



PREPARING FOR **DSCSA** Drug Supply Chain Security Act

March 2024

Serialized Transaction Information

Dear McKesson Customer,

As the DSCSA Nov. 27, 2024, effective date approaches, we want to share the latest details on timing and actions underway to help you continue to prepare for it.

This FAQ is designed to answer questions about serialized transaction data and what McKesson is taking to ensure you have access to important DSCSA details and reporting.

If you have additional questions about serialized transaction information or how DSCSA will impact your business, please contact your McKesson Sales team member or Customer Support.

Answers to Your Top Questions

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DSCSA Overview & FAQ

GENERAL DSCSA INFORMATION

Q1 **What is DSCSA?**

The Drug Supply Chain Security Act, signed into law on November 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 **What is McKesson's official response to the August 25, 2023, FDA Announcement?**

On Friday, August 25, 2023, the U.S. Food and Drug Administration (FDA) announced through a compliance policy that it would not take action to enforce the Enhanced Drug Distribution Security requirements of the Drug Supply Chain Security Act (DSCSA), section 582(g)(1) of the Federal Food, Drug, and Cosmetic Act until November 27, 2024. The FDA is providing a one-year "Stabilization Period" from the statutory deadline of November 27, 2023. This Stabilization Period will allow all key players within the supply chain (manufacturers, distributors, dispensers and trading partners) to mature processes and refine operations that are required to comply with these specific package-level tracing requirements. The FDA will continue to enforce the other DSCSA requirements during this Stabilization Period.

The FDA expects all parties to continue progressing toward stabilization and maturing the implemented systems during this Stabilization Period. McKesson will continue to roll out enhanced DSCSA capabilities including:

- Sending enhanced DSCSA Transaction Information using customer portals and EPCIS (Electronic Product Code Information Services) data files
- Providing additional educational tools to help prepare dispensers for the full DSCSA implementation

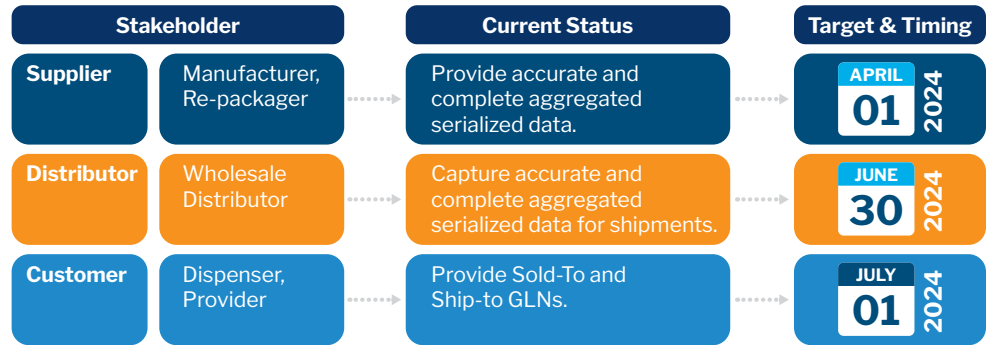
During this Stabilization Period, McKesson will continue to provide the lot-level DSCSA Transaction Information, Transaction History and Transaction Statements using the existing portals and DSCSA enabled EDI files.

McKesson will continue to monitor the FDA's policy and requirements for DSCSA serialization implementation and will adapt its processes as needed.

Given the FDA announcement of the Stabilization Period, the following is an overview of McKesson's key dates.

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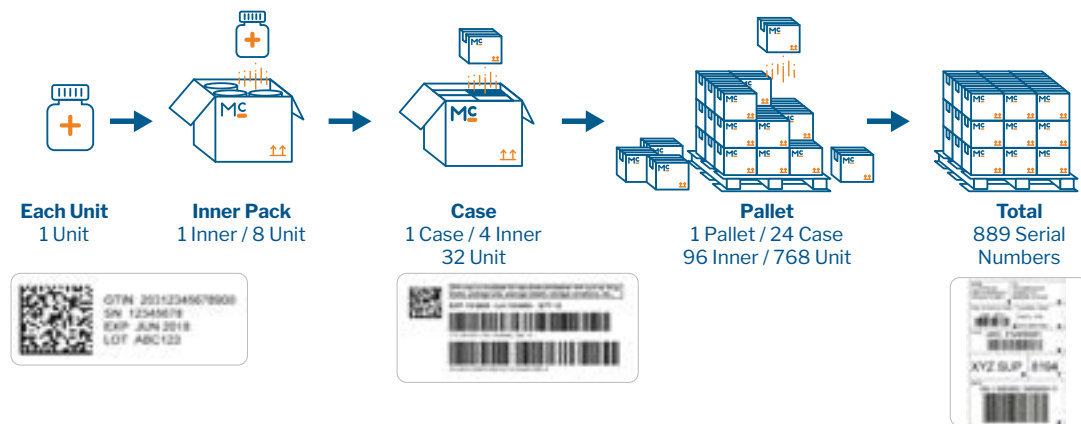
McKesson Key Action Dates for DSCSA Enforcement



Q3 What traceability changes will be implemented during the Stabilization Period?

During the Stabilization Period, all DSCSA Transaction Information for in-scope products will continue to be shared in a lot-based format and, as it is made available, in a serial-based format. On November 27, 2024, in addition to the previous requirements for DSCSA Transaction Information, **serialized product identifier information for in-scope products must be added** to the DSCSA Transaction Information.

- A new serial number is provisioned by the manufacturer at each salable product unit (e.g., pallet, case, box, each) of packaging to be uniquely identified.
- Each serial number must be tracked through all transactional events across the supply chain (events can include packing, shipping, receiving, returns, etc.)



Beginning on November 27, 2024, the current Lot-based Transaction History will be sunset and electronic-based approaches will be used among all trading partners to meet the enhanced requirements.

McKesson will use the FDA recommended Electronic Product Code Information Services (EPCIS) standard to provide and maintain the data associated with Transaction Information and Transaction Statements.

DSCSA Overview & FAQ

Q4 **How will in-scope products/ items and trading partners be identified in the new interoperable electronic exchange?**

GS1 (Global Standard 1) 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).

Q5 **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.

Q6 **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 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 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 product page of all McKesson ordering portals.

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Q7 *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, customers should cross reference the indicator in your ordering portal against data provided in your Transaction History to determine if the product is subject to DSCSA.

SERIALIZED TRANSACTION INFORMATION

Q8 *When will the FDA begin enforcing serialized transaction data?*

The FDA will require serialized data for DSCSA in-scope products to be shared effective November 27, 2024. McKesson began sharing limited serialized data for DSCSA in-scope products in December 2023, through the same portals from which you receive lot-level data today.

Q9 *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 until November 27, 2024. 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. Important note: McKesson is requesting all customers to have their GLNs on file by July 1, 2024.

Q10 *When will I be able to access serialized transaction data for DSCSA in-scope product?*

Limited serialized transaction data for in-scope product will begin to be available to all McKesson customers in December 2023. When the information goes live, you will 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.

Q11 *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.

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Q12 *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 throughout the Stabilization Period, which ends November 27, 2024. 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 will depend 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 November 27, 2024, 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.

Q13 *When will all data be serialized?*

McKesson is working with our supplier partners to obtain DSCSA serialized data for all DSCSA in-scope products. We are also implementing DSCSA serial number capture capabilities in our distribution centers, which will enable 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. The majority of McKesson distribution centers will have this capability by April 2024.

Q14 *Is McKesson planning on aggregating the serialized data so that we can scan just the external tote, instead of each bottle, to verify all the DSCSA compliant data was received?*

McKesson will be 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.

Q15 *How will McKesson provide DSCSA serialized data?*

McKesson is making DSCSA transaction data available through our customer-facing portals (Connect, ERA, Customer Center, Lynx and SupplyManagersm online). McKesson’s data repository called ATTP (Advanced Track and Trade for Pharmaceuticals) 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.

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MCKESSON PORTAL ACCESS TO DSCSA SERIALIZED DATA

Q16

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 will appear when you attempt to access the DSCSA data in the portal for the first time and then periodically thereafter to re-verify 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.

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.

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Q17 *Does the DSCSA Transaction Data in the McKesson portals provide lot numbers?*

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 DSCSA Transaction Data. Starting November 27, 2024, the Transaction Data must contain the lot number, serial number and expiration date of DSCSA in-scope product. McKesson will be incrementally providing this Transaction Data during the Stabilization Period as it tests and matures its systems.

Q18 *How do we retrieve older DSCSA data created before the new processes?*

McKesson is phasing in a new data and analytics platform called Enterprise Reporting & Analytics or ERA for short. Because it is a new tool, McKesson will be building to six years on the new system as older data currently in McKesson Connect will not be transferred over. Older data will still be accessible on McKesson Connect. All portals are under a six-year record retention requirement for lot-level traceability, which began on January 1, 2015. Additionally, ATTP will be managed to maintain six years of record retention as McKesson builds up data. This will be a function of the ATTP archiving and management.

CONNECTING THROUGH A THIRD-PARTY PROVIDER

Q19 *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 will be using a third-party solution provider for your transaction data, you should first contact your Sales representative 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
- Expected readiness date (the first date the customer & third-party provider want to receive data from McKesson) or desired date for contact to kick off onboarding

The Sales representative will complete the enrollment process and submit to serializationIT@mckesson.com. You will receive a notification of progress and completion of onboarding.

The process takes approximately:

- 7-10 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.

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TRANSACTION DATA FOR COMPLEX ORDERING

Q20 *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.

Q21 *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.

Q22 *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 is building functionality to enable it to receive the drop ship serial DSCSA data from the manufacturer and pass it onto the customer. This functionality is in development and 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.

Q23 *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 portal or provide to a customer's third-party DSCSA solution.

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NEXT STEPS AND WHAT TO EXPECT

Q24 *What changes do I need to make prior to the DSCSA serialization enforcement date of November 27, 2024?*

Please use the FDA link to find a full list of actions that should be taken at <https://www.fda.gov/drugs/drug-supply-chain-integrity/drug-supply-chain-security-act-dscsa>

In summary, McKesson recommends the following:

- Prior to November 27, 2024, you should make changes, including but not limited to the following:
- All customers (dispensers, health systems, pharmacies, etc.) should be prepared to respond directly to regulators if asked about tracing information for DSCSA in-scope products they purchased.
- 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.
 - Beginning in the Summer of 2024, DSCSA transaction data where available will be accessible through McKesson portals or your in-house or third-party system where you requested this information to be transferred.
- All trading partners 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.

Your pharmacy should have procedures to identify and investigate suspect and illegitimate product according to the requirements in DSCSA. The DSCSA transaction data may assist you in conducting these investigations. Additional information for dispensers from NACDS, NCPA, HDA and NABP about dispenser requirements is available at www.dscsa.pharmacy.

IMPORTANT NOTE: For some of these processes, McKesson will provide a more detailed process communication to enable testing of our systems and processes prior to November 27, 2024.

Q25 *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.

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Q26 **Will a pharmacy be able to sell to doctor's offices or clinics as of November 27, 2024?**

Please refer to the FDA guidance found here: <https://www.fda.gov/drugs/drug-supply-chain-integrity/drug-supply-chain-security-act-dscsa>

Q27 **Do I need to purchase scanners to receive DSCSA in-scope product as of November 27, 2024?**

No, scanners are not required to receive DSCSA in-scope product. McKesson does not supply or sell scanners.

Need more information or have further questions?

As McKesson continues to prepare for DSCSA serialization implementation, we will update these FAQs. Our internal project team overseeing this effort is working diligently to refine processes, mature systems, and facilitate the build of interoperable data flows to be prepared for the November 27, 2024, enforcement date.

IMPORTANT NOTE: For some of these processes, McKesson will provide a more detailed communication outlining our expectations of our customers to enable interoperable testing of our respective systems and processes prior to November 27, 2024.

McKesson online ordering platforms will be updated as information is available. For questions regarding DSCSA you can also contact us via email.

- For our Community Pharmacy & Health Mart, Health Systems, Large Retail and National Accounts Government customers, email DSCSA-PharmaCustomerSupport@McKesson.com
- For MPB specific questions, email DSCSA-MPBCustomerSupport@McKesson.com
- For Specialty Provider and the US Oncology Network related questions, email DSCSA-ProviderSolutions@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 US 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, 3-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.