

# PREPARING FOR DSCSA

August 2025

### Most Frequently Asked Questions

This document contains a collection of the most asked questions about DSCSA. For more detailed information on DSCSA topics, please refer to the other six FAQ documents available on your ordering portal, which are organized into the following categories: General Overview, FDA Exemptions, Receiving and Returns, Serialized Transaction Information, Small Dispenser FAQ and GLNs.

# General Drug Supply Chain Security Act (DSCSA) Information

- Where can I find information relating to DSCSA?
   In your ordering portal, refer to the dedicated DSCSA page for the latest information.
- 2. 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.
- 3. 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 manufacturers notify McKesson teams 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.



# 4. 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."



### Global Location Numbers (GLN)

#### 5. What is my GLN?

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.

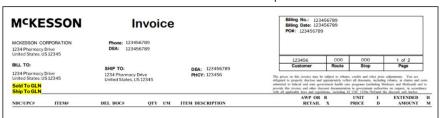
Establishing and submitting your GLN(s) is imperative to continue to conduct business with McKesson. We are requesting all customers to have one or more GLNs on file with McKesson to allow the parties in the supply chain to mature and test their systems and processes.

Please be aware that McKesson may not be able to see customer GLNs in the GS1.org portal.

#### 6. Where can I find my GLN?

You can find your GLN in a few ways:

- a) Visit the my.GS1US.org website to search for your GLN.
- b) Visit McKesson Connect, and search for your GLN by going to Enterprise Reporting Analytics (ERA), then Account Configuration.
- c) Contact your McKesson Customer Support team.
- d) McKesson has begun printing **Sold-To** and **Ship-To** GLN's on invoices for many pharmacy customers. If we do not have a GLN on file for you, these fields will populate with a series of zeroes. **Here is a sample invoice**:



#### 7. How do I update my GLN?

If you would like to change the GLN currently loaded to the McKesson system, please work with your sales representative or account executive. Large groups of 10 or more facilities will need to correct GLNs through GS1.org. Customers will need to additionally follow up with McKesson with their new GLN.

Any requests for edits to your GLN for address, Sold-To and Ship-To, should also be directed to your sales representative.



### Serialized Transaction Data

#### 8. Why am I not receiving EPCIS data?

All data that is available to McKesson will be accessible through the ordering portals. If data is unavailable when attempting to access EPCIS data from a third-party solution provider, customers should contact their respective provider directly for assistance.

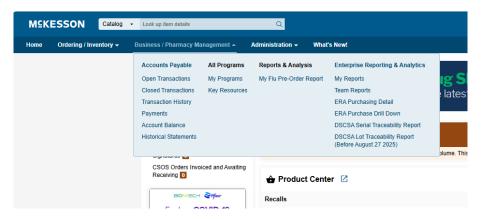
#### 9. Does McKesson have my drop ship EPCIS data?

McKesson has built functionality to enable it to receive the drop ship serial DSCSA data from the manufacturer and pass it onto the customer. This functionality depends on the manufacturer sending the DSCSA data to McKesson. Even if McKesson provides this service, the manufacturer retains the ultimate obligation to send the data.

#### 10. Where can I find my EPCIS data in McKesson Connect?

McKesson is making DSCSA transaction data available through our customer-facing portals.

In McKesson Connect, you will be able to find your EPCIS data in the **DSCSA Serial Traceability Report** and **DSCSA Lot Traceability Report** (before Aug. 27, 2025) under Business / Pharmacy Management, as shown below.

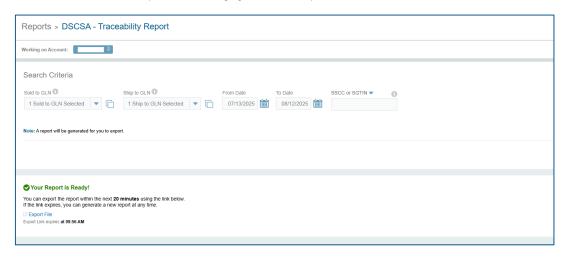


McKesson's data repository, also known as Advanced Track and Trade for Pharmaceuticals (ATTP), will store serialization data from McKesson and allow searching, downloading and printing upon requests made through the customer-facing portals, provided that the customer has the required GLN(s). McKesson customers may use our portal link to manage their DSCSA transaction data during the six-year DSCSA record retention requirement. Additionally, customers may opt to have the data transmitted daily using an EPCIS file to their in-house or third-party DSCSA repository for storage.



#### 11. How do I access DSCSA traceability reports in Customer Center?

- a. Log in to Customer Center.
- b. Click on Reports.
- c. Select DSCSA Traceability Report.
- d. Use the GLN dropdowns to choose the appropriate location.
- e. Click Search to generate the report.
- f. Once the report is ready, you can export it.



# 12. I have chosen to use a third-party solution provider for my transaction data. What is the process for ensuring that my transaction data is sent to my third-party provider?

If you are using a third-party solution provider for your transaction data, you should first contact your sales representative or account manager to complete the enrollment process. Have the following details to share with your representative:

- Contact name for serialization responsible party (name of third-party solution provider)
- Contact email address
- Your GLN(s) and global corporate prefix if you have 10 or more locations
- Expected readiness date (the first date the customer and third-party provider wants to receive data from McKesson) or desired date for contact to kick off onboarding

The sales representative will complete the enrollment process, and you will receive a notification of progress and completion of onboarding.

#### The process takes approximately:

- 30 business days to onboard a customer and start sending EPCIS files through an existing solution provider with an established and certified connection
- 3-4 weeks to complete onboarding of a new solution provider.



### Receiving and Returns

#### 13. How do I process a serialized shortage, overage or mispick on McKesson Connect?

For customers using **Customer Center**, please reach out to the Customer Care team to process a serialized shortage, overage or mispick.

For customers using McKesson Connect and Mobile Companion, following the steps below, you can take advantage of the self-service option to process serialized shortages, overages or mispicks:

- To create a return, select Ordering and Inventory.
- Under Returns, click Create a McK Return.
- Enter the return PO number (if applicable).
- Hit Go.
- If available, scan the item's barcode (with a scanner for McKesson Connect or handheld device or phone with Mobile Companion) or you can search for the item.
  - o For DSCSA items, scan the 2D barcode.
  - Note: In the case of a shortage, a barcode will not be available to scan.
     Shortages should be entered manually in McKesson Connect or Mobile Companion.
- Select Return Type.
- Select Invoice to return against (manual entry is an option).
- Item is added to the return order.
  - o DSCSA items will display the serial number captured from the scan.
- Repeat scanning products to add additional items to return order.
- Save changes.
- Submit return order.

To process a serialized shortage, overage or mispick on McKesson Connect or Mobile Companion, customers should be prepared to work with their dedicated Customer Support team and have the following information ready:

- Global Trade Item Number (GTIN)
- Serial number
- McKesson customer account number
- Sold-To and Ship-To GLNs
- Description of the issue (e.g., shortage, overage, mispick)
- Supporting documentation or screenshots, if available

Note: McKesson will request the serial, lot number and expiration date for any overage to investigate whether the product was previously picked and assigned to another customer, allowing for direct follow-up with that customer if necessary.



# 14. If an item is omitted from the order and the invoice indicates "DSCSA Data Not Received," will the order ship once data is received or do I need to reorder?

If a product was omitted and you see this message on your invoice, you should reorder the omitted product if still desired.

#### 15. What information do I need to provide to process a serialized return?

DSCSA creates additional obligations on distributors, including McKesson, for saleable returns of DSCSA in-scope products. After the DSCSA serialization compliance date on Aug. 27, 2025, this process will go into effect:

- As a customer, we will ask you to confirm that the serial number of the item being returned was purchased from McKesson.
- McKesson must verify the product identifier of the returned package against the manufacturer's assigned data.
- McKesson must also associate the returned product with its original DSCSA transaction data at the serial product identifier level from McKesson's initial sale to the customer.
- McKesson will not be able to accept any saleable product returns where McKesson cannot verify or associate the product with the original DSCSA transaction data from the initial sale.

#### 16. What are the reasons my saleable return might be rejected?

As of Aug. 27, 2025, if a DSCSA in-scope product is not purchased from McKesson, McKesson cannot receive the product as a saleable return. Verification and association must be completed to confirm the Sold-To GLN that is returning the product is the Sold-To GLN that has purchased the product.

Additionally, saleable returns may be rejected if items are found to be in a condition that is not returnable due to a broken seal, case, box or carton.

#### 17. Are we required to match each product/item we receive with the serialized data?

The law requires DSCSA in-scope drugs to be traced as they move through the supply chain, and pharmacies should:

- Only accept DSCSA in-scope drugs that are accompanied by DSCSA transaction data. If the trading partner you purchased the drugs from does not provide the DSCSA transaction data, work with them to promptly get it.
- Store the DSCSA transaction data you receive for six years.
- Generate and provide all DSCSA transaction data at or prior to the transaction if you sell a prescription drug to a trading partner. You do not need to provide this information when you dispense a prescription drug to a patient or if you sell to a pharmacy for dispensing for a specific patient need.



#### 18. What do I need to do to return a DSCSA in-scope product after Aug. 27, 2025?

McKesson will only be able to accept returns from the customer it originally sold the specific product identifier to, and all saleable return items must have a readable and scannable product identifier barcode. To ensure you purchased the product being returned before initiating a return authorization, you can revalidate the serial product identifier number in McKesson Connect, which ensures the Sold-To GLN that is returning the product is the Sold-To GLN that has purchased the product.

For customers using **Customer Center**, please reach out to the Customer Care team to process a return.

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 <a href="mailto:PharmaCustomerSupport ContactUs@McKesson.com">PharmaCustomerSupport ContactUs@McKesson.com</a>.
- 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.

