The Drug Supply Chain Security Act (DSCSA) (DSCSA)  
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In November 2013, the Drug Supply Chain Security Act (DSCSA) was signed into law. The purpose of the law is to protect consumers from drugs that may be counterfeit, stolen, contaminated, or otherwise harmful. The law requires tracing of certain prescription drugs throughout the supply chain in order to:

• Enable verification of the legitimacy of drug products,  
• Enhance detection and notification of illegitimate products, and  
• Facilitate a more efficient drug recall process.  

Specific requirements of the law will be phased in over a 10 year period. Requirements that go into effect in 2015 include the following:

• Provide transaction information, history, and statements for each drug transferred/sold  
• Quarantine and investigate suspect products  
• Notify the FDA and trading partners if illegitimate product is found  

Drug Product Tracing  
The DSCSA requires “trading partners” to provide product tracing information (including lot number) to the receiving party that includes information about each prior transaction back to the manufacturer. The information may be in paper or electronic form. Trading partners are manufacturers, repackagers, wholesale distributors, third party logistics (TPL) providers, and dispensers (including pharmacies). Transactions are any transfer of a product where a change of ownership occurs. Products covered by this law are prescription drugs in finished dosage forms for administration to patients without further manufacturing (e.g., tablets, capsules, liquids, powder for reconstitution). In addition, trading partners are required to keep product tracing information for at least 6 years after the date of the transaction.

There are certain types of drug products and transactions that are exempt from the DSCSA. Drug products exempt from the requirements include the following:

• Blood or blood products intended for transfusion  
• Imaging agents  
• Radioactive drugs and biologics  
• Medical gases  
• Homeopathic drugs  
• Certain IV products (e.g., plain IV fluids, dialysis solutions, irrigation solutions)  
• Compounded drugs  

Transactions exempt from the law include, but are not limited to the following:

• Drugs dispensed for a prescription to a specific patient  
• Distribution among hospitals under common control  
• Distribution of drug samples  
• Minimal quantities by a licensed pharmacy to a licensed practitioner  
• Public health emergencies  

Investigating and Reporting Suspect Products  
Trading partners, including pharmacies, must implement systems to quarantine and investigate suspect products.
Suspect products are those for which there is a reason to believe they are potentially counterfeit, diverted, stolen, adulterated, subject of a fraudulent transaction, or appear otherwise harmful. Suspect products must be quarantined and an investigation conducted to determine if they are any of the above. If a product is determined to be illegitimate, the FDA and all trading partners of the product must be notified within 24 hours. The FDA is notified by completing Form FDA 3911.

Ways to identify and assess suspect products include the following.
- Discuss observations and concerns about suspect product with trading partners
- Contact regulatory authorities, law enforcement, or other resources to aid in the determination, if needed
- Education and vigilance of staff to identify suspect products

A key component to identifying suspected products in pharmacies is ongoing vigilance by all staff, not just the purchasing manager. Policies and procedures should be developed outlining systems for the verification and handling of suspect and illegitimate products. Staff should be oriented to the policies and procedures and educated about strategies to identify suspect products. Notices and other information received from trading partners and regulatory agencies regarding stolen, counterfeit, diverted, and adulterated drugs should be shared with staff.

Strategies staff can use to identify potential suspect products include the following:
- Watch out for offers of products at low prices that are "too good to be true", especially from a source that you have not done business with before.
- Examine the package and transport container for irregularities such as
  - Signs of compromised integrity such as broken or repaired seals
  - Package inserts missing or do not correspond to the product
  - Shipping addresses, postmarks, or other signs indicating the product came from an unexpected source
- Examine the labels on the package and the individual drug containers for
  - Missing information such as lot number, NDC number, or strength of drug
  - Misspelled words
  - Lack of an Rx symbol
  - Foreign language with little or no English
  - Product name differs from FDA-approved drug or is the product name for a foreign version of the drug
  - Lot numbers and expiration dates on product containers do not match lot numbers and expiration dates on outer carton
- Look for finished dosage forms that are suspicious (e.g., different shape, imprint, or color from FDA-approved product, tablets with chipped coatings)

Additional resources and information about the DSCSA are available at

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1. T  F  The DSCSA applies to all drug products.
2. T  F  Repackagers of drug products are exempt from the requirements of the DSCSA.
3. T  F  Pharmacies must quarantine and investigate drug products suspected of being counterfeit.
4. T  F  If a drug product is determined to be stolen or diverted, the FDA and all trading partners of the product must be notified.
5. T  F  A strategy to identify potential suspect drug products is to examine the package or container label for missing or incorrect information.

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