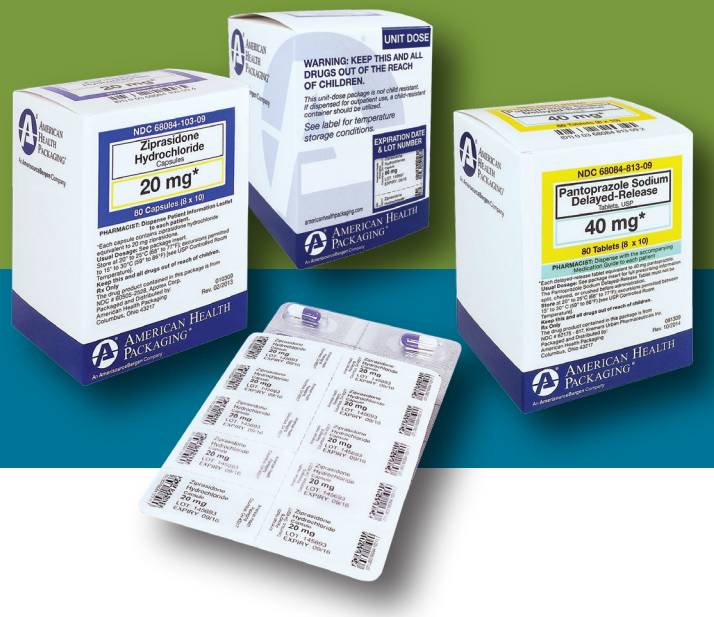
AMERICAN HEALTH PACKAGING®

An **AmerisourceBergen** Company

Complying with the Drug Supply Chain Security Act

What your pharmacy needs to know today



Meeting product serialization requirements

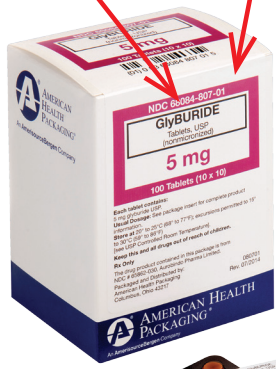
The Drug Supply Chain Security Act (DSCSA) deadline for serializing drug products is 2017 for manufacturers and 2018 for repackagers. To comply, American Health Packaging has adopted GS1 standards and HDMA Barcode Implementation Guidelines.

Our packaging is not only in compliance ahead of the DSCSA deadline, but it's designed to make it easier for you to use and dispense. For added safety, color-coded labels and tall man lettering distinguish between similar products within a family.

Plus, our packages include a window in the back for easier barcode scanning—so you can receive and stock pharmaceutical products faster.

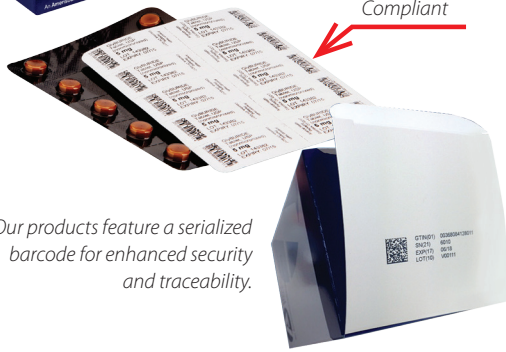
Color-coded Labels

Tall Man Lettering



Back Panel Window for Easy Scanning

GS1 Barcode Compliant



Our products feature a serialized barcode for enhanced security and traceability.

Evolving the Prescription Drug Supply Chain Timeline 2014 – 2023

2014
State preemption

2015
January 1 – Transactional information provided by manufacturer, wholesaler and repackager
May 1 – FDA enforcement discretion ends
July 1 – Transactional Information accepted by dispensers
Federal licensure standards for distribution raised

2016

2017
Manufacturers serialize

2018
Repackagers serialize

2019
Wholesalers accept/sell serialized products and validate serialized number on salable returns

2020
Dispensers accept serialized product

2021

2022

2023
Phase II: Complete traceability

Keeping you in compliance

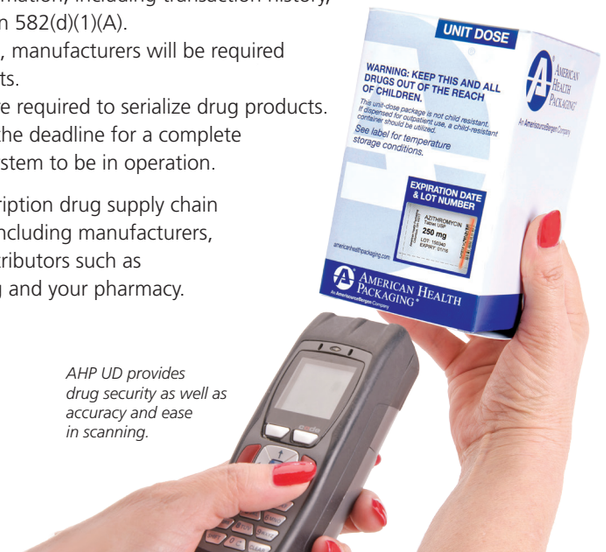
Signed into law in November 2013, the Drug Quality and Security Act (DQSA) establishes requirements for the compounding safety and security of pharmaceutical products. This federal law preempts state pedigree requirements and places the industry under the supervision of the Food and Drug Administration (FDA).

Title II of DQSA is the Drug Supply Chain Security Act (DSCSA) which mandates the consistent traceability of pharmaceutical products through the national supply chain, from manufacturers to your pharmacy. The aim is to transition the healthcare industry to an electronic, inter-operable traceability system for products by 2023.

DSCSA establishes multiple phases of compliance along the way:

- On January 1, 2015, manufacturers, repackagers and wholesalers were required to begin exchanging transactional data. Dispensers and pharmacies were required to have a system in place to investigate and quarantine suspect and illegitimate products.
- On July 1, 2015, pharmacies and dispensers were required to accept and maintain the transactional data and hold it for a six-year period.
- On June 30, 2015, the FDA announced Enforcement Discretion until November 1, 2015 in reference to the Drug Supply Chain Security Act (DSCSA) and transactional data requirements for dispensers and pharmacies.
  - This means that the law went into effect on July 1, 2015, but regulatory agencies do not intend to take action against dispensers or pharmacies on the regulatory requirements until November 1, 2015.
  - Section IV of the document: This compliance policy does not extend to transactions in which dispensers must provide the subsequent owner with product tracing information, including transaction history, as required by section 582(d)(1)(A).
- By late November 2017, manufacturers will be required to serialize drug products.
- In 2018, repackagers are required to serialize drug products.
- November 27, 2023 is the deadline for a complete electronic traceability system to be in operation.

Every member of the prescription drug supply chain is affected by the DSCSA, including manufacturers, repackagers, wholesale distributors such as American Health Packaging and your pharmacy.



AHP UD provides drug security as well as accuracy and ease in scanning.

How the DSCSA directly affects your pharmacy

Here's how the law specifically impacts pharmacies and dispensers, including hospital pharmacies, independent retail pharmacies and alternative-care facilities:

- **Authorized trading partners:** As of January 1, 2015, hospital pharmacies can accept products only from trading partners that have a valid registration or license.
- **General product tracing:** As of July 1, 2015, hospital pharmacies must accept and maintain records for six years of each product's Transactional Data. *See listing in the gray column for a description of Transactional Data.*
- **Product tracing (request for information):** If there is an audit by the appropriate federal or state officials, transactional data must be provided within two business days of the date requested.
- **Suspect products:** As of January 1, 2015, your pharmacy must have a method to verify suspect products and a system in place to quarantine and investigate them. By November 27, 2020, you need to verify the suspect product lot number—and the verification must involve the greater of three packages or 10% of the suspect products.
- **Removal and notification of illegitimate products:** As of January 1, 2015, pharmacies are required to remove confirmed illegitimate products from the supply chain and retain a sample for further analysis by the appropriate party.
- **Returns (salable returned products and non-salable returned products:**
  - Customers may return salable products to American Health Packaging if they received the product from us.
  - Customers may return non-salable products to American Health Packaging, to a returns processor, or to a person acting on behalf of American Health Packaging.
  - In both cases – customers do not need to provide the transactional data with a return under the law's requirements.
- **Product serialization:** Starting November 27, 2020, all products that you engage with must be encoded with a product identifier.
- **Enhanced drug distribution security (unit-level traceability):** By November 27, 2023, your pharmacy must have an electronic, inter-operable system that can trace products at the package level.

What's the difference between 'suspect' and 'Illegitimate'?

A 'suspect' product is believed to be potentially counterfeit, diverted, stolen, intentionally adulterated, part of a fraudulent transaction or otherwise unfit for distribution for patient safety reasons.

An illegitimate product is confirmed to be one of the above.

What is Transactional Data?

As of July 1, 2015, your pharmacy must capture and maintain the following data for six years:

Transaction Information (TI)

- Product name
- Product strength and dosage form
- NDC
- Product container size
- Number of containers
- Lot number*
- Transaction date*
- Shipment date
- Name and address of previous and subsequent business owner

**Wholesalers that purchase directly from a manufacturer, an exclusive distributor of the manufacturer, or re-packager that purchased directly from manufacturer—are exempt from passing the above (*) data elements.*

Transaction History (TH)

- May be a paper or electronic statement
- Includes the transaction information for each prior transaction, tracing back to the manufacturer point of origin.

Transaction Statement (TS)

Demonstrates the transfer of product ownership, verifying that:

- Product is authorized under DSCSA
- Product was received from an authorized party
- TI and TH were received from the previous seller
- Entity did not knowingly ship suspect or illegitimate product
- Entity has systems and processes to capture and investigate suspect product
- Entity did not knowingly provide false or altered transaction data

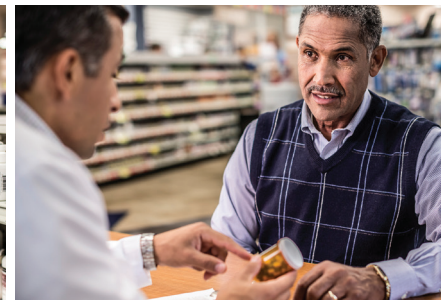
Products exempt from the DSCSA

You don't need to provide the TI, TH and TS data for:

- Over the counter (OTC) products
- Blood and blood components intended for transfusion
- Radioactive drugs and radioactive biologics
- Imaging drugs
- Intravenous products
- Medical gas
- Compounded drugs
- Dispensing drugs pursuant to a prescription
- Medical convenience kits and combination products
- Sterile water and products intended for irrigation

How the DSCSA affects borrowing between pharmacies

The change of ownership between trading partners triggers the requirements for providing the transactional data. If you loan products to a pharmacy that is owned by another entity, you'll need to provide the transaction data. The exception is if you're loaning products pursuant to a specific patient need.



Efficient Pharmacy:
Powered by American Health Packaging

For more information:

Visit the following websites for further details about the DQSA and DSCSA. American Health Packaging customers can also contact their sales representatives for additional resources and strategies for compliance.

- **Knowledgedriven.com**, sponsored by AmerisourceBergen. You'll find several articles and podcasts with the latest information.
- **healthcaredistribution.org** — HDMA website
  - Click on "Issues" > "Pharmaceutical Traceability."
- **fda.gov** — FDA website
  - For DQSA: Click on "Drugs" > "Guidance, Compliance & Regulatory Information" > "Compounding."
  - For DSCSA: Click on "Drugs" > "Drug Safety & Availability" > "Drug Supply Chain Integrity" > "Drug Supply Chain Security Act."

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