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

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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

Rhode Island State Board of Pharmacy. Pharmacy an Drug Laws. Department of Health. Providence (RI).

What defines a controlled substance?

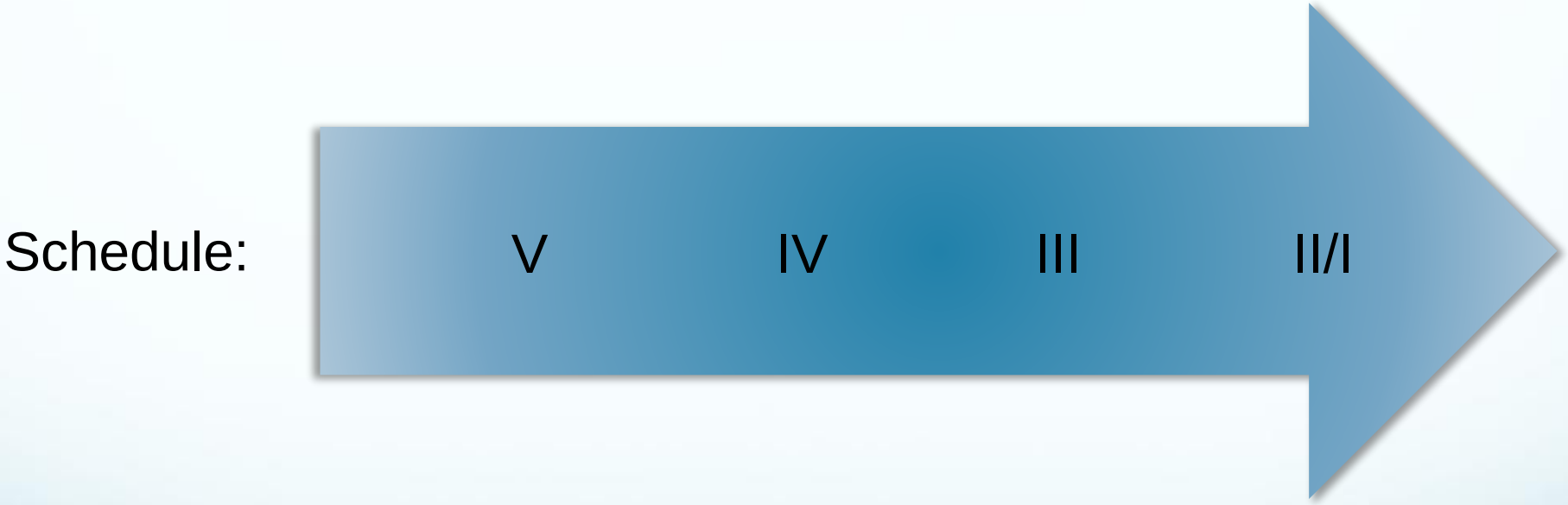
- Subject to regulation by the Drug Enforcement Agency (DEA)
- Scheduled based on potential for abuse and dependence
- Access is restricted (e.g. quantity limits)
- Increased documentation and inventory requirements

Controlled Substance Prescription

Can change	Cannot change
• Strength • Directions • Patient Address • Quantity	• Patient name • Date written • Drug name • Signature

Rhode Island State Board of Pharmacy. Pharmacy an Drug Laws. Department of Health. Providence (RI).

Scheduling of Controlled Substances



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

Rhode Island State Board of Pharmacy. Pharmacy an Drug Laws. Department of Health. Providence (RI).

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

Rhode Island State Board of Pharmacy. Pharmacy an Drug Laws. Department of Health. Providence (RI).

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

Rhode Island State Board of Pharmacy. Pharmacy an Drug Laws. Department of Health. Providence (RI).

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

Rhode Island State Board of Pharmacy. Pharmacy an Drug Laws. Department of Health. Providence (RI).

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

Kelly PS. Controlled Substances and Pharmacist Responsibilities. [Presentation] RIPA Spring Seminar 2013. Rhode Island Pharmacist Association.

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

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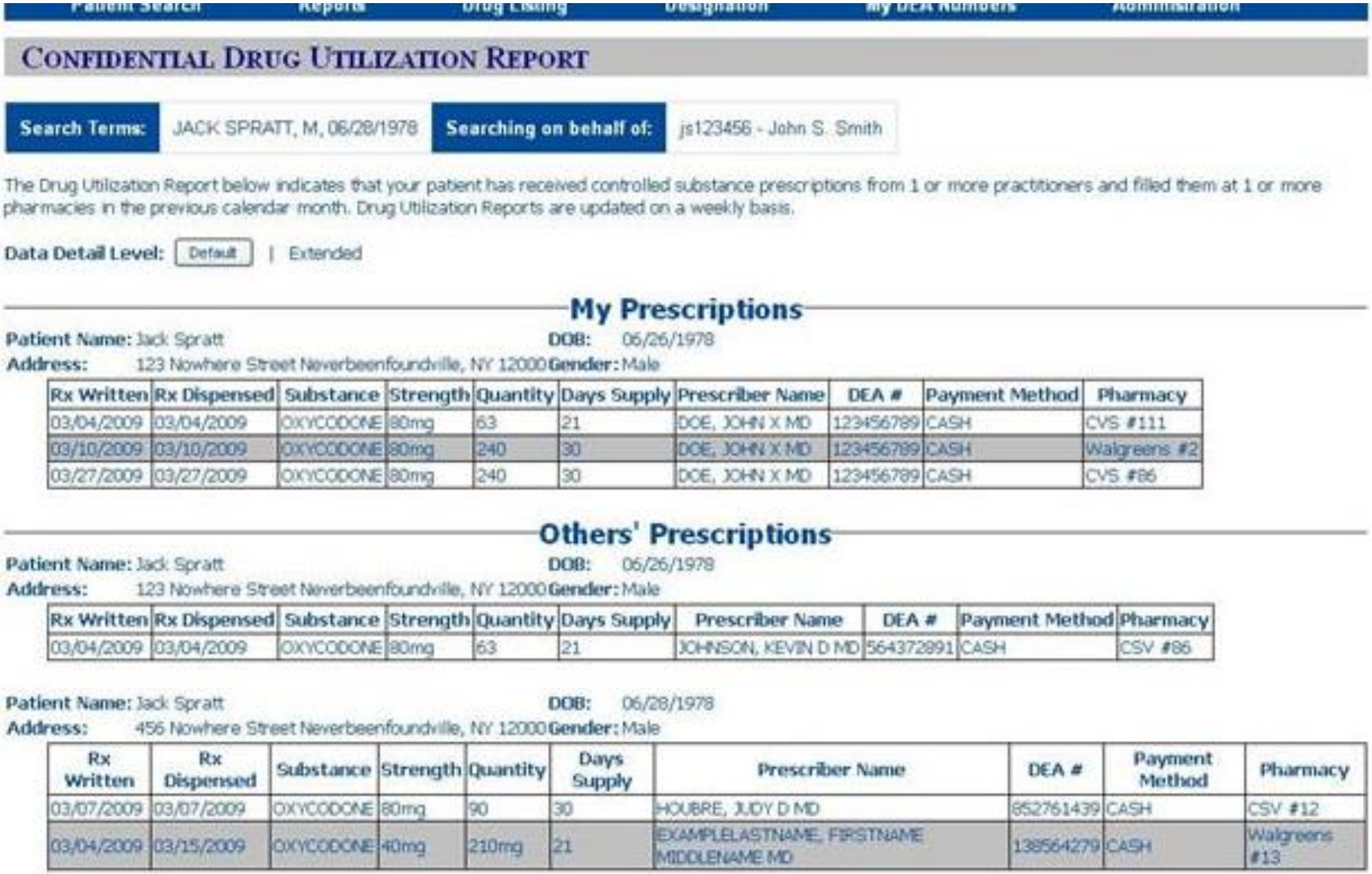

Patient Search | Reports | Drug Listing | Designation | My DEA Numbers | Administration

CONFIDENTIAL DRUG UTILIZATION REPORT

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

The Drug Utilization Report below 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

Patient Name: Jack Spratt **DOB:** 06/26/1978
Address: 123 Nowhere Street Neverbeenfoundville, NY 12000 **Gender:** Male

Rx Written	Rx Dispensed	Substance	Strength	Quantity	Days Supply	Prescriber Name	DEA #	Payment Method	Pharmacy
03/04/2009	03/04/2009	OXYCODONE	80mg	63	21	DOE, JOHN X MD	123456789	CASH	CVS #111
03/10/2009	03/10/2009	OXYCODONE	80mg	240	30	DOE, JOHN X MD	123456789	CASH	Walgreens #2
03/27/2009	03/27/2009	OXYCODONE	80mg	240	30	DOE, JOHN X MD	123456789	CASH	CVS #86

Others' Prescriptions

Patient Name: Jack Spratt **DOB:** 06/26/1978
Address: 123 Nowhere Street Neverbeenfoundville, NY 12000 **Gender:** Male

Rx Written	Rx Dispensed	Substance	Strength	Quantity	Days Supply	Prescriber Name	DEA #	Payment Method	Pharmacy
03/04/2009	03/04/2009	OXYCODONE	80mg	63	21	JOHNSON, KEVIN D MD	564372891	CASH	CSV #86

Patient Name: Jack Spratt **DOB:** 06/28/1978
Address: 456 Nowhere Street Neverbeenfoundville, NY 12000 **Gender:** Male

Rx Written	Rx Dispensed	Substance	Strength	Quantity	Days Supply	Prescriber Name	DEA #	Payment Method	Pharmacy
03/07/2009	03/07/2009	OXYCODONE	80mg	90	30	HOUBRE, JUDY D MD	852761439	CASH	CSV #12
03/04/2009	03/15/2009	OXYCODONE	40mg	210mg	21	EXAMPLELASTNAME, FIRSTNAME MIDDLENAME MD	138564279	CASH	Walgreens #13

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

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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

Drug Diversion

- Illegal distribution of prescribed medication
- May involve multiple persons or entities
- Prescribed medication likely not intended for personal use
- Wider health implications

Drug Dependence

- Physical or psychological need to take a substance
- Occurs on an individual basis
- Prescription was for a legitimate condition
- Tolerance, withdrawal symptoms, addiction, overdose are concerns

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

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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