

# PREPARING FOR DSCSA

August 2025

# Serialized Transaction Information

#### 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

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### FDA EXEMPTION INFORMATION

On Oct. 9, 2024, the U.S. Food and Drug Administration (FDA) announced new deadlines for DSCSA compliance for eligible manufacturers, distributors and pharmacies.

### FDA-Granted Exemptions

The FDA-granted exemptions from certain DSCSA requirements to connected trading partners that meet the exemption conditions 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. 2026. Here is the link to the full FDA exemption announcement.

### GENERAL SERIALIZED TRANSACTION INFORMATION

When will the FDA and states begin enforcing serialized transaction data?

The DSCSA serialization dates for compliance depend on the eligibility and election of trading partners under the Oct. 9, 2024, FDA Exemption document. McKesson distributors will use that exemption to fully comply with their DSCSA serialization obligations by Aug. 27, 2025. McKesson will continue to share lot-level data until Aug. 27, 2025, and where available, will share serialized data for DSCSA in-scope products through the same portals from which you receive lot-level data today.

What action is required for our pharmacy to receive serialized transaction data?

In order to receive any serialized transaction data for DSCSA in-scope products from McKesson, you must have a Sold-To and Ship-To GLN on file with us. The serialized transaction data is tied directly to your GLN. You will continue to receive lot-level transaction data from McKesson distributors until Aug. 27, 2025. Additionally, if you select to use a third-party DSCSA solution provider as your repository, you must complete the enrollment process by contacting your sales team member.



# When will I be able to access serialized transaction data for DSCSA in-scope product?

Limited serialized transaction data for in-scope product became available to all McKesson customers in December 2023. You may access your serialized data the same way that you access your lot-level data from your designated McKesson ordering portal or, if you have contracted with a third-party provider, through their service.

# How long will McKesson keep a record of my serialized transaction data for DSCSA in-scope products?

Per DSCSA requirements, McKesson will maintain a record of your serialized transaction data for DSCSA in-scope products for six years.

# How long will McKesson transmit both lot-level and serialized data information for DSCSA in-scope products?

McKesson will transmit lot data for DSCSA in-scope products until Aug. 27, 2025, as per the Oct. 9, 2024, FDA Exemption document. Limited serialized data for DSCSA in-scope products became available in December 2023. The availability of a customer's serialized transaction data for such products depends on the manufacturer's ability to provide full EPCIS data and the McKesson shipping distribution center's capability to capture and transmit that serialized data.

As of Aug. 27, 2025, only serialized transaction data for DSCSA in-scope product will be gathered and distributed. McKesson will maintain lot and serial DSCSA data for six years after the transaction date for such data as required by the DSCSA.

### When will all data be serialized?

McKesson utilized the FDA's extension period through Aug. 27, 2025, to ensure compliance. All DSCSA data will be provided through your portal and may also be accessible via third-party solution providers, if applicable.

McKesson works with our supplier partners to obtain DSCSA serialized data for all DSCSA in-scope products. We also implemented DSCSA serial number capture capabilities in our distribution centers, which enables serial DSCSA data to become available in the McKesson portals and to be able to send serial DSCSA EPCIS files to customers who request this service, provided we have that serial information from our suppliers. All McKesson distribution centers have this capability.





### Is McKesson aggregating the serialized data so that we can scan just the external tote, instead of each bottle, to verify all the DSCSAcompliant data was received?

McKesson is aggregating the serial information of the individual DSCSA in-scope products to their totes and including that level of detail in the DSCSA transaction data. It is the dispenser's decision how to use this information. Recent FDA guidance has suggested that customers should confirm DSCSA transaction data was received.



### How will McKesson provide DSCSA serialized data?

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

McKesson's data repository called 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.

### MCKESSON PORTAL ACCESS TO DSCSA SERIALIZED DATA



# What is the agreement that pops up the first time I try to access transaction data?

The "Agreement to Maintain DSCSA-Required Transactional Data" is necessary for McKesson to manage and retain DSCSA data in the McKesson portals for customers. This licensing agreement appears when you attempt to access the DSCSA data in the portal for the first time and then periodically thereafter to reverify the license agreement. You must accept the agreement to access the data. The agreement can also be printed. Below is a copy of the agreement (next page).



#### AGREEMENT TO MAINTAIN DSCSA-REQUIRED TRANSACTIONAL DATA

THIS AGREEMENT TO MAINTAIN DSCSA-REQUIRED TRANSACTIONAL DATA constitutes the written agreement described in Section 582(d)(1)(B) of the Drug Supply Chain Security Act ("DSCSA"), between McKesson Corporation ("McKesson") and the company or other entity that you represent ("Dispenser"). This agreement is effective as of the later of July 1, 2015 or the date Dispenser executes this agreement (the "Effective Date"). Dispenser is responsible for maintaining a copy of this agreement and entering into this agreement does not relieve Dispenser of its obligations under Section 582(d)(1) of DSCSA.

- 1. Subject to the termination provisions below, McKesson agrees to confidentially maintain for six (6) years the transaction information, transaction history and transaction statements required to be maintained by Dispenser under subsection 582(d) of DSCSA at no additional charge to Dispenser. Dispenser may access the maintained transactional data via McKesson's proprietary McKesson Connect system. Only transactional data for applicable products sold to Dispenser by McKesson will be maintained pursuant to this agreement. Dispenser agrees that it is responsible for maintaining for six (6) years the transactional data required by DSCSA for applicable product it receives direct from the manufacturer (e.g., by drop shipment) or from any source other than McKesson.
- 2. This agreement will automatically terminate upon termination or expiration of the distribution relationship that Dispenser has with McKesson. In addition, either party may terminate this agreement at any time upon thirty (30) day written notice of termination to the other party.
- 3. The transactional data maintained by McKesson may be exported by Dispenser at any time up to thirty (30) days following termination of this agreement. McKesson will provide the maintained transactional data to Dispenser in an export file upon request at termination of this agreement.
- 4. NEITHER MCKESSON NOR ANY OF ITS EMPLOYEES, AGENTS, DIRECTORS OR REPRESENTATIVES WILL BE LIABLE FOR UNAUTHORIZED ACCESS TO THE MAINTAINED TRANSACTIONAL DATA, UNLESS AND ONLY TO THE EXTENT THAT THIS DISCLAIMER IS PROHIBITED BY APPLICABLE LAW. MCKESSON DOES NOT WARRANT THAT THE SERVICES WILL BE UNINTERRUPTED, ERROR-FREE OR THAT ALL DEFECTS WILL BE CORRECTED. EXCEPT AS EXPRESSLY REQUIRED BY LAW NEITHER MCKESSON NOR ANY OF ITS EMPLOYEES, AGENTS, DIRECTORS OR REPRESENTATIVES WILL BE LIABLE FOR ANY PUNITIVE, INDIRECT, CONSEQUENTIAL OR SPECIAL DAMAGES, OR FOR ANY LOST DATA, LOST BUSINESS OR DAMAGE TO GOODWILL, EVEN IF ADVISED OF THE POSSIBILITY OF SAME, AND REGARDLESS OF WHETHER THE CLAIMS ARE BASED IN CONTRACT, TORT, STRICT LIABILITY, INFRINGEMENT, OR ANY OTHER LEGAL OR EQUITABLE THEORY.
- 5. This agreement shall be governed, construed and enforced in accordance with the laws of the State of California, without regard to its conflict of laws rules. McKesson on one hand, and Dispenser on the other, are each independent parties. This agreement does not create an agency, joint venture, or partnership between McKesson and Dispenser, and does not constitute legal advice from McKesson to Dispenser with respect to Dispenser's obligations under the DSCSA. McKesson recommends that Dispenser contact its attorney for advice regarding its obligations under the DSCSA.

Please indicate Dispenser's agreement and understanding of this agreement to maintain DSCSA transactional data by signing on behalf of Dispenser in the space provided below. By signing on behalf of Dispenser, you represent and warrant that (i) you are duly authorized to and have full legal authority to bind Dispenser to this agreement and (ii) you agree, on behalf of Dispenser, to this agreement.



### Does the DSCSA transaction data in the McKesson portals provide lot numbers?

Currently, when McKesson purchases DSCSA in-scope product directly from the manufacturer, we provide a Direct Purchase Statement in lieu of providing the lot number in the lot level DSCSA transaction data. Under the Oct. 9, 2024, FDA Exemption document, starting Aug. 27, 2025, the transaction data from McKesson distributors will contain the lot number, serial number and expiration date of DSCSA in-scope product. McKesson has been incrementally providing this transaction data during the stabilization period and will continue to do so through this FDA exemption dataperiod (i.e., Nov. 27, 2024 – Aug. 27, 2025) as it tests and matures its systems.

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### How do we retrieve older DSCSA data created before the new processes?

Data is currently being stored on all ordering portals. Storage platforms will retain the data for six years.

For Pharma customers, McKesson will be managing two data storage platforms in parallel, with the newer data being stored on Enterprise Reporting and Analytics (ERA). Older data will be retained on McKesson Connect. All data will be retained for six years.

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# 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



### Will DSCSA remove the attestation portion of the returns process?

No, DSCSA will not remove the attestation portion of the returns process.



### Will the serialized product number be on invoices?

No, the serialized product number will not appear on invoices.





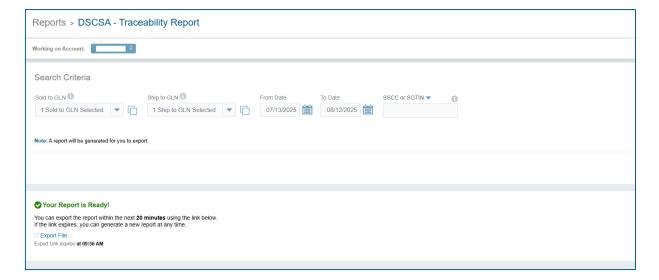
### Why am I not receiving EPCIS data?

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.



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

- 1. Log in to Customer Center.
- 2. Click on Reports.
- 3. Select DSCSA Traceability Report.
- 4. Use the GLN dropdowns to choose the appropriate location.
- 5. Click Search to generate the report.
- 6. Once the report is ready, you can export it.

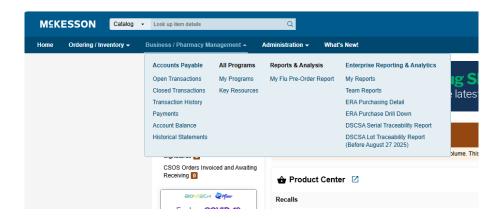




### Where can I find my EPCIS data in McKesson Connect?

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.

### TRANSACTION DATA FOR COMPLEX ORDERING



# Is it possible to get a copy of the third-party agreement for the storage of transaction data for our files?

McKesson would not have access to the agreement between the customer and the customer's third-party service provider to manage and store the customer's DSCSA transaction data. Please contact your service provider directly for a copy of the agreement.





# Who receives the EPCIS serialized data for 340B DSCSA in-scope product? Where does McKesson send the information? What is McKesson's process when there is an error, and the pharmacy needs a new EPCIS file?

EPCIS data for 340B purchases will be provided to the covered entity, not the contract pharmacy. The covered entity can grant access to EPCIS data to their contract pharmacies, but this must be handled by the covered entity and the contract pharmacy.



### Will 340B contract pharmacies be able to access DSCSA serialized data?

340B contract pharmacies may access DSCSA serialized data only when the covered entity provides explicit authorization for McKesson to share it. DSCSA requires that EPCIS data be supplied to the purchasing party, which is typically the covered entity. If a contract pharmacy wishes to receive this data, the covered entity must authorize McKesson to share it. This data sharing is optional and not mandated by DSCSA. McKesson is currently facilitating outreach to covered entities to support this process and help ensure continuity for contract pharmacies.



### How will the drop ship process work for DSCSA data?

The ordering process for drop shipments of DSCSA in-scope products will remain the same as it is now. The manufacturers shipping your product will send you the lot-level DSCSA transaction data. McKesson currently does not provide this data. Our ordering lot-level DSCSA system will indicate a drop shipment occurred but will not have complete DSCSA information as the manufacturer must provide that detail.

To improve the process for serialized DSCSA transaction 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.



### Does McKesson have visibility to the serialization data of drop ship orders? Does McKesson have a role in the chain of ownership for drop ship orders?

For drop ship orders of DSCSA in-scope products, McKesson owns the product prior to transferring that ownership to the customer. However, since McKesson does not possess the product in a drop ship situation, the DSCSA transaction data is created by the shipper. We do expect the shipper to share the data with us which, if received, we will load into our ordering portal or provide to a customer's third-party DSCSA solution.





### 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.



# Where can I find more information on the requirements of a pharmacy, and related best practices, to comply with DSCSA?

We recommend that you refer to the FDA.gov website for more information. The American Society of Health-System Pharmacists (ASHP) and National Community Pharmacists Association (NCPA) also may have relevant resources. For more helpful resources go to DSCSA.pharmacy.

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 <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.



# 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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