



PREPARING FOR **DSCSA**

Drug Supply Chain Security Act

August 2025

Countdown to DSCSA Compliance Checklist

The Drug Supply Chain Security Act (DSCSA) is a federal law designed to enhance the security of the pharmaceutical supply chain. It requires trading partners, including manufacturers, wholesale distributors, repackagers and dispensers, to exchange serialized product data and verify product legitimacy to prevent counterfeit, stolen or contaminated drugs from entering the supply chain.

Starting in August (for wholesale distributors) and November (for larger dispensers) 2025, DSCSA serialization compliance will require:

- Electronic traceability of in-scope prescription drugs.
- Verification of returned in-scope products before resale.
- Serialized data exchange using **EPCIS (Electronic Product Code Information Services)** standards.
- GLN matching for returns and transactions.

Key Dates:

- **Aug. 27, 2025** – Enforcement for wholesale distributors

By this date, McKesson must:

- Receive and verify serialized data from suppliers.
- Share serialized information with customers.
- Manage returns in full compliance with DSCSA.

By this date, customers can expect:

- As it relates to **receiving**, customers are expected to have a process to confirm product is physically received and matches serialized transaction data.
- **For saleable returns** of in-scope DSCSA products invoiced on or after Aug. 27, 2025, McKesson will require:
 - **Association:** Linking a returned product to its original purchase record to ensure traceability.
 - **Verification:** Confirming that the product's unique identifiers are valid and match manufacturer records.
- Products shipped **before Aug. 27, 2025**, will not require validation for saleable returns.
- **Non-saleable returns** (e.g., outdated, recalled, defective) are exempt from serial number validation.

- **Nov.27, 2025** – Enforcement for dispensers with 26+ full-time employees. Dispensers must fully comply with electronic traceability, package-level serialization and verification mandates.
- **Nov. 27, 2026** – Small dispensers with 26 or less full-time employees are exempt from certain DSCSA requirements until Nov. 27, 2026, after which they must fully comply with electronic traceability, package-level serialization and verification mandates.

Key Changes for DSCSA In-scope Product Returns ordered after August 27, 2025

- **Return authorization (RA):** You must obtain an RA via your McKesson ordering portal or by contacting Customer Support.
- **Saleable product returns:** Only **saleable DSCSA in-scope product** with valid serial numbers are eligible for return. Returns must include correct serial numbers that match McKesson's original DSCSA transaction data. We must associate the returned product with its original sale record.
- **Cold chain items:** Unsolicited or unassociated controlled room temperature product will be returned to you. If a returned product requires cold chain storage or is a controlled substance, it will be processed as an unsaleable return and the product will be destroyed. Additionally, product(s) may only be returned by the purchasing party. This impacts 340B products, as only the covered entity that purchased the product may receive returned credit for 340B replenishment purchases.
- **340B contract pharmacies:** Under DSCSA regulations, only covered entities may return serialized, saleable product. 340B contract pharmacies are NOT eligible to initiate returns, as they are not the purchasing party and may only access serialized data if explicitly authorized by the covered entity. For more details, see the Receiving and Returns FAQ on your ordering portal.
- **If your returned product is unable to be processed,** a letter that includes the explanation code will be included with the returned product. Unsolicited returns or products not listed on an RA or with unverifiable serial numbers will be returned to you. Note: Controlled substances or cold chain items will NOT be returned and will be processed as unsaleable. For more details, see the Receiving and Returns FAQ on your ordering portal.

DSCSA In-scope Product Returns Checklist

Please ensure the following before initiating a return:

- ☐ Product is in **saleable condition**, not expired, damaged or defective.
- ☐ Product was **purchased from McKesson**.
 - ☐ Must match **original GLN** used for purchase.
 - ☐ Internal transfers must also match GLNs.
- ☐ **Serial number** matches McKesson's DSCSA transaction data.
- ☐ **Sold-To/Ship-To GLN** matches the original purchase.
- ☐ Return authorization is completed via **your McKesson ordering portal** or Customer Support.
- ☐ Serial numbers are collected and verified before shipment.

Follow these instructions to ensure your DSCSA in-scope product returns are processed smoothly and efficiently.

Step 1: Obtain a return authorization (RA)

- To obtain an RA, you may use your McKesson ordering portal or reach out to Customer Support for assistance.

Step 2: Collect and verify product serial numbers

- Verify that the serial numbers of each item you want to return are on the RA. You can access your DSCSA transaction data through your McKesson ordering portal. For step-by-step instructions on how to access your DSCSA reporting, use the iGuide training resources available on your portal.

Step 3: Complete the return authorization (RA)

- Complete the required information on the RA, matching product to purchase date and order number.

Step 4: Prepare your return package

- Check that the serial numbers on the items in your return package match those listed on your DSCSA transaction data obtained through your McKesson ordering portal or sourced from the Customer Support team. Only include these items in your return package.

Resources and References

To learn more about these changes and how to access helpful tools:

- McKesson is introducing a new feature beginning Aug. 27, 2025: real-time serial number validation for DSCSA products being returned as saleable. Available through McKesson Connect, McKesson Specialty Health's Customer Center and by phone with Customer Support, this feature enables you to verify if your product was originally purchased from McKesson before initiating an RA.
- Review the customer letter that complements this checklist and the Most Asked Questions document available on your McKesson ordering portal. Each ordering portal has a dedicated page for details on DSCSA. There you can find a series of helpful FAQs by topic.
- Use the iGuide training resources available on your McKesson ordering portal under the respective help and training section for step-by-step instructions on how to access your DSCSA reporting.
- Watch the [DSCSA Webinar Recording – Countdown to Compliance](#).

We're here to support you through this transition. Thank you for your continued partnership. If you have any questions, please contact your **sales team member** or **Customer Support**.