The Controlled Substance Dilemma: Health Care or Health Threat?
Tammie Lee Demler, PharmD, MBA, BCPP

Live Activity Handout
4 slides per page

freeCE
The Controlled Substance Dilemma: Health Care or Health Threat?

ACTIVITY DESCRIPTION
Pharmacy has been thrust into the national spotlight as solutions are sought to manage the inappropriate distribution of prescription medications. This session seeks to explore various tools available to the pharmacy staff to combat illicit distribution, while maintaining appropriate and legitimate patient access to prescribed medications. The effectiveness and limitations of state Prescription Drug Monitoring Programs (PDMPs) are discussed in the context of "red flag" behaviors that may suggest inappropriate distribution. The session further seeks to identify current trends in the use and misuse of controlled substances from multiple professional, sociological, and regulatory perspectives.

TARGET AUDIENCE
The target audience for this activity is pharmacists, pharmacy technicians, and nurses in hospital, community, and retail pharmacy settings.

LEARNING OBJECTIVES
After completing this activity, the pharmacist will be able to:
• Identify the role, proper use, and limitations of state Prescription Drug Monitoring Programs (PDMPs) in determining appropriate access to controlled substance medications.
• Identify common ‘red flags’ that should initiate further investigation when considering the validity of a controlled substance prescription, including the assessment of appropriate therapeutic value.
• Appropriately identify regulatory standards related to the Comprehensive Drug Abuse Prevention and Control Act.
• Identify current trends related to the abuse of prescription drugs.

After completing this activity, the pharmacy technician will be able to:
• Identify the role, proper use, and limitations of state Prescription Drug Monitoring Programs (PDMPs) in determining appropriate access to controlled substance medications.
• Identify common ‘red flags’ that should initiate further investigation when considering the validity of a controlled substance prescription, including the assessment of appropriate therapeutic value.
• Appropriately identify regulatory standards related to the Comprehensive Drug Abuse Prevention and Control Act.
• Identify current trends related to the abuse of prescription drugs.

ACCREDITATION
Pharmacy
PharmCon, Inc. is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Nursing
PharmCon, Inc. is approved by the California Board of Registered Nursing (Provider Number CEP 13649) and the Florida Board of Nursing (Provider Number 50-3515). Activities approved by the CA BRN and the FL BN are accepted by most State Boards of Nursing.

CE hours provided by PharmCon, Inc. meet the ANCC criteria for formally approved continuing education hours. The ACPE is listed by the AANP as an acceptable, accredited continuing education organization for applicants seeking renewal through continuing education credit. For additional information, please visit:
http://www.nursecredentialing.org/RenewalRequirements.aspx

Universal Activity No.: 0798-0000-17-173-L03-P
Credits: 2.0 contact hour (0.2 CEU)

Release Date: 7/26/2017
freeCE Expiration Date: 7/26/2020
ACPE Expiration Date: 7/26/2020

ACTIVITY TYPE
Knowledge-Based Live Webinar

FINANCIAL SUPPORT BY
Pharmaceutical Education Consultants, Inc.
ABOUT THE AUTHOR

Kevin T. Hope, RPh is a Clinical Education Specialist with the PharmCon team in Conway, SC. Kevin began his career in pharmacy at an early age and has practiced as a pharmacist in a variety of settings, beginning with a retail pharmacy experience at Eckerd Drug Corporation in York, SC. Kevin transitioned from a retail setting to a Charleston, SC nuclear pharmacy setting in 2002, where he practiced for over 13 years. Kevin has served as an adjunct faculty member for the South Carolina College of Pharmacy, having coordinated and instructed the college’s ‘authorized user’ program for nuclear pharmacy. In addition, Kevin has direct experience in the education of pharmacy technicians, having directed the pharmacy technology program at Horry Georgetown Technical College in Myrtle Beach, SC prior to joining the PharmCon team.

Kevin has received several professional awards, including the Pfizer Leadership Award and the Innovative Pharmacy Practice Award from the South Carolina Pharmacy Association. Having served as a corporate communications trainer for Triad Isotopes, Kevin has presented to a variety of audiences, including a nuclear pharmacy symposium at the American Pharmacists Association annual meeting. Kevin has served as an independent editor for several Paradigm Publishing textbooks, and currently serves on the professional advisory board for Paradigm Publishing. Kevin’s passions lie in helping students achieve and surpass personal educational goals.

FACULTY DISCLOSURE

It is the policy of PharmCon, Inc. to require the disclosure of the existence of any significant financial interest or any other relationship a faculty member or a sponsor has with the manufacturer of any commercial product(s) and/or service(s) discussed in an educational activity. Kevin Hope reports no actual or potential conflict of interest in relation to this activity.

Peer review of the material in this CE activity was conducted to assess and resolve potential conflict of interest. Reviewers unanimously found that the activity is fair balanced and lacks commercial bias.

Please Note: PharmCon, Inc. does not view the existence of relationships as an implication of bias or that the value of the material is decreased. The content of the activity was planned to be balanced and objective. Occasionally, faculty may express opinions that represent their own viewpoint. Participants have an implied responsibility to use the newly acquired information to enhance patient outcomes and their own professional development. The information presented in this activity is not intended as a substitute for the participant’s own research, or for the participant’s own professional judgement or advice for a specific problem or situation. Conclusions drawn by participants should be derived from objective analysis of scientific data presented from this activity and other unrelated sources.

Neither freeCE/PharmCon nor any content provider intends to or should be considered to be rendering medical, pharmaceutical, or other professional advice. While freeCE/PharmCon and its content providers have exercised care in providing information, no guarantee of it’s accuracy, timeliness or applicability can be or is made. You assume all risks and responsibilities with respect to any decisions or advice made or given as a result of the use of the content of this activity.
The Controlled Substance Dilemma: Health Care or Health Threat

Faculty: Kevin T. Hope, RPh

Early Medicine In America

Mrs. Winslow’s Soothing Syrup

“Contains one grain (65 mg) of morphine per fluid ounce, cannabis, heroin, and powdered opium”

- removed from the market in 1938

Objectives

• Identify the role, proper use, and limitations of state Prescription Drug Monitoring Programs (PDMPs) in determining appropriate access to controlled substance medications.
• Identify common ‘red flags’ that should initiate further investigation when considering the validity of a controlled substance prescription, including the assessment of appropriate therapeutic value.
• Recognize commonly applied laws and rules related to the prescribing and dispensing of controlled substances
• Describe current trends related to the abuse of prescription drugs.

Review of Basic Federal Controlled Substance Regulations

State laws may be more stringent than federal law
Early Medicine In America

Food, Drug, and Cosmetic Act (1938)
- introduced NDA
- must prove safety

Durham-Humphrey Amendment (1951)
- established idea of ‘legend drugs’

Kefauver-Harris Amendment (1963)
- must prove safety AND efficacy

- established the idea of DEA enforcement
- introduced 5 classes of controlled substances:
  - CII drugs not permitted refills
  - CIII – CIV drug are allowed 5 refills with a validity of 6 months

Kefauver-Humphrey Amendment (1951)
- established idea of ‘legend drugs’

Kefauver-Harris Amendment (1963)
- must prove safety AND efficacy

Review of Basic Federal Controlled Substance Regulations

Who may prescribe a controlled substance?
- must be authorized in the state of licensure
- must be registered or exempt from DEA registration
- prescriptive authority can not be delegated
- issued for a legitimate medical purpose within the scope of professional practice

Review of Basic Federal Controlled Substance Regulations

What information may a pharmacist NOT correct on a C-III, C-IV, or C-V medication?
- patient’s name
- controlled substance prescribed
- prescriber’s signature
- orders may be written, faxed, electronic, or oral

What about Schedule-II prescriptions?
- caution: varies significantly from state to state
- written or electronically prescribed
- oral orders or facsimile orders only under emergency circumstances if specific criteria is met
- partially fills permitted only if specific criteria is met
Review of Basic Federal Controlled Substance Regulations

What about controlled substance inventory?
- Inventory is required prior to a new business opening and every 2 years thereafter
  - exact count required for C-I and C-II; estimates allowed for C-III, C-IV, and C-V unless the container holds more than 1,000 units
  - new controlled substance drugs are inventoried on the effective date of scheduling


Review of Basic Federal Controlled Substance Regulations

What about DEA forms?
- **DEA 222 form**: Used to order C-I and C-II drugs
  - Must be kept separate from all other records for 2 years
- **DEA 41 form**: Used to request disposal of controlled substance drugs
- **DEA 106 form**: Used to report theft or significant loss of controlled substances


Prescription Drug Monitoring Programs (PDMPs)

- Electronic state databases used to track the prescribing and dispensing of controlled prescription drugs to patients
  - patient’s controlled substance prescription history
  - identifies patients at high-risk who would benefit from early interventions
    - Universal Use
    - Real-Time
    - Actively Managed
    - Easy to Use and Access

https://www.cdc.gov/drugoverdose/pdmp/index.html

Prescription Drug Monitoring Programs (PDMPs)

Demonstration of Virginia’s NarxCare® Program

Typical PDMP data:
- Patient name
- Dispensing Pharmacy
- Day’s Supply Dispensed
- Cash vs. Insurance Transaction
- Prescribing Provider’s Name
Prescription Drug Monitoring Programs (PDMPs)

Components of a Strong Prescription Monitoring Program

1. Wide schedules of drugs monitored
   - does it only track controlled substances? Other drugs of concern?

2. Proactive Provision of Information
   - proactively contacting the appropriate agency under reasonable suspicion
   - provides information for public research, policy and education purposes

3. Individuals Allowed to Request Information from PDMP
   - dispensers, prescribers, law enforcement officials, occupational licensing officials

4. Effective training program for PDMP users
   - responsible and proper use of the system
   - resources for referral of patients addicted to controlled substances

5. Continuous evaluation of PDMP
   - establishment of an advisory board

6. Appropriate Provisions for Confidentiality of Patient Information
   - should not be open to public or open record laws
   - identifies penalties for improper disclosure of information
   - Kentucky: release of data to anyone not authorized by the state’s statute is a Class D felony

7. Effective training program for PDMP users
   - pharmacies delivering to an address of a user in another state
   - Provisions for mail order pharmacies / internet pharmacies
   - Earlier “Western States Network”
   - “InterConnect”
   - Legal Agreements Among States
   - Federal Entities Not Reporting to State PDMP
PMP InterConnect®

- Developed by NABP
- Facilitates the transfer of prescription monitoring program (PMP) data across state lines
- Currently 44 participating states

New York & Tennessee

- Within 1 year of requiring prescribers to check the state’s PDMP:
  - Marked decline in patients seeing multiple prescribers for the same drugs
    - Tennessee: 36% decline
    - New York: 75% decline

Prescription Drug Monitoring Programs (PDMPs)

- Legislation in Many States, including Wisconsin.

Prescription Drug Monitoring Programs (PDMPs)

**Not a Flawless System...**
**Recognize the limitations of the tool!**

- Error was fixed in the dispensing pharmacy's computer system, but somehow did not update to the PDMP database
- Wrong doctor selected
- Patient name misspelled
- Wrong patient, address, days supply, etc.
Drug Abuse & Our Youth

“Drugs affect all sectors of society in all countries; in particular, drug abuse affects the freedom and development of young people, the world’s most valuable asset.”

Drug Abuse & Our Youth

- ~ 9% of US youth (age 12-17) report being current illicit drug users
  - ~ 10% report using nonprescribed pain relievers at least once
    - ~ 49% of these youth reported having used two or more illicit drugs (compared to 4% of youth who did not use nonprescribed pain relievers)
    - Marijuana > nonmedical use of Rx medications
    - Some sources now cite opioids > marijuana being used as a “first high”
    - “pharming”

- Nearly all illicit drug use can be tracked back to preadolescent and adolescent years
  - Statistically, if a person has not used illicit drugs during this period, he/she never likely will

Method of Obtaining Opioids for nonmedical use, respondents age 18-25 meeting dependence criteria:

<table>
<thead>
<tr>
<th>Method of Obtaining Opioids</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>From a friend or relative, at no cost</td>
<td>37.5%</td>
</tr>
<tr>
<td>From a friend or relative, paid</td>
<td>19.9%</td>
</tr>
<tr>
<td>Prescription from one prescriber</td>
<td>13.6%</td>
</tr>
<tr>
<td>Purchased from a dealer or stranger</td>
<td>12.5%</td>
</tr>
<tr>
<td>Stolen from a friend or relative</td>
<td>6.3%</td>
</tr>
<tr>
<td>Prescriptions from more than one prescriber</td>
<td>2.8%</td>
</tr>
<tr>
<td>Purchased on the Internet</td>
<td>1.3%</td>
</tr>
</tbody>
</table>

The United States as an Opioid Consumer

- 80% of the world’s consumption
  - The population in the US currently represents ~ 4.6% of the world’s population
  - Clinical decision making
  - Government policies

Balance between clinical use versus potential for abuse
A Matter of Perspective

Health Care?  
Heath Crisis?

Pain Paradigm Shift

Prior to the 1990’s: “patients given prescription opioids for chronic pain have a high risk of developing an addiction”
- many patients were undertreated

1990’s: “the risks of addiction are very low for patients with chronic pain”
- false sense of security
- good data from acute pain, but results were disappointing for the treatment of chronic pain


Pain Paradigm Shift

• Paradigm shift was embraced by the drug industry
  • Janssen Pharmaceutical: “relatively rare” incidents of addiction in treating chronic pain with Duragesic®
  • Endo Pharmaceuticals: termed the risk “very rare” in presentations to hospital pharmacists
  • Purdue Pharma: “Some patients may be afraid of taking opioids because they are perceived as too strong or addictive, but that is far from actual fact. Less than 1% of patients taking opioids actually became addicted.”

Pain Paradigm Shift

Often cited study from 1980:
“... only four cases of addiction among 11,882 hospitalized patients ...”

• Study did not follow patients after they left the hospital
• Did not address outpatient settings

Pain Paradigm Shift

Limitations:
There had been no studies investigating the experience of pain patients who used opioids for extended periods of time.

Survey data was frequently taken out of context and applied to the treatment realm of chronic pain.


United States Data: 1999 - 2011

- Consumption of hydrocodone doubled
- Consumption of oxycodone increased by nearly 500%
- Opiate related deaths increased four fold

“The worst drug overdose epidemic in U.S. History”
- Centers for Disease Control and Prevention

Pain Control: The Prescriber’s Dilemma

- 60% of abused opioids are obtained through a physician's prescription
- Patients care surveys
- Doctors who refuse to prescribe opioids to certain patients out of concern about abuse are likely to get a poor rating from those patients.


Pain Control: The Prescriber’s Dilemma

- Treating pain pays; treating addiction does not
- Prescribers are often evaluated on the numbers of patients
- Limited resources for addiction referral

“I know I’m addicted to (opioids), and it’s the doctors’ fault because they prescribed them. But I’ll sue them if they leave me in pain.”

The “Pill Broker”

“We gather in open-air drug markets, usually strip malls, pharmacy parking lots, and outside methadone clinics to buy, sell, and trade prescription drugs. A variety of transactions occur, including the purchase of prescription drugs for cash, and trades for crack and heroin. We sometimes buy fentanyl patches from nurses who have stolen them from pain patients. Some frequent the market to barter their oxycodone for other opioids or benzodiazepines, typically alprazolam.”


Street Costs of Prescription Drugs

http://streetrx.com/

“Allows buyers and sellers to anonymously report prices of prescription pills on the street in communities around the country”

Brand name prescription drugs routinely carry a higher street value than generic equivalents

Economic Impact of Prescription Opioid Abuse

<table>
<thead>
<tr>
<th>Non-abusers:</th>
<th>Opioid Abusers:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average annual healthcare costs: $1,830</td>
<td>Average annual healthcare costs: $15,884</td>
</tr>
</tbody>
</table>


Why Opioids to Heroin?

**Oxycodone, extended release**

- An abuser with a high tolerance may use 400mg of the drug daily.
  - Average cost: $400

**Heroin**

- Comparable dose is approximately 2 grams
  - Average cost: $132 - $200

Florida Mortality Rates for Selected Drugs

Drug Overdose Deaths

- Leading cause of death among Americans under 50!
- Evidence suggests the problem has continued to worsen in 2017
- Disproportionally larger increases in drug overdose deaths in states along the East Coast, particularly Maryland, Florida, Pennsylvania, Maine and Ohio.

Heroin: Relationship to Prescription Drug Abuse in Florida

- Four in five new heroin users began misusing prescription pain medications.
- Deaths caused by heroin increased 79.7 percent in 2015 when compared with 2014
Social Costs of Drug Addiction

Every additional dollar invested in drug abuse treatment saves taxpayers $7.46 in societal costs.

Domestic enforcement efforts cost 15 times as much as treatment to achieve the same reduction in societal costs.

State of Florida

76.2% reduction in "multiple provider episodes"

23% decline in drug poisoning deaths from 2010 to 2013, ranking it first among states and one of only two states that experienced a decrease from 2010 to 2014.

Substance Abuse Treatment Admissions Data for Florida

Hydrocodone as a C-II Drug:

One year after hydrocodone became a schedule II:

22.9% fewer hydrocodone Rxs from primary care MDs
38.4% fewer hydrocodone Rxs from surgeons
17.2% fewer hydrocodone Rxs from emergency medicine
7.2% more hydrocodone Rxs from pain medicine
The problem within ...

McAuliffe et al reported:
46% of pharmacists use prescription drugs without a prescription
62% of pharmacy students surveyed had used a prescription drug with no prescription
20% of pharmacists reported they had used a prescription drug without a prescription 5 or more times in their lives.

"We receive 750 to 1,000 complaints each year involving diversion of controlled substances from legal outlets. About 450-500 of the complaints typically result in the arrest and prosecution of individuals in state or federal court. Approximately 25 percent of those prosecuted are health care professionals."
- South Carolina Department of Health and Environmental Control Website

The problem within ...

• 2/3 of impaired pharmacists were discovered by their local state board of pharmacy, a peer, or another health care professional
• 11-15% of pharmacists are confronted with alcohol or drug dependency problems at some time in their careers.

Signs and Symptoms of Substance Abuse:

• Personality changes or mood swings
• Frequent absences from work
• Volunteering to check in narcotics or do inventory on them
• Long or frequent disappearances from the work station
• Increase in medication errors
• Changes in physical appearance (e.g., weight loss or poor hygiene)
• Showing signs of forgetfulness, irritability, and tardiness
• Decrease in work performance
• Excessive ordering of certain drugs
• Overreaction to criticism
• Increased complaints from patients
Addiction: A Medical Disorder

Does NOT stem from a lack of motivation, willpower, or character
• Distinct pattern in signs and symptoms
• Common tendency for relapse
• Cravings that result in repeated relapse, even in the presence of powerful consequences and strong motivation
• Causes specific changes to key regions of the brain


Access to Controlled Substances

• Chronic Pain (non-cancer related)
  • ~9% of Americans
  • ~90% of these patients receive opioids to control pain
  • One study suggests that ~32% of these patients misused opioids over the course of one year
Access to Controlled Substances

Posted to Reddit.com:

"I am a board certified interventional pain management physician. So, the other day I got a referral from a spine surgeon and the patient tells me a few days prior Walgreens refused to fill the hydrocodone prescription he received on the basis of the spine surgeon who wrote the Rx was no longer taking care of him. I talked to the surgeon's staff, and they verified that Walgreens had called snooping about the patient's plan of care, wanting the ICD 10 code - but Walgreens didn't tell them they were going to cancel the prescription. This guy is basically your grandpa and hadn't had to take any pain medications for 8 months, his prescription record was normal and his pain was real. Ok, fine. I write a new prescription for him and he takes it to the same Walgreens. He's going to be seeing me on a monthly basis now so surely they will accept it, right? No, they reject it again. This time they don't even bother to call my office to ask about it. I called the Walgreens to find out what was happening, and the pharm tech told me that their pharmacy manager makes the decision of whether or not they dispense "those kinds of medications." I am incredibly angry. The pharmacist humiliated my patient, twice. I don't think it is up to him to decide whether a pain medication is appropriate when there are no red flags (like a record of multiple different prescriptions at different pharmacies - this guy hadn't fill anything in months).

Walgreens fined

Fined $80 million in 2013 for "failing to properly control the sales of narcotics at some outlets"

Access to Controlled Substances

Posted to Reddit.com:

"I'm a pharmacist, too. You are absolutely correct about what's going on with the DEA, but I disagree that it's no big deal. The problem is that Pharmacists ourselves have no real legal lobbying protection (nothing even close to the AMA or resources of big companies like Walgreens or CVS. That means legislation ends up throwing us under the bus, leaving us as the guy stuck between a rock and a hard place. Fill the scripts and get attacked by the DEA, and your company leaves you out to dry, or don't fill the scripts and fail as health care professionals. I'm not even talking about scripts that are sketchy, we wouldn't fill those anyway. There's a culture of fear in our profession. We are scared to put our career and family income on the line to fill these scripts.

Access To Controlled Substances

Pharmacist Concerns Over Supply Issues
Pharmacist Refusal to Fill Rx

DEA Response:

“The Board of Pharmacy recognizes that it is important for the patients of the State of Florida to be able to fill valid prescriptions for controlled substances. In filling these prescriptions, the Board does not expect pharmacists to take any specific action beyond exercising sound professional judgement … The pharmacist shall attempt to determine the validity of the prescription and resolve any concerns about its validity by exercising his/her independent professional judgement.”

Florida Statute 64B16-27.831

Incorporation Into State Pharmacy Practice Acts

“When a pharmacist validates a prescription, neither a person or licensee shall interfere with the exercise of the pharmacist’s independent professional judgement … If the pharmacist determines that in his/her professional judgement concerns with its validity cannot be resolved, the RPh shall refuse to fill the prescription.”

Florida Statute 64B16-27.831

Minimum Standards Before Refusing to Fill a Prescription (Florida):

1. Initiate communication with the patient or patient’s representative to acquire information relevant to the concern with the validity of the prescription.
2. Initiate communication with the prescriber or prescriber’s agent to acquire information relevant to the pharmacist’s concern with the validity of the prescription.
   • In lieu of either 1 or 2 but not both, the pharmacist may decide to access the Prescription Monitoring Program’s Database to acquire relevant information regarding the pharmacist’s concern with the validity of the prescription.
   • If a RPh is unable to comply with 1 and 2 due to refusal of the patient or prescriber to cooperate, the minimum standards for refusing to fill a prescription shall not be required.

Florida Statute 64B16-27.831
Ensuring Patient Access and Effective Drug Enforcement Act of 2016

- Clarifies DEA factors for consideration in registering applicants to manufacture or distribute prescription drugs
- Describes the circumstances under which the Attorney General can suspend a registration
- Establishes corrective opportunities prior to revocation of registration


Detecting Forged Prescriptions

**Prevention Techniques**

- Know the prescriber and his or her signature
- Know the prescriber’s DEA registration number
- Know the patient
- Check the date on the prescription order

Detecting Forged Prescriptions

Types of Forged Prescriptions

• Stolen prescription pads
• Legitimate prescription is altered
• Legitimate doctor printed with a different call back number that is answered by an accomplice to verify the prescription
• False telephoned prescription orders, giving their own telephone number as a call back confirmation.
• Use of technology to create or to copy prescriptions

Characteristics of Forged Prescriptions

• Prescription looks “too good”; the prescriber’s handwriting is too legible
• Quantities, directions or dosages differ from usual medical usage
• Prescription does not comply with the acceptable standard abbreviations or appear to be textbook presentations
• Prescription appears to be photocopied
• Directions written in full with no abbreviations
• Prescription written in different color inks or written in different handwriting

Using ‘Red Flags’ as a tool to assess prescriptions for appropriate therapeutic value

Using ‘Red Flags’ as a tool to assess prescriptions for appropriate therapeutic value

What is Our Professional Role?

• Patient Advocate?
• Detective?
• Counselor?
• Bouncer?
• Mediator?
• Whistle blower?
• Scribe?
• Organizer?
• Social Worker?
• Educator?
• Political Advocate?
A Matter of Perspective

Health Care?  
Heath Crisis?

"Yesterday is gone. Tomorrow has not yet come. We have only today. Let us begin."

- Mother Teresa

Sources Cited

- https://nabp.pharmacy/initiatives/pmp-interconnect/