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Objectives

- Review Controlled Substance Laws and Regulations
- Provide an overview of Drug Diversion
- Give Best Practice tools for preventing / responding to diversion of controlled substance medications

Classification of Drugs by the DEA

I: substance has a high potential for abuse w/ no current medically acceptable use and lacks acceptable safety standards

II: the drug has a legitimate medical use, but carries a high risk for abuse w/ potential for severe psychological or physical dependence

III: the substance has a legitimate medical use w/ slightly lower risk for abuse w/ moderate to low physical dependence or high psychological dependence

Classification of Drugs by the DEA

IV: legitimate medical use w/ low potential for abuse and abuse leads to limited physical / psychological dependence

V: legitimate medical use w/ even lower potential for abuse w/ limited risks for physical and psychological dependence

- Can even be OTC's
- Often combined w/ other substances that help limit the potential for abuse

Common Controlled Substances by Class

I: illegal drugs: heroin, cocaine

II: opiates or amphetamines:

- Morphine, codeine, oxycodone, hydrocodone
- Amphetamine, dexamphetamine, methylphenidate

III: acetaminophen w/ codeine

IV: benzodiazepine and barbituates

- Alprazolam, clonazepam, lorazepam
- Phenobarbital
- Tramadol

Common Controlled Substances by Class

V: prescription meds: Vimpat®, Lyrica®, Potiga®, diphenoxylate w/ atropine

- OTC's: pseudoephedrine containing products, guaifenesin w/ codeine

Rules and Regulations

- Goal: to set enough regulation to prevent or decrease misuse of controlled substances w/o interfering / or unduly burdening healthcare practitioners from providing valid treatment and care to their patients
- Federal Controlled Substance Act was enacted in 1970

Requirements for a CII Rx

- Must be a handwritten prescription
- Definition of a Rx: must be written for a specific patient, include the medication being prescribed, the strength, directions for use, and quantity of the medication, and then be hand signed by the prescriber and dated.
- Exceptions: a Rx can be faxed if the patient resides in a SNF or is enrolled in a Hospice program

Requirements for a CII Rx

- Chart orders are not acceptable (often lack all the requirements to be a true Rx, especially quantity to dispense)
- NOT refillable
- CII's can be partially dispensed for a SNF or Hospice patient
- Rx is only valid for 60 days from the date written
- Can never be predated

Emergency Dispensing of a CII

- This is the only time a verbal order for a CII substance can happen
- Must occur directly between the prescriber and the dispensing pharmacist
- Max day supply of 72 hours
- Prescriber must provide a written Rx for the verbal order w/in 7 days
- Failure to reorder a routine CII medication is often not considered an acceptable reason for an "Emergency Dispensing"

Requirements for CIII – V Rx

- Can be written, verbal or faxed if hand signed
- Must still meet all requirements to be a valid prescription
- Expire w/in 6 months of date written
- Can only be filled a max of 5 times

Requirements of Facilities

- Delivery: Pharmacy must lock all CS deliveries to a SNF in a locked box
- Proof of Use Sheets: document containing the following info:
 - Resident's name, physician's name, name & dose of medication, date & time of administration, signature of person administrating the dose, and balance of medication remaining
 - Pharmacy must include a Proof of Use sheet with all CS to a SNF, but only for CII's to ALF
 - Designated person at the facility should verify amount being received on delivery and record on the proof of use sheet, sign & date
 - Proof of use sheets must be audited at least daily, but best practices recommend per shift

Requirements of Facilities

- Contingency:
 - Only allowed at SNF's
 - Can have CS in contingency, usually in its own locked kit
 - Kit must be stored in a locked area
 - Amount shall not exceed 10 units of any medications
 - Under control of the pharmacy
 - When medication is removed, a copy of the pharmacy communication shall be placed in the contingency storage kit

Requirements of Facilities

- Storage:
 - CII substances must be separately locked in a secure compartment within the locked medication area
- Destruction:
 - SNF:
 - Must be done w/in 72 hrs of the discontinuation of the order, resident's discharge, resident's death, or medication outdating
 - All destructions must be documented and witnessed, signed & dated by at least 2 licensed staff
 - CBRF:
 - Must not be held in the facility for more than 30 days
 - Stored in a separate area away from other medications in a locked area w/ access limited to administrator or designee
 - All destructions must be performed by the administrator or designee and witnessed by another employee, documented, signed & dated

Drug Diversion

- Definition: the use of legal drugs for illegal purposes
- DEA data from 2000-2003 est that nearly 28 million dosage units of medications were diverted
- It is important to note that diversion can occur at any place during the drug supply process (from manufacturer to patient)
- It is est that drug diversion and abuse costs insurers over \$72 billion / yr (costs get passed on to the consumer)

Drug Diversion

- Most common types of medications diverted
 - Narcotic Pain Relievers
 - Benzodiazepines
 - Stimulants
 - Some antipsychotic medications like quetiapine
- Hydrocodone containing products are the #1 prescription drug of abuse in the US
- Increase CS use in noncancer patients has increased total # of prescriptions available

Prescription Drug Monitoring Program (PDMP)

- Established in 2013
- WI is 1 of 49 states w/ a monitoring program
- All pharmacies and dispensing practitioners must report
- Collects data related to CS dispensing
- In 2013, 2191 individual pharmacies and dispensing practitioners dispensed enough doses of monitored prescription drugs to medicate the entire population of WI for almost 40 days
- 2013 data:
 - # of patients receiving a monitored Rx: 1,873,192
 - # of Rx's dispensed: 10,283,125
 - Hydrocodone accounts for about 20%

Reasons for Drug Diversion

- Recreational purposes for self, "getting high"
 - Taking compulsively due to addiction
 - Self-medicating for mood, sleep, & / or pain
 - Monetary gain
- *Most nurses that divert prescription medications do it for self use vs. selling for monetary gain
- *Prescription drugs are now the most common drug used for recreational purposes after marijuana

Drug Diversion Risks

- User:
 - Prescription drug overdose deaths now exceed the # of deaths related to heroin and cocaine use combined
- Patient:
 - Pt receives substandard care by an impaired healthcare worker
 - Pt receives inadequate pain control
 - Risk of infection if injectable medications are tampered with

Preventing Drug Diversion

- Follow all rules and regulations governing CS
- Implement policy and procedures that exceed minimal requirements
- Be aware of all reporting requirements and have a process in place to contact local, state and federal law enforcement
- Organizational leadership should clearly communicate expectations to staff to report suspicions of diversion
- Organizational leadership is supportive to employees that raise awareness to potential diversion

Preventing Drug Diversion

- Staff has a way to anonymously report suspicions
- Utilize pre-employment background checks and drug testing
- Develop a “for cause” drug testing policy
- Terminate all employee access to CS upon employment termination in a timely manner
- Prohibit the sharing of pass codes
- Encourage staff to attend CS diversion training
 - Ex. National Association of Drug Diversion Investigators (NADDI)

Preventing Drug Diversion

- Provide awareness training to recognize signs of diversion
- Provide resources to employees (EAP) (Federal Substance Abuse and Mental Health Services Administration)
- Do annual CS policy and procedure training for all employees
- Never leave CS unattended, CS should be locked at all times
- Limit access to CS by authorized staff only
- Implement a process for controlling and accounting for keys at all times

Preventing Drug Diversion

- Never leave prescription pads/ paper in an unlocked location
- Have patient supply of CS medication not being used returned home immediately
- Utilize camera surveillance especially in high risk areas
- Remove only one CS for one patient at a time during a med pass
- Return reusable CS to the pharmacy in a timely manner
- Destroy unusable CS as quickly as possible
- Do periodic chart reviews of prn drug use

Preventing Drug Diversion

- Use coded locks on emergency CS contingency boxes
- Audit that the lock code has not changed
- Follow destruction policy for disposing of used fentanyl patches
- Administrators should periodically make unexpected rounds, and keep in touch with staff and patients

Reacting to Diversion

- Legal responsibility to report drug diversion if the facility is governed by the Division of Quality Assurance
- Failure to report could enable a caregiver to continue to work in a setting where they are able to divert
- Diversion may be considered caregiver misconduct and / or a criminal violation

Reacting to Diversion

- Investigate: even when least expected you may find info that leads to conclusive information
- Follow all of your previously laid out policy and procedure
- Be willing to send a message
