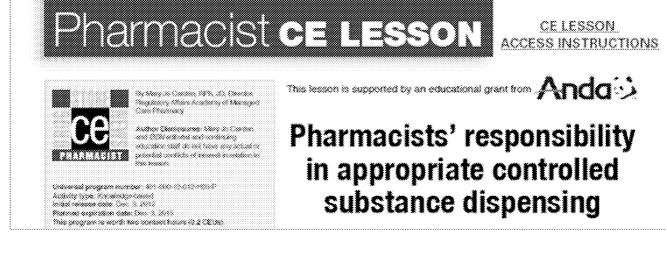
From: Sent: To:	Fenster, Ken <kenneth.fenster@actavis.com> Tuesday, December 11, 2012 8:17 PM #Anda Pharmacy Group; Spina, Alissa; Albertsson, Amanda; Divita, Annette; Motyka, Carl; Wendt, Christina; Schmidt, Christopher; Hess, Cynthia; Daniel Reddinger; Hoover, Darlene; Bridges, David; Hiser, David; Floro, Dominic; Adamczyk, Donelle; Emily K Pietrzyk; Matter, Jacob; James O'Connell; Tierney, Jeremy; Johnson, Jessica; Jackson, John; Costanzo Iii, Joseph; Thorsby, Josephine; Ross, Karen; Mcdonough, Karen; Hayes, Keira; Vento, Kelli; Rohrback, Kelly; Moshier, Kimberly; Kimberly B Duscher; Curione, Krista; Morgan, Kristy; Czerniak, Laurene; Grinham, Leigh; Schipani, Lisa; Serafini, Lisa; Grillo, Mary Jo; Spanbauer, Michael; Mcarthur, Michelle; Pannullo, Michelle; Weinstein, Michelle; Nanette Waller; Guarnieri, Nicholas; Sposato, Nicole; Stephens, Paul; Sciortino, Paul; Barlow, Rebecca; Mort, Renee; Gazy, Robert; Sara E McMaster; Sirianni, Tara; Paonessa, Therese; Tia Tomlinson; Clock, Alan; Centrella, Amy; Leon-Laurent, Christine; Shefferman, Elizabeth; Vives, Elizabeth; Elizabeth Zimmerli; Melendez, Elvira; Bishop, Gregory; Howard, Jane; Jaumotte, Jennifer; Hayer, Joshua; Saintlouis, Kay-Tania; Harrington, Leslie; Alcantar, Maria; Fleischhauer, Michelle; Dodes, Norman; Vance, Rachelle; Patton, Ryan; Plummer, Shaeen; Melendez, Susana; Tara L Daniels; Maher, Mary; Mangus, Vicki; Versosky, William; Lewis, Andrew; Hulsey, Caleb; Rochin, Donna L.; Perez, Edwardo; Travieso, Gian; Falzone, Joseph; Coley, Mary; Suh, Patricia; Sandeep Kapoor; Aguilar, Shane</kenneth.fenster@actavis.com>
Cc: Subject:	 #Anda Marketing; #Anda Purchasing Department; #Anda Pricing; Cochrane, Michael; Brown, Robert (Andanet); Schultz, Emily; Solis, Sabrina; Samuels, Latoya; Barber, Mary; O'Reilly, Arlene H.; Mendoza, Cynthia; Jean-Charles, Natashia; Bautista, Sandra; Alejandro, Wilda; Esteves, Alberto; Spellman, Jay; Cochrane, Patrick; Paonessa, Albert; Jordan, Ana; Perez, Dessie; Jennifer L Young-Campbell; Hankin, Krista; Gross, Rebecca; Martin-Brown, Sophia; Hellsten, Asa; Sanchez, Blanca; Barnett, Bradley; Zamora, Denis; Delgado, Jaime; Nodarse, Jason; Cazzell, Morris; Jefferson, John; Lebron, Luis; Mcdaniel, Michelle; Marchalleck, Nicholas; Warner, Robert; Victor A Duarte; Mclean, Althea; Isabella, Anita; Oliveros, Cristina; Mattson, Kathleen; Trotman, Lorrie; Saldarriaga, Monica; Bonnie R Lipischak; Erik P Ello; Mercedes, Isadelle; Haines, Margaret; Tauber, Meagan; Spencer, Anna-Lisa; Harrinauth, Babita; Beverly Miller- Wishart; Ciocan, Doina; Ahuja, Haresh; Larralde, Hilda; Piderit, Jennifer; Fajardo-Pastor, Jorge; Malorie Chery; Restrepo, Michell; Nelson, Rasheed; Baldeviso, Rhett; Millan, Ryan; Reyes, Selena; Shauneen R Morgan; Silvia Jimenez; Stephen D Gordon; Chen, Tricia Hew; Gurfinkel, Zlata Important CE Lesson: Pharmacists' Responsibility in Appropriate Controlled Substance
-	Dispensing
Attachments:	CE Lesson DSN - Anda - Preview & Instructions.pdf



1

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CCSF v Purdue Pharma, et al. 3:18-CV-7591 AND-SF-00036 Admitted:

AND-SF-00036.00001

- We are pleased to announce that Anda is sponsoring a Continuing Education (CE) program for Drug Store News, a leading retail pharmacy publication. The CE lesson is live and is titled *"Pharmacists' responsibility in appropriate controlled substance dispensing."* The CE is <u>FREE of charge</u> and worth two contact hours (0.2 Continuing Education Units) for all licensed pharmacists. Licensed pharmacists will need to achieve a score of 70% in order to obtain a statement of credit. The lesson has a planned expiration date of December 3rd, 2015.
- As you may know, each state board of pharmacy requires a *different* number of CE credits in order for pharmacists to renew their license (many states require about 15 credit hours each year or 30 credit hours every two years)
- The CE is designed to answer many of the questions that our customers have raised regarding the requirements for wholesalers to "know their customers" and pharmacists' "corresponding responsibility," to ensure the legitimacy of all controlled substance prescriptions in response to increased prescription drug abuse throughout the U.S.

The lesson will help the pharmacist gain insight into the following areas:

- ✓ Responsibilities of the pharmacist when dispensing controlled substance prescriptions
- ✓ A brief overview of the current federal/state relationship for oversight of controlled substance prescriptions
- ✓ Overview of the due diligence necessary for the pharmacist to fulfill his or her corresponding responsibility when filling a prescription
- ✓ Recognition of potentially fraudulent prescriptions or patient behavior that might suggest opioid abuse
- ✓ Tools and resources available to assist the pharmacist to appropriately dispense opioids

CE Access Instructions



- Secure cradit card payment
- , Increased visibility to available R¥ Amduors in Shari Supply

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    CE Lesson: Pharmacists' responsibility in
appropriate controlled substance dispensing
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If any of your pharmacy customers are interested in completing this CE, please direct them to the **www.andanet.com** log in page. Within the ABOUT ANDANET.COM section, click on the link **CE Lesson: Pharmacists' responsibility in appropriate controlled substance dispensing.**

Or, within the Check This Out! section, click on the link "Controlled Substance CE Lesson"

When the link is clicked, a preview of the CE and easy instructions will be provided (see attached) explaining how to complete the CE and obtain the statement of credit through the Drug Store News CE website. *If your customers have any questions regarding CE registration, statements of credit or other CE issues, please direct them to Drug Store News Customer Service at 1-800-933-9666.*

Please inform your pharmacy customers about the availability of this CE through AndaNet. Drug Store News and Anda marketing will be promoting the CE through various journal advertisements, e-mail and fax blasts during the next few months.

Your manager will provide you with a copy of the full CE lesson. We encourage you to read the full CE in order to gain better insight into this very important topic in our industry.

Ken Fenster Director, Marketing

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AND-SF-00036.00003

Pharmacist **ce lesson**

By Mary Jo Carden, RPh, JD, Director, Regulatory Affairs Academy of Managed Care Pharmacy

Author Disclosures: Mary Jo Carden and DSN editorial and continuing education staff do not have any actual or potential conflicts of interest in relation to this lesson.

Universal program number: 401-000-12-012-H03-P Activity type: Knowledge-based Initial release date: Dec. 3, 2012 Planned expiration date: Dec. 3, 2015 This program is worth two contact hours (0.2 CEUs).

Target Audience

Pharmacists in community-based practice.

Program Goal

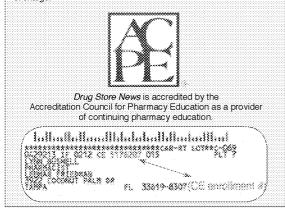
To provide pharmacists with tools and tips on fulfilling their role in appropriate controlled substance dispensing.

Learning Objectives

- Upon completion of this program, the pharmacist should be able to 1 Explain the Drug Enforcement Administration's definition of the "corresponding responsibility" between prescribers and pharmacists to ensure that controlled substance medications are
- pharmacists to ensure that controlled substance medications are only dispensed to patients based on prescriptions written for a legitimate medical purpose and in the normal course of professional practice, including the pharmacist's responsibility in conducting due diligence.
- Describe current initiatives by the DEA. Food and Drug Administration, Office of National Drug Control Policy and general state policies to curb misuse, abuse and diversion of controlled substances and their relationship to pharmacy practice.
- 3 List current initiatives by third-party payers, the Medicare Part D program and state Medicaid programs to curb misuse, abuse and diversion of controlled substances.
- 4. Understand practical approaches and actions that can be taken by the pharmacist and the pharmacy staff to reduce the likelihood of misuse, abuse and diversion of controlled substances
- Develop a checklist for the pharmacy staff to use in conducting due diligence, including identifying prescribers and patients that may be involved in potentially inappropriate prescribing.
- Discuss available resources to develop effective, comprehensive controlled substance dispensing protocols in pharmacies.

To obtain credit: A minimum test score of 70% is needed to obtain a statement of credit. Submit your answers online at www.CEdrugstorenews.com, and receive your statement of credit in your CE account folder immediately

Questions regarding statements of credit and other customer service issues should be directed to (800) 933-9666. This lesson is free of charge.



1 • NOVEMBER/DECEMBER 2012

This lesson is supported by an educational grant from And

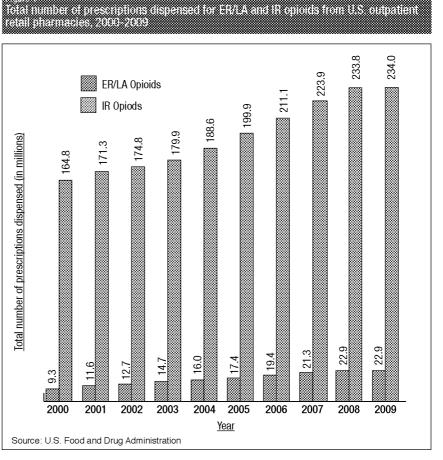
Pharmacists' responsibility in appropriate controlled substance dispensing

INTRODUCTION

Dispensing controlled substances in community pharmacies continues to increase as the number of opioid analgesic prescriptions has continued to grow steadily each year since 2000.¹ There was a slight reduction of these prescriptions reported in 2011 among teens, young adults ages 18 years to 25 years and workers' compensation claims.² This reduction may be related to more readily available consumer education and aggressive actions by federal, state and local officials to curb prescription drug abuse, particularly for opioid analgesics. The news, however, is not completely positive; prescriptions containing hydrocodone and acetaminophen in combination remained the most prescribed medications in the United States between 2007 and 2011. Prescriptions for products containing oxycodone as a single agent also increased in 2011 (Figure 1).

CE LESSON ACCESS INSTRUCTIONS

Översight and authority of controlled substance prescribing and dispensing



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Pharmaoist GE LESSON

is conducted by a combination of federal and state law enforcement, regulatory agencies and payers. The U.S. Drug Enforcement Administration, the agency with primary authority over regulation and oversight of controlled substances in the United States, places responsibility on both prescribers and pharmacists to ensure that prescriptions for controlled substances meet all legal requirements of a prescription and are appropriate for the condition prescribed. The pharmacist has both a professional and ethical responsibility to ensure appropriate dispensing and to reject invalid prescriptions. How should the pharmacist conduct the due diligence necessary for ensuring appropriate controlled substance prescriptions? Should the pharmacist simply assume that all opioid prescriptions are improper until proven otherwise? Certainly not; according to the DEA, the pharmacist must exercise "sound professional judgment" to determine the legitimacy of controlled substance prescriptions.3 This lesson will provide the pharmacist with guidance regarding the current state of federal controlled substance legislation and regulation; an overview of actions in states and by third-party payers and other healthcare professionals to curb inappropriate prescribing and dispensing; and tools available to help the pharmacist make a sound professional judgment and perform due diligence when dispensing controlled substance prescriptions.

Part 1 will consider the pharmacist's responsibility and requirements performing the due diligence necessary to ensure appropriate dispensing of opioid prescriptions. Part 2 will examine partnerships among DEA and other government agencies, including the Office of National Drug Control Policy within the White House and the Food and Drug Administration; third-party insurers; the Medicare and Medicaid programs; and initiatives among healthcare professionals to ensure appropriate dispensing and prescribing. Finally, the lesson describes federal and state sanctions and disciplinary actions that may be taken against the pharmacist for failure to comply with controlled substance laws and regulations.

A newly licensed pharmacist receives his first assignment in a community pharmacy. The company provides formal training to the pharmacist regarding company policies and procedures, and he also receives "informal" training from the pharmacist in charge, or PIC, regarding the pharmacy operations and customers. The PIC informs the new pharmacist that several very ill patients regularly receive controlled substance medications for managing chronic pain and that these patients should not cause alarm for the pharmacist when he receives their prescriptions. After his first month practicing, the pharmacist encounters one of the patients, J.M., and mentally notes that J.M. is one of the very old, frail and sick patients with cancer identified by the PIC. Each month, the patient presents a prescription for a supply of a Schedule II controlled substance that is filled by the pharmacist with no questions asked. During the new pharmacist's fourth month on the job, local law enforcement officials present themselves at the pharmacy with a warrant to search records related to J.M.'s prescriptions. They tell the pharmacist that they have a reasonable basis to conclude that all of his narcotic prescriptions dating back approximately one year were fraudulent and that he used several pharmacies to receive the same prescription medication. The new pharmacist is shocked at this revelation and the ensuing information that he learns during the investigation. In reviewing hard copy prescription records, it is apparent that the handwriting on prescriptions from more than a year ago "written by the same doctor" is completely different from the prescriptions in question, and upon further investigation into the pharmacy's database, the patient paid cash for certain prescriptions while others were covered by a third party.

Discussion

Consider the issues presented by this case. Did the pharmacist conduct appropriate due diligence in filling prescriptions, or does the PIC's word regarding several patients' condition suffice? Did the pharmacist behave unethically? What other steps could the pharmacist and pharmacy staff have taken to ensure the validity of the prescriptions? Was the pharmacist wrong in assuming that a sick, frail patient would automatically present valid prescriptions? Should the pharmacist question every prescription going forward?

The pharmacist should review this case prior to beginning the lesson and consider the action or inaction by the pharmacist in question. What issues does the pharmacist see in this scenario? Then, after reviewing Part 1 of the lesson, how should the pharmacist apply this information to scenario one?

The pharmacist should not have simply taken another pharmacist's word for the status of the patients. While both pharmacists have put the health of the pharmacy's patients first, the pharmacist should have taken additional steps to verify the prescription. While in this case, the pharmacist might not have immediately concluded that a call to the prescriber was necessary, he had a reasonable basis to review a prescription monitoring program database if available in the state. Further, he could have reviewed the prescriptions as entered in the pharmacy's database and determined the inconsistent payment methodology ---- as some paid by cash, while some paid by a third party. These actions might have then prompted the pharmacist to contact the prescriber for verification.

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Before beginning the lesson, consider the actions or inactions taken by the pharmacist in Patient Scenario 1. This lesson will help the reader analyze the pharmacist's shortcomings in this scenario and will describe ways to improve in the future.

PART 1: THE PHARMACIST'S ROLE IN APPROPRIATE DISPENSING

Overview of types of fraudulent prescriptions

The DEA has provided a summary of the types of fraudulent prescriptions that the pharmacist may encounter. These include the following:

- Legitimate prescriptions with alterations made by a patient;
- Stolen prescription pads from a legiti-

Table 1 Criteria to determine appropriate controlled substance prescriptions^{2, 4}

PRESCRIBER CONSIDERATIONS

- Consider whether the prescriber writes for a quantity or prescribes controlled substances with more frequency than others in the area:
- Consider whether the prescriber writes prescriptions for depressants, (e.g., benzodiazepines/ barbiturates) or stimulants (e.g., methamphetamine) in conjunction with narcotic analgesics. Drug abusers often request "uppers" and "downers" at the same time; and
- Consider whether a number of patients appear at the pharmacy within a short period of time with the same or similar controlled substance prescriptions from a single prescriber.

PATIENT CONSIDERATIONS

- Review patient's history in PMP if available in the state:
- Query the patient about his medical history and the need for the medication,
- Consider the frequency that the patient receives the opioid analgesic;
- Consider whether the patient receives prescriptions from a number of prescribers and uses different prescribers for noncontrolled substances;
- Consider whether the patient pays cash for narcotic prescriptions while receiving others through insurance;
- Consider whether the patient insists on brand name narcotics because these often have a greater street value compared to generics because of name recognition; and
- Question prescriptions that suddenly appear from individuals who are not usual customers or who do not live in the community or area around your pharmacy.
 - CHARACTERISTICS OF POTENTIALLY FORGED PRESCRIPTIONS REQUIRING FOLLOW-UP BY E MARIANA BISTIS DE PRESISTINA DE LA COMPANYA DE L
- Quantities, directions or dosages appear different from usual medical usage;
- Prescription does not use standard medical abbreviations for directions, dosages or names of medication;
- Photocopied prescriptions; and Prescriptions written in different colors or inks with
- different handwriting

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Collaborative Care

IF YOU WOULD LIKE TO COMPLETE THE CE LESSON "PHARMACISTS' RESPONSIBILITY IN APPROPRIATE CONTROLLED SUBSTANCE DISPENSING," PLEASE FOLLOW THE STEPS BELOW:

This CE lesson is worth 2 contact hours (0.2 Continuing Education Units)

- Go to WWW.CedrugStorenews.com and if this is your first visit to our site please click on CREATE ACCOUNT FOR PHARMACIST.
- Under the heading I am from a non-participating organization click on CREATE AN ONLINE ACCOUNT.
- Complete your personal information on this screen including creating a password.
- CE Registration will confirm account creation and provide your enrollment number.
- Use the enrollment number and the password you created to login on the left hand side.

- You can use SEARCH ENGINE, browse all lessons which is under the lesson categories tab, or look under newly released lessons to locate the lesson.
- If you have any challenges setting up your enrollment number or password please contact DRUG STORE NEWS CUSTOMER SERVICE AT 1-800-933-9666.
- Click the link to the lesson and this will bring you to the lesson information page.
- 🕮 🗴 In the top left of this screen click PDF to read the lesson.
- 🕷 🕼 🗴 Scroll to the bottom left of the screen to take test.
- After passing the test you will be able to print your statement of credit.

