



DSCSA for Dispensers: What to Do in Everyday Pharmacy Practice

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Compliance Summary Checklist

What is DSCSA?

The Drug Supply Chain Security Act (DSCSA) applies every time most prescription drugs change ownership. For dispensers (pharmacies) this includes transactions for most prescription drugs, including buying, selling, trading, transferring, returning, and donating.

This reference is intended to identify the policies and procedures to efficiently operationalize DSCSA's requirements into pharmacy management and workflow.

Compliance touchpoints for dispensers mostly happen at:

- Purchasing
- Receiving
- Verifying
- Returning or transferring product
- Identifying suspect and illegitimate product

Purchasing

Know your trading partners. DSCSA requires that you only do business with authorized trading partners.

Do you have policies and procedures to:

Confirm the seller is authorized.

- If buying directly from a manufacturer, check that they are registered with Food and Drug Administration (FDA).
- If you are buying from a wholesaler, check that they are licensed in your state and either by the state where they are located or FDA.

Confirm your trading partners are licensed if you are transferring product to another pharmacy that is not under your common ownership.

Receiving

Electronic product tracing information. Prior to accepting ownership of each product, dispensers must receive electronic tracing information. Depending on how your system is set up, you may receive this directly from the seller, through a DSCSA provider or other vendor integrated with your pharmacy management system, or your wholesaler may store your data in a portal.

- If asked for an investigation, you must be able to retrieve the data within 2 business days.
- Retain the data for each product for 6 years.
- If you do not receive product tracing information, do not accept ownership.
- If you do not receive correct product tracing information, quarantine product, reconcile with trading partner, and determine if suspect or illegitimate.

Unique product identifier: Each product has a National Drug Code and a unique serial number embedded in a 2D barcode and printed on the package. This product identifier should also be included in the product tracing information.

- Some older products in the supply chain may not have a unique product identifier. Your supplier should confirm that it is exempt if it is not included.

Do you have policies and procedures to:

- Retrieve your tracing information for each product.
- Retain tracing information for 6 years for each product.
- Ensure receipt of tracing information for each product before accepting ownership.
- Ensure that the tracing information includes a unique product identifier for each product.
- Reconcile and take steps (eg, quarantine) if you did not receive appropriate tracing information for each product.
- Ensure that key personnel know how to retrieve information within 48 hours if asked for an investigation.

Verifying

Verify the product identifier. If there is reason to question whether the product is suspect or illegitimate, verify the product identifier by checking with the manufacturer or through a system such as Pulse by NABP™.

Do you have policies and procedures to:

- Check product identifier 2D barcodes.
- Subscribe to and know how to use NABP's Pulse.
- Identify red flags for suspect and illegitimate product (see Identifying and Managing Suspect and Illegitimate Product).
- Manage suspect and illegitimate product (see Identifying and Managing Suspect and Illegitimate Product).
 - Quarantine suspect and illegitimate product.
 - Clear product if not suspect or illegitimate.
 - Notify immediate trading partners if suspect or illegitimate product is found.
 - Notify FDA using an FDA Form 3911 if illegitimate product is found.
 - Maintain records of suspect and illegitimate product investigations.

Returning or Transferring Product

Wholesalers can only accept returns from the trading partner they sold it to, which means that the unique product identifier must match when dispensers return product.

Dispensers can sell or transfer to other dispensers without providing the tracing information if the transaction is to fulfill a specific patient need and is not to stock inventory in anticipation of a potential need.

Do you have policies and procedures to:

- Manage returns to the original wholesaler.
- Manage dispenser-to-dispenser transactions.

Identifying and Managing Suspect and Illegitimate Product

Decision 1: Is there a basis to question the product's authenticity, source, or integrity?

No	Yes
No special treatment is needed.	<p>Immediate steps:</p> <ol style="list-style-type: none"> 1. Do not dispense. 2. Physically quarantine the product. 3. Document why the product is suspect.
	<p>Next steps:</p> <ol style="list-style-type: none"> 1. Review tracing information. 2. Contact trading partner. 3. Reconcile discrepancies with trading partner. 4. Check for recalls or alerts for the product. 5. Document steps taken.

Decision 2: Is the product illegitimate?

No	Yes
<p>Clear.</p> <ol style="list-style-type: none"> 1. Remove from quarantine. 2. Return to inventory for dispensing. 3. Document steps taken. 	<ol style="list-style-type: none"> 1. Keep product in quarantine. 2. Do not dispense. 3. Within 24 hours: <ul style="list-style-type: none"> • Notify FDA on a Form 3911. • Notify immediate trading partners. 4. Coordinate with manufacturer/wholesaler for product disposition. 5. Check 3 of 10 product identifiers for existing product in inventory. 6. Maintain records for 6 years.



Suspect

There is reason to believe that the product is potentially counterfeit, diverted, stolen, intentionally adulterated, subject to a fraudulent transaction, or otherwise unfit for distribution and would result in serious adverse consequences or death to humans.



Illegitimate

There is credible evidence to show that the product is potentially counterfeit, diverted, stolen, subject to a fraudulent transaction, or intentionally adulterated or otherwise unfit for distribution and would result in serious adverse consequences or death to humans.

Red Flags

Be aware of the following warning signs of suspect and illegitimate products. These common red flags are ways to assess products entering the pharmacy.

- Based on your professional judgment, something is not right
- Product tracing information missing or does not match with product received
- Missing product identifier
- Looks different
- Damaged or broken seal
- Missing information on label
- Missing security or anti-counterfeiting features
- Questionable finished dosage form: imprint, odor, color, poor quality issues (chips, cracks, smeared imprint, bubbling on label surface)
- Missing “Rx only” symbol
- Misspelled words
- Missing/wrong package insert
- Unusual or excessive adhesive residue on container
- Foreign identification features