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.

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 many articles and podcasts with the latest information.
- healthcaredistribution.org — HDMA website
- 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 Security Act" > "Drug Supply Chain Security Act.”

Efficient Pharmacy: Powered by American Health Packaging

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Keeping you in compliance

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

Title II of DQSA is the Drug Supply Chain Security Act (DSCSA) which mandates the electronic tracking and tracing system for products through the supply chain to the manufacturer to your pharmacy. The aim is to establish a healthcare industry best practice for electronic, interoperable product tracking and tracing 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 tracking drug products through the distribution chain by maintaining records for six years and making information available to customers.
- On July 1, 2015, drug manufacturers must ensure that product identifiers are encoded on product containers and that data requirements for dispensers and pharmacies are met.
- On November 27, 2015, wholesale distribution centers were required to begin accepting “transactional data” for each transaction involving the transfer of product ownership.
- On January 1, 2016, repackagers are required to serialize drug products.
- By late November 2017, manufacturers will be required to have a system in place to investigate and quarantine suspect and illegitimate products.
- On January 1, 2018, repackagers are required to serialize drug products.
- By November 27, 2020, manufacturers are required to have a system in place to quarantine and investigate them.
- On November 27, 2023, your pharmacy must have an electronic, inter-operable system that can accept transactional data and hold it for a six-year period.

- Section IV of the document: This compliance policy does not extend to products exempt from the DSCSA, including manufacturers, wholesalers, compounding entities, independent retail pharmacies, hospital pharmacies, and alternative-care facilities.

- The law went into effect on July 1, 2015, but regulatory agencies do not intend to take action against dispensers or pharmacies on the failure to have a system in place to investigate and quarantine suspect and illegitimate products.

- 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 failure to have a system in place to investigate and quarantine suspect and illegitimate products.

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 identifier
- Product strength and dosage form
- NDC
- Uni-locally traceable
- Number of containers
- Shipment date
- Transaction date
- Shipments data
- Name and address of previous and subsequent business owner

**Entity Transaction Data (ETD)**
- Product is authorized under DSCSA
- TI and TH were received from the previous seller
- Product is not counterfeit, diverted, stolen, intentionally adulterated, part of a fraudulent transaction or otherwise known to be potentially counterfeit, diverted, stolen, intentionally adulterated
- Product is not counterfeit, diverted, stolen, intentionally adulterated
- Customer name and address
- Date of the transaction
- Product strength and dosage form
- Product container size
- Product identification
- Product lot number
- Product expiration date
- Transaction date
- Wholesalers that purchase directly from a manufacturer, an exclusive authorized agent, or repackager—products from these sources are exempt from passing the above (*) data elements.

<table>
<thead>
<tr>
<th>Transaction Information (TI)</th>
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**Product Serialization**

By November 27, 2023, all products that you engage in the transactions of will 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 product information to the package level.

**What is the difference between ‘support’ and ‘legitimate’?**

- A ‘support’ product is one that is not in compliance with must be encoded with a product identifier.
- A ‘legitimate’ product is one that is in compliance with must be encoded with a product identifier.

**What is a ‘suspect’ and a ‘legitimate’ product?**

- A ‘suspect’ product is believed to be potentially counterfeit, diverted, stolen, intentionally adulterated, part of a fraudulent transaction or otherwise known to be potentially counterfeit, diverted, stolen, intentionally adulterated
- A ‘legitimate’ product is not counterfeit, diverted, stolen, intentionally adulterated

**Products exempt from the DSCSA**

- Dispensing drugs pursuant to a prescription
- Medical gas
- Compounded drugs
- Medical concurrence kits and combination products
- Sterile water and products intended for irrigation

**Keeping you in compliance**

- The change of ownership between trading partners triggers the requirement for providing the transactional data. If you are a pharmacy that is owned by another entity, you’ll need to provide the transactional data to your new pharmacy in addition to you’re being ‘bundling’ products pursuant to a specific patient need.

**What is the prescription drug supply chain timeline?**

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
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<tbody>
<tr>
<td>2016</td>
<td><strong>Evolving the Prescription Drug Supply Chain Timeline 2014 – 2023</strong></td>
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<td>2017</td>
<td><strong>State preemption</strong></td>
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<td>2018</td>
<td><strong>Supply Chain Timeline 2014 – 2023</strong></td>
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<td>2019</td>
<td><strong>Evolution of the Prescription Drug Supply Chain Timeline 2014 – 2023</strong></td>
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<td>2020</td>
<td><strong>Keeping you in compliance</strong></td>
</tr>
<tr>
<td>2021</td>
<td><strong>What is Transactional Data?</strong></td>
</tr>
<tr>
<td>2022</td>
<td><strong>What is the difference between ‘support’ and ‘legitimate’?</strong></td>
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<td>2023</td>
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Keeping you in compliance

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Title II of DQSA is the Drug Supply Chain Security Act (DSCSA) which mandates the establishment of a secure electronic, inter-operable traceability system for products by 2023.

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What your pharmacy needs to know today

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