The Role of Prescription Drug Monitoring Programs in Combatting Controlled Substance Abuse

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  – No relevant financial relationships.
  – No conflicts of interest.
Objectives

• Discuss the scope of the prescription drug abuse problem nationwide.

• Identify characteristics of “pill mills” and doctor shoppers.

• Review Corresponding Responsibility of the pharmacist regarding questionable prescribing.

• Describe the goals and features of Prescription Drug Monitoring Programs (PDMPs).

• Discuss the KASPER program’s evolution and success.

• Review the status of state PDMPs.
Controlled Substance Abuse
Misuse, Abuse, Diversion

• Misuse:
  – When a schedule II – V substance is taken by an individual for a non-medical reason.

• Abuse:
  – When an individual repeatedly takes a schedule II – V substance for a non-medical reason.

• Diversion:
  – When a schedule II – V substance is acquired and/or taken by an individual for whom the medication was not prescribed.
A National Perspective

• Opioid pain relievers involved in more than 15,000 deaths in the United States
• 1 in 20 people in the U.S. reported using prescription painkillers for nonmedical reasons in the last year
• Enough prescription painkillers were prescribed in 2010 to medicate every adult American around the clock for a month

Source: U.S. Centers for Disease Control and Prevention, Vitalsigns newsletter, November 2011.
A National Perspective

- About 50 Americans die each day from prescription painkiller overdoses
- Sales of prescription painkillers quadrupled from 1999 to 2010
- Fatal poisonings from prescription painkillers more than quadrupled between 1999 and 2010

Source: Trust for America’s Health, *Prescription Drug Abuse 2013: Strategies to Stop the Epidemic*
A National Perspective

• ED visits for prescription drug misuse more than doubled between 2004 and 2011
• Prescription painkillers responsible for more than 16,000 deaths and more than 475,000 ED visits each year

Source: Trust for America’s Health, Prescription Drug Abuse 2013: Strategies to Stop the Epidemic
Motor vehicle traffic, poisoning, drug poisoning, and unintentional drug poisoning death rates: United States, 1999 – 2010

Drug poisoning death rates by age: United States, 2010

<table>
<thead>
<tr>
<th>Age Range</th>
<th>Deaths per 100,000 population</th>
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<tbody>
<tr>
<td>15-24</td>
<td>8.2</td>
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<tr>
<td>25-34</td>
<td>18.4</td>
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<tr>
<td>55-64</td>
<td>15.0</td>
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<tr>
<td>65 and over</td>
<td>4.3</td>
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</tbody>
</table>

Drug Overdose Mortality Rates (per 100,000)

1999 Rates

North Dakota
2010 Rank: Lowest
2010 Mortality Rate (per 100,000): 3.4
1999 Mortality Rate (Per 100,000): N/A
Rate Change 1999 - 2010: N/A

Source: Trust for America’s Health, Prescription Drug Abuse 2013: Strategies to Stop the Epidemic
Drug Overdose Mortality Rates (per 100,000)

2010 Rates

Arizona
2010 Rank: Sixth Highest
2010 Mortality Rate (per 100,000): 17.5
1999 Mortality Rate (Per 100,000): 10.6
Rate Change 1999 - 2010: increased by 65 percent

Source: Trust for America’s Health, Prescription Drug Abuse 2013: Strategies to Stop the Epidemic
Generation Rx

- 19% of teens report abusing prescription medications to get high.
- 40% of teens agree that prescription medicines, even if not prescribed by a doctor, are safer than illegal drugs.
- 29% of teens believe prescription pain relievers are not addictive.
- 62% of teens say prescription pain relievers are easy to get from parents’ medicine cabinets.

Kitson Clothing Collection

JUST WHAT THE DOCTOR ORDERED.

A PORTION OF THE PROCEEDS FROM THE SALES OF THIS COLLECTION WILL BE DONATED TO THE MEDICINE ABUSE PROJECT.

Story: WXIX Fox 19 Digital Media Staff, June 21, 2013
“Pharm Parties”

• Short for pharmaceutical party, often attended by teens and young adults.
• Bowls and baggies of random prescription drugs called “trail mix”.
• Collecting pills from the family medicine cabinet called “pharming”.
• Internet chat rooms are used to share “recipes” for getting high with prescription drugs.

Reported by Donna Leinwand, USA Today, June 13, 2006
Hydrocodone

• DEA believes hydrocodone the most abused prescription drug in the U.S.¹
  • Usage increased 400% in last 10 years
  • Hydrocodone attributed ER visits increased 500% in last 10 years
• The U.S. has approximately 4.6% of the world’s population and consumes 99% of all the hydrocodone produced ²
• The “Cocktail”: hydrocodone, Xanax and Soma

Oxycodone

• Street names: OC, Oxies, Roxies, Oxycotton, Hillbilly Heroin, Blue
• Highly addictive opioid
• OxyContin, Percodan, Percocet
• The U.S. consumes 83% of all the oxycodone produced \(^1\)

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“Study Drugs”: Adderall & Ritalin

• Highly addictive amphetamine based stimulants used to treat ADHD
  – 2 - 4% of college students on ADHD medication (1)
  – An estimated 5 – 10% of youth are misusing or abusing ADHD medications (2)

• As many as 20% of college students have use Adderall and Ritalin to study, write papers and take exams (1)
  – Most obtained from fellow students
  – Pill prices increase during exam time

(1) Source: Adderall Used for Recreation and Study on UMass Campus, Michelle Williams, The Massachusetts Collegian, December 7, 2010.
(2) Source: Dr. Timothy Wilens, Center of Addiction Medicine, Massachusetts General Hospital, August 15, 2012.
Fentanyl

- Synthetic opioid delivered via transdermal patch or lozenge \(^1\) (fentanyl lollipops - Actiq)
  - 50 to 100 percent more potent than morphine
- Patches stolen from nursing home patients
- Methods of abuse:\(^1\)
  - Applying multiple patches to the body at one time
  - Eating or sucking on a patch
  - Extracting the drug from a patch, mixing it with an alcohol solution, and injecting it with a hypodermic needle

“Pill Mills” and Doctor Shoppers

Kentucky
UNBRIDLED SPIRIT
Prescription Drug Abuse in Kentucky

• 2009-2010 data:
  – 6.6% of Kentuckians (ages 12+) have used prescription pain relievers for nonmedical reasons in past year. (KY tied for 2nd in nation)
  – National average = 4.9%

• 2010-2011:
  – 4.48% of Kentuckians (ages 12+) have used prescription pain relievers for nonmedical reasons in past year. (KY dropped to 31st in nation)
  – National average = 4.6%

Source: Data from the 2007, 2008 and 2009 National Surveys on Drug Use and Health, published by the U.S. Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Behavioral Statistics and Quality.

IN TOUGH TIMES, FLORIDA'S TOURISM INDUSTRY GETS CREATIVE...

HOW ABOUT THAT... COMPLIMENTARY PAIN PILLS ON THE PILLOW!

Chan Lowe, South Florida Sun-Sentinel August 29, 2009
Jeff and Chris George

Photos from Palm Beach Post
Dr. Paul H. Volkman

Doctor Shopping

• Doctor shopping is when controlled substances are acquired by deception.
• Legal definition and punishment for conviction varies among state code, statutes, and regulations

• What RPh can do to aid law enforcement:
  – Know your state laws
  – Know your law enforcement officials
  – Utilize all tools at your disposal, including PDMP
  – Trust your gut instinct
Doctor Shopping

Typical Behaviors:

• Early refills
• Emergency Department hopping
• Late night or weekend new patients
• “Insurance doesn’t cover it…I’ll just pay cash”
• Allergic to other alternatives
Corresponding Responsibility
Corresponding Responsibility

Code of Federal Regulations
Section 1306.04 Purpose of issue of prescription.

(a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.
Prescriptions may not be for legitimate use if:

- Prescriber’s pattern is different from other prescribers in the area
  - More prescriptions for CS
  - Rx for larger quantities
- Prescriber writes for antagonistic combo
  - Phentermine and zolpidem
- Prescriber has multi-faceted practice:
  - Addiction, pain management, and dispensing weight loss drugs at office
Prescriptions may not be for legitimate use if:

- Large number of patients suddenly show up with the same rxs (drug, qty, etc.) from same prescriber
  - May try to give a non-controlled rx first to see if you will fill it if the prescriber is from out of town. As soon as you do, then they give you the controlled rxs
Poll Question

Do you utilize your PDMP as part of fulfilling your corresponding responsibility?

Yes
No
Prescription Drug Monitoring Programs

Overview
Prescription Drug Monitoring Programs

• Description
  – Programs that collect, manage, analyze, and provide prescription data under the auspices of a state, territory, district, or commonwealth

• Purpose
  – Provide a tool for curtailing drug abuse and diversion while ensuring controlled substance access to patients with legitimate medical need
Prescription Drug Monitoring Program Goals

- Ensure access to controlled substances for legitimate medical purposes
- Provide education & information regarding drug abuse and diversion issues
- Support public health initiatives
- Identify potential misuse and abuse to support early intervention & treatment
- Enable more efficient investigation & enforcement
Prescription Drug Monitoring Program History

• First PDMP’s
  – 1939- 1943 - California, Hawaii

• Duplicate/Triplicate Prescription Forms

• 1991- Oklahoma first electronic program
Prescription Information Collected

• Patient Information
  – Name, address, date of birth, gender, method of payment

• Prescriber Information
  – DEA registration number
  – Date Rx issued

• Dispenser Information
  – DEA registration number
  – Date Rx dispensed

• Drug Information
  – National Drug Code (drug name, type, strength, manufacturer)
  – Quantity
  – Days supply
  – New or refill
Types of PDMP Reports

• Typical PDMP reports include:
  – Patient
  – Prescriber
  – Pharmacy

• Solicited – all PDMPs (except PA)

• Unsolicited – not all states

• States may also run specialized reports (e.g., by drug or region)
Use by Prescribers/Pharmacists

- Prescription history of a current or prospective patient
  - Risk of misuse or addiction
  - “Doctor shoppers”
  - Drug interactions
  - Compliance with pain contracts

- Practitioner prescribing history
  - Fraudulent scripts
Use by Law Enforcement Agencies

• Unlawful sale of controlled substances/prescriptions
• Unlawful prescribing/dispensing
• Organized forgery rings
• Organized doctor shopper rings
Use by Boards/Licensing Agencies

- Investigations of licensees
- Meeting Standard of Care
- Identification of prescribing trends
- Monitoring compliance of prescribers/dispensers currently under board orders
- Monitoring compliance of dispensers reporting information to PDMPs
Other Use of PDMP Reports

- Public Health
  - Research, prevention & education
- Drug Courts
  - Assist in monitoring compliance of participants
- Medical Examiners
  - Assist in identifying cause of death in drug overdose cases
- Impaired Professional Programs
  - Assist in monitoring compliance of health care professionals
- Medicaid
  - Drug Utilization Review Boards
  - Identify other sources of drugs (forms of payment)
  - Restrict members to single practitioner/pharmacy
Challenges

• User Authentication
  – Standardize process

• Ease of Access
  – Sub-accounts/delegate accounts

• Data Collection
  – Multiple versions of ASAP standard in use
  – Inconsistent data collection timeframes
  – Inconsistent drug schedules tracked
  – Poor quality of data reported by dispensers
  – Lack of unique patient identifier
Challenges

- Standardize Practitioner/Pharmacist PDMP Reports
  - Reports from states should all be similar

- Interstate Data Sharing
  - Drug seekers are not constrained by state borders
  - State statutes must permit data sharing
  - Multiple hub-based data sharing solutions exist
    - Prescription Monitoring Information Exchange
Poll Question

If your state PDMP is sharing data with another PDMP, do you take advantage of this feature when requesting the report?

Yes

No
PDMP Enhancements

• Proactive notifications
  – Prescribers
  – Dispensers
  – Licensure boards

• Integration with Health Information Exchanges
  – Allow access as part of normal workflow

• Increased use of data for studies and research/prevention
  – Aggregate data nationally
Prescription Drug Monitoring Programs

KASPER
KASPER Operation

• KASPER tracks most Schedule II – V substances dispensed in KY
  – Over 11 million controlled substance prescriptions reported to the system each year

• KASPER data is 1 to 3 days old
  – Dispensers have 1 business day to report

• Reports available to authorized individuals
  – Available via web typically within 15 seconds
  – Available 24/7 from any PC with Web access
• KASPER registration is mandatory for Kentucky practitioners or pharmacists authorized to prescribe or dispense controlled substances to humans.
KASKPER Prescriber Usage

• Query eKASKPER for previous 12 months of data:
  – Prior to initial prescribing or dispensing of a Schedule II controlled substance, or a Schedule III controlled substance containing hydrocodone
  – No less than every three months
  – Review data before issuing a new prescription or refills for a Schedule II controlled substance or a Schedule III controlled substance containing hydrocodone

• Additional rules/exceptions included in licensure board regulations
2012 KASPER Reports Requested

Number of Reports in Thousands

- 2006: 186
- 2007: 274
- 2008: 362
- 2009: 418
- 2010: 708
- 2011: 811
- 2012: 2,691
- 1H 2013: 2,253

Cabinet for Health and Family Services
KASPER Usage 2012

- Pharmacists = 2.1%
- Law Enforcement = .5%
- Judges, Other = .1%
- Prescribers = 97.3%
KASPER Prescriber Reports

- CS prescribers can obtain an eKASPER report on themselves:
  - To review and assess the individual prescribing patterns
  - To determine the accuracy and completeness of information contained in eKASPER
  - To identify fraudulent prescriptions
## Controlled Substance Dispensing – One Year Comparison

<table>
<thead>
<tr>
<th>Drug</th>
<th>August 2011 through July 2012</th>
<th>August 2012 through July 2013</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrocodone</td>
<td>239,037,354</td>
<td>214,349,392</td>
<td>-10.3%</td>
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<tr>
<td>Oxycodone</td>
<td>87,090,503</td>
<td>77,022,586</td>
<td>-11.6%</td>
</tr>
<tr>
<td>Oxymorphone</td>
<td>1,753,231</td>
<td>1,138,817</td>
<td>-35.0%</td>
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<tr>
<td>Alprazolam</td>
<td>71,669,411</td>
<td>62,088,568</td>
<td>-13.4%</td>
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<tr>
<td>Methylphenidate</td>
<td>10,659,840</td>
<td>11,454,025</td>
<td>+ 7.5%</td>
</tr>
<tr>
<td>Amphetamine</td>
<td>13,795,147</td>
<td>15,065,833</td>
<td>+ 9.2%</td>
</tr>
<tr>
<td>All Controlled Substances</td>
<td>739,263,679</td>
<td>676,303,581</td>
<td>-8.5%</td>
</tr>
</tbody>
</table>

Figures shown in doses dispensed

Cabinet for Health and Family Services
Prescription Drug Monitoring Programs

State Summary
Poll Question

How often do you use your PDMP?

a. Daily
b. Once a week
c. Once a month
d. Never
COMPILATION OF STATE PRESCRIPTION MONITORING PROGRAM MAPS

This project was supported by Grant No. G1299ONDCP03A, awarded by the Office of National Drug Control Policy. Points of view or opinions in this document are those of the author and do not necessarily represent the official position or policies of the Office of National Drug Control Policy or the United States of Government.
Status of State Prescription Drug Monitoring Programs (PDMPs)

*The operation of Nebraska’s Prescription Monitoring Program is currently being facilitated through the state’s Health Information Initiative. Participation by patients, physicians, and other health care providers is voluntary.


This information was compiled using legal databases, state agency websites and direct communications with state PDMP representatives.
Breakdown of Housing Entities*

* This information is based on the agency the PMP statute or regulation indicates is required to establish the PMP.

This information was compiled using legal databases, state agency websites, and direct communications with state PDMP representatives.
Prescription Drug Monitoring Programs
States With Authority to Monitor Schedule II Substances

This information was compiled using legal databases, state agency websites and direct communications with state PDMP representatives
Iowa’s PDMP monitors Schedule III and IV substances that the advisory council and the Board of Pharmacy determine can be addictive or fatal if not taken under the proper care or direction of a prescribing practitioner.
Tennessee’s law authorizes the monitoring of Schedule V substances which have been identified by the controlled substances database advisory committee as demonstrating a potential for abuse.
Please note that although a state may have statutory authority to monitor Non-controlled/Non-Scheduled substances, that state may not currently be monitoring prescriptions for such substances and may in fact require implementation of additional regulations before that monitoring can commence.
New York has passed legislation that will allow access to dispensers as soon as is practicable but no later than August 27, 2013.
Types of Authorized Recipients – Law Enforcement Officials

Probable cause, search warrant, subpoena, or other judicial process
Pursuant to an active investigation
May only receive information from professional licensing boards
Upon request from law enforcement officials

1 Law enforcement requests must be approved by the Office of the Attorney General. Law enforcement officials do not have direct access.
2 Law enforcement officers must make a declaration that probable cause exists, but there is no judicial process involved.
Types of Authorized Recipients – Judicial and Prosecutorial Officials

Probable cause, search warrant, subpoena, or other judicial process in criminal cases

Probable cause, search warrant, subpoena, or other judicial process in criminal and civil cases

Pursuant to an active investigation or prosecution

Both judicial process or pursuant to an active investigation

Upon request of the grand jury

Upon request from judicial or prosecutorial officials

1 The Pennsylvania provision pertains only to cases involving criminal investigations into violations of state or federal drug laws, health care fraud, or insurance fraud statutes.

This information was compiled using legal databases, state agency websites, and direct communications with state PDMP representatives.
Types of Authorized Recipients – Medicare, Medicaid and/or State Health Insurance Programs or Health Care Payment/Benefit Provider or Insurer


This information was compiled using legal databases, state agency websites, and direct communications with state PDMP representatives.

The Alabama provision goes into effect on September 1, 2013.
Types of Authorized Recipients – Patient, Parent or Guardian of Minor Child, Health Care Agent or Attorney on Behalf of Patient


This information was compiled using legal databases, state agency websites and direct communications with state PDMP representatives.

1 The New York provision goes into effect August 27, 2013.
States that Require All Licensed Prescribers and/or Dispensers to Register with PMP Database*

* Many states require that persons requesting access to the state PMP database first register as an authorized user. This map and the memorandum located on the NAMSDL website are concerned with only those states that require all practitioners licensed in the state to also register to use the PMP database.

1 The Vermont provision goes into effect on July 1, 2013. Health care providers and dispensers will have until November 15, 2013 to register. The Delaware provision goes into effect on March 1, 2014, but all dispensers and prescribers must be registered with the program by January 1, 2014. 2 Alabama only requires physicians with or seeking a pain management registration to be registered with the PMP.

This information was compiled using legal databases, state agency websites, and direct communications with state PDMP representatives.
States that Require Prescribers and/or Dispensers to Access PMP Information in Certain Circumstances*

* Please see the accompanying memorandum for specifics as to the circumstances under which a prescriber and/or dispenser is obligated to access the PMP database in each state.

1 The New York law goes into effect on August 27, 2013. The Delaware requirement that dispensers check the database goes into effect on March 1, 2014.
2 Vermont will require mandatory use for replacement prescriptions beginning October 1, 2013 and in other circumstances beginning November 15, 2013.

This information was compiled using legal databases, state agency websites, and direct communications with state PDMP representatives.
Unsolicited PMP Reports/Info to Prescribers, Pharmacists, Law Enforcement and Licensing Entities

1 The New York provision goes into effect August 27, 2013. Until then, New York will provide unsolicited reports to prescribers only.
2 North Carolina provides unsolicited reports to the Attorney General who has the discretion to forward the information to law enforcement.
3 Michigan send alerts to physicians when a patient surpasses the threshold but does not send the actual report.


This information was compiled using legal databases, state agency websites, and direct communications with state PDMP representatives.
Data Collection Interval

1 New York requires the submission of data monthly until August 27, 2013, after which time they will implement real time reporting.
2 Ohio requires submission from pharmacies weekly and from wholesalers monthly. 3 Utah requires submission weekly, but for those participating in the statewide pilot program, submission is required daily.

This information was compiled using legal databases, state agency websites, and direct communications with state PDMP representatives.
QUESTIONS?

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State and Federal Files:

- Difference between what the State and Federal control substance status (scheduling of control substances, which are stricter by the State standards) are
  - Sudafed is a Schedule 3 in Mississippi and Oregon, a Schedule 5 in Kansas and Louisiana
- MedGuide flags and associated MedGuides
  - These are required for any dispensed prescription where applicable
- Patient Package Insert (PPI) flags with mandatory or permissive indicators
- Black Box flags with codified reasons
- REMs flags with codified descriptions that are unique to Gold Standard Drug Database
  - Risk Evaluation and Mitigation Strategies
State and Federal Files:

• The State and Federal Modules are available as raw data for self programming, or by an API (application programming interface) for a true ease of use capability.
• Data is updated daily and is available any time the client would like to update their system content.
• Normalized data allows for ease of programming and simpler implementations.
• Critical updates are available generally the same day it is released by the States or the FDA.
## State and Federal Files Components:

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<thead>
<tr>
<th>Federal State Data</th>
<th>Boxed Warning</th>
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<tbody>
<tr>
<td>Federal State Data</td>
<td>DEA Classification</td>
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<td>Federal</td>
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<tr>
<td>Federal State Data</td>
<td>IV Container Material</td>
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<td>Federal State Data</td>
<td>Legend Status</td>
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<td>License Type</td>
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<td>Package State Legend Status</td>
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<td>Patient Package Insert</td>
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<td>Product REMS</td>
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<td>REMS</td>
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QUESTIONS?

Thank you!

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