Controlled Substance Prescribing Laws, The Prescription Monitoring Program, and Preventing Drug Diversion

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South County Hospital and Healthcare System
Disclosures

- I have no financial disclosures.
Objectives:

• Define what constitutes a legal control prescription and be able to identify potential pitfalls in filling controlled substance prescriptions.

• Recall the purpose of the Prescription Monitoring Program, how it can be used effectively in a retail setting, and its limitations.

• Define the role of retail pharmacy in the prevention of drug diversion.
Controlled Substance Laws in Rhode Island
Overview

• Review what constitutes a legal prescription

• Discuss controlled substances and the restrictions placed on their use.

• Differentiate between the different schedules of controlled drugs.

• Identify potential issues when dispensing controlled substances
A Legal Prescription Requires...

- Name and address of patient
- Name, address, DEA number of prescriber
- Date written
- Drug name, strength, dosage form, quantity, directions
- Authorized number of refills allowed
- Signature if written or electronic
What defines a controlled substance?

- Subject to regulation by the Drug Enforcement Agency (DEA)
- Scheduled based on potential for abuse and dependence
- Access is restricted (e.g. quantity limits)
- Increased documentation and inventory requirements
## Controlled Substance Prescription

<table>
<thead>
<tr>
<th>Can change</th>
<th>Cannot change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strength</td>
<td>Patient name</td>
</tr>
<tr>
<td>Directions</td>
<td>Date written</td>
</tr>
<tr>
<td>Patient Address</td>
<td>Drug name</td>
</tr>
<tr>
<td>Quantity</td>
<td>Signature</td>
</tr>
</tbody>
</table>

Scheduling of Controlled Substances

Schedule:

- Schedule V: Lower potential for abuse, Lesser risk of dependence
- Schedule IV: Lower potential for abuse, Greater risk of dependence
- Schedule III: Higher potential for abuse, Lesser risk of dependence
- Schedule II/I: Higher potential for abuse, Greater risk of dependence
Schedule II Prescriptions

- Examples:
  - Opioids: morphine, oxycodone, etc.
  - Stimulants: amphetamines, methylphenidate

- Valid within 90 days of date written

- Cannot be refilled and limited to 30 day supply
  - Can write two additional prescriptions at once

- Cannot be prescribed electronically or by facsimile
  - Exceptions: long term care (LTC) and hospice patients

- Cannot be prescribed orally except for emergency period

- Partial fills must be completed within 72 hours
  - Exceptions: LTC and hospice

Schedule III Prescriptions

- **Examples:**
  - Opioids: codeine, hydrocodone (with acetaminophen)
  - Testosterone formulations

- **Valid for 180 days after date written or for 5 refills**

- **Maximum 30 day supply and 100 units per fill**

- **Cannot be prescribed electronically**

- **Can be prescribed orally and by facsimile**
Schedule IV and V Prescriptions

- Examples (IV):
  - Benzodiazepines: alprazolam, lorazepam
  - Hypnotics: zolpidem, Lunesta®

- Examples (V):
  - Cough syrups with codeine
  - Lyrica®

- Valid for 180 days after date written or for 5 refills
- May dispense up to a 90 day supply
- Maximum of 360 units per fill
- Cannot be prescribed electronically
- Can be prescribed orally or by facsimile
Common issues with controlled prescriptions

- Excessive filling
- Multiple doctors/pharmacies
- “Cash claims”
- Forgeries or altered prescription information
- “Pill mills”

Underlying issue: drug dependence and diversion

The Prescription Monitoring Program
Overview

- Review the purpose and basic elements of the Prescription Monitoring Program (PMP).

- Discuss how to effectively use the PMP and examine a patient case-based example.

- Identify limitations of the PMP.
Purpose

- Opioid overdose is the number one cause of unintentional death in Rhode Island
- Caused by both street and prescription drugs
- The Prescription Monitoring Program can help detect and monitor controlled substance use
- Identifies overprescribing and excessive filling

Participation

- Prescribers
- Pharmacists
- Law Enforcement
- Regulatory agents
- Pharmacies in Rhode Island
How it works

- Schedule II and III drugs only
- Information is submitted and updated monthly
- The history report is patient specific
- Independent of third party claims
- Provides vital details to identifying suspicious prescription activity
### Confidential Drug Utilization Report

**Search Terms:** JACK SPRATT, M, 06/28/1978  
**Searching on behalf of:** js123456 - John S. Smith

The Drug Utilization Report indicates that your patient has received controlled substance prescriptions from 1 or more practitioners and filled them at 1 or more pharmacies in the previous calendar month. Drug Utilization Reports are updated on a weekly basis.

**Data Detail Level:** Default | Extended

### My Prescriptions

<table>
<thead>
<tr>
<th>RX Written</th>
<th>RX Dispensed</th>
<th>Substance</th>
<th>Strength</th>
<th>Quantity</th>
<th>Days Supply</th>
<th>Prescriber Name</th>
<th>DEA #</th>
<th>Payment Method</th>
<th>Pharmacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>03/04/2009</td>
<td>03/04/2009</td>
<td>OXYCODONE</td>
<td>80mg</td>
<td>63</td>
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<td>CASH</td>
<td>CVS #86</td>
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</table>

### Others’ Prescriptions

<table>
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<th>RX Dispensed</th>
<th>Substance</th>
<th>Strength</th>
<th>Quantity</th>
<th>Days Supply</th>
<th>Prescriber Name</th>
<th>DEA #</th>
<th>Payment Method</th>
<th>Pharmacy</th>
</tr>
</thead>
<tbody>
<tr>
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<table>
<thead>
<tr>
<th>RX Written</th>
<th>RX Dispensed</th>
<th>Substance</th>
<th>Strength</th>
<th>Quantity</th>
<th>Days Supply</th>
<th>Prescriber Name</th>
<th>DEA #</th>
<th>Payment Method</th>
<th>Pharmacy</th>
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</thead>
<tbody>
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<td>CASH</td>
<td>Walgreens #13</td>
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</table>

http://www.mssny.org/mssnycfm/mssnyeditor/File/2013/In_the_News/April_26/I-Stop_Screen_Shot.jpg
Effective Use of the PMP

- Every patient filling a controlled prescription should be checked (Ideally)
- Suspicious activity should be double-checked with the PMP
- Use upon initial receipt of prescription or at final verification
- Use to aid in medication reconciliation in institutions
- Prescriber should be contacted for any significant findings
- A registered pharmacist has the right to refuse to fill a prescription
- Board of Pharmacy can be contacted to report suspicious prescribing activity
Patient case

- A regular patient brings in a prescription for hydrocodone 10/325 mg, 1-2 tablets every 4 to 6 hours as needed, #100 with 3 refills.
- Patient always pays with cash due to a lack of insurance.
- The patient’s profile shows a previous refill 5 days prior, though states he is out of medication due to worsening of his back pain.
- The Pharmacist on duty checks the PMP and finds consistent filling of the same medication (different prescription) at the independent pharmacy next door.
- The previous month showed two prescriptions for the same medication filled only two days apart on three occasions.
- The prescriber was contacted for an explanation, the situation was explained and the prescriber agreed to stop writing for the medication and ordered a cancellation on the current prescription.
Limitations of the PMP

- Does not account for other states
- Updated monthly (working to become weekly)
- Only covers schedule II and III drugs
- Requires participation from individual pharmacists and prescribers
- Requires internet access
- Time restrictions
Preventing Drug Diversion
Overview

• Compare and contrast drug diversion and dependence.

• Discuss potential signs of drug diversion and examine a patient case-based example.

• Review methods to prevent drug diversion.

• Recognize the limitations of combating drug diversion and examine a second patient case-based example.
## Drug diversion versus drug dependence

<table>
<thead>
<tr>
<th>Drug Diversion</th>
<th>Drug Dependence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Illegal distribution of prescribed medication</td>
<td>Physical or psychological need to take a substance</td>
</tr>
<tr>
<td>May involve multiple persons or entities</td>
<td>Occurs on an individual basis</td>
</tr>
<tr>
<td>Prescribed medication likely not intended for personal use</td>
<td>Prescription was for a legitimate condition</td>
</tr>
<tr>
<td>Wider health implications</td>
<td>Tolerance, withdrawal symptoms, addiction, overdose are concerns</td>
</tr>
</tbody>
</table>
How to identify potential drug diversion

- Pattern of early refills with no medication or dose changes
- “Cash claims”
- Prescriber unable to recall or provide a reason for early refills
- Substantial increase in dispensed controlled substances with no obvious explanation
- Out of state prescriptions (e.g. “pill mills” in Florida)
- Prescription for large quantity of high dose opioids
- Patient does not fit the profile for the treated condition

Patient case

- A middle aged couple with longstanding chronic pain has regularly filled the same pain medications (Vicodin®) for years at the pharmacy. Prescriber discovered that drug diversion was a strong possibility after discovering a negative urine test despite the consistent refills.

- The prescriber alerted the pharmacy to the situation and cancelled further refills on the medication.
How can drug diversion be prevented?

- Pay increased attention to scheduled prescriptions
- Examine the patient’s fill history
- Effective communication with the Pharmacist on duty
- Get to know your patients, competitor pharmacies, and prescribers in the area
- Stay up to date with relevant alerts (e.g. stolen Rx pads, revocation or suspension of prescriber licenses)
- Suspicious activity should be reported by the pharmacy.
On the other hand…

- Controlled substances do have legitimate use
- Restricting access can be detrimental to the patients in need
- Be wary of placing judgment on your patients
- We are the gatekeepers, not the police
- Getting to know your patients can prevent unnecessary confrontation
Patient case

- A patient’s husband brings in a prescription for OxyContin® 40 mg BID on a Sunday. The prescription is three days early, but the husband claims they are traveling the next day.

- The patient in question is well-known by the regular staff and is undergoing treatment for metastatic breast cancer. However, a floating Pharmacist was on duty, and questioned the validity of the prescription. The patient was noted to have frequently changing doses of OxyContin® and two different prescribers (working in the same office) writing the prescriptions.

- The Pharmacist did not have access to the PMP. However she did her due diligence and insisted on contacting the prescriber before filling. She refused to dispense the medication until she confirmed it with the doctor. The medication was eventually dispensed an hour and a half later.
To Summarize

- Controlled substances have a potential for abuse and/or dependence and are therefore subject to increased regulation.

- The continuing issue of prescription drug abuse and diversion triggered the use of the Rhode Island Prescription Monitoring Program.

- The PMP is a useful tool for identifying suspicious drug use and prescribing, but is still a work in progress.

- Simple measures can be taken by Pharmacy technicians to help the Pharmacist identify and deter drug diversion.
Thank you for attending!

- Contact me via email if you have any further questions or concerns: mhalse@schospital.com