

PREPARING FOR DSCSA

August 2025

What Do I Need to Know About GLNs?

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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ALL ABOUT GLNs

Q1

What is a 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.

Q2

What does a GLN look like?

A GLN is a 13-digit number consisting of a company prefix, a location reference and a check digit.

Q3

How do I obtain my GLNr?

GLNs are typically created by the customer who has purchased a license to create GLNs from Global Standards 1 (GS1) or under GS1's managed GLN program based on submissions by wholesalers or group purchasing organizations.

Each customer should obtain a GLN for:

- · Sold To represents the party acquiring ownership of the DSCSA in-scope product shipped.
- Ship To represents the physical location where the DSCSA in-scope products are being delivered.

These numbers may be the same for some customers if their Sold-To and Ship-To addresses are identical.

If you have not created a GLN or need assistance retrieving a GLN, visit <u>gs1us.org</u>. Please be advised that a registration fee is involved.



Following are more details about the GLN retrieval process for each segment.

Community Pharmacy and Practitioners

To aid in the adoption of GLNs for DSCSA purposes, McKesson and other distributors purchased a group license from GS1 for the identification of independent and small customers with nine or fewer locations (excluding government facilities). Based on data submitted by McKesson and other distributors, GS1 is creating GLNs and posting those GLNs to the GS1 Data Hub tool for these independent and small customers. McKesson and other distributors will have visibility to those GLNs. The goal was to eliminate the work necessary for independent and small customers to speed up identification. Customers who meet these criteria did not need to take any action now with respect to GLN.

Customers with more than nine locations must create their own GLNs. Please visit gs1us.org.

Health Systems and Clinics

Many health systems, through their group purchasing organizations, have GLNs in the GS1 Data Hub, which was used to identify such customers.

Large Retail and National Accounts

Most Large Retail and National Accounts generated GLNs using their Global Company Prefix (GCP) from GS1. The saccounts were to contact GS1 for assistance in generating the necessary GLNs if all locations did not have individual GLNs.

Specialty Provider Customers and The US Oncology Network

McKesson conducted a review to determine which practices required GLNs and, assigned GLNs to those practices.



Q4

How can I find my GLN on the GS1.org site?

GS1 has a search function to help locate the GLN: Search by Party Name | GEPIR (gs1.org). The search is available by company or GLN.

Q5

For health system-covered entities, do contract pharmacies count as locations?

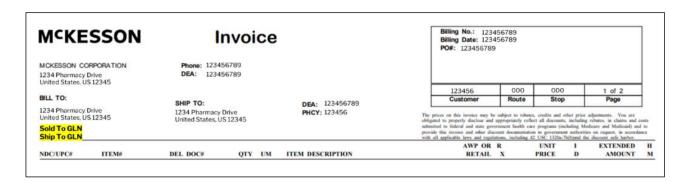
If the health system-covered entity owns the contract pharmacy, then the contract pharmacy is a location within the health system. If, on the other hand, the contract pharmacy is separate, it will need to have its own Ship-To GLN. In that situation, the Sold-To GLN will be the health system-covered entity.

Q6

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:







How do I request a GLN?

Before requesting a GLN, please be sure to confirm that you do not already have a GLN by searching the my.GS1US.org website or by contacting your McKesson Customer Support team to see if we have the GLN(s) assigned to your account loaded in our system.

If you are unable to locate your GLN:

McKesson can assist independent and small businesses with nine or fewer locations (with the exception of government facilities) in getting their GLN(s) as a GS1 US GLN issuing partner. This is at no cost to you.

Customers with more than nine locations will need to visit the my.GS1US.org website to create a GLN(s).

Q8

How can I identify if a distributor created a GLN?

GLNs created by GS1 based on information provided by distributors or GPOs begin with either 1100 or 1200. Additionally, some GS1 issued Single Location GLNs also begin with 1100 or 1200.

Q9

Is my GLN the same for all locations?

If you have more than one Ship-To location or if your Sold-To location is separate from your Ship-To location, you will need a GLN for each distinct location. If your Sold-To and Ship-To location are the same, you only need one GLN.

Q10

What if the GLN I have in my records is different from what McKesson has on file or if there are multiple GLNs assigned to my location?

A particular location only needs a single GLN to identify itself. The same GLN should be used for all suppliers servicing that location. If the GLN(s) you have are different from the ones McKesson has on file, please contact your McKesson Customer Support team.





What if McKesson assigned a GLN to my business and I don't want to use that GLN?

If for any reason you desire to secure your GLN at your own expense or maintain it with GS1 yourself, we can deactivate the McKesson-assigned GLN. Before attempting to secure your own GLNs from GS1, to avoid receiving an error that a GLN already exists, your McKesson-assigned GLN will need to be deactivated. Please contact your McKesson Customer Support team 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 <u>MSH.CustomerCare-MSPL@McKesson.com</u>.
- If the ownership or name of a pharmacy or facility changes, does the GLN transfer with this information change?

For most ownership, location and name changes, a new GLN will need to be procured. For more information on the rules regarding GLNs, visit the <u>GS1 GLN allocation rules</u> document.

Does my GLN stay the same no matter what distributor I use?

Yes, GLNs are universal. All suppliers and distributors, that have elected to use GLNs as customer identifiers, will use the same GLN for common customers.

O14 How long does it take for me to get a new GLN assigned?

McKesson has a direct connection with the GS1 US Data Hub system to check for previously assigned GLNs and, where appropriate, to assign GLNs when one is needed. The process takes just a couple of minutes when we receive a request to assign or correct a GLN.

If I have multiple locations under one GLN indicating common ownership, can I transfer DSCSA in-scope product between locations?

Yes, you may transfer DSCSA in-scope products between locations that share the same Sold-To GLN, which indicates common ownership and control. Should a product be returned following such a transfer, McKesson will complete an association test to verify that the returned product matches our historical DSCSA record with the correct Sold-To GLN and product serial number.

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Q16

Will McKesson still be able to assist in requesting GLNs for customers with nine or less locations under the GS1 Managed GLN program?

Yes, McKesson will still be able to assist in requesting GLNs for customers with nine or less locations under the GS1 Managed GLN program, with the exception of all government facilities. GS1 will create GLN(s) for the customer based on information provided by McKesson and McKesson will load the GS1 created GLN to the customer account.

Q17

If a Federally Qualified Healthcare Center (FQHC) has more than nine contract pharmacies, are they responsible for obtaining GLNs for those contract pharmacies?

The covered entity only needs to have a GLN as the Sold-To location. The contract pharmacies have their own Ship-To GLNs.

Q18

How does a GLN for a contract pharmacy need to be provided since a hospital and pharmacy is involved?

 $Entities under common ownership frequently use the same Sold-To GLN. For a 340B replenishment account, \\McKesson loads the covered entity GLN as the Sold-To GLN and the contract pharmacy GLN the Ship-To GLN.$

Q19

Do I input my GLN in the ordering system and how does the GLN transmit through the ordering process?

The ordering process for a customer will remain exactly as it is today. You do not need to enter your GLN. Ordering is done by account number.

Q20

What is an sGLN?

An sGLN has a slightly different format from the 13-digit GLN for use in EPCIS files. It has all the similar identifiers as found in the GS1-issued GLN: Sold-To, Sold-By, Ship-To and Ship-From. It is different in format because EPCIS is based on the JSON computer language, which requires this formatting. 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.

Q21

There are GLNs in GS1 that were established by McKesson. If I would like to make a change, but I'm not the "owner" of the GLN, how do I make changes?

There is an option in GS1 Data Hub to request a change of "ownership" of the GLN. When you request a change of ownership in the GS1 Data Hub, the GS1 Data Hub automatically sends this request to the entity that owns that GLN.

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I have five 340B contract pharmacies where McKesson distributes DSCSA in-scope products. The 340B covered entity is a separate company, the purchaser of the products and a customer of McKesson. Will I be able to comply with DSCSA regulations by not being the purchaser of the drugs?

For 340B replenishment programs, the purchaser is the covered entity, which generally bears the responsibility for the DSCSA Drug Traceability requirements. The covered entity may enter into an agreement with the contract pharmacy(ies) to share the responsibility for DSCSA compliance.



Is McKesson using Bill-To GLNs?

McKesson is not using Bill-To GLNs for DSCSA. The Pharma Distribution team uses Sold-To and Ship-To GLNs in our reporting. Sold-To is used to represent the customer's legal entity (corporation, LLC, etc.). The Ship-To is the physical location receiving the product. The Sold-To and Ship-To can be the same if the billing and shipping addresses are the same.



What should a dispenser do prior to their DSCSA serialization compliance date?

Please use the FDA link to find a full list of actions that should be taken at https://www.FDA.gov.

In summary, McKesson recommends the following:

- All trading partners, including dispensers, are expected to be able to search the repositories where their serial DSCSA transaction information and transaction statements are stored and retrieve the requested information upon request.
- Know how to access DSCSA transaction data through McKesson portals or your in-house or third-party system where you requested this information to be transferred.
- Dispensers must confirm that the serial number of the saleable DSCSA in-scope product they intend to return was purchased from McKesson before initiating the return.
- DSCSA in-scope product returns where McKesson is unable to verify or associate the serial number of the product cannot be accepted as a saleable return under the DSCSA.

Additional information for dispensers from NACDS, NCPA, HDA and NABP about dispenser requirements is available at www.dscsa.pharmacy.





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 <u>FDA.gov</u> website for more information. The American Society of Health-System Pharmacists (ASHP) and National Community Pharmacists Association (NCPA) may also have relevant resources.

- Q26
- Will a pharmacy be able to sell to doctor's offices or clinics?

Please refer to the FDA guidance found here: https://www.FDA.gov.

- Q27
- Am I required to scan all DSCSA in-scope product upon receiving?

Please refer to the FDA guidance found here: https://www.FDA.gov.

Q28

We supply emergency meds to a treatment facility. Does that facility need a GLN?

The DSCSA defines "wholesale distribution" as the distribution of a drug to a person other than a consumer or patient. However, the law provides for certain exceptions to this definition, including the distribution of minimal quantities of drugs by a licensed retail pharmacy to a licensed practitioner for office use. For transactions exempt under this minimal quantity exception, a GLN is not necessary as there is no need for an EPCIS file with transaction data from the dispenser to the practitioner.



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.

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

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- 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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