PHARM TECH BASICS · ONE-PAGER

DSCSA: Tracing, Verification and Quarantine

What the Drug Supply Chain Security Act asks of a pharmacy: authorized partners, tracing documents, the product identifier, suspect and illegitimate product, the dates that apply now, and receiving

22 sources + more detail
pharmtechbasics.com/sheets/pharm-dscsa.html
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1 The law in brief

The Drug Supply Chain Security Act (DSCSA, Title II of the Drug Quality and Security Act, signed November 27, 2013) builds an electronic way to identify and trace prescription drugs, package by package, from manufacturer to pharmacy. It replaced the old PDMA 'pedigree' rule in 2015. It binds four trading partners: manufacturers, repackagers, wholesale distributors and dispensers (pharmacies). It is federal law, and states may not add their own tracing rules on top of it.

COVERED	NOT COVERED
Prescription drugs in finished dosage form (such as tablets, capsules, and lyophilized products before reconstitution)	OTC drugs, animal drugs, blood for transfusion, radioactive and imaging drugs, certain IV fluids, medical gases, certain homeopathics, compounded drugs

2 What the pharmacy (dispenser) must do

DUTY	IN PRACTICE
Authorized trading partners only	Buy from and sell to only FDA-registered manufacturers and repackagers, licensed wholesalers and third-party logistics providers (3PLs), and state-licensed pharmacies
Accept only with tracing documents	Transaction information and a transaction statement must come before or with the shipment
Keep records 6 years	Tracing documents, suspect-product investigations and illegitimate-product dispositions
Pass documents on when selling	To another pharmacy or trading partner, yes; not when dispensing to a patient or filling a specific patient's need
Product identifier	Handle only products that carry one (unless grandfathered or exempt)
Suspect product	Quarantine it and investigate promptly with trading partners
Illegitimate product	Remove it from supply and notify FDA and trading partners within 24 hours

3 The product identifier and the documents

TERM	WHAT IT IS
Product identifier	NDC + serial number + lot + expiration date, in a 2D data matrix barcode on each package and in human-readable text
Standardized numerical identifier	The NDC plus a unique serial number of up to 20 letters and numbers
Transaction information (TI)	Product name, strength, dosage form, NDC, container size, number of containers, lot, dates, seller and buyer
Transaction statement (TS)	The seller's attestation: it is authorized, bought from authorized partners, got TI and TS, did not knowingly ship suspect or illegitimate product
Transaction history (TH)	The chain back to the manufacturer; no longer exchanged since November 27, 2023

EXAM TIP A QR code is not a DSCSA product identifier. Packages need a 2D data matrix barcode; sealed homogeneous cases may use a linear or 2D data matrix barcode.

4 Suspect versus illegitimate

	SUSPECT PRODUCT	ILLEGITIMATE PRODUCT
Standard	Reason to believe it is potentially counterfeit, diverted, stolen, intentionally adulterated, from a fraudulent transaction or unfit	Credible evidence shows it is one of these
Action	Quarantine; investigate with the wholesaler and manufacturer	Quarantine and disposition; keep a sample if asked; help partners remove it
Tell FDA?	No; only if FDA asked for the verification does a cleared-product notice go to FDA	Yes, within 24 hours of the determination (Form FDA 3911)
If cleared	May be dispensed; keep the investigation record 6 years	Ending a notification needs consultation with FDA

5 Dates that apply now (November 2026)

DATE	WHAT IT MEANS
Nov 27, 2023	Enhanced (electronic, package-level) tracing took effect by law; FDA allowed a stabilization year to Nov 27, 2024
Nov 27, 2025	FDA's exemption for dispensers with 26 or more full-time employees ended; the enhanced rules now apply to them (barring a company's own waiver)
Nov 27, 2027	Small dispensers (25 or fewer full-time pharmacists and technicians, company-wide) are exempt from the enhanced rules until this date

Small dispensers still buy only from authorized partners, receive and keep TI and TS for 6 years (current methods are allowed), quarantine and investigate suspect product, and notify FDA and trading partners within 24 hours of deciding a product is illegitimate.

6 At receiving

1. Check the tote or case: seal and tamper tape intact, no damage, cold-chain items still cold.
2. Match the products, NDCs, lots and counts to the invoice and the tracing data.
3. Look at each package: 2D barcode and printed NDC, serial, lot and expiration; label and carton look normal.
4. Report clerical mismatches (wrong count, missing address) to the wholesaler, resolve them together within 10 business days, and document it.
5. Anything that looks wrong goes to the marked quarantine shelf (with an electronic hold in the system where possible), never into stock; tell the pharmacist.

SAFETY A broken case seal or duplicate serial numbers make product suspect. A missing lot or expiration date, a mostly foreign-language label or a price 'too good to be true' are red flags: set the product aside and report it. The pharmacist decides suspect or illegitimate and releases quarantine, per the pharmacy's procedure.

7 Exam pearls

EXAM TIP Six years for DSCSA records. 24 hours to tell FDA after deciding a product is illegitimate; suspect product is quarantined, not reported. Product identifier = NDC, serial number, lot, expiration. Transaction history ended in 2023; TI and TS remain. No tracing documents when dispensing to a patient. Questions may treat November 27, 2023 as the date electronic tracing began: that is the date in the law.

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