The Drug Supply Chain Security Act: Improving the Integrity of Drug Distribution

Post-test/Rationale

EDUCATIONAL OBJECTIVES

Upon completion of this activity, pharmacists and pharmacy technicians should be able to:

1. Review how the Drug Supply Chain Security Act (DSCSA) will improve the integrity of the drug supply distribution chain;
2. Describe the “track and trace” language in the DSCSA;
3. List DSCSA requirements and their effective dates;
4. Explain what documentation has to “move” with the product; and
5. Describe methods for identifying suspect product delivered to the pharmacy.

1. The Drug Quality and Security Act of 2013:

A. Has 3 Titles
B. Has a Title for Product Returns
C. Has a Title for Barcoding
D. Has a Title for Drug Tracking and Tracing***

Correct answer: D

The Drug Quality and Security Act has the following 2 titles: Title 1 of the DQSA addresses compounding provisions through the Compounding Quality Act (CQA); Title 2 of the DQSA is the Drug Supply Chain Security Act and it creates a uniform, national standard for tracing pharmaceutical products through the supply chain.
2. Under *Drug Supply Chain Security Act (DSCSA)* requirements, dispensing pharmacies must:

A. Keep a transaction history for products they buy starting July 1, 2015***

B. Establish systems to verify products and handle suspect or illegitimate products by December 31, 2014

C. Verify that trading partners have a valid license and/or registration by federal or state law by March 1, 2015

D. Engage in transactions with only serialized product by November 27, 2023

**Correct answer: A**

By July 1, 2015, dispensers must be able to receive tracking and tracing documentation, capture information, and maintain documentation for 6 years.

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3. The DSCSA addresses which of the following?

A. Traceability: It establishes a national system for tracing pharmaceutical products through the supply chain

B. Licensing: It sets national licensing standards for wholesale distributors and third party logistics providers (3PLs)

C. Preemption: It immediately preempts all state laws and regulations for pedigree requirements and state laws on wholesale and 3PL licensure

D. All of the above***

**Correct Answer: D**

The DSCSA immediately preempts any and all state requirements that differ from the federal language. It begins the transitions to lot-based tracing and then to serialized item traceability over a 10-year period that impact all supply chain members: manufacturers, wholesalers, 3PLs, repackers, and
dispensers. The DSCSA also establishes federal licensure standards for wholesalers and it creates a federal license for states that opt not to conform and license wholesalers on their own.

4. To which of the following has the FDA extended enforcement discretion until November 1, 2015?

A. Requirement to only purchase from authorized trading partners
B. Record-keeping for purchases under DSCSA***
C. Quarantine of suspect product
D. Record-keeping for sales under the DSCSA

Correct answer: B

Because many dispensers may not be aware of or ready to comply with the DSCSA provisions for tracing, on June 30, 2015, the FDA announced that it does not intend to take action against dispensers who, prior to November 1, 2015, accept ownership of product without receiving the product tracing information required by the DSCSA.

5. Which of the following situations requires a pharmacy to create a DSCSA document?

A. Selling an overstock drug to another pharmacy for an anticipated need***
B. Transferring a drug to another unrelated pharmacy for a “specific patient need”
C. Transferring a drug to a related pharmacy
D. Sending a unsaleable drug to a reverse logistics processor

Correct answer: A

There are several exceptions to the DSCSA tracing requirements, including pharmacy sale to another pharmacy for a “specific patient need.” A specific patient need means that an identified patient exists; it does not include transfers for the purpose of increasing or replenishing the quantity of a product in anticipation of a potential need. If a drug is sold for an “anticipated need,” normal record-keeping requirements would be in effect.
6. What is the DSCSA definition of a saleable return under the DSCSA?

A. Sending a drug to a reverse logistics provider
B. Sending a drug to a licensed distributor
C. Sending a drug to the immediate trading partner from it came
D. Sending a drug to the manufacturer

Correct answer: C

For saleable returns, a dispenser may return product to the trading partner from whom they purchased the product without providing the requisite information. For non-saleable returns, a dispenser may return product to the manufacturer or repackager, to the wholesale distributor from whom the product was purchased, to a returns processor, or to a person acting on their behalf without providing the requisite information.

7. How long must a dispenser maintain DSCSA records?

A. 2 years
B. 4 years
C. 6 years
D. 8 years

Correct answer: C

Each seller must provide the transaction information (TI), transaction history (TH), and transaction statement (TS) to the subsequent owner for each transaction and each buyer must store the TI, TH, and TS that it receives. These records must be store by each for a period of 6 years.
8. Which of the following is not part of the DSCSA tracing requirements?

A. Transaction information
B. Transaction summary
C. Transaction history
D. Transaction statement

Correct answer: B

The transaction records that are part of the DSCSA’s tracking and tracing requirements are 3-fold: transaction history, which refers to who has owned the product; transaction information, which refers to product description or other identifiable information; and transaction statement, which is a statement attesting that the transaction is correct and that the information is accurate.

9. The pharmacy provisions of the DSCSA that became effective on July 1, 2015 require a pharmacy not to accept ownership of a product unless the previous owner provides transaction history, transaction information, and a transaction statement.

A. True
B. False

Correct answer: A

As of July 1, 2015, dispensers must be able to receive tracking and tracing documentation, capture information, and maintain documentation for 6 years.
10. Which of the following is not a step a pharmacist or pharmacy technician may take to identify suspect product?

A. Carefully examining packages that are delivered to the pharmacy when unpacking orders

B. Buying from the least expensive source of supply and taking advantage of caller “specials”***

C. Avoiding purchasing deals that seem “too good to be true”

D. Looking at the product during the filling process and being alert to the altered appearance of a product

Correct answer: B

Pharmacists and pharmacy technicians play an important role in helping to identify suspect product by using several strategies that the FDA recommends in the guidance. In particular, the pharmacist should be alert for offers of product for sale at a very low price or an offer that is “too good to be true.” When receiving product, the pharmacy technician should closely examine the package and the transport container to look for signs that it has been compromised, see if it has changed since it was last received for an unexplained reason, see if product inserts are missing or do not correspond to the product, and look for shipping addresses, postmarks, or other materials indicating that the product came from an unexpected foreign entity or source.