

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

March 2024

DSCSA Overview & FAQ

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 prepare for it.

As a reminder, the FDA provided a one-year "Stabilization Period" beyond the legal deadline of the November 2023 date. This period allows all those within the supply chain (manufacturers, distributors, dispensers and trading partners) to mature processes and refine operations that are required to comply with the specific package-level tracing requirements. The FDA will continue to enforce the other DSCSA requirements during this Stabilization Period.

This FAQ is specifically designed to share an overview of 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.

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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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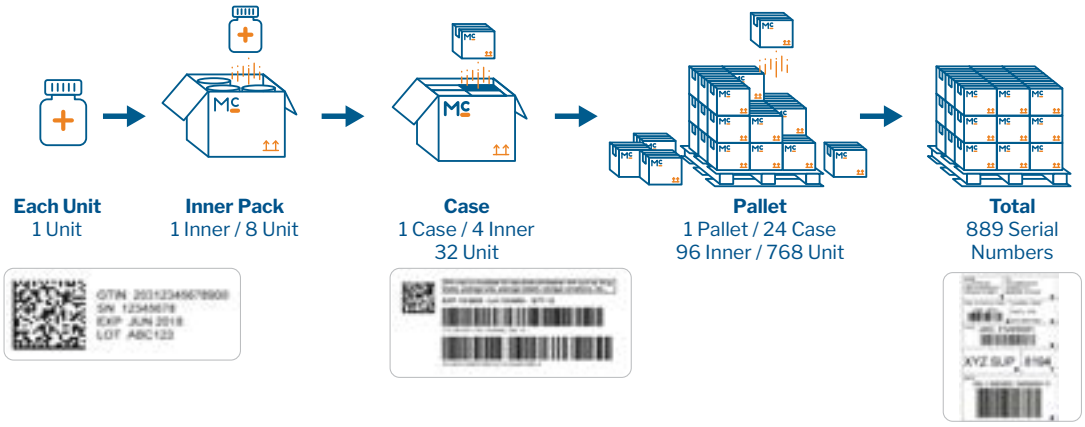
McKesson **Key Action Dates** for DSCSA Enforcement

Stakeholder		Current Status	Target & Timing
Supplier	Manufacturer, Re-packager	Provide accurate and complete aggregated serialized data.	APRIL 01 2024
Distributor	Wholesale Distributor	Capture accurate and complete aggregated serialized data for shipments.	JUNE 30 2024
Customer	Dispenser, Provider	Provide Sold-To and Ship-to GLNs.	JULY 01 2024

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.)



Each Unit
1 Unit

Inner Pack
1 Inner / 8 Unit

Case
1 Case / 4 Inner
32 Unit

Pallet
1 Pallet / 24 Case
96 Inner / 768 Unit

Total
889 Serial Numbers

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.

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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.

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.

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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 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.

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