



PREPARING FOR **DSCSA**

Drug Supply Chain Security Act

August 2025

DSCSA General Overview and 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?

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DSCSA Overview and FAQ

GENERAL DSCSA INFORMATION

Q1 *What is DSCSA?*

The Drug Supply Chain Security Act, signed into law on Nov. 27, 2013, outlines steps to achieve interoperable, electronic tracing of products at the package level to identify and trace certain prescription drugs as they are distributed in the United States. These requirements will enhance the FDA's ability to help protect consumers from exposure to drugs that may be counterfeit, stolen, contaminated or otherwise harmful. Implementation of these requirements will also improve the detection and removal of potentially dangerous drugs from the drug supply chain to protect U.S. consumers.

Q2 *To be DSCSA compliant, do we need to report which lot goes to each patient?*

Requirements for record keeping for dispensed products are established by various State Boards of Pharmacies and may differ from one jurisdiction to another. Please check with your State Board of Pharmacy about recording lot numbers in your dispensing records. DSCSA defines transactions which are subject to track and trace and states: "EXEMPTIONS. — The term 'transaction' does not include—(iv) the dispensing of a product pursuant to a prescription executed in accordance with section 503(b)(1);" DSCSA HR3204, 2013.

Q3 *How do we know if we are an entity that is required to follow DSCSA?*

The DSCSA defines a dispenser subject to the requirements of the DSCSA as "(3) DISPENSER.— The term 'dispenser'— "(A) means a retail pharmacy, hospital pharmacy, a group of chain pharmacies under common ownership and control that do not act as a wholesale distributor, or any other person authorized by law to dispense or administer prescription drugs, and the affiliated warehouses or distribution centers of such entities under common ownership and control that do not act as a wholesale distributor;" DSCSA, HR3204, 2014

Q4 *As a pharmacy, do I have to track product by serial number as it is dispensed to a specific patient?*

DSCSA requires product transaction data for changes of ownership but excludes dispensing to a patient from the definition of what is a DSCSA transaction. Refer to [DSCSAEdu](#) for more information.

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Q5 *How will DSCSA in-scope products/items and trading partners be identified in the DSCSA interoperable electronic exchange of transaction data?*

Global Standard 1 (GS1) standard identifiers will be used for product and party/location identification in the interoperable electronic exchange.

Products will be identified by a Global Trade Identification Number (GTIN). Trading partners will be identified by the Global Location Number (GLN).

Q6 *Will NDC numbers continue to be on bottles or will GTINs replace NDC numbers?*

In-scope DSCSA product will continue to have NDC numbers. The GTIN includes the NDC.

Q7 *Which drugs fall under the DSCSA requirements for product tracing, product identifier, authorized trading partner and verification?*

DSCSA requirements do not apply to nonprescription drugs (over-the-counter drugs) or animal drugs (drugs subject to section 512 of the Federal Food, Drug and Cosmetic Act (FD&C Act)). Drugs that fall under the DSCSA requirements are defined by the FD&C Act.

Product tracing, product identifier, authorized trading partner and verification requirements in Section 582 of the FD&C Act apply to product as defined by Section 581(13) of this Act. Product means “a prescription drug in finished dosage form for administration to a patient without substantial further manufacturing (such as capsules, tablets and lyophilized products before reconstitution).”

The section 582 requirements do not apply to:

- Blood or blood components intended for transfusion
- Radioactive drugs or biologic products
- Imaging drugs
- Certain intravenous (IV) products
- Medical gases
- Certain homeopathic drugs
- Lawfully compounded drugs

There are also exclusions, refer to the definition of transaction noted in section 581(24) of the FD&C Act. This list of applicable DSCSA drugs is dynamic and is subject to change.

This information is available on the item search and detail screens of all McKesson ordering portals with indicators displayed as a Y/N field labeled “DSCSA.”

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Q8 *What is the website where I can find the standard operating procedure (SOP) for managing suspect products?*

There is a website on DSCSA that is maintained by several trade groups to aid dispensers with compliance. The website contains some sample SOPs. It is [Resources - DispenserEDU](#).

Q9 *If a manufacturer is granted an exception to the DSCSA requirements and does not need to provide serialized data, how will we distinguish between an FDA-granted exception and a case of missing data?*

To distinguish between an FDA-granted exception and a case of missing data, you should cross reference the indicator in your ordering portal against data provided in your DSCSA transaction data to determine if the product is subject to DSCSA.

Q10 *When DSCSA is fully implemented, will patients have access to the serial information?*

The serial number wouldn't be on a patient medication bottle, but they likely would never need it. Only direct customers will be able to access the serial data and transaction data.

Q11 *What are the requirements for outpatient physician offices and medical groups that are owned by a larger hospital system?*

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Q12 *What actions is McKesson taking to provide serialized data and avoid order omits?*

McKesson requires serial DSCSA transaction data from suppliers when purchasing DSCSA in-scope products. McKesson then supports customers by capturing serialized product identifiers in the order fulfillment process to generate DSCSA transactional data, ensuring compliance and traceability. All customers are provided access to view, search, download and export their DSCSA transaction data, including the option to receive an industry-standard EPCIS file pushed to their chosen solution. To meet DSCSA data retention requirements, historical lot-level transaction information will remain available on customer portals for six years.

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Q13 *Are all flagged DSCSA in-scope products updated in ordering portals?*

The DSCSA products are identified in product attributes posted on McKesson Connect. The DSCSA flag is updated when the manufacturers notify us in writing identifying if an item is or is not subject to DSCSA. This will be visible in the catalog view as a Y/N field in the column labeled DSCSA. “Y” indicates DSCSA in-scope product.

The DSCSA in-scope product indicator in Customer Center and Masters is under development and expected to be deployed soon.

Q14 *Will DSCSA requirements apply to small provider groups that buy and bill specialty medications directly from distributors? Are there any differences between these groups and the requirements for pharmacies?*

Distributors are required to be compliant with DSCSA as of Aug. 27, 2025. Customers who purchase DSCSA in-scope product from distributors will be required to comply with data serialization as it relates to receiving product and initiating saleable returns.

Q15 *Can McKesson provide us with guidance on our DSCSA obligations?*

While McKesson provides tools and data to support compliance — such as access to serialized product information and transaction records — customers are responsible for interpreting regulatory obligations. Any information in this document regarding a customer’s DSCSA obligations is not, and should not be received as, legal advice. We strongly recommend consulting your own legal counsel to ensure your organization meets all DSCSA requirements appropriately.

Q16 *Where can I find information relating to DSCSA?*

In your ordering portal, refer to the dedicated DSCSA page for the latest information.

Q17 *Where are the U.S. Food and Drug Administration (FDA) guidelines located online?*

For easy reference, all FDA links can be found at the bottom of the DSCSA page in your ordering portal.

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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. |