DSCSA FAQs - Frequently Asked Questions

What is DSCSA?

The Drug Supply Chain Security Act (DSCSA), outlines critical steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States. Its goal is to enable complete tracking of a product from the manufacturer to the dispenser. Information about each previous owner of a product must be forwarded to the new owner and this continues all the way to the dispenser.

This is sometimes referred to as Track & Trace or ePedigree.

It was signed into law on November 27, 2013. The official wording for DSCSA is at: http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm376829.htm

It is Title II of the Drug Quality and Security Act (DQSA). The DQSA is a set of federal prescription medication safety regulations made to primarily address the issue of counterfeit and illegitimate medications. Also in response to compounded medications such as what caused the New England Compounding Center (NECC) meningitis tragedy.

Implementation of DSCSA is a 10 year process. As part of this manufactures are required to place a scannable 2D barcoded product identifier on the product. The DSCSA regulations require that manufacturers place a serial number on each package by November 27, 2017.

By November 27, 2017 all of the Track & Trace information (transaction data, transaction history and transaction statement together known as T3) must be available electronically.

It will eventually lead to a better drug recall process because the location of each lot and serial number of a drug will be known. Who owned a product throughout its lifespan will also be known.

New parts of the regulations roll out every year until 2023.

Is there a link to the DQSA regulations?

Yes, it is at:
https://www.gpo.gov/fdsys/pkg/PLAW-113publ54/pdf/PLAW-113publ54.pdf

When does DSCSA take affect?

The full regulations take affect over several years. The initial requirements for manufacturers started January 1, 2015. On July 1, 2015 dispensers needed to be able to receive and archive Track & Trace information and be able within 48 hours to provide the Transaction Statement (T3) information for any medication to federal investigators. The actual enforcement of the dispenser's requirements started March 1, 2016.

What is the definition of a Dispenser?

A dispenser is anyone that dispenses prescription products to a patient. For example:

A retail pharmacy, hospital pharmacy, a group of chain pharmacies under common ownership and control that do not act as a wholesale distributor, clinics, long-term care facilities or any other person authorized by law to dispense or administer prescription drugs (physician, nurse practitioner etc.), and the affiliated warehouses or distribution centers of such entities under common ownership and control that do not act as a wholesale distributor.

What is the definition of a Wholesale Distributor?

- A entity/person (other than a manufacturer, a manufacturer's co-licensed partner, a third-party logistics provider (3PL) or repackager) engaged in wholesale distribution (as defined in the DSCSA and FD&C Act)
- Wholesale distribution is distribution of an Rx product to an entity/person other than a patient

Is there anything I need to do with the track and trace information when we receive our order?

Yes, you must compare the track & trace information against the product that was shipped to them. This adds a step to your product receiving procedures. You should ask yourself things like:
"Do the products listed and the quantities for each match?
"Does anything look suspect / questionable, could it be counterfeit or improperly stored before or during transported to you."

You need to have SOP outlining how your staff is to deal with discrepancies.

Who do these regulations affect?

Any organization that is a new owner of a prescription product when they take possession of it. For example: Manufacturers, wholesalers, repackagers, local outpatient pharmacy, inpatient pharmacy such as a hospital pharmacy. *Note: Transferring product between locations owned by a single entity does not require the transaction information to be forwarded to the new location.*

What is a general timeline from for the DSCSA's various parts implementation?

January 1, 2015: All trading partners must have a process and procedures in place to identify/quarantine suspect & illegitimate product. Dispensers purchase only from authorized trading partners

July 1 2015: Dispensers must be able to receive and store TI/TH/TS (T3) documentation
Must store this information for 6 years. The dispenser may use a third party to hold the documentation. There must be a written agreement between the dispenser and third party

November 27, 2017: Manufacturers must affix a product identifier to each individual package and homogenous case

November 27, 2017: Manufacturer shall provide the transaction information, transaction history, and transaction statement in an electronic format.

November 27, 2018: Repackagers must affix a product identifier to each individual package and homogenous case

November 27, 2019: Wholesale distributors must only buy & sell products or accept return of products that contain the required product identifier; and verify the product identifier before redistributing the returned product

November 27, 2020: Dispensers may only buy products that contain the required product identifier. You must save the serial number because officials may now ask for documentation based on the serial number.
Additional requirements start for investigating suspect and illegitimate products

November 27, 2022: FDA completes small business assessment

November 27, 2023: Unit level traceability. The TI documentation must include the product identifier. Additional requirements start for investigating suspect and illegitimate products

What is a "product identifier"

The DSCSA requires drug manufacturers and repackagers (as defined in sections 581(10) and 581(16) of the FD&C Act, respectively) to affix or imprint a ***product identifier*** on packages for certain prescription drugs for human use. Under section 581(14) of the FD&C Act, a "product identifier" is a standardized graphic that includes, in both human-readable form and on a machine-readable data carrier, the "standardized numerical identifier," lot number, and expiration date of the product. The standardized numerical identifier, a component of the product identifier, is comprised of the NDC and a serial number.

May a dispenser return a product?

Yes under the following conditions

1) A dispenser may return a product to the trading partner from which the dispenser obtained the product without providing the product's TI/TH/TS (T3) documentation
2) A dispenser may return a product to the trading partner from which the dispenser DID NOT obtained the product as long as they provide the trading partner with the product's TI/TH/TS (T3) documentation

How do I handle products returns?

You do not need to provide the Track & Trace information for:

Saleable product - If it is being returned to the original supplier

Non-saleable product – Items that are damaged, expired or soon to be expired may be returned to the original supplier or to a returns processing company.

If I return an item or send it to a returns processor do I need to keep a Track & Trace record of having done so?

By law you are not required to do so, however, as a matter of caution you may want to. In the case of an official request for information about a medication you can provide a complete answer as to where all of it is or has gone.

May I sell or trade items?

Yes, however you will need to provide the new owner with the proper Transaction (T3) information.

Does the Transaction (T3) information have to be supplied with the product as it is transferred between locations within our organization?

No, the information may be stored at a single location. However, it needs to be accessible within 48 hours to the dispensers at any location in case that location is visited by officials. Electronic records of the Transaction (T3) information makes this simpler.

What happens if we do not comply with the DSCSA requirements?

Failure to comply with a DSCSA requirement is a prohibited act" under the FD&C Act. Commission of a prohibited act subjects a party to:

- Civil and criminal fines and penalties. This may include jail.
- Injunction of unlawful activity
- Seizure of goods

May also involve state penalties.

Are there any videos about DSCSA

Yes, here is a list of some.
http://www.healthcaredistribution.org/publications/webinar-dscsa-for-association-partners

What types of products does DSCSA NOT require tracking of?

Blood or blood components, Compounded drugs under 503A or 503B, Homeopathic drugs, Imaging drugs including imaging intravenous products, Medical Gases, non-prescription drugs

What is the Track and Trace information made up of?

There are 3 main components and these are required to be provided in a single document (paper or electronic):

Transaction information (TI):

Name of the product, strength, dosage form, NDC#, container size, number of containers, lot numbers*, transaction date*, shipment date (if more than 24 hours after the Transaction date), name & address of the previous owners and purchaser

* Wholesalers that purchase directly from a manufacturer, an exclusive distributor of the manufacturer, or a re-packager that purchased directly from a manufacturer are exempt from providing these data elements

Transaction history (TH) – Paper (allowed until 4/27/2017) or electronic statement that includes the transaction information for each prior transaction for a product back to the manufacturer.

Transaction statement (TS) – Paper or electronic attestation by the entity transferring ownership of the product that it:

- Is authorized under the Act
- Received the product from an authorized party
- Received the TI and TS from the previous owner of the product
- Did not knowingly ship suspect or illegitimate product
- Selling entity has systems and processes in place to perform verification

- Selling entity did not knowingly provide false transaction information and did not alter the transaction history

An example statement is:
"Seller has complied with each applicable subsection of FDCA Sec. 581(27)A through (G)."

Is this a boring topic?
YES, but we have to know it and comply with the regulations

I have received a request from the FDA for information on a particular lot number of a drug, what do I have to do?

If the FDA or other agency requests information you must provide that information to the agency requesting within 2 business days.

What type of barcode scanner will I need to read the new square barcode?

You will need a two-dimensional (2D) barcode reader. The manufacturers are required to place a 2D matrix barcode on the product by November 2017. It needs to contain the NDC #, lot number, expiration date and eventually a serial number.

What type of barcode does the DSCSA require the manufacturer to place on its products?

The manufacturers are required to place a 2D matrix barcode on the product by November 2017. It needs to contain the NDC #, lot number, expiration date and eventually a serial number.

How long must I keep the Track & Trace information?

You must retain the information for 6 years minimum, starting from the date you received the product.

What form do I have to save the Track & Trace (T3) information in?

The records may be in electronic or paper form.

May I transfer a product to a different, non-related pharmacy?

Yes, however you must provide the Transaction information for the product to the new pharmacy unless the medication is for a specific patient. All of the information must be contained in a single paper or electronic document.

If I transfer a medication to another location or owner should I make a record of the transfer?

Highly recommended that you do so that if you are asked by officials about the medication you can provide a complete answer as to where all of it is or has gone.

Do I have to provide the track & Trace information for products I provide to non-related licensed practitioners offices for office use?

If the product is provided in minimal quantities you do not.

How do I access the Transaction (T3) information

WWW.T3Rx.com is accessed using a supported web browser.

Do I have to do anything to update T3Rx.com?

No, since it is a web based application we do all of the updating.

Why should I use T3Rx.com?

Now that the 1st part of the DSCSA regulation's enforcement started on March 1, 2016 if you take possession of a medication you need to be compliant with the most current regulation. We are a one stop shop for becoming compliant.
Our DSCSA prescription drug track and trace compliant software is offered as Software-as-a-Service (SaaS) solution. It also enables you to track your loan and barrows with other hospitals, post for sale your overstocks and short dated drugs and purchase other's overstocks and short dated drugs. We enable the appropriate electronic transfer and receipt of the track and trace documentation when you loan, barrow, buy or sell drugs.

Remember, federal investigators at any time could ask you to show them by lot number the Track & Trace history for a medication.

What is Drug Serialization?

Over the next few years each medication package will have a unique serial number along with a lot number. For example the manufacturer makes 1000 vials of a particular lot number. Each vial of that lot number will also have its own unique serial number.

What role do the wholesalers have in storing the track and trace information?

Wholesalers are required to store the track and trace information for the medications you receive from them, however, most hospitals receive medications from more than just their primary wholesaler.

The RxScan T3 Repository is a central repository of all of your track and trace documentation regardless of where you received the medication from. Because we have an Electronic Date Interface (EDI) interface with all of the major manufacturers and wholesaler if you switch suppliers you do not have to worry about storing the track and trace information from any previous supplier.

Additionally, they typically will not help you with other parts of the regulations such as the documentation of suspected medications and their quarantine documentation.

What suppliers, (wholesalers, manufacturers, distributors) does RxScan's T3Rx.com gather track and trace information from?

We interface with all suppliers. By November 27, 2017 all manufacturers, suppliers, wholesalers and distributors are required to supply the information electronically.

Do the wholesalers charge me for access to the T3 information?

No, they provide this information by EDI as part of the services they provide their clients. We query their ordering system to receive a copy of the track and trace information for the orders you receive from them.

What do I do if I receive a drug that I suspect may be illegitimate/counterfeit?

You are required to have a process to identify and quarantine any suspected medications. You must notify your supplier and the FDA. Also, you must keep your records on a suspect product for 6 years after the investigation of the product is complete. The means you will keep the information longer than the original 6 years that started when you first receive the product. (Link to government information on Identification of Suspect Product & Notification.

https://www.fda.gov/media/88790/download

How long does it take to get T3Rx.com setup with our suppliers?

After the contract is signed and you have supplied us with your list of suppliers typically 10 -14 business days are needed to bring your suppliers with EDI capability on line. As part of the process we request your historical information from them. This is done so that the T3Rx.com track and trace repository has your historical purchase information for medications purchased from them. You may have to "encourage" them to supply all of your historical information.

Can I see a demo?

Absolutely, please contact us to schedule one. 800-572-2648 x 2

What does a subscription to T3Rx.com cost?

Please contact us so we can discuss your needs? 800-572-2648 x 2

How do I get started?

Please contact us so we can walk your through the subscription process. 800-572-2648 x 2

