Pharmacy Law Home Study for Pharmacists and Pharmacy Technicians

“The History and Implications of the Drug Supply Chain Security Act”

UAN #0374-0000-16-030-H03-P-T (Knowledge-Based CPE Activity)

No sponsorship was received for this law program

Program Goal and Objectives
The purpose of this home study activity is to provide comprehensive education for pharmacists on the history and implications of the Drug Supply Chain Security Act (DSCSA). In this activity, the key factors that led to the DSCSA are discussed including the drug shortage epidemic and its potential cause and impact leading to a response from the government; generic price increases warranting FDA action and Congress intervention; and the gray market various states and wholesalers.

At the completion of this program pharmacists will be able to: explain the history of the Drug Supply Chain Security Act and the new requirements imposed by the Act; define key terms, including pedigree, Drug Supply Chain Integrity, and product tracing; describe the gray market that has emerged and its meaning in the legal and ethical context; explain the clinical and economic impact of drug shortages.

At the completion of this program pharmacy technicians will be able to: summarize processes to secure the drug-supply chain, prevent harm from counterfeit drugs, and to understand and adhere to the new “Track and Trace” provisions of the Drug Supply Chain Security ACT; explain the impact of the Act as it relates to the pharmacy’s relationship with vendors, patients, and third party insurances; apply good practices to prevent legal issues in the purchase of medications.

Continuing Education Credit:
Release Date: 10/07/2016
Expiration Date: 10/07/2017 No credit will be give after the expiration date

Fee: The fee for this educational activity is $20

Program Audience: Registered Pharmacists and Pharmacy Technicians

Rutgers Biomedical and Health Sciences is accredited by the American Nurses Credentialing Center (ANCC), the Accreditation Council for Pharmacy Education (ACPE), and the Accreditation Council for Continuing Medical Education (ACCME), to provide continuing education for the healthcare team.
This program is approved for 0.10 CEU (1.00 contact hour) law continuing education credit. In order to receive 1.00 law contact hour of CE credit, the participant must read the slides, complete the post-test questions with at least a score of 70% and complete the evaluation form. If participant fails first time, may retake the post-test questions at an additional fee of $20. Continuing education credits (paperless) can be viewed at www.MyCPEmonitor.net two weeks after passing the post-test questions. The Universal Activity Number is 0374-0000-16-030-H03-P-T
“The History and Implications of the Drug Supply Chain Security Act”

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Please contact Gerry Murphy, Program Coordinator, should problems related to the content or functioning of the continuing education activity arise:

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Post-Test Questions
(Circle your answers on the Post-Test Answer Form on page 5)
(Mailing instructions are also on page 5)

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1. Which of the following are potential causes of a national drug shortage crisis?
   A. Manufacturer discontinuation of production
   B. Increased demand of medication
   C. Recalls of defective lots
   D. All of the above

2. Which of the following is NOT a typical impact that drug shortages can have?
   A. Sub-optimal patient therapy
   B. Rising costs to a healthcare facility
   C. Decreased costs to a healthcare facility
   D. Medication errors

3. Wholesale businesses are regulated by:
   A. Both the laws of the state in which the wholesaler is located and the state into which the wholesaler is sending goods
   B. Laws of the state in which the wholesaler is located only
   C. Laws of the state into which the wholesaler is sending goods only
   D. There are no laws that specifically govern the practice of wholesale

4. Which if the following is NOT a good practice to prevent legal issues in the event of a drug shortage?
   A. Report suspect medications and pedigree violations to the BOP, FDA, and FTC
   B. Develop an institutional policy on how to deal with gray vendors
   C. Always buy from the cheapest available vendor
   D. Purchase only from authorized distributors or a verified-accredited wholesale distributor

5. True or False: Documentation required under the Drug Supply Chain Security Act should be received prior to or at the time of the transaction.
   A. True
   B. False

6. Under the Drug Supply Chain Security Act, Pharmacies must maintain documentation for how long?
   A. 2 years
   B. 5 years
   C. 6 years
   D. There is no such requirement

THE END
Pharmacy Program Post-Test Answer Form
(Circle answers and mail this page with Name Form and Evaluation Form on pgs. 6 & 7)

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This form must be completed to receive law continuing education credit. Circle your answers to the questions at the right. You can either email Post-Test Answer Form and Evaluation Form to: gemurphy@pharmacy.rutgers.edu or fax to: 732-445-5767 with credit card info – fee $20

or

Mail Name Form, Post-Test Answer Form, Evaluation Form and $20 check made payable to: Rutgers, The State University of New Jersey

Mail to:
Rutgers, The State University of New Jersey
Continuing Education
Ernest Mario School of Pharmacy
160 Frelinghuysen Road
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NAME FORM

Name________________________________________________________________________
(Print only)

Check one, if applicable:

R.Ph. _______ Pharm.D. _______ Other (specify)____________________________________

YOU MUST Provide: NABP e-Profile #_____________ Date of Birth:_____________

(to acquire a NABP #....... please go to: http://www.nabp.net)

Home Address______________________________________________________________

City_____________________________State___________________ Zip Code_____________

Telephone
(work)________________________________(home)________________________________

Email________________________________________________________________________

Credit Card Information

Name of Credit Card:________________________ Credit Card #:________________________

Expiration Date:___________________ 3 or 4 digit code on back of card:__________________

OR

If paying by check: Check Number:________________________
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Rutgers, The State University of New Jersey, Ernest Mario School of Pharmacy would appreciate your comments on the quality of this educational activity. Please rate the following by using a 5-point grading system, with 1 being the lowest rating (strongly disagree/poor) and 5 being the highest rating (strongly agree/excellent).

**Did this program meet the following learning objectives?**

1. Explain the history of the Drug Supply Chain Security Act and the new requirements imposed by the Act?
   1  2  3  4  5

2. Define key terms, including pedigree, Drug Supply chain Integrity, and product tracing?
   1  2  3  4  5

3. Describe the gray market that has emerged and its meaning in the legal and ethical context?
   1  2  3  4  5

4. Explain the clinical and economic impact of drug shortages?
   1  2  3  4  5

5. Summarize processes to secure the drug-supply chain, prevent harm from counterfeit drugs, and to understand and adhere to the new “Track and Trace” provisions of the Drug Supply Chain Security Act?
   1  2  3  4  5

6. Explain the impact of the Act as it related to the pharmacy’s relationship with vendors, patients, and third party insurances?
   1  2  3  4  5

7. Apply good practices to prevent legal issues in the purchase of medications?
   1  2  3  4  5

What aspects of this activity were of most interest to you?

____________________________________________________________________

Do you have any comments or suggestions for this or future activities?

____________________________________________________________________

Thank you for your interest in Rutgers, The State University of New Jersey, Ernest Mario School of Pharmacy (Knowledge-based CPE activity)