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

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Objectives
- Discuss recent regulatory changes in Massachusetts to curb prescription drug abuse
- Understand the pharmacist’s corresponding responsibility when filling prescriptions for controlled substances
- Describe the online Prescription Monitoring Program and how it will affect prescribing and dispensing of controlled substances.
- Identify when a pharmacist should access the Prescription Drug Monitoring Program.
- Identify ways patients can dispose of unwanted or expired medications.

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 McQueeney
Section 4
Out of State Prescriptions
• Became 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.
3/17/2014

Search Criteria
To search for an individual, complete the following required fields:
1. last name
2. first name
3. date of birth (ddmmyyyy, no dashes)
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

PMP CASE
Rx was hand written for #600 Oxycodone 10mg
Pharmacist accessed PMP
Looked up PMP
Patient received 64 prescriptions in 12 months
Rx’s filled at 9 different pharmacies
2 Prescriber
#300 Oxycodone 30mg
#90 Oxycontin 80mg
#20 Exalgo 16mg
#120 MS Conitin 30mg
#100 Nucynta 75mg
#90 Lyrica 200mg
#100 Percocet 10/325

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
Interstate PMP Data sharing through NABP PMP Interconnect
- 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
- Pharmacist and Physicians log into their PMP program and check of additional states, information comes back in one report.

20 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 2014
  - 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

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

NYC ER Drug Seeker
https://www.youtube.com/watch?v=EUDJXQNP9yg&feature=player_detailpage
**DEA Proposed Rule**

Rescheduling Hydrocodone

- Published in the Federal Register on Feb 27, 2014
- Proposed rule making
- Public comment
- FDA approved
- Congress approved
- ASHP supports it
- APhA, NACDS, NCPA are against it.
- Concerns are patient access to refills, additional storage, record keeping and inventory management

**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 and paid 80 million in fines
- Agreement with the DEA to follow “Good Faith Practices” when dispensing controlled substances
  - Check PMP
  - Check DEA Registry
  - Obtain diagnosis on prescriptions
  - Treatment plan
  - 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
- Stakeholders met at NABP in October and again in Dec at AMA headquarters
### Stakeholders
- American Academy of Family Physicians
- American Medical Association
- American Osteopathic Association
- Cardinal Health
- CVS
- Federation of State Medical Boards
- National Association of Chain Drug Stores
- National Community Pharmacists Association
- Pharmaceutical Care Management Association
- Pharmaceutical Research and Manufacturers Association
- Rite Aid
- Walgreen Co.

### Press Release issued Feb 4, 2014
Coordination and Collaboration must be improved to ensure that the public health problem is addressed and that patients receive responsible and effective patient care.

- Document to identify “red flags” that warrant the need to review the legitimacy of controlled substance prescriptions
- Document to outline action taken to improve dialogue so that such “red flags” are addressed and in compliance with federal and state law.
- Make sure we are all on the same page

### DEA 10 Red Flags
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.
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

Wife works in the MD office
Patient/Physician relationship
Scope of Practice
Diagnosis
Counseling

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?

Cocktail Case

Pharmacy repeatedly fills “cocktail” prescriptions for multiple patients from the same physician.
Cocktail known as “home run” includes:
  - Hydrocodone 10mg
  - Carisoprodol 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
Where People who abuse prescriptions painkillers get their drugs.

Obtained from a friend, relative, or retailer, 5.6%
Got from drug dealer or stranger, 4.4%
Took from fellow or relative without asking, 3.4%
Received from a formal or relative, 17.4%
Prescribed by solo doctor, 17.3%

Drug Disposal: What’s in your Medicine Cabinet?

Obtained from Friends and Relatives for FREE

Current Disposal Recommendations
- National Take Back Events
- Law Enforcement Collection
- House Hold Disposal
  - Kitty Litter
  - Used Coffee Grounds
- Disposal by flushing
  - FDA List
  - Fentanyl

DEA Drug Disposal Proposed Rule
- Secure and Responsible Drug Disposal Act of 2010
- Provides a secure way for patient to dispose of controlled substances
- Take Back Events
- Mail-Back Programs
- Collection - Box locations
- Long Term Care Facilities
- Controlled Substance must be disposed of in a “non-retrievable” state
- Comment period is over-Final Rule by Sept

Drug Receptacle

Medication Disposal
Charlestown Against Drugs
June 2013