Small Dispenser FAQ

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
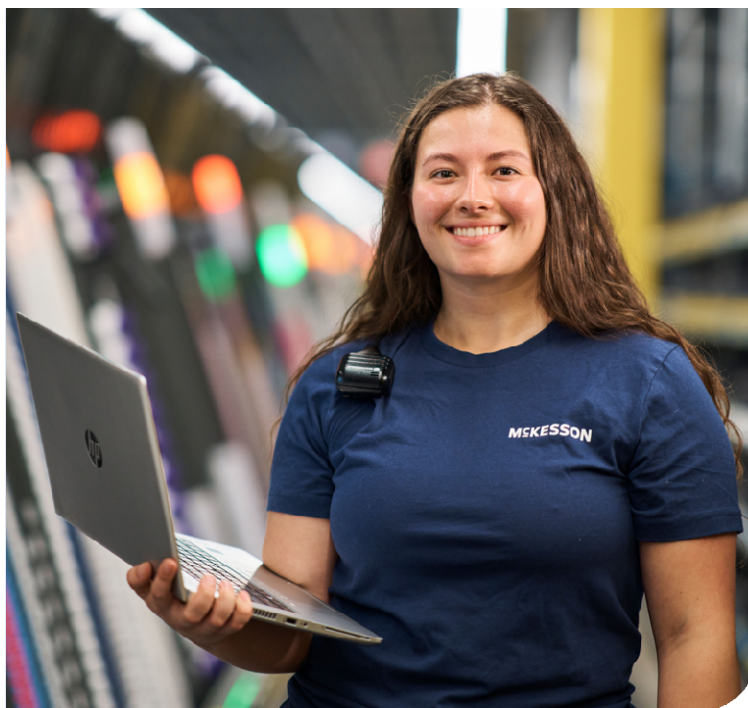- Small Dispenser FAQ
- What Do I Need to Know About GLNs?

Answers to Your Top Questions

INTERACTIVE PDF
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DSCSA Small Dispenser FAQ

Q1 *What does the Small Dispenser Exemption mean?*

According to the FDA, "The Food and Drug Administration…is using authority under section 582(a)(3) of the Food, Drug and Cosmetic Act (FD&C Act) to exempt certain dispensers - and, where noted, those dispensers' trading partners - from certain requirements in section 582 of the FD&C Act as outlined below until Nov. 27, 2026."

Read the full text of the FDA Small Dispenser Exemption.

Q2 *To determine whether the small dispenser exemption applies to me, do I evaluate the covered entity's or the contract pharmacy's qualification for the exemption?*

According to the FDA, "a dispenser is considered a small dispenser, for the purposes of these exemptions, if, as of Nov. 27, 2024, the company that owns the dispenser has 25 or fewer full-time employees licensed as pharmacists or qualified as pharmacy technicians." The dispenser in a DSCSA transaction is the party acquiring ownership of the DSCSA product. For a 340B replenishment, this would be the covered entity. Refer to the FDA website for more information.

Q3 *On the FDA website, it states that small pharmacies with less than 25 employees are exempt from DSCSA serialization enforcement until 2026. Is that accurate?*

The FDA has granted small dispensers an exemption until Nov. 27, 2026, from the following for DSCSA product:

- Verifying the product identifier of the statutorily designated proportion of suspect or illegitimate product.

- Exchanging transaction information and transaction statements in a secure interoperable, electronic manner in accordance with the agency standards established under section 582(h)(2) and (3) of the FD&C Act.

- Requiring exchanged transaction information to include the product identifier at the package level for each package.

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DSCSA Small Dispenser FAQ

- Using systems and processes for verification of product at the package level, including the standardized numerical identifier, in accordance with the agency standards established under sections 582(a)(2) and 582(h)(2), (3) and (4) of the FD&C Act.

- Using systems and processes necessary to promptly respond with the transaction information and transaction statement for a product upon request from a federal or state regulator.

- Using systems and processes necessary to promptly facilitate gathering the information necessary to produce the transaction information for each transaction going back to the manufacturer upon request from a federal or state regulator or a trading partner.

Read the full text of the FDA Small Dispenser Exemption.

Q4 What are the exemption details and changes for small dispensers?

The FDA is using authority under section 582(a)(3) of the FD&C to exempt certain dispensers - and, where noted, those dispensers' trading partners - from certain requirements in section 582 of the FD&C Act until Nov. 27, 2026.

Q5 How do the DSCSA serialization requirements impact product transfers between two covered entities under common ownership and control?

The DSCSA's definition of transactions states, in part: "EXEMPTIONS. —The term 'transaction' does not include— (ii) the distribution of a product among hospitals or other healthcare entities that are under common control." Drug Supply Chain Security Act of HR3204, 2013.

Q6 Do I need to report my status to McKesson to take advantage of the Small Dispenser Exemption?

No, it is not necessary to report your election to use the Small Dispenser Exemption to McKesson.

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DSCSA Small Dispenser FAQ

For questions regarding DSCSA, reach out to McKesson 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.

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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, SSCC, 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.

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