



PREPARING FOR **DSCSA**

Drug Supply Chain Security Act

August 2025

FDA Grants Exemptions from Certain DSCSA Requirements

Dear McKesson customer,

This is one of seven FAQ documents designed to share information about the Drug Supply Chain Security Act (DSCSA) and a glossary of important terms used in reference to it. If you have additional questions about how DSCSA will impact your business, please contact your McKesson sales team member or Customer Support.

Categorized FAQs available:

- DSCSA Most Frequently Asked Questions
- DSCSA General Overview and FAQ
- FDA Grants Exemptions from Certain DSCSA Requirements
- Receiving and Returns FAQ
- Serialized Transaction Information
- Small Dispenser FAQ
- What Do I Need to Know About GLNs?



INTERACTIVE PDF

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FDA Exemptions FAQ

FDA-Granted Exemptions

For eligible trading partners that meet the U.S. Food and Drug Administration (FDA) exemption's conditions, the FDA granted exemptions from certain DSCSA requirements until the following dates:

- For manufacturers and repackagers: May 27, 2025
- For wholesale distributors: Aug. 27, 2025
- For dispensers with 26 or more pharmacists and technicians: Nov. 27, 2025
- Dispensers with 25 or fewer pharmacists and technicians were previously exempted until Nov. 27, 2026.

Here is the [link to the full FDA exemption announcement for small dispensers](#).

Q1 *Why did the FDA grant exemptions from certain DSCSA requirements?*

The FDA recognized that trading partners who had initiated their systems and processes and had established electronic DSCSA data connections with their trading partners might need additional time beyond Nov. 27, 2024, when the FDA stabilization period ended.

Q2 *Is the Wholesale Distribution Exemption an extension of the stabilization period?*

The DSCSA stabilization period had been in place since Nov. 27, 2023, and ended on Nov. 27, 2024. On Oct. 9, 2024, the FDA published the FDA exemption, which granted additional time, in phases, across the supply chain for eligible trading partners to exchange complete and accurate serial DSCSA transaction data.

Q3 *Did McKesson to make use of the Wholesale Distribution Exemption?*

McKesson's distribution businesses (McKesson distributors) planned to make use of the FDA exemption for wholesale distributors, in accordance with the criteria and conditions outlined in the exemption. The letter titled "FDA Grants Exemptions from Certain DSCSA Requirements," sent in November 2024, served as notice to our customer trading partners of this intention. This document was made available on the DSCSA page within your designated ordering portal.

FDA Exemptions FAQ

Q4

What wholesale distributor exemptions are in place for DSCSA- eligible products transacted from Nov. 27, 2024, until Aug. 27, 2025?

FDA Exemption for Wholesale Distributors states, in part:

- 582(g)(1)(A) “that the transaction information and the transaction statements be exchanged in a secure, interoperable, electronic manner...”
- 582(g)(1)(B) “that the transaction information required to be exchanged include the product identifier (e.g., the National Drug Code, serial number, lot number and expiration date) at the package level for each package included in the transaction.”
- 582(g)(1)(C) “that systems and processes for verification of product at the package level, including the standardized numerical identifier, be in accordance with the standards established under the guidance issued...”
- 582(g)(1)(D) “for systems and processes necessary to promptly respond with the transaction information and transaction statement for a product upon a request by the Secretary, or other appropriate Federal or State official.”
- 582(g)(1)(E) “for systems and processes necessary to promptly facilitate gathering the information necessary to produce the transaction information for each transaction going back to the manufacturer...”
- 582(g)(1)(F) “that each person accepting a saleable return have systems and processes in place to allow acceptance of such product and may accept saleable returns only if such person can associate the saleable return product with the transaction information and transaction statement for the product.”
- 582(c)(4)(D) “to verify the product identifier, including the standardized numerical identifier, upon receipt of saleable returned product prior to further distribution.”

Q5

What was the expectation of McKesson manufacturers and repackagers for receiving complete and accurate serialized DSCSA transaction data?

McKesson expected to receive complete and accurate serialized DSCSA transaction data for all DSCSA product purchases from manufacturers and repackagers by May 27, 2025.

Q6

When do McKesson distributors expect to provide complete and accurate serialized DSCSA transaction data?

McKesson distributors expect to provide complete and accurate serial DSCSA transaction data for all DSCSA in-scope product sales to their customers as of Aug. 27, 2025.

FDA Exemptions FAQ

Q7 *When are saleable returns processes effective?*

Under the FDA exemption, the new DSCSA requirements for saleable returns for all DSCSA-in-scope product is effective as of Aug. 27, 2025.

Q8 *Small and large dispenser exemption dates go into effect after the distributor exemption effective date of Aug. 27, 2025. When will saleable return requirements be implemented for dispenser returns?*

While large dispensers (26 or more pharmacists/technicians) have an exemption from certain DSCSA serialization requirements until Nov. 27, 2025, and small dispensers (25 or less pharmacists/technicians) have an exemption from certain DSCSA serialization requirements until Nov. 27, 2026, the DSCSA requirements for distributors for saleable returns are effective as of Aug. 27, 2025.

Q9 *How can I stay updated on the latest DSCSA developments?*

McKesson will continue to update resources located in your ordering portals. We remain committed to assisting you where possible during any FDA exemption period.

For questions regarding DSCSA, reach out to Customer Support or contact us via email.

- For our Community Pharmacy & Health Mart, Health Systems, Large Retail and National Accounts Government customers, please contact your Customer Support team at 855.625.6285 or email PharmaCustomerSupport.ContactUs@McKesson.com.
- For MPB-specific questions, please contact your MPB Customer Service team at 877.625.2566 or email MPB@mckesson.com.
- For Specialty Provider and The US Oncology Network-related questions, please contact your Provider Solutions Customer Care team at 800.482.6700 or email MSH.CustomerCare-MSPL@McKesson.com.

What do I do if I do not receive a response on an inquiry?

Please allow 24 hours for a reply to any inquiry sent to one of the DSCSA mailboxes. If you do not receive a follow-up, please contact Customer Support directly via your toll-free number.

DSCSA Acronym List and Definitions

ACRONYM	TERM	DEFINITION
ATTP	Advanced Track and Trace Pharmaceuticals	A global repository called ATTP will store serialization data from McKesson and will allow searching, downloading and printing upon request. Customers may use the portal link to manage DSCSA transaction data during the six years of record retention period.
DSCSA	Drug Supply Chain Security Act	Among other things, establishes requirements for electronic product tracing and verification of prescription pharmaceuticals at the package level in the U.S. drug supply chain from manufacturer to dispensers.
DSR	Digital Serialized Repository	A system with data from manufacturers.
EPCIS	Electronic Product Code Information Services	EPCIS is the standard for creating, capturing and storing information to trace and track DSCSA in-scope products through the supply chain.
GCP	Global Company Prefix	A licensed number of four to twelve digits issued by GS1 member organization to a user company to entitle that user company to create any of the GS1 identification keys (GTIN, GLN, SCCC, etc.).
GLN	Global Location Number	A GLN, or Global Location Number, is a unique identifier that lets businesses know who is involved in transactions and where things are located throughout the supply chain.
GPO	Group Purchasing Organization	A GPO is an entity that helps healthcare providers and practices realize efficiencies and savings by aggregating purchasing volumes to negotiate discounts with manufacturers, distributors and other vendors.
GS1	Global Standards 1	GS1 standard identifiers provide a common language and help to create seamless work processes that allow businesses to identify, capture and globally share information.
GTIN	Global Trade Identification Number	Products are identified by a Global Trade Identification Number. The GTIN can be used to identify types of products at any packaging level.
NDC #	National Drug Code #	A unique, three-segment numeric identifier assigned to each medication listed under Section 510 of the U.S. Federal Food, Drug and Cosmetic Act. The first segment of the NDC identifies the labeler (i.e., the company that manufactures or distributes the drug).
RA	Return Authorization	Permission by McKesson to allow the customer to return a product to us. Products cannot be returned without a return authorization.
Serialization	Serialization	Serialization is the practice of generating a unique identifier for pharmaceutical products and printing the code on the label or packaging prior to distribution.
sGTIN	Serialized Global Trade Identifier Number	A serialized Global Trade Identification Number. It is a combination of a Global Trade Item Number (GTIN) plus a serial number.
sGLN	Serialized Global Location Number	The GLN and sGLN both point to the same GS1-issued GLN, but sGLN has decimals in the middle of it and the GLN is a straight 13-digit string of integers.
SSCC	Serialized Shipping Container Code	A barcode used as universal identifier for freight across the supply chain. SSCC barcodes are unique labels that identify a freight item or logistics unit (pallet, container, etc.) to provide important delivery information including contents, destination and other handling criteria.
UAT	User Acceptance Testing	Testing conducted to determine if the requirements of a specification or design are met.