U.S. Drug Supply Chain Security Act (DSCSA)
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The U.S. Drug Supply Chain Security Act (DSCSA) was signed into law on November 27, 2013. It outlines the steps to build an electronic interoperable system by November 27, 2023. The DSCSA will identify and trace certain prescription drugs as they are distributed within the U.S. The electronic interoperable system that will be established under the DSCSA will enhance the U.S. Food and Drug Administration’s (FDA) ability to:

- Help protect U.S. consumers by improving detection and removal of potentially dangerous products from the pharmaceutical distribution supply chain.
- Help prevent such products from entering the supply chain in the first place.
Purpose of the DSCSA

The DSCSA facilitates the tracing of products through the pharmaceutical distribution supply chain by requiring trade partners (manufacturers, repackagers, wholesale distributors, and dispensers) to exchange the 3T’s:

- **Transaction Information (TI)**
- **Transaction History (TH)**
- **Transaction Statement (TS)**
The 3T’s – Transaction Information (TI)

► Transaction Information includes:
1. Product name
2. Strength and dosage form
3. NDC number
4. Container size
5. Number of containers
6. Lot number
7. Transaction date
8. Shipment date, name and address of the business’ previous and subsequent owner.
The 3T’s – Transaction History (TH)

- Transaction History includes:
  - Paper or electronic statement that includes the transaction information for each prior transaction back to the manufacturer.
The 3T’s – Transaction Statement (TS)

- Transaction Statement for a FFF as a wholesale distributor includes:
  - “...a transaction statement, which shall state that such wholesale distributor, or a member of the affiliate of such wholesale distributor, purchased the product directly from the manufacturer...”
The requirement went into effect on **January 1, 2015** for manufacturers, repackagers, and wholesale distributors.

The FDA postponed enforcement for manufacturers, repackagers, and wholesale distributors until May 1, 2015.

The requirement will go into effect on **July 1, 2015** for dispensers.
Trade Partner Requirements

► Manufacturers, repackagers, wholesale distributors, and dispensers will be required to capture and maintain the 3T’s for at least six (6) years after the transaction date, whether as the buyer or the seller.

► They will also be required to provide the subsequent purchaser with the 3T’s for certain prescription drugs in either paper or electronic format.

► Beginning November 27, 2017, manufacturers will be required to provide the 3T’s in an electronic format for certain transactions.
How FFF Customers Can Meet DSCSA Requirements

- As an FFF customer, there are four (4) options to help you meet the DSCSA requirements. All you have to do is pick one (1)!
  - Option 1 – Paper Packing Slips
  - Option 2 – Email Shipment Notifications
  - Option 3 – TraceLink Web Portal
  - Option 4 – Electronic data interchange (EDI) to receive Advanced Shipping Notifications (ASNs)