Myths vs. Realities about DSCSA[1]

MYTH 1 The DSCSA doesn't apply to dispensers.

Reality: False! Here are some of the DSCSA obligations for dispensers.

- Only purchasing covered products that have product identifiers unless the product is excluded, subject to a waiver or grandfathered per Section 582(d)(2).
- Accepting ownership of a product only when the previous owner provides, at the time of the transaction, transaction information (TI) and a transaction statement (TS) per Section 582 (d)(1)(A)(i). Until November 27, 2023, the seller must also provide applicable Transaction History (TH). After November 27, 2023, the seller must provide the product identifier for each package and homogenous case of covered products it sells to a dispenser in a covered transaction.
- Capturing and storing the Transaction History (TH), TI and TS for at least six years per 582(d)(1)(A)(iii). (Dispensers can contractually have a third party, like a wholesale distributor or service provider, hold a dispenser's transaction data for them, pursuant to a written agreement.)
- Responding to certain requests for information from the secretary (typically FDA) or another appropriate federal or state official within two business days, per Section 582 (d)(1)(D).
- Only transacting with trading partners who are Authorized Trading Partners, per Section 582 (d)(3).
- Having systems and processes to verify products, including conducting suspect product investigations, verifying the product identifier on suspect product and sending notifications of illegitimate products per Section 582(d)(4). Dispensers also must maintain these records for six years. In a suspect product investigation, beginning November 27, 2023, a dispenser must:
  - Be able to verify that the product identifier of at least three packages or 10 percent of such suspect product (whichever is greater) or all packages, if there are fewer than three, corresponds with the product identifier for such product;
  - Validate any applicable TI, TH and TS in its possession; and,
  - Otherwise investigate to determine whether the product is an illegitimate product.

MYTH 2 DSCSA applies to all medications provided for patient treatment.

Reality: False! The DSCSA applies to prescription drugs in finished dosage form that are for human use.

Over-the-counter (OTC) drug products, samples, medical devices, kits, medical gases and other products are outside the scope of the DSCSA.

1– This checklist is not intended to provide legal advice. The reader is cautioned that it cannot cover all elements of the DSCSA. Refer to FDA, the DSCSA (and implementing guidance) and/or to your own legal counsel for more information.

MYTH 3 I have to scan every product I receive.

Reality: It depends! There is no explicit requirement in the DSCSA that you scan every product on inbound.

Some dispensers may decide to do so for inventory control purposes. Trading partners do need to have received TI and TS for the covered products they purchased, and the FDA has stated that it expects trading partners to reconcile products to the data received. All trading partners must have systems and processes to ensure that they have received TI for the products they purchased.

MYTH 4 There's only one portal for sharing product data from the wholesale distributors to dispensers.

Reality: False! A portal is specific to transactions between a dispenser and its wholesale distributor.

Only the TI and TS for the products that a single wholesale distributor sells to that dispenser will be in the wholesale distributor's portal. A wholesale distributor's portal will only be for that dispenser customer and if a dispenser purchases from multiple wholesale distributors, it could have multiple portals maintained by each of those wholesale distributors.

A dispenser may elect to have a service provider hold all its transaction data, in which case all of that dispenser's wholesale distributors would send TI and TS to that repository.

MYTH 5 All transaction data will be automatically stored for dispensers and they have no real data storage requirements under DSCSA.

Reality: Not quite! Transaction data will be stored for a dispenser ONLY if it has a written agreement with its wholesale distributor or if the dispenser has arranged for its service provider to hold the data.

The parties should sign and date the agreement and the dispenser should retain a copy in its files. A dispenser must provide the agreement when/if a regulator requests it. Furthermore, if the dispenser has a data storage arrangement with a wholesaler or service provider, the dispenser still needs to know how to access and/or produce the data when necessary.

MYTH 6 I do not have to use EPCIS.

Reality: True! EPCIS is an international standard for exchanging data and it will be used by trading partners in the U.S. pharmaceutical supply chain to send and receive TI and TS.

The FDA has announced that it supports the use of EPCIS to satisfy 2023 requirements for the interoperable, electronic exchange of transaction TI and TS. Currently, trading partners across the supply chain are updating their data and systems to support EPCIS and are working together to enable the business-to-business connections for sending and receiving EPCIS files that will hold TI and TS, including product identifiers.

Some dispensers want to receive their TI and TS via EPCIS and are working with their suppliers to establish those connections. These dispensers will receive TI and TS and store it in repositories they or their service provider will maintain.

However, other dispensers are entering into written agreements with their suppliers through which the supplier will post TI and TS to a portal that the supplier maintains. That portal will have the TI and TS for the products that the supplier sold to that dispenser (and nothing else). You should speak to your wholesale distributor if you would like it to maintain a portal for the transaction data for the products it sells to you.

MYTH 7 Dispensers are required to provide transaction data for loaning and borrowing product to other pharmacies and hospitals and to be licensed as wholesale distributors.

Reality: True! The DSCSA requires that when a dispenser transfers ownership of a covered product to someone other than a consumer or a patient, the dispenser is engaged in wholesale distribution. The dispenser's distributor must be licensed as a wholesale distributor and provide the subsequent owner with TI, TH and TS until November 27, 2023 (and TI and TS thereafter).

There are certain exemptions where a dispenser can transfer ownership to someone other than a patient or consumer without being engaged in wholesale distribution. It is not wholesale distribution when you:

- Make an intracompany transfer to an affiliate;
- Sell to healthcare practitioners for office use if no more than 5 percent of your sales;
- Sell or loan product to another dispenser to fill a specific patient need; and,
- Transfer products among hospitals or other health care entities that are under common control.

Transferring ownership of products in a shortage situation is wholesale distribution unless the shortage is the result of a medical or public health emergency. There are other exceptions; talk to a knowledgeable advisor to make sure your sales activities are not wholesale distribution that require you to send TI and TS and be licensed as a wholesale distributor

MYTH 8 A dispenser will only be able to return products to a wholesaler if it provides TI and TS.

Reality: It depends! If you are returning a product to the wholesale distributor you purchased the product from, this is a saleable return and you do not have to provide TI and TS or be a wholesale distributor.

The wholesale distributor, though, will know whether it sold that product to you and won't and can't accept the product if it didn't. If you try to return the product to a different wholesale distributor, this is a transaction under the DSCSA, and you have to provide TI and TS and be licensed as a wholesale distributor.

MYTH 9 VRS is not required for dispensers.

Reality: True! In a suspect product investigation, beginning November 27, 2023, a dispenser must be able to verify the product identifier of at least three packages or 10 percent of such suspect product, whichever is greater, or all packages, if there are fewer than three, corresponds with the product identifier for such product. A dispenser could use the Verification Router Service, or VRS, to conduct this verification.

The VRS is a privately maintained and operated (though open source) network built by only a few manufacturer and wholesale distributor trading partners and service providers to enable verification of saleable returns. The goal of the VRS is for an authorized wholesale distributor or dispenser to be able to scan the identifier on a product and the VRS is able to route that query to a Look-up Directory that sends the query to the appropriate manufacturer's data repository, which then sends a response back to the initiating trading partner that the product identifier is (or is not) verified. You can speak to your service provider about participating in the VRS, or, you may be able to initiate a verification request manually, by contacting the manufacturer of the product. If you make a manual request, you can expect the manufacturer to confirm that you are authorized and that you have the product in your possession. The manufacturer will need all the information in the product identifier, including the Global Trade Identification Number (or GTIN), the serial number, lot number and expiration. All this information will be on the product label.

MYTH 10 Dispensers have no obligation to report suspect product.

Reality: True! However, while dispensers are not required to report suspect product, they MUST investigate suspicious or suspect products.

This investigation must include:

- Coordinating with the manufacturer;
- Verifying that the product identifier, including the standardized numerical identifier, of at least three packages or 10 percent of such suspect product, whichever is greater, or all packages, if there are fewer than three, corresponds with the product identifier for such product; and,
- Validating any applicable TI you have in your possession.

Upon completion of a suspect product investigation, if you have credible evidence that the product is illegitimate, dispensers have the obligation to report the illegitimate product within 24 hours to FDA on the Form FDA 3911 and ***"all immediate trading partners that the dispenser has reason to believe may have received such illegitimate product."***

MYTH 11 DSCSA does not apply to healthcare practitioners who may be responsible for dispensing and/or administering a drug.

Reality: True! This is outlined under section 582(d)(5) in the law.

"Notwithstanding any other provision of law, the requirements under paragraphs (1) and (4) shall not apply to licensed health care practitioners authorized to prescribe or administer medication under State law or other licensed individuals under the supervision or direction of such practitioners who dispense or administer product in the usual course of professional practice."