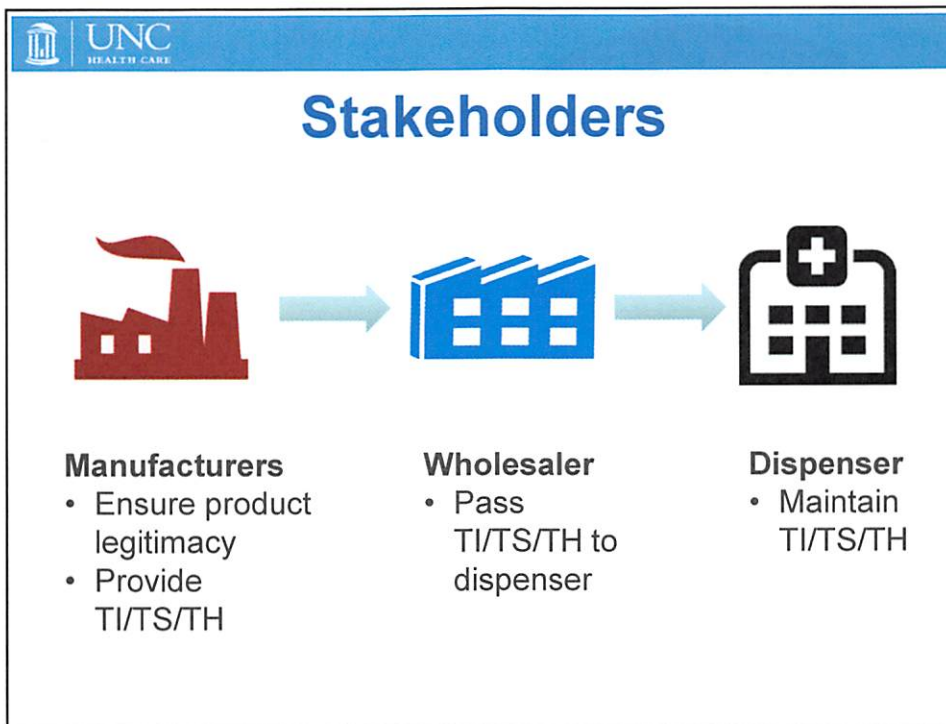
Manufacturers & Wholesalers


- **Jan 2015**
 - Must provide transaction data to purchasers of drug products in paper or electronic format
 - Transaction Information, Transaction Statement, Transaction History
- **Nov 2017**
 - Must place a unique product identifier on prescription drug packages
 - Product Identifier: NDC, serial number, lot number, expiration date
- **Jan 2019**
 - Must deliver transaction data in electronic format



Dispensers

- **July 1, 2015**
 - Shall not accept ownership of product from wholesaler without TI/TH/TS
 - Must provide subsequent owner with TI/TH/TS plus lot number and expiration date
 - Must retain records of inbound and outbound TI/TH/TS for no less than 6 years
 - Must respond to request for TI/TH/TS in the case of suspect or illegitimate product within 2 business days




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DSCSA Transactions

- Applies to **transactions**
- Transaction = change in ownership
- Certain situations are listed as exempt in the law:

Out of Scope
• Distribution of product among hospitals or health care entities under common control
• Distribution for emergency medical reasons
• Distribution of product pursuant to a sale or merger of a pharmacy or wholesale distributor
• Distribution of samples
• Distribution of minimal quantities by a licensed pharmacy to a licensed practitioner

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Returns

Returns in Years 1-6	Returns Years 6-10
<ul style="list-style-type: none"> • Returns from dispenser or repackagers between trading partners • Dispensers return saleable items to entity from which they were purchased • Subsequent TH starts with accepting wholesaler 	<ul style="list-style-type: none"> • Enhanced returns: a wholesaler can only accept returns from a dispenser or repackager if they can associate/verify the TI and TS for that product • Subsequent TH starts with the accepting wholesaler



Product Verification

- January 1, 2015: Trading partners must maintain systems and processes for investigating and quarantining products that are suspect or illegitimate
- If a product is determined to be illegitimate, the partner must:
 - Quarantine and investigate suspect product to determine if illegitimate
 - Notify the Secretary and its trading partners
 - Respond to notifications of illegitimate products
- Manufacturers, wholesale distributors, dispensers, and repackagers must only utilize “authorized trading partners”



Suspect vs. Illegitimate Product

- **Suspect Product** – reason to believe that product potentially:
 - Counterfeit, diverted, or stolen
 - Subject of a fraudulent transaction
 - Intentionally adulterated such that the product would result in serious adverse health consequences or death to humans
- **Illegitimate Product** – credible evidence that the product actually is any of the above

Scenarios

- Purchasing from a source new to the trading partner
- Receiving an unsolicited sales offer from an unknown source
- Purchasing on the Internet from an unknown source
- Purchasing from a source that provides incomplete or suspicious TI/TH/TS
- Product in high demand (e.g. drug shortage)
- Product packaging has foreign terms or is missing information

Product Identification (Serialization)

- No later than 4 years (11/27/17), manufacturers, followed by repackagers (11/27/18), shall place a unique product identifier on certain prescription drug packages
 - » 2D bar code
- Product identifier
 - » NDC
 - » Serial number
 - » Lot number
 - » Expiration date
- After 6 years (11/27/19), wholesalers, followed by dispensers (11/27/20), will trade only products with product identifiers



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Dispensers' Plan for Action


1. Understand the law and your supply chain
2. Assess Impact
 - » Identify special cases
3. Develop Policies & Procedures
 - » Work with suppliers
 - Wholesalers, distributors, manufacturers... etc.
4. Implement and Educate

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Understanding Your Supply Chain

Primary Vendor


- Wholesaler
- Distribution Center, Dropship
- 90+% of products




The diagram shows a linear flow from left to right. On the left is a red icon of a factory with smokestacks, labeled 'Manufacturers'. A blue arrow points to a blue icon of a warehouse with multiple bays, labeled 'Distribution Center'. Another blue arrow points to a black icon of a building with a cross on top, labeled 'Dispenser'.

Secondary Vendors

- Secondary wholesalers and direct from manufacturers
- <10% of products



The diagram shows two parallel paths from left to right. On the left are two red icons of factories with smokestacks. A blue arrow points from the top factory to a blue icon of a warehouse with multiple bays, labeled 'Distribution Center'. Another blue arrow points from the bottom factory to a black icon of a building with a cross on top, labeled 'Dispenser'.

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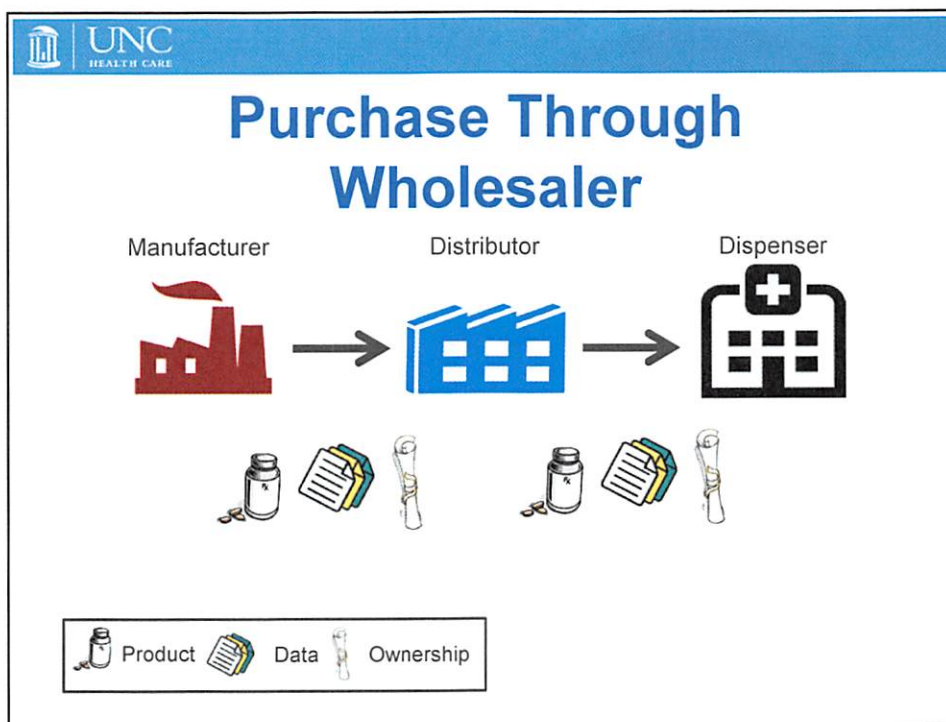
Wholesaler Distribution

Distribution Center

- Utilize online platform to retrieve TI/TH/TS
 - How long is this information available?
 - Is there a cost to store the information for 6 years?
 - Do you feel comfortable retrieving from them?
 - Where are you going to keep your information?

Specialty Arm of Wholesaler

- Likely also an online platform
 - Is it the same or different?
 - Same questions





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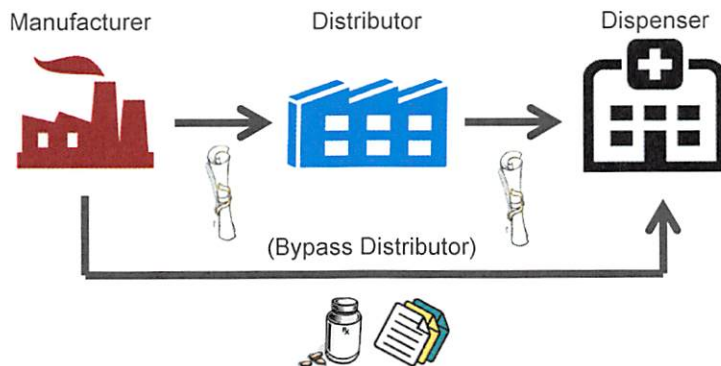
Wholesaler Dropship


- Occurs when wholesaler does not have product in their warehouse
 - Wholesaler facilitates our order through the manufacturer
 - Drug is shipped directly to the customer via common courier
 - Wholesaler manages the invoice and payment
- TI/TH/TS is contained on packing slips by the manufacturer with delivered orders or in online portal
- How will you track these?



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Drop Shipment: Manufacturer to Dispenser




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Secondary Wholesalers and Manufacturers

- Order directly from these vendors
- T3 information often on packing slips or online portal
 - More likely to be using online portal for ordering



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Systems to Help

- Programs available to assist in tracking transaction data
 - » rfXcel
 - » RxTrace
 - » Tracelink
 - » TrackTraceRx
- Collect information from suppliers electronically or by manual input by dispenser
- Maintain transaction information for future retrieval or for communicating for further transactions

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Special Cases

Centralized
Storeroom



340B
Contract
Pharmacy




Dispenser to
Dispenser

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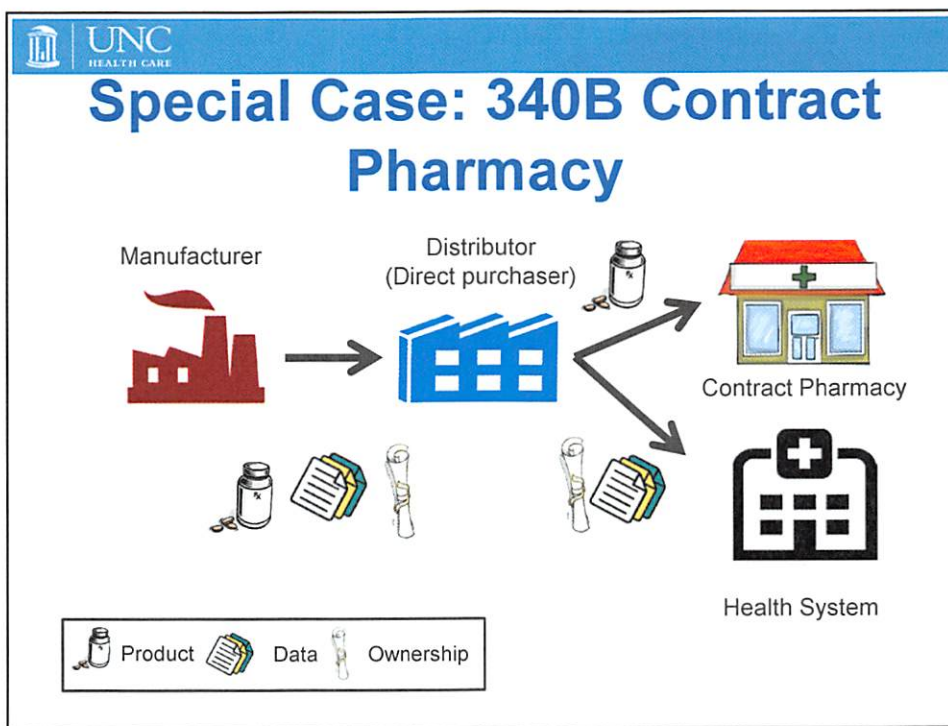
Special Case: Centralized Storeroom


- Transaction data does not have to be provided for distribution of product among hospitals or pharmacies under common ownership
 - Eg. Within UNC Health Care System there are no requirements to track within pharmacies
- Data must be maintained by central storeroom


Shared Services Center Pharmacy





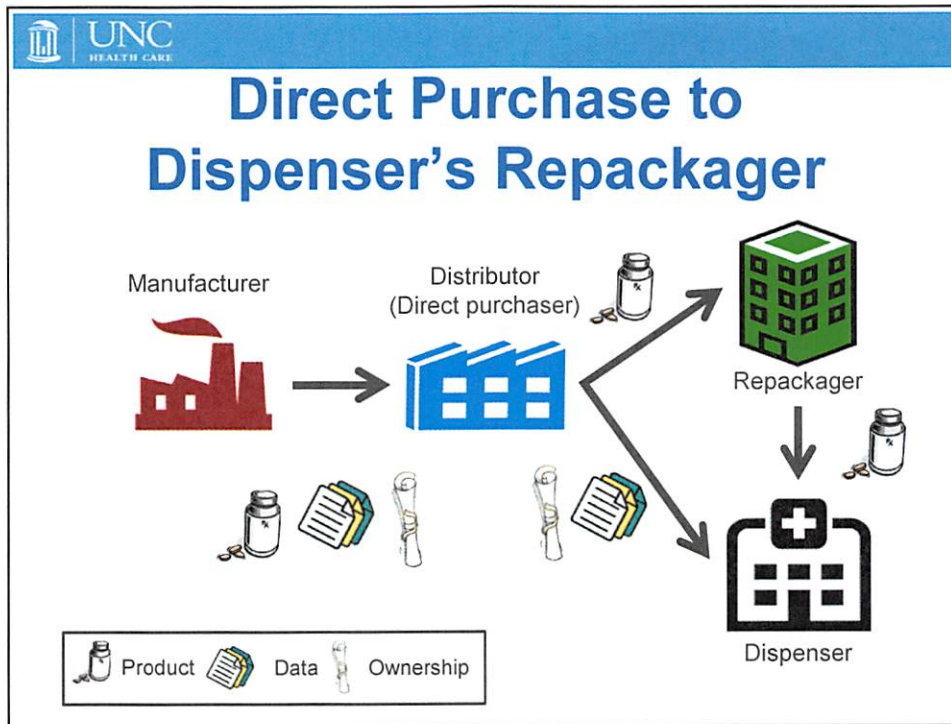
Special Case: 340B Contract Pharmacy

- How do we define ownership? Financial? Physical?
- Financial
 - » 340B entity must collect transaction data for contract pharmacy inventory
- Physical
 - » Contract pharmacy must have access to transaction data prior to accepting physical product
- If suspect product is identified, who reports it?
- If the FDA requests information, who has it?
- Need to have procedures in place for identification and reporting



Special Case: Repackaging

- Two kinds of repackagers:
 1. Those who buy medications and resell in new packaging
 - These must act like manufacturers and wholesalers including transaction data with each product movement
 2. Those who never take ownership of medication
 - Dispenser purchases and then sends product to repackager
 - Ownership remains with the dispenser, so TI, TH, and TS remain with the dispenser as well



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Policy and Procedure

- Dispensers must have policy and procedure for how to collect and maintain this information for 6 years
- Components include
 - Procedure for investigating possible suspect/illegitimate product
 - Validation of TI/TH/TS
 - Document and share record keeping
- Trading partners must have systems in place that enable them to promptly conduct an investigation to determine whether a suspect product is illegitimate within 2 business days



Implement and Educate

- Where will you be storing your transaction data?
- Does your staff know what your policies and procedures are?
 - » What to do they do if they need product from another pharmacy?
 - » Do they know how to identify potentially illegitimate drug and how to report it?
 - » Do you require competencies?
 - » Do you have a back up in place to retrieve information if primary contact is out of the office?



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