

# Drug Tracing – Frequently Asked Questions

As of July 1, 2015, dispensers of prescription drugs have been required to access and have the ability to maintain for six years transaction information, transaction history and a transaction statement – collectively known as transaction data – for products eligible under the Drug Supply Chain Security Act (DSCSA).

Cardinal Health provides several resources, such as videos and a user guide, to help customers understand their requirements under the DSCSA. We will continue to provide updates as well as respond to questions that customers send to [drugtracing@cardinalhealth.com](mailto:drugtracing@cardinalhealth.com).

Click any of the below for answers to the most frequently-asked questions we have collected through recent webinars and feedback. This information does not constitute legal advice. Please seek legal counsel to determine how the law applies to your specific circumstances.

- **Enforcement Discretion**
- **DSCSA Product Exemptions**
- **Lot Number and Expiration Date**
- **End-User Agreement**
- **Leaving Cardinal Health**
- **Capturing and Maintaining Transaction Data**
- **Discrepancies**
- **Returns**
- **Purchases from Alternate Suppliers**
- **EDI ASN**
- **Cardinal Health Specialty Pharmaceutical Distribution**
- **Cardinal Health Medical Distribution**
- **Product Sharing/Borrowing**
- **Specific Patient Need**
- **Ambulance Services/EMS**
- **Providing Transaction Data for Subsequent Distributions**
- **PharMEDium**
- **Physician Offices and Clinics**
- **340B**
- **SafeCor**
- **White Bagging**
- **Additional Questions**

## Enforcement Discretion

### Didn't the July 1, 2015 deadline get extended due to Enforcement Discretion?

On October 29, 2015, the U.S. Food and Drug Administration (FDA) issued a guidance announcing that it was extending the previously issued Enforcement Discretion Policy from November 1, 2015 to March 1, 2016 because dispensers expressed that they need additional time. The FDA announced that it did not intend to take action against dispensers, who, prior to March 1, 2016 either accept ownership of product without receiving the transaction data or do not capture and maintain the transaction data.

## **DSCSA Product Exemptions**

### **Are over-the-counter (OTC) medications exempt?**

Yes. These products are outside the scope of the DSCSA. The DSCSA applies to prescription drugs in finished dosage form that are for human use.

### **Are radiological contrast agents exempt?**

Contrast media is considered an “imaging agent” and would be out of scope.

### **What about sample medications?**

The distribution of product samples by a manufacturer or a licensed wholesale distributor is not considered a transaction.

### **What fits into the “blood product” category? Is IVIG (immune globulin) and/or blood factors (factor VII – VIII – IX) considered in this category and exempt?**

No. Cardinal health is receiving and passing transaction data on IVIG (immune globulin) and blood factors.

### **Which IV solutions are exempt?**

Under the DSCSA, the definition of product does not include:

- Intravenous products that are intended for the replenishment of fluids and electrolytes or calories
- Intravenous products used to maintain the equilibrium of water and minerals in the body, such as dialysis solutions
- Products intended for irrigation, or sterile water, whether intended for such purposes or
- for injection.

### **Does Dermabond® fall into the exempt category?**

Yes. Dermabond® is considered a wound closure device, not a drug; therefore transaction data is not required.

### **Why do certain C5 scheduled drugs like Guaifenesin and Codeine Phosphate and Cheratussin AC not appear on the Track and Trace report?**

These products are OTC and therefore exempt. DSCSA applies to prescription drugs as defined by 503(b)(1). This definition refers to drugs that are not safe for use except under the supervision of a practitioner. If the FDA classifies an item as an OTC drug, even if it is customarily dispensed with an Rx, one is not required and it would not be in scope for DSCSA.

## Lot Number and Expiration Date

### **Please explain why lot numbers do not appear on the transaction data report for direct purchases by Cardinal Health.**

The transaction data report will not show lot number, previous transaction date or previous ship date if an asterisk (\*) appears next to the NDC. The asterisk indicates the product was a direct purchase. Under the DSCSA, when a wholesale distributor purchases “direct,” they receive a primary wholesaler allowance and are not required to include lot number, previous transaction date or previous ship date in the transaction data that they pass to customers. A wholesale distributor that purchases “direct” is buying from a manufacturer, a repackager that purchased direct or an exclusive distributor.

### **How will we respond to requests for information if we do not receive lot number?**

As dispensers, when responding to FDA requests, you do not need to provide the lot number as part of transaction history if it was not originally included in your transaction data report.

### **Why doesn't expiration date appear on the transaction data report?**

Expiration date is not a current regulatory requirement for transaction information under the DSCSA. But it will be a part of the product identifier (the 2D barcode that manufacturers will apply to each individual package) so the field is included on the report as a placeholder for future requirements.

### **Does Cardinal Health know what lot numbers they send to what institution?**

Cardinal Health tracks the inbound lot numbers of product received into our distribution centers, however we do not track outbound lots shipped to customers for product purchased direct.

### **When will lot number and expiration date be available?**

While manufacturers will affix the product identifier (2D barcode) that contains lot number and expiration date on their product beginning in November 2017, there is no requirement to exchange the unit level traceability information until 2023.

## End-User Agreement

### **Will Cardinal Health automatically retain the transaction data without a customer signing a written agreement?**

Customers do not have to enter into an agreement with Cardinal Health to view their transaction data, which is available today on Order Express or via the web portal on [cardinalhealth.com/trace](http://cardinalhealth.com/trace). We will maintain the information for six years and it will be accessible to customers at no cost regardless of whether they sign an agreement with Cardinal Health.

### **Why would I need to sign a written agreement?**

The DSCSA allows for dispensers to enter into an agreement with a third party, like Cardinal Health, to maintain the transaction data on their behalf. It is up to the customer to produce a copy of the agreement when/if a regulator asks for it. We created the End User Agreement for customers to use for that purpose.

### **Does Cardinal Health have a template of the written agreement that needs to be maintained?**

Yes. A copy is available on the Cardinal Health Pharmaceutical Tracing homepage, [cardinalhealth.com/trace](http://cardinalhealth.com/trace).

### **Who should sign the agreement? Where should we send the signed agreement?**

Customers who want to enter into the agreement can sign, date and retain it for their files. The agreement can be signed by any authorized representative of the customer. The signed agreement does not need to be returned to Cardinal Health. It is for the customer's benefit because it is up to the dispenser to produce the agreement when/if a regulator asks for it.

### **Does an agreement form need to be filled out for each account number or is it just by facility?**

One agreement for all the account numbers or for the entire health system would suffice. If there are multiple locations, each of the individual sites should have access to it.

### **Do we need to have signed agreement with the entities we supply to, such as EMS, etc.?**

No, you do not need to have a signed agreement unless you intend to maintain the transaction data on behalf of the entity.

## Leaving Cardinal Health

### **What happens if we terminate our service agreement with Cardinal Health? Will access to the reports still be available for six years?**

Access to the transaction data would not continue to be available via Order Express or Specialty Online. However, you have the ability to export your transaction data to an Excel or .csv file that you can upload into another database for future access.

## Capturing and Maintaining Transaction Data

### **How soon does transaction data get loaded to the portal and how often is the information updated?**

Transaction data is posted throughout the day as orders are invoiced and shipped so that information is available on the portal when customers receive their shipment.

### **How long do you retain the transaction data? Do we need to retain paper documents?**

We will automatically maintain transaction data for six years for eligible product you buy from Cardinal Health. The information is available online where you may access it at your convenience, so you do not need to print and store individual reports. However, you are responsible for maintaining transaction data for six years for any items you receive direct from the manufacturer or from a wholesale distributor other than Cardinal Health.

## Discrepancies

### **In the event that the initial transaction data is not accurate or complete, for example, a different number of packages are received vs. what is indicated in the transaction report, what is our reporting obligation or how is this corrected?**

In the event of a shortage, where the number of containers identified in the transaction information (TI) is more than the number of containers shipped, you would be able to receive the quantity shipped, because it has the required transaction data. You would use standard business processes to reconcile the quantity not received (i.e. call customer service to request a credit for product not received). For an overage, you would have the option to return the product or we would create a bill only transaction that would then post new transaction data to cover the amount of overage. Picking errors would be handled similarly to overages. Product could be returned or we would provide new transaction data to cover miss-picked item/lot via a bill only transaction. Transaction data for the bill only corrections will be available on Order Express so the audit trail will be preserved.

## Returns

### **What transaction data needs to be tracked for outdated medications returned to a pharmaceutical return program, waste company or reverse distributor?**

On non-saleable returns, a dispenser can return product to the wholesaler or, the manufacturer they acquired it from or to a return processor without the need to provide transaction data.

### **When a product is recalled, will we have to provide the transaction data when sending back the item?**

No.

## **Purchases from Alternate Suppliers**

### **How do alternate suppliers provide track and trace information to a pharmacy?**

Most of the large wholesale distributors are providing the transaction data either through a web portal, similar to Cardinal Health, or via an ASN 856. Most manufacturers have indicated that they will include the transaction data for direct shipments and drop shipments on the packing list shipped with the product. You should contact your trading partners to understand how they are providing the transaction data. Remember that you are required to maintain the transaction data received from alternate suppliers for six years.

### **Do we have to keep the actual packing slips or can we scan them into our shared drive?**

For purposes of maintaining the information, data can be either held in hard copy or filed electronically (including scanned documents.)

### **Are you developing functionality to allow customers to scan and upload packing lists for direct purchases to your server?**

Not at this time.

## **EDI ASN**

### **Please explain an EDI ASN.**

The 856 Advance Ship Notice (ASN) is a notification of pending deliveries, similar to a packing list but it is sent electronically via Electronic Data Interchange (EDI). The ASN format was modified to include additional fields so it could be used to transmit DSCSA TI/TH/TS. Our EDI team has begun work to modify our ASN 856 outbound maps to accommodate the required DSCSA information for shipments from Cardinal Health. If a customer prefers to receive the transaction data in this format instead of through the web portal, we can work with them to make the appropriate changes on their end to allow receipt of transaction data via an ASN 856.

## **Cardinal Health Specialty Pharmaceutical Distribution**

### **Will the tracing information be loaded for SPD items?**

Yes. Customers can access transaction data for Specialty Pharmaceutical Distribution (SPD) drop ships through their PD account number either through Order Express or the web portal, which is available from [cardinalhealth.com/trace](http://cardinalhealth.com/trace).

## **Cardinal Health Medical Distribution**

### **Our Material Management also receives IV fluids and some other product purchased through Cardinal Health Med/Surg. Is track and trace information needed for those purchases? What process is in place for them?**

If the IV product meets the exemption criteria listed above in the Product Exemptions section, you would not need transaction data. For any other product, the Cardinal Health Medical Distribution business segment and Baxter Healthcare are complying with the DSCSA by providing transaction data to customers on the outbound pack slip. This information is not maintained on the web portal.

## Product Sharing/Borrowing

### **What procedure do we use for borrowing from other hospitals?**

The DSCSA requires that when a dispenser transfers ownership of a product (not including dispensing or returns) they provide the subsequent owner transaction information, transaction history and a transaction statement, collectively known as transaction data. This does not apply to sales by a dispenser to another dispenser to fulfill a specific patient need. Also, if the entities involved are all under common control, then the distributions between them would exempt under the DSCSA.

### **Is there a definition of what is considered "common control" or affiliated facilities?**

Under the DSCSA, transactions do not include:

- Intracompany distribution of any product between members of an affiliate
- Distribution of a product among hospitals or other health care entities that are under common control
- The term "affiliate" means a business entity that has a relationship with a second business entity if, directly or indirectly
- One business entity controls, or has the power to control, the other business entity; or
- A third party controls, or has the power to control, both of the business entities.

### **If a hospital does not "sell" the drugs to a non-affiliated entity, does transaction data still need to be provided?**

A change of ownership can occur even if there is no financial exchange. The specifics of the situation should be reviewed by legal counsel to determine the appropriate action under the law.

### **If we borrowed some product from another hospital not related to our hospital, do we need to receive a copy of transaction data?**

Yes. You would need to receive transaction data from the other entity unless the product was borrowed for a specific patient need.

## Specific Patient Need

### **If a non-affiliated hospital asks to buy product specifically to fulfill an order they are dispensing to a specific patient, do we need to send transaction data with the product?**

No. Sales by a dispenser to another dispenser to fulfill a specific patient need are exempt. The term "specific patient need" refers to the transfer of a product from one pharmacy to another to fill a prescription for an identified patient. It does not include the transfer of a product from one pharmacy to another for the purpose of increasing or replenishing stock in anticipation of a potential need.

### **Do we have to document if a medication is obtained from another hospital if it was for a specific patient's need? Does the seller need to record the patient name?**

The law does not specify how to document specific patient need. No direction has been provided on needing the name of the patient – most likely due to HIPAA (patient privacy) requirements. Documenting that the receiving entity stated the need was for a specific patient should meet the requirement.

### **When returning a medication that was borrowed for a specific patient need, do we need to provide transaction data?**

When product is returned, it is no longer for a specific patient need. It is replenishing stock so the transaction data would need to be provided.

## Ambulance Services/EMS

### **Is it true that providing medications to ambulance services is now exempt from the track and trace requirements?**

On 2/29/16, the FDA posted new guidance called “Requirements for Transactions With First Responders Under Section 582 of the Federal Food, Drug, and Cosmetic Act—Compliance Policy; Guidance for Industry”. In this guidance, the FDA indicates that they do not intend to take action against a dispenser who does not provide product tracing information to first responders in certain situations, provided that:

- The dispenser captures and maintains the product tracing information for such transaction for not less than six years after the transaction.
- The dispenser provides such product tracing information to the first responder or secretary, if requested, not less than two business days after receiving the request.

This seems to imply that the enforcement discretion is really for the first responder – they do not need to receive, capture, or maintain transaction data – but the dispenser still needs to create and maintain it.

## Providing Transaction Data for Subsequent Distributions

### **What information needs to be transferred with the distribution of drugs from a hospital pharmacy to a non-affiliated entity?**

Transfer/sale of product to a non-affiliated entity is considered as subsequent distribution. When a dispenser further distributes product, they are required to provide the subsequent owner with transaction information, transaction history and a transaction statement, collectively known as transaction data.

### **Is there a standard form we should use if we are distributing to a non-affiliated facility?**

No. The DSCSA indicates that you must provide the subsequent owner with transaction information, transaction history and a transaction statement. Transaction Information includes:

- The proprietary or established name of the product
- The strength and dosage form of the product
- The NDC
- The container size
- The number of containers
- The lot number of the product
- The date of the transaction
- The date of the shipment, if more than 24 hours after the date of the transaction
- The name and address of the person from whom ownership is being transferred
- The name and address of the person to whom ownership is being transferred.

Transaction history includes the transaction information for each prior transaction going back to the manufacturer of the product. The transaction statement is a statement from the owner indicating adherence to DSCSA requirements.

### **Please give an example of the transaction statement that can be used when loaning product?**

The transaction statement is a statement that the entity transferring ownership:

- Is authorized (licensed)
- Received the product from an authorized person
- Received transaction information and a transaction statement from the prior owner of the product, as required
- Did not knowingly ship suspect or illegitimate product
- Had systems and processes in place to comply with verification requirements
- Did not knowingly provide false transaction information, and
- Did not knowingly alter the transaction history.

You may want to consider using the following abbreviated transaction statement: Seller has complied with each applicable subsection of FDCA Sec. 581(27)(A)–(G).

**Can we use Cardinal Health transaction data and forward it to a nearby facility when we send nonspecific patient need product or do we have to make our own sheet?**

The Cardinal Health transaction data report you received would include the prior transaction history for the product going back to the manufacturer, however you would still need to provide transaction information and a transaction statement for the transaction between the you and the other facility.

**Will you create a template form that we could send out if we further distribute product?**

You can create your own blank transaction data report from an existing Cardinal Health transaction data report.

- Open a report.
- Click the “export” icon in the upper left of the page.
- From the drop-down, change the file format to “Excel” and click “export.”
- An Excel file will open that contains the format and appearance of the original report. Replace the Cardinal Health specific information with the hospital information.

The blank template can then be used for future transactions with other entities. Remember, when filling out the blank form, the previous seller name and address should be Cardinal Health (if product was acquired from us) and the previous transaction date is when Cardinal Health sold the product to you. You could then attach the original Cardinal Health Transaction Report for the product to show the history going back to the manufacturer.

**Does the receiving entity have to sign this form every time we sell product to them?**

There is no requirement for a signature.

## **PharMEDium**

**What are the requirements for entities like PharMEDium, which do customized pharmacy sterile compounding for hospital intravenous and epidural therapies?**

Under the DSCSA, compounded drugs are exempt from the definition of product. That would likely capture a significant majority of the products they are distributing. In the event they are also distributing drugs that do not fall within the definition of compounded drugs, for those, they would need to provide transaction data.

## **Physician Offices and Clinics**

**How does the law affect physician offices or clinics?**

Physician offices or clinics licensed as a practitioner are included in the definition of dispenser under the DSCSA. But there is an exemption for licensed health care practitioners authorized to prescribe or administer medication under state law. Practitioners have no requirement to receive or capture transaction data, investigate suspect product or respond to requests for information. Practitioners are required to only do business with authorized or licensed trading partners.

Then in 2020, the requirement to trade only in serialized product (with a 2D barcode/product identifier) will also apply to a practitioner. Despite this exemption, distributors still need to provide transaction data to physician offices and clinics.

## **340B**

### **Please review how 340B contract pharmacies are affected?**

Under the DSCSA, Cardinal Health has the responsibility to provide the transaction data to the owner of the drugs, which is the covered entity (the Hospital). This creates complexity in the contract pharmacy environment where the contract pharmacy is not the true owner of the drug, but is actually housing and dispensing the product on behalf of the covered entity. Since the contract pharmacy never takes ownership – they only dispense the product to 340B program-eligible patients on behalf of the covered entity, they shouldn't need the transaction data, but they may want or expect it because they are the ones that have custody of the drugs.

The dispenser community recognized this challenge as it relates to the 340B contract pharmacy and asked the FDA to grant an exemption for 340B ship to/bill to arrangements.

On March 1, 2016, the FDA denied their request indicating that industry mechanisms already exist for entities to meet obligations to maintain tracing information. Specifically, Cardinal Health has implemented a report enhancement that enables us to share DSCSA transaction data with both the ship to (contract pharmacy) and sold to (covered entity) accounts via our online systems (Order Express, Specialty Online and the web portal available at [cardinalhealth.com/trace](http://cardinalhealth.com/trace).)

## **SafeCor**

### **If I ship to SafeCor (from my shelf) drugs I bought from Cardinal Health, do I have to send transaction data?**

As of July 1, 2015, if a dispenser transfers ownership (other than dispensing to a patient or returns), they would have to pass transaction data. If you are not transferring ownership to SafeCor and only using them for repackaging services, you would not need to provide transaction data.

### **Does SafeCor need to send the hospital any data?**

SafeCor would only need to provide transaction data if there was a change in ownership.

## **White Bagging**

### **Does a specialty pharmacy that is “white bagging” product to an infusion service have to provide transaction data?**

Anything that is received that is patient-specific would be out of scope for the DSCSA because at that point it is dispensing and not distribution.

## **Additional Questions**

### **Who can we contact if we have additional questions?**

You may send questions to the Cardinal Health Drug Tracing team at [drugtracing@cardinalhealth.com](mailto:drugtracing@cardinalhealth.com).