Review of Controlled Substances

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Objectives

• Review the five schedules of controlled substances
• Review and discuss dispensing and record keeping laws regarding controlled substances
• Discuss the technician’s role in preventing diversion of narcotics by other healthcare workers
Background

- Society confronts the problem of drug addiction and abuse as they arise
- Americans first discovered morphine, heroin, and cocaine in the 19th century
  - Food and Drug Act of 1906 made so these substances and others had to be listed on the label as “dangerous drugs”
- The Comprehensive Drug Abuse Prevention and Control Act replaced all previous laws
  - Categorized drugs based on abuse and addiction potential compared to their therapeutic value
Schedules of Controlled Substances

Schedule I Controlled Substances

- Substance shall be placed in Schedule I if:
  - Has high potential for abuse
  - Has no accepted medical use in treatment in the United States or lacks accepted safety for use in treatment under medical supervision
Examples of Schedule I Substances

- Tetrahydrocannabinols (THC) or synthetic equivalents
  - Spice (K2, Yukatan Fire, Skunk, Moon Rocks)
- Methamphetamine
- Peyote
- Gamma hydroxybutyric acid (GHB)
- Heroin

Schedule II Controlled Substances

- Substance shall be placed in schedule II if:
  - The substance has high potential for abuse
  - The substance has currently accepted medical use in treatment in the United States, or currently accepted medical use with severe restrictions
  - The abuse of the substance may lead to severe psychic or physical dependence
Examples of Schedule II Substances

- Oxycodone
- Morphine
- Hydrocodone**
- Fentanyl
- Methadone
- Methylphenidate

Schedule III Controlled Substances

- A substance will be placed in schedule III if:
  - The substance has a potential for abuse less than the substances in schedules I and II
  - The substance has currently accepted medical use in treatment in the United States
  - Abuse of the substance may lead to moderate to low physical dependence or high psychological dependence
Examples of Schedule III Substances

- Testosterone
- Dronabinol
- Butorphanol
- Butalbital
- Amobarbital
- Ketamine

Schedule IV Controlled Substances

- A substance shall be placed in Schedule IV if:
  - The substance has a low potential for abuse relative to schedule III
  - The substance has currently accepted medical use in the United States
  - Abuse of the substance may lead to limited physical dependence or psychological dependence relative to the substances in schedule II
Examples of Schedule IV Substances

- Alprazolam
- Carisoprodol
- Clonazepam
- Diazepam
- Zolpidem
- Phenobarbital
- Lorazepam
- Phentermine

Schedule V Controlled Substances

- A substance shall be placed in schedule V if:
  - The substance has a low potential for abuse relative to the controlled substances listed in schedule IV
  - The substance has currently accepted medical use in treatment in the United States
  - The substance has limited physical dependence or psychological dependence liability relative to the controlled substances listed in schedule IV
Examples of Schedule V Substances

- Lacosamide
- Pregabalin
- Cheratussin® (guafenesin/pseudoephrine/codeine) syrup
- Diphenoxylate w/ atropine

Idaho Law Regarding Dispensing

- Schedule II
  - A Schedule II Rx may not be dispensed pursuant to a faxed order, with the faxed copy serving as the original except:
    - To be compounded for direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion
    - For a resident of a long term care facility
    - For a patient enrolled in a hospice program
    - Must indicate on the Rx that patient is hospice patient
Idaho Law Regarding Dispensing

- **Schedule II**
  - Patient may receive up to 90 day supply
  - The prescriber writes multiple prescriptions and the pharmacy fills multiple prescriptions
  - Provider must provide written details on each prescription indicating the earliest date on which a pharmacy may fill each prescription
  - A Schedule II must not be filled or dispensed more than 90 days after its date of issue
  - There is no maximum quantity that can be dispensed

- **Schedule III, IV, V**
  - Rx may be dispensed pursuant to a faxed order, with the faxed order serving as the original
  - A prescription drug order must not be filled or refilled more than six months after its date of issue
  - There is no maximum quantity that can be dispensed
  - Schedule III an IV can have a maximum of five refills
Inventories and Records Maintenance

- Records must be maintained as required and retained in a readily retrievable form and location for 3 years
- Readily retrievable: able to be completely and legibly produced upon request within 72 hours
- Paper prescription drug orders for Schedule IIIs must be maintained at the registered location in a separate prescription file
- Paper prescription drug orders for Schedules III, IV, and V must be maintained in a separate file or in a readily retrievable manner

Examples of Diversion

Sacred Heart pharmacy tech arrested, suspected of stealing 100,000 pain pills

A Spokane pharmacy technician who police say stole 100,000 pain pills faces criminal charges for drug dealing and the potential loss of his career.

Spent Wednesday night in Spokane County Jail before being released without bond. He faces charges of possession of hydrocodone with intent to deliver and possession of codeine with intent to deliver.

http://www.spokaner.com/stories/2013/jul/18/sacred-heart-pharmacy-tech-arrested-stealing-100000/
Examples of Diversion

Coeburn pharmacy technician’s license suspended; accused of theft of drugs

Pharmacy Tech Indicted for Stealing Prescription Drugs
Leonardtown, MD - 2/20/2013

Morehead City pharmacist charged for prescription drug diversion

http://www.tricities.com/news/article_3c0aa51a-1c0c-11e4-92c4-0017a43b2370.html
http://coastalnc.twcnews.com/content/news/700836/morehead-city-pharmacist-charged-for-prescription-drug-diversion/

Diversion Prevention

• Large-scale diversion
  • By nature an inside job within a pharmacy
  • Typical scenario:
    • One or more pharmacy technicians or pharmacists use their position of trust to divert large amounts of controlled substances from the pharmacy
    • They then sell it to another party who has connection for illicit distribution

• Although it is important for the pharmacist-in-charge to take the lead in preventing diversion, pharmacy technicians must also take an active role in preventing diversion
Logistics of Diversion

- **What?**
  - The drugs targeted for large scale diversion are typically oral dosage forms of opioids, sedatives, and stimulants
  - Drugs targeted for personal use would more likely be IV formulations
- **Who?**
  - Typically the most trusted pharmacy employees
    - Must hold position of trust and have access to divert
  - Gender not a determining factor

Logistics of Diversion

- **Why?**
  - Prescription drug abuse is “the fastest growing drug problem in America.”
  - Abusers may feel that prescription medications are safer than home-manufactured drugs
  - Because health care can sometimes be viewed as a large business, some pharmacy employees with modest salaries may not feel bad stealing from a corporation as opposed to an individual person
Logistics of Diversion

- How? – Examples of Methods of Diversion
  - Disappearing Invoices – diverter opens up a separate invoice for controlled substances, then destroys it
  - Incomplete invoice – diverter takes the last page of the invoice
  - Diverter takes controlled substance prior to it being stored in the narcotic safe
  - Diverter takes the controlled substance off a shelf and smuggles it from the pharmacy

Strategies for Prevention of Diversion

- Screening and Re-screening of pharmacy employees
  - Criminal background tests
  - Urine drug tests
    - Should be focused on health care professionals
    - Should include prescription drugs of abuse
  - Keep in mind that diverters will not test positive on drug screens
Strategies for Prevention of Diversion

- Divide Duties
  - Separate CS ordering and CS receiving
    - Do not allow somebody to control both functions
  - Cross train staff and have them rotate through these separate roles
    - Prevents a single staff member from having sole control
    - Allows for different perspectives in the procedure to see if there are any vulnerabilities

- Limit Access to Controlled Substances
  - Control the number of pharmacy personnel who order and handle bulk controlled substances
  - In Idaho, it is not required to keep Schedule III, IV, and V controlled substances in a controlled substance storage vault
    - Most hospitals already keep all controlled substances in a storage vault
    - Almost all retail pharmacies keep some sort of controlled substance out of a storage vault
Strategies for Prevention of Diversion

- Optimize the use of CS automation
  - Simplified reporting and auditing
  - Take advantage of all the security features offered

- Improve surveillance

- Install door controls such as electronic badge readers that track employee’s entry

Diversion Case

- You have worked with John for 5 years at a local outpatient pharmacy. Although you share many of the same duties, John has worked there longer and was given the responsibility of reconciling the Schedule II controlled substances. Recently you notice that John has been taking longer than usual documenting in the log book, and although you haven’t personally witnessed anybody stealing, you have noticed recently that the pharmacy always seems to be running out of oxycodone and hydromorphone even though the number of patients hasn’t increased. You are worried that John may be stealing, but you don’t want to accuse him without knowing for sure.
Summary

- Knowing and being able to differentiate between the different schedules of controlled substances is an essential part in the role of a pharmacy technician.
- Knowledge of and compliance with the laws regarding dispensing and record keeping of controlled substances will allow you to be more efficacious in your role.
- Vigilance to your surroundings is crucial in prevention of diversion within the workplace.

References