Combating Prescription Drug Abuse in Massachusetts and Use of the Prescription Monitoring Program

Karen Ryle, MS RPh
Associate Chief of Massachusetts General Hospital
Disclaimer

Although I am currently the President of National Association of Boards of Pharmacy and President Elect of Massachusetts Board of Pharmacy, I am not giving this presentation as an official representative of either organization.
Objectives

1. Discuss recent regulatory changes in Massachusetts to curb prescription drug abuse
2. Understand the pharmacist’s corresponding responsibility when filling prescriptions for controlled substances
3. Describe the online Prescription Monitoring Program and how it will affect prescribing and dispensing of controlled substances.
4. Identify when a pharmacist should access the Prescription Drug Monitoring Program.
Massachusetts Oxycontin and Heroin Commission Nov 2009

- Members of the commission included legislative and Gubernatorial appointments
- 71 page report to the State House
- Opioid overdose has become the leading cause of injury death in Massachusetts
- “The commonwealth is in the midst of a serious and dangerous epidemic.”
- “Addiction is a medical disorder and we have a public health epidemic on our hands that is bigger than the flu epidemic.”
- The panel made 20 recommendations that include updating the Prescription Monitoring Program (PMP), to deter “Doctor Shopping” and “Over Prescribing”.
- Will require tampers resistant prescriptions
Regulatory Changes to curb Prescription Abuse

• Chapter 244 of the Acts of 2012 (Prescription Drug Omnibus) passed legislation in August 2012
• An Act Relative to Prescription Drug Diversion, Abuse and Addiction.
• Effective January 2013
• Designed to help prevent the diversion and abuse of prescription drugs.
  – Changes in DEA 106 filing
  – Pharmacies will be required to distribute a pamphlet raising awareness about addiction risks
  – Pharmacies can only fill prescriptions for narcotics outside of Mass from contiguous states and Maine within 5 days of prescribing - delayed until December
  – Tamper Resistant Prescriptions
Section 2: DEA 106

- Pharmacy discovers a theft or loss of controlled substances that requires filling out a DEA 106 form
- Simultaneously file a copy with Massachusetts State Police

Massachusetts State Police
6 West St.
Norwell, MA 02031
Attn: Sergeant David McQueeny
Section 4
Out of State Prescriptions

- Effective December 1, 2013
- Pharmacies may fill out-of-state prescription for Schedule II narcotics ONLY if prescriber is licensed in Maine or in a contiguous states: Rhode Island, Connecticut, New York, Vermont, and New Hampshire.
- Rx has to be issued within the past 5 days
- Law does not change Non-narcotic Schedule II
- Stimulants can still be filled from all states
- Rx’s for Schedule II Narcotics can still be filled within 30 days from prescribers in Massachusetts.
Section 5: Educational Materials

- Requires the Department of Public Health to develop a pamphlet for consumers relative to narcotic drugs.
- The pamphlet shall include educational materials on risks related to opioid drugs and addiction treatment services.
- A pharmacist shall distribute the pamphlet when dispensing Schedule II and III controlled substances.
Section 6: Locked Boxes

• Post a sign 4-5 inches stating:
  – “Lock Boxes for securing your prescription medications are available at this pharmacy”.
  – New law deletes the requirement that Lock Boxes shall be available within 50 feet of the Pharmacy counter.
Section 7: Tamper Resistant Prescription Forms

• Effective July 1, 2013
• Consistent with Federal requirement for Medicaid
• Requires prescribers to utilize tamper-resistant prescription forms for all prescriptions
• Changes will be made to 105CMR 721.020
• Tamper resistant features:
  - Category 1-prevent unauthorized copying
    • Ex. Micro printing-font 0.5 or less
  - Category 2-prevent erasure or modification
    • Ex. Border characteristics ****
  - Category 3-counterfeit resistant
    • Ex. List of security features
• Excluded: E-prescriptions, Fax Rx, Phone Rx
Section 8
Continuing Education

• Effective January 1, 2013
• Requires the Board of Pharmacy to promulgate regulations requiring continuing education (CE) for pharmacists specific to training in the use of the prescription monitoring program (PMP).
• Expectation is a one-time CE requirement to be completed by December 31, 2014.
Changes to PMP

- Prescribers will be required to enroll in the state PMP upon license renewal.
- Prescribers will be required to check the PMP before prescribing a narcotic to a new patient.
- Most useful in the ER
- Pharmacists will be educated on the use of the PMP program
  - 1 hour CE program before December 2014
- Requires PMP to connect with other states
Doctor Shopping and Overprescribing
On Line Prescription Monitoring Program (PMP)

• Where to Access PMP Application
  – http://www.mass.gov/dph/dcp/onlinepmp

• Pharmacists and Prescribers enroll through the virtual gateway

• Database contains over 4 million Rx’s now of just C2’s

• Will be updated monthly and include all schedules

• Barriers were removed for easy access to PMP
  – CVS
  – Notary
When should a pharmacist access the PMP?

Based on Professional Judgment
Ohio Regulations: Pharmacist should review the PMP if they becomes aware of a person currently:
1. Multiple Prescribers (doctor shopping)
2. Longer than 12 consecutive weeks
3. Abusing or misusing
   Over-utilization
   Early refills
   Appears overly sedated when presenting Rx
   Unfamiliar patient requesting specific name, street name, color, identifying marks
4. Patient or Prescriber is located out of state or outside usual geographic area
When not to access the PMP Program

- Friends
- Family
- Neighbors
- Famous People
- You must have a prescription for a patient in order to look up the PMP.
On Line PMP

Can look up a single patient at a time
Detailed record of Controlled Rx’s
  – Fill date
  – Quantity
  – Prescriber
  – Pharmacy
  – Includes both insurance and cash
Instructions for Enrollment

To logon to the Virtual Gateway (VG), go to www.mass.gov/vg and click on Logon to the Virtual Gateway.
Search Criteria
To search for an individual, complete the following required fields:
1. last name
2. first name
3. date of birth (ddmmyyyy, no slashes)
Click Search.
Record Overview

The record overview shows information about each prescription filled. Click on the patient’s name to see a Person Summary. You also have the option to return to the main screen if you want to search for another record. Or you can logout from this page.
PMP CASE

• Rx was hand written for Adderall XR
• Pharmacist intuition
• Looked up PMP
• Patient received 60 prescriptions in 10 months
  – 5 years worth
• Rx’s filled at 10 different pharmacies
• 1 Prescriber
• Patient known to Pharmacist
• Police notified
• Patient went into rehab
States differ in PMP programs

- Purpose of all PMP’s is to collect dispensing data for Schedule II – V controlled substances into a central statewide database for use in preventing diversion and abuse by “doctor and pharmacy shopping”
- Some PMP programs do not require positive ID
- Mostly used by physicians and pharmacists, also by regulators and law enforcement in some states
- States differ in the drugs that must be reported, frequency that pharmacies/dispensers must report, and who can access the database
List of States with PMP Programs

Legend:
- PMP: PMP InterConnect Participant
- Memorandum of Understanding Executed
- Pending PMP: PMP InterConnect Participant
- Prospective PMP: PMP InterConnect Participant
- No PMP in Place
• Interstate PMP Data sharing through NABP PMP Interconnect is now available
• It provides a way for States to report into ONE database
• Interconnected hub
• Used only to facilitate the communication process.
• NABP does not retain any prescription data
• Purpose:
  – Reduce prescription drug abuse
  – Reduce doctor shopping
  – Early detection, intervention and prevention of substance abuse and diversion of controlled substances
• Creates interoperability for individual state PMPs via a hub system
• Physicians and pharmacists log into their own state PMP and check boxes for other participating states from which they want data
• The hub routes the requests to the various states and the information back to the physician or pharmacist in one collated report
16 PMPs are actively sharing data

Arizona, Colorado, Connecticut, Illinois, Indiana, Kansas, Kentucky, Louisiana, Michigan, New Mexico, North Dakota, Ohio, South Carolina, South Dakota, Tennessee, and Virginia

7 more PMPs should be connected and sharing data by the end of 2013

Delaware, Idaho, Minnesota, Mississippi, Nevada, West Virginia, and Wisconsin

2 have executed MOUs to participate

Arkansas and Utah

4 more states are in process of signing MOUs
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N/R: N=New, R=Refill  
Pay: IIt=Insurance, W=C=Workers Comp

Prescribers for prescriptions listed (These are fictitious practitioners)

- C Gardner: Charles Gardner, 2139 Auburn Ave, Anytown USA
- D White: David White, DC, Family Medicine Group, 8787 Medicine Ave, Somtown
- G Green: George Green, MD, 872 Main St, Anytown USA
- J Smith: Joseph Smith, MD, Health Care Office, 3123 Brown Drive, Anytown USA
- M Black: Michael Black, MD, 672 Main St, Anytown USA
- Saint P: St Paul Hospital, 987 Market St, Somtown

Pharmacies that dispensed prescriptions listed (These are fictitious pharmacies)

- CVS1234: CVS PHARMACY #1234, 11611 Medicine Ave, Somtown, OH; Pharmacy phone number
- K-Mart: K MART PHARMACY #153, 1217 Brown Dr, Anytown, OH; Pharmacy phone number
- Sams Club: Sams Club Pharmacy #123, Anytown, IN
- Target: Target Pharmacy, 4321 Fifth St, Somtown, OH; Pharmacy phone number
- Walgreens: Walgreen Co #22, 9775 Auburn Ave, Anytown, OH; Pharmacy phone number
- WalMart: Wal-Mart Pharmacy #432, 128 Main St, Anytown, OH; Pharmacy phone number
Access to PMP Data – Integration Method
Narxscore calculated from data provided by the State Prescription Monitoring Program (PMP)
1st 2 digits, percentile risk based on overall analysis of prescriptions as reported by the PMP
3rd digit represents the number of active prescriptions
Patient Score of 821
75% patients fall below 200
95% patients fall below 500
99% patients fall below 650
provides decision support
NYC
ER Drug Seeker

PREScribing Opioid Painkillers
IN THE EMERGENCY DEPARTMENT

People sometimes misuse opioid painkillers, either by taking them in ways they weren't prescribed or by taking someone else's prescription. In New York City, one in four overdose deaths involves opioid painkillers. Our emergency department will only provide pain relief options that are safe and appropriate.

FOR YOUR SAFETY, WE DO NOT:

* Prescribe long-acting opioid painkillers, such as oxycodone (OxyContin®), morphine (MS Contin®), hydromorphone (Hemorphine®) or methadone.
* Prescribe more than a short course of opioid painkillers.
* Refill lost, stolen or destroyed prescriptions.

Prescription opioid painkillers can be just as dangerous as illegal drugs:

- Opioid painkillers can cause confusion, drowsiness and increased sensitivity to pain.
- People can become physically or psychologically addicted to opioid painkillers.
- An overdose of opioid painkillers can cause a person to stop breathing and die.

Keep your prescription opioid painkillers safe!

- Keep opioid painkillers in their original labeled containers.
- Keep opioid painkillers out of reach and out of reach of children, preferably in a locked cabinet or on a high shelf.
- Get rid of opioid painkillers you are no longer using by flushing them down the toilet.

Problem with painkillers?
Help is available – call 1-800-LIFENET

NYC
Opioid Overdose Deaths

DPH Initiative

• Opioid Overdose still a considerable public health crisis
• September 26, 2013
• 2,000 Opiate overdose reversal announced due to innovative naloxone program
• National leader
• Saving Lives
• Family and friends
• Has been distributed by DPH
• Can be dispensed with a prescription
Naloxone Kits
Naloxone Intranasal
Walgreen’s Initiative

• DEA accused Walgreen’s of endangering public safety
• Stopped shipment of Oxycodone from Jupiter, Fl Distribution Center
• Signed agreement to avoid fines
• Agreement with the DEA to follow “Good Faith Practices” when dispensing controlled substances
  – Check PMP,
  – Check DEA Registry
  – Obtain diagnosis on prescriptions
    • Treatment plans
    • Taper
  – Focusing on Oxycodone, Methadone, Hydromorphone
American Medical Association Resolution

• AMA adopted a resolution at its 2013 annual meeting
• Inappropriate inquiries relating to verification of prescriptions is interfering with the practice of medicine and is unwarranted.
• Pharmacist duty is only to make sure a prescription is legitimate.
• Develop appropriate policy for Pharmacists to work with Physicians to reduce drug diversion and inappropriate dispensing.
• Don’t call us, we will call you attitude
• Meeting planned Oct 2nd.
Florida Case

Accused of over prescribing controlled substances to at least 2 patients that both died, now up for 2 counts of manslaughter

Daniel Joseph Lewis- 31 yr old Prescribed
– 1070 Alprazolam,  
– 1040 Methadone  
– 670 Lortab in 4 months

Travis Bryan Walls- 25 yr old Prescribed
– 1938 Methadone  
– 996 Alprazolam as well as Lortab and Ultram
Methadone Case

• 3 month supply of Methadone
• Visited 13 different pharmacies
• Schedule of pharmacy visits
• Paid cash, never early
• No PMP in place in Florida in 2008
• Both died of multiple drug overdose
• Does the pharmacist share responsibility?
• If the pharmacies had access to a prescription monitoring program, could it have prevented the death of these 2 individuals?
1. Repeatedly dispensing “cocktailed” prescriptions
2. No individualization of dosing by the Prescriber
3. Filling multiple prescriptions for the strongest formulations
4. Request for early refills
5. Doctors located 100 miles away from pharmacy
6. A large proportion (75%) of prescriptions filled by the pharmacy were controlled substances written by one particular physician

7. Pharmacist doesn’t reach out to other Pharmacists to see why they aren’t filling the particular doctor’s prescription

8. Patients travel in groups to the pharmacy

9. Filling a large percentage of cash prescriptions

10. “verification” of a prescription as “legitimate” was not satisfied simply because the practitioner said so.
Pharmacist Corresponding Responsibility

• CFR, Title 21 sec 1306.04, Purpose of Issue of Prescription
  • 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 shall be upon the prescribing practitioner, but a corresponding responsibility shall rest with the pharmacist who fills the prescription
Violation of CFR, 21,1306.04

A prescription purporting to be a prescription issued NOT in the usual course of professional treatment and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violation of the provisions of law relating to controlled substances.
Cocktail Case

Pharmacy repeatedly fills “cocktail” prescriptions for multiple patients from the same physician.

Cocktail known as “home run” includes:
- Hydrocodone 10mg
- Carisprobol 350mg
- Alprazolam 2mg

No individualization of dosing by the prescribing physician

Prescribing and dispensing the strongest formulations
Question

Is the pharmacist violating “Corresponding Responsibility” by filling these prescriptions?

1. Yes
2. No
What is Legitimate Medical Purpose?

- Methadone 40mg daily (for pain?)
- Fentanyl Rx from the Dentist
- Rx’s for “The Holy Trinity”:
  - Opiate, Benzodiazepine and Carisoprodol
- Chairman of Texas Pain Society “No medical purpose”
- Make an informed decision
- “purple drank”
Oxycodone 30mg

In 2010 43% of ALL Oxycodone 30mg was distributed to Florida
Does your patient really need OXY 30’s ????
Is it for a Legitimate Medical Purpose?
Medication Disposal
Charlestown Against Drugs
June 2013
Legitimate Medical Purpose

Pharmacy receives prescription from patient for Fentanyl 75 mcg patch for back pain (not indicated on Rx)
New to pharmacy
Rx written from Ophthalmologist
Pharmacy fills Rx
Patient expires within 48 hours from overdose of Fentanyl
Discussion

Patient works in the MD office
Patient/Physician relationship
Scope of Practice
Diagnosis
Counseling
Corresponding Responsibility
Federal Case

• U.S.A vs. Nick Tran, March 2010
• Based on Corresponding Responsibility
• Independent Pharmacy Owner
  – Upscale pharmacy
• Located in a strip mall in Mississippi
• Family Medical Center located in the same mall
  – Dr. Trieu and Dr. Van
• Pharmacy filled approx. 250 Rx’s per day
• Very rarely filled a prescription for a Schedule II
• Filled Rx’s for Patients;
  – Promethazine with codeine 4-8 ounces
  – Antibiotic
  – Steroid Inhaler/Antihistamine
U.S.A vs. Nick Tran

• Rx’s faxed from Medical Center
  – No question about validity
• Rx’s for the same medications were filled at all other pharmacies in the area
• Promethazine with Codeine
  – Mixed with Mountain Dew
  – “Purple Drank”
  – $200 per pint
• Family Medical Center-150 patients per day
  – Questionable Physical exams
• Sting operation-under cover officers posing as patients
U.S.A vs Nick Tran

• Dr. Trieu- 8 years in prison
• Dr. Van- 1 year in prison
• Prescribing narcotics outside the scope of practice
• Nick Tran found “Not Guilty” of 43 counts 5/10
• Question of conspiracy
• Hung Jury on 11 Counts
• Second trial for 11 counts -10/10
• Found Guilty of participating in drug conspiracy that involved hundreds of prescriptions from Medical Family Center
• “Legitimate Medical Purpose”
• Should have known
• Sentenced to 10 years in prison
Question

• Do you feel that Mr. Tran should have been found guilty?

• Does the punishment fit the crime?
Medical Marijuana
Medical Marijuana

• Law specifies written certification from a physician
• Cancer, glaucoma, AIDS, hepatitis C, ALS, Crohn’s disease, Parkinson’s, multiple sclerosis, and other conditions determined by a qualifying patient’s physician.
• Patient can possess up to 60-day supply for personal use
• 60 day supply is up to 10 ounces.
• Bona fide physician-patient relationship
Medical Marijuana

- Monday, Sept 23
- DPH will announce the list of applicants for Registered Marijuana dispensaries (phase 2)
- [www.mass.gov/medicalmarijuana](http://www.mass.gov/medicalmarijuana)
- DPH will allow 35 non-profit registered marijuana dispensaries across the state the 1st year.
- No more than 5 per county
- Allowed to cultivate, process, and provide marijuana and marijuana-infused products to qualified patients.
- Patients and Physicians will be registered
- Database will track patients and physicians registrants
Questions?