How does this new DSCSA law relate to previous "pedigree" or "Epedigree" requirements?

Before this federal law was signed, a few states had enacted their own product traceability laws known as a "pedigree" (e-pedigree or electronic pedigree) requirements. E-pedigree is an electronic document which provides a history trail of a particular batch of prescription drugs. This trail shows transactions for every change of ownership in a supply chain. DSCSA preempts any state pedigree requirements and replaces them with new federal 3T's track and trace requirements.

What are the potential penalties of noncompliance with DSCSA?

FDA and state governmental authorities have broad discretion under the Food, Drug & Cosmetic Act to enact a wide range of penalties for violation of DSCSA, however exact guidance on any penalties has yet to be announced.

INFINITRAK
Track & Trace with Infinite Reach

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The following are the various definitions of Trading Partners:

Manufacturers: A person (or co-licensed partner or affiliate) who holds an application approved under section 505 of the law or a license issued under section 351 of the Public Health Service Act for such product, or if such product is not the subject of an approved application or license, the person who manufactured the product. Generally, includes a NDA holder – (New Drug Application); ANDA Holder – (Abbreviated New Drug Application) or BLA Holder – (Biologic License Application).

Repackagers: A company that repacks and re-labels a product or a package for sale or for distribution. This also includes in-house repackaging departments within hospital networks.

Dispensers: A company that dispenses drugs directly to patients, such as a retail pharmacy, hospital pharmacy, a group of chain pharmacies under common ownership and control that do not act as a wholesale distributor, or any other person authorized by law to dispense or administer prescription drugs, and the affiliated warehouses or distribution centers of such entities under common ownership and control that do not act as a wholesale distributor.

Wholesale Distributors: An organization or company that engages in wholesale distribution of prescription drugs.

Third-Party Logistic Provider (3PL): An entity that provides or coordinates warehousing or other logistics services of a product on behalf of other organizations but does not take ownership and disposition of the product.

Trading Partner: A manufacturer, repackager, wholesale distributor or dispenser who accepts direct ownership of a prescription drug. Additionally, 3PLs who accept direct possession but not ownership of the product are identified as a second type of Trading Partner.

DSCSA Compliance Timeline

November, 2014
FDA published guidance sets standards for interoperable exchange of product tracing information at lot-level.

January 1, 2015
Manufacturers are required to provide 3T data of their drug product at a lot level to downstream stakeholders.

– This info can be in paper or electronic method as long as it is "interoperable" until cutover to all electronic transmission in **2017**.

– All trading partners, including dispensers, will be required to only conduct business with authorized wholesalers and have a process to validate a trading partner's credentials.

– All trading partners must identify suspect products, have a process in place to conduct an investigation and provide transactional data within **1 business day** but not to exceed **48 hours** upon FDA request.

July 1st, 2015
FDA began enforcement of 3T data transmission by manufacturers and distributors. Additionally, dispensers must be able to receive 3T data and store it for **6 years**.

March 1, 2016
FDA began enforcement of 3T data collection requirements for dispensers.

November 2018
Manufacturers will need to encode their products with a unique identifier paving the way for serialization and verification at the package level.

November 2019
Distributors transact only serialized product
Returns are verified

November 2023
Products will need to be serialized at the unit level for track and trace.

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Drug Supply Chain Security Act (DSCSA) Pocket Guide

An Overview of New FDA Regulations

The Drug Supply Chain Security Act (DSCSA) is a new law that is being implemented by the FDA. It outlines critical steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States.

Ten years after enactment, the system will facilitate the exchange of information at the individual package level about where a drug has been in the supply chain.*

This is a complex law and brings significant change to the way most pharmacies will track and trace their products. As of March 1, 2016, traceability requirements are in place and being enforced. This pocket guide is a first step in understanding the regulations and enabling your organization to be compliant.

***http://www.fda.gov/drugs**

What is the Drug Supply Chain Security Act (DSCSA)?

On November 27, 2013, President Obama signed into law The Drug Quality and Security Act (DQSA) as an ambitious overhaul of federal drug safety regulations. The second half of this new law, Title II of the DQSA, is known as the Drug Supply Chain Security Act (DSCSA). The DSCSA outlines the incremental requirements necessary to build a national electronic interoperable system over the next decade that can track and trace types of prescription drugs as they are sold and distributed in the United States.

Who needs to comply with the Drug Supply Chain Security Act?

- **Manufacturers**
- **Repackagers**
- **Dispensers**
- **Wholesale Distributors**
- **Third-Party Logistic Providers (3PL)**
- **Trading Partners**

Any company involved in the sale or purchase of prescription drugs (commonly known as a Trading Partners) has specific mandates under the DSCSA. DSCSA's impact is vast and spans from manufacturers to nonobvious entities at the end of the supply chain that store and dispense pharmaceuticals, such as nursing homes, assisted living facilities, and physicians selling retail products from their offices.

What are the basic requirements of DSCSA?

The DSCSA contains three basic requirements:

Verification
Establish a process to verify Trading Partners are authorized and properly licensed to sell/trade pharmaceuticals

Transaction Data Capture/Retention
Receive track and trace transactional data and store such information with ready access for 6 years

Quality Inspection and Reporting
Establish a process to inspect, investigate and quarantine any suspect or potentially adulterated or counterfeit product and quickly communicate this information up and down the supply chain

The FDA announced two delays in enforcement of transaction data product tracing requirements for dispensers which went into effect July 1, 2015. As of March 1, 2016, all delays have expired and all Trading Partners, including dispensers, are required to comply with all aspects of the law.

What are the new track and trace transaction data requirements?

DSCSA requires the logging and record maintenance of all pharmaceutical product change of ownership information. Just as a car title keeps record of every prior owner of a motor vehicle and the date of sale, the transaction data will identify every change of ownership for pharmaceutical products throughout the supply chain. The exchange of transaction data may initially be made via paper but will be required to be transmitted in electronic format by November, 2017.

For the first 10 years of this law, data will be tracked and traced at the lot level but thereafter will be tracked down to the unit level. The transactional data must be stored for a period of 6 years and remain retrievable within 24- 48 hours.

The transaction data, nicknamed 3T's, is further defined as Transaction Information (TI), Transaction History (TH), Transaction Statement (TS).

Transaction Information (TI): Basic informational data of the product, including product name, unit numbers, strength, dosage, size, NDC, container size and numbers, lot number, transaction date, shipment date, business names of seller/ purchaser.

Transaction History (TH): A statement in paper or electronic form, including the Transaction Information for each prior transaction going back to the manufacturer of the product. It is important to note that there is an exception in TH requirements for a wholesale distributor who bought the drug *directly from the manufacturer*. A direct purchase wholesale distributor is not required to pass along manufacturers' lot number and transaction/shipment date. Instead, the TS from the wholesale distributor must indicate that the drug was acquired directly from the manufacturer.

Transaction Statement (TS): A statement, in paper or electronic form, in which transferring entity verifies:

- entity transferring ownership in a transaction is authorized
- entity receiving product is authorized
- entity received Transaction Information and Transaction Statement from the prior owner of the product
- entity did not knowingly ship a suspect product or illegitimate product
- entity had systems and processes in place to comply with DSCSA verification requirements
- entity did not knowingly provide false Transaction Information
- entity did not knowingly alter the Transaction History
- In some cases, an indication that the entity, or an affiliate, purchased the product directly from the manufacturer, exclusive distributor or re-packager that purchased the product directly from the manufacturer.

The Transaction Statement acts as a certification that all DSCSA due diligence requirements have been met.

What formats are acceptable for transfer of Transaction Data between Trading Partners?

Transaction Information can be transferred between Trading Partners in the following formats:

- Paper
- Invoice
- PDF
- Email
- Web Portal
- Electronic Data Interchanges (EDI) standards – such as Advance Ship Notice (ASN)
- Electronic Product Code Information Services (EPCIS)

All of the above transport methods are valid as long as the information is captured, maintained, and provided in compliance with section 582 of the law.

The FDA requires that the exchange of tracing information must encompass "interoperability," which is the ability to exchange tracing information accurately, efficiently and consistently among trading partners to maintain product tracing information in paper or electronic format.