DSCSA – Frequently Asked Questions

Since July 1, 2015, dispensers of prescription drugs have been required to receive and maintain for six years transaction information (TI), transaction history (TH) and a transaction statement (TS) – collectively known as transaction data – for products eligible under the Drug Supply Chain Security Act (DSCSA). Starting November 27, 2023, there will be additional enhanced DSCSA requirements that will impact all trading partners in the supply chain.

These frequently asked questions will help Cardinal Health customers understand their requirements under the DSCSA. This information does not constitute legal advice, and customers should seek legal counsel to determine how the law applies to their specific circumstances.

For more information, visit the Cardinal Health Pharmaceutical Tracing website. If you have questions, please contact your Cardinal Health representative or email dscsainfo@cardinalhealth.com.

General

How do the November 2023 regulations impact dispensers? What are the major changes?

- Cardinal Health will be required by the law to send DSCSA transaction data (including global trade item numbers (GTIN), serial number, lot and expiry) to our customers via EPCIS (Electronic Product Code Information Services), replacing today's ASN or via Cardinal Health's web portal.
- Customers will need a standard location identifier called a GLN (Global Location Number) to receive the serialized transmissions.
- Cardinal Health will only accept a product return into saleable inventory if we sold that specific GTIN, serial number, lot and expiration date to a customer.
- Customers will need systems and processes in place for the verification of product at the package level and be able to respond to the U.S. Food and Drug Administration (FDA) or regulatory requests in the event of a recall or for investigating suspect or illegitimate product.

How is Cardinal Health working with manufacturers and preparing its warehouse systems for the November 2023 DSCSA enhancements?

Cardinal Health is establishing connections between trading partners and deploying changes to warehouse management systems to guarantee DSCSA compliance, all of which require significant time, effort and resources, including:

- Working with approximately 500 suppliers on point-to-point connections to receive aggregated, serialized production data via EPCIS and evaluate data quality.
- Preparing our distribution center teams to receive inbound serialized product, scan 2D barcodes on outbound product and verify saleable returns, which will require an estimated 15 percent increase in staffing at our distribution centers.

- Developing exception handling processes with trading partners to keep product moving safely through the supply chain.

What items are in scope for DSCSA?
The DSCSA applies to prescription drugs in finished dosage form for human use. A limited number of Rx products are exempt, including:

- Animal medications
- 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

Exchange of serialized data

How will Cardinal Health provide DSCSA compliance data, transaction information and transaction statements to dispensers after the new requirements go into effect in November 2023?
In November 2023, Cardinal Health dispenser customers will have the option of receiving DSCSA serialized transaction data via EPCIS (Electronic Product Code Information Services) replacing today's transaction information (TI), transaction history (TH) and transaction statements (TS) using a third-party EPCIS vendor or accessing the data via a web portal. Cardinal Health customers who do not have the system capabilities to accept EPCIS messages may choose to use Cardinal Health as a solution provider to receive, store and access DSCSA transaction data.

The current transaction data reports provided by Cardinal Health do not contain some of the information needed for the new November 2023 requirements (ex: lot number, expiration date, serial number). Will Cardinal Health update these reports before November to reflect the new requirements?
Yes. In 2023, the DSCSA requires supply chain stakeholders to electronically track product at the individual package level using the product identifier (the 2D barcode that manufacturers now apply to each individual package). Cardinal Health reports will be updated to comply with the new requirements.

After November 27, 2023, will the transaction information contain the GTIN, serial number, lot number, and expiration date (Product Identifier) in human readable format for each package in an order?
Yes, the serial number, lot number and expiration date will be required as part of the DSCSA transaction information beginning November 27, 2023. All required fields will be included on Cardinal Health's web portal report and/or transmitted via EPCIS.

Global Location Number

What is a Global Location Number (GLN)?

The GLN is a unique identifier assigned by GS1. It is necessary to properly identify the "sold to" and "ship to" parties in the EPCIS (Electronic Product Code Information Services) transaction. It is not wholesaler specific. GLNs are standard identifiers that can be shared with all trading partners.

Will all Cardinal Health customers be required to have a GLN?

Yes, the GLN will enable Cardinal Health to electronically capture the DSCSA transaction data down to the package level, which will be required beginning November 27, 2023.

How do I obtain a GLN?

For information about how to obtain a GLN, please visit the GS1 website: https://www.gs1us.org/industries-and-insights/standards/global-location-number/get-a-global-location-number

Once I obtain a GLN, how do I send it to Cardinal Health?

Cardinal Health is developing a process to efficiently collect GLNs from our customers. We will send information to customers about this process in April or May.

Will Cardinal Health obtain the GLN for their customers as part of their business practice?

The Managed GLN Subscription Program, sponsored by Cardinal Health and our partner wholesalers, enables Cardinal Health to obtain GLNs on behalf of small independent pharmacy customers.
Cardinal Health will not obtain GLNs for all customers. Dispensers will need to work through their individual organizations to identify and/or obtain their GLNs and communicate that information to Cardinal Health so it can be added to their account information.

Are GLNs shared between all wholesalers or is it wholesaler specific?

GLNs are not wholesaler specific. The GLN is specific to the customer and may be used by multiple wholesalers.

What is the difference between a Health Industry Number (HIN) and a GLN?

While a HIN, provided by the Health Industry Business Communications Council (HIBCC), also is a standardized identifier that enumerates healthcare entities, it cannot be used with EPCIS. EPCIS, which the U.S. Food and Drug Administration (FDA) has recommended as the global standard to ensure compliance with the November 2023 requirement to provide serialized transaction information (TI) and transaction statements (TS), requires the use of a GLN.

Product tracing

What is the responsibility of the dispenser as it relates to product tracing when the new enhanced security requirements go into effect this November?

Traces are executed to support suspect and illegitimate, or recalled, product investigations. Requests may come from a regulatory agency, such as the U.S. Food and Drug Administration (FDA), State Board of Pharmacy (BOP), or an authorized trading partner. Dispensers are expected to respond with transaction information (TI) or transaction statements (TS) they received. They would be able to use the Cardinal Health web portal to search for the serialized transaction data and print a copy for the requestor.

Verification

What will the new requirements be as it relates to verification and what is my role as a dispenser?
Dispensers investigating suspect product must:

- Verify* the lot number.
- Verify the product identifier, including the standardized numerical identifier, of at least three packages or 10 percent of the suspect product, whichever is greater, or all packages, if there are fewer than three.
- Validate any applicable transaction history and transaction information in their possession.
- Otherwise investigate to determine whether the product is illegitimate product.

*Verify means determining whether the product identifier (2D barcode) affixed to a package corresponds to the National Drug Code (NDC), serial number, lot number and expiration date assigned to the product by the manufacturer. Customers may use a third-party solution provider to make the verification request though an automated system such as a Verification Router Service (VRS) or they may contact the manufacturer directly with a verification request. Wholesale distributors are unable to perform verification requests on behalf of customers.

Returns

How will the new requirements impact the returns process for a dispenser?
To comply with the law after November 27, 2023, Cardinal Health will need to confirm that the product being returned is a product that Cardinal Health sold to a customer with the corresponding transaction information (TI) or transaction statement (TS). We will only be able to accept a return into saleable inventory if we sold that specific GTIN (Global Trade Item Number), serial number, lot and expiration date to a customer. To support this process, Cardinal Health will add checks at the time of Material Return Authorization (MRA) requests to ensure the specific serial number being returned was sold to the customer returning the product.

How will the new requirements impact returns for 340B products?
After November 27, product returned to a wholesale distributor must be associated with the original TI and TS provided. To comply with enhanced requirements, 340B products must be returned under the 340B account. The return may not be submitted under the non-340B accounts at the same address and/or licensure.

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