**Objectives:**
- Outline the laws & regulation for controlled substances
- Identify Schedule I, II, III, IV & V substances
- Understand CII ordering process and record keeping
- Describe the storage requirements for controlled drugs
- Explain the refill policy for controlled drugs

---

**Current Federal Rules and Regulations**

1. **Controlled Substances Act of 1970**
   - Defined drugs that have an abuse potential.
   - Established the Drug Enforcement Administration (DEA)
   - Established 5 groups (or schedules) of such drugs and put a strict guideline on their distribution.
   - Requires all parties involved in the distribution of controlled drugs to register with the DEA.
Schedules of Controlled Drugs

• Schedule I
  • High abuse potential, no recognized medical value
  • Heroin, GBH, LSD, marijuana, methaqualone

• Schedule II
  • High abuse potential, demonstrated medical value
  • Analgesics – morphine, oxycodone, fentanyl
  • ADD treatments – Ritalin, Adderall, Vyvanse

• Schedule III
  • Lesser abuse potential, demonstrated medical value
    • Anabolic steroids, combination products containing codeine or hydrocodone with Tylenol
    • Some barbiturates

• Schedule IV
  • Low abuse potential relative to III and demonstrated medical value
    • Benzodiazepines – diazepam, alprazolam, lorazepam
Schedules of Controlled Drugs

- Schedule V
- Lower abuse potential relative to IV and demonstrated medical value
  - Combination products containing small amount of codeine.

Drug Enforcement Administration

- Branch of the U.S. Justice Department responsible for regulating sale and use of drugs with abuse potential.
  - Responsible for enforcing laws regarding both legal and illegal addictive substances.
  - Directs most of its efforts toward illegal drug trafficking.
  - Supervises legal use of narcotics and other controlled substances.
DEA Regulation

- CSA is a closed system of distribution.
- The cornerstone is registration of all parties involved in handling controlled substances.
- All parties must maintain accurate inventories and records regarding the movement of CS.
- All parties must ensure the security for CS.

DEA Registration

- Issues licenses
  - To medical practitioners to write prescriptions for scheduled drugs.
  - To pharmacies to order scheduled drugs from wholesalers.
  - Distributors to distribute controlled substances.
- Inspects medical facilities, including pharmacies.
- Tracks narcotics from manufacturer to warehouse to pharmacy.
DEA Registration

- Each pharmacy registers.
  - Pharmacy employees are not required to register.
  - Registration varies from 1 to 3 years in length.
- Laws vary from state to state.
  - Some state laws are more stringent than the federal CSA. We will cover Massachusetts law later.
  - The most stringent of the laws will be followed
    - If federal law is more stringent, it is followed.
    - If state law is more stringent, it is followed.

DEA - Ordering

- Pharmacy must be registered (DEA-224)
- Must renew registration every 3 years (DEA-224A)
- Ordering C-IIIs
  - Order must be signed by a designated person
  - One or more pharmacists usually authorized to order C-IIIs in a pharmacy
- Ordering can be done on paper or electronically
DEA Ordering - Form 222

- DEA-222 used to order C-I and C-II.
- Must be signed by a registered person.
- Three copies:
  - Copy 1: Blue copy is retained by the supplier.
  - Copy 2: Green copy is sent to the DEA.
  - Copy 3: Brown copy is kept for your records.
- Must be kept in a separate file from other invoices.
- Form has its own unique serial number.
- Forms can be requested online.
DEA CSOS Electronic Ordering

- Controlled Substance Ordering System
- Registrant (i.e., the pharmacy) appoints a CSOS coordinator for a site
- The Coordinator acts on behalf of the registrant
- The CSOS certificate is valid until the DEA registration expires.
- Benefits of this system:
  - Easy of ordering
  - Speed of ordering and receipt of drugs
  - You can "see" live what is available.

DEA Record Keeping - Orders

- Schedule II
  - Retain for 2 years
  - Keep DEA-222 with the invoice attached
  - Readily retrievable
  - Not intermingled with other files
DEA Record Keeping - Orders

- Schedules II through V
  - Retain for 2 years
- Storage
  - Schedule III-V can be stored other files, but must be clearly marked as Controlled.
  - Mark with a large **RED C** for easy identification

DEA Record Keeping - Inventory

- Schedule II
  - Initial inventory upon change of personnel.
  - Biannual Inventory.
  - Daily/weekly inventory.
  - Counts must be actual (hard count) not estimate.
- Records of inventories should be maintained in a readily retrievable location.
DEA Record Keeping - Inventory

- Schedules III – V
  - Biannual Inventory
  - Bottle > 1000 units may be estimated
- Records of inventories should be maintained in a readily retrievable location.

DEA Record Keeping - Inventory

- Bi-annual inventories are not sent to the DEA
- Inventories should be kept with C-II files and be readily retrievable.
DEA Record Keeping - Inventory

• Theft or Significant Loss of C-lls
  • Definition of “Significant Loss” is fuzzy and depends upon the pharmacist’s judgment
  • Some states have specific guidance as to what constitutes “Significant Loss”
  • Theft
    • Immediately notify DEA using a form 106
    • Local police

DEA - Storage

• Storage
  – Schedule II – should be kept separately from all other inventory in a locked, and tamper-proof narcotic cabinet secured to the floor or wall.
  – Schedule III-V can be stored on the shelf with other prescription drugs.
Dispensing of Schedule II Drugs

- Prescriptions for Schedule II substances must be hand-signed by the prescriber except in emergencies.
  - Exceptions where the Rx can be faxed
    - IV pain therapy, LTC and Hospice Care
- One Rx per blank
- Tamper proof Rx paper

Dispensing of Schedule II Drugs

- Emergency supply of a Schedule II drug
  - A short supply, 72 hour supply can be provided to a patient without a written prescription in most states.
  - Reduce to writing the emergency Rx.
  - Ensure that it was from a valid prescriber.
  - Prescriber must supply a written Rx with the notation "Emergency Supply Rx" within 7 days.
Dispensing of Schedule II Drugs

- Who may prescribe C-IIIs?
  - Physician, dentist, podiatrist, veterinarian, or mid-level practitioner who is licensed to prescribe in the state
- Mid-level practitioners include:
  - Nurse practitioners, mid-wives, anesthetists
  - Physician assistants
  - Optometrists
  - Ambulance services

May a practitioner prescribe C-IIIs for him/herself?
- NO!

May a practitioner prescribe C-IIIs for a family member?
- Yes, BUT… It is strongly discouraged.
Dispensing of Schedule II Drugs

• May a practitioner write a prescription for a CII for the purpose of general dispensing to patients?
  • NO!

Dispensing of Schedule II Drugs

• Patient’s: Full name and physical address
• Prescriber’s: Name, address, DEA #
• Drug name, strength, dosage form, quantity, directions for use, no refills (for schedule II)
• Must be written in ink, indelible pencil, or typewritten
• Must be dated the date of issuance
Dispensing of Schedule II Drugs

- **REFILLS** are not allowed on **Schedule II** prescriptions.
- When filling the prescription, the pharmacist draws a line across the prescription indicating it has been filled.
- Partial filling of a C-II prescription must be completed within 72 hours.
- Stock is inventoried upon completion of fill.

---

**DEA Record Keeping - Inventory**

<table>
<thead>
<tr>
<th>Drug/Strength</th>
<th>mdg</th>
<th>Date/Route Dispensed/Name</th>
<th>Invoice #</th>
<th># Res</th>
<th>Balance</th>
<th>Tech</th>
<th>RPh</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Dispensing of Schedule II Drugs

- Partial filling of a C-II prescription is allowed, but...
  - The fill must be completed within 72 hours.
  - If not completed within 72 hours, the remainder cannot be dispensed.
- Example:
  - Rx calls for 90 tablets, but pharmacy has 50
  - The 50 can be dispensed
  - The remaining 40 can be dispensed if available within 72 hours

DEA Numbers

- Assigned to prescribers for controlled drugs.
- Two letters and seven digits.
- First letter is a code identifying the type of registrant.
  - A, B, M
- Second letter is the initial of the registrant's last name.
- Seven digits with the 7th digit being a "checksum" that is calculated.
DEA Numbers

- Example: AR434279
  - Add 1st + 3rd + 5th number = ___
  - Add 2nd + 4th + 6th number = ___ multiply by 2 = ___
  - Then add ____ + ____ = ____

- The total should be a number whose last digit is the same as the last digit of the DEA number.
- AR4342799
  - (4+4+7=15, 3+9=12, 12x2=24 then 15+24=43).

DEA Regulations for III - V

Schedule III, IV, and V Prescriptions
- May be verbal, written, or faxed and may be refilled if authorized by the prescriber.
- Schedule III and IV may be refilled up to 5 times within 6 months.
- Schedule V may be refilled as directed by the prescriber.
DEA Regulations for III - V

- Partial fill Schedule III, IV, and V Prescriptions
  - May be filled as a partial
  - May exceed the 5 refills as long as the total number of units dispensed does not exceed the original Rx.
  - Eg. Suboxone Films, 2 used daily #20 5 refills
    - Total 120 can be dispensed
    - Expensive so person requests #10 @5 day intervals.

- Manufacturers must label controlled drugs using the letter “C.”
  - e.g. C-II, C-III, etc.

- Storage
  - Schedule drugs III-V can be stored on the shelf with other prescription drugs.
Massachusetts Rules & Regulations

• In general Massachusetts Law largely parallels Federal.
• We will review the Mass Law to look at the differences.

Massachusetts Rules and Regulations

• Mass has 6 schedules for drugs rather than 5.
• Schedules I – V parallel the federal schedules.
• Schedule VI covers all other prescription medications, i.e. they are non-controlled, but prescription medications.
Federal law does not have an expiration on a prescription for CIIs. Federal law does not have a day supply limit, but directs the pharmacist to use judgment in the dispensing of CIIs. Federal law allows for verbal transmission of III – V prescriptions.

Massachusetts Law allows a CII to be filled within 30 days of prescribing. Massachusetts allows verbal Rx for III – V, but requires a written Rx follow up within 7 days. Massachusetts allows fax Rx for III – V prescriptions without any follow up.
Massachusetts Rules and Regulations

- Massachusetts law restricts CII and III to a 30 day supply with two exceptions.
  - 60 day supply of d-amphetamine or methylphenidate when used for specific conditions e.g. ADHD or narcolepsy
  - 90 day supply for implantable pumps for pain meds

- CII prescriptions for narcotics written by a physician from Maine and contiguous states (Vermont, NY, RI, Conn, NH) written within 5 days may be filled.
- Massachusetts law allows transfer of CIII – V once only, unless…
  - The transfer is between electronically linked computer systems.
<table>
<thead>
<tr>
<th>A</th>
<th>B</th>
<th>C</th>
<th>D</th>
<th>E</th>
<th>F</th>
<th>G</th>
<th>H</th>
<th>I</th>
<th>J</th>
<th>K</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rx number</td>
<td>Prescribing physician</td>
<td>Date</td>
<td>Patient Name</td>
<td>Drug Name, strength, dosage form</td>
<td>Pharmacy Name, Address, phone number</td>
<td>Quantity</td>
<td>Number of refills remaining</td>
<td>k of the drug</td>
<td>Expiration date</td>
<td>Directions for use</td>
</tr>
</tbody>
</table>

**Summary of Differences**

- **Federal**
  - Schedules I – V
  - Verbal III – V
  - Schedule II no expiration on Rx
  - No day limit on supply

- **Massachusetts**
  - Schedules I – VI
  - Verbal III – V with follow up Rx
  - Schedule II Rx good for 30 days
  - Schedules II & III fill for 30 day supplies with some exceptions
Massachusetts Prescription Monitoring Program

• PMP – Prescription Monitoring Program
• Purpose is to monitor prescribing and dispensing of CII – V drugs
  • Pharmacy must submit a report to the state
  • Usually this is an electronic file
  • Reported every 7 days
  • Some systems submit the data “real-time”
• Data is in a format that can be shared with other states PMP programs.

The state monitors the information and may report to law enforcement if there is reasonable cause to believe a violation occurred.

• Data can be released to authorized:
  • Prescribers
  • Dispensers
  • Patient
  • Regulators
  • Law enforcement
Massachusetts Prescription Monitoring Program

- What can we determine from this database?
  - Multiple sources for controlled drugs
  - Cash purchase and insurance purchase
  - Repeated early fills
  - Using multiple pharmacies
  - Duplicate therapy from parallel sources

Permitted – Prohibited Changes

- Which information may be changed on a prescription for controlled (CII -VI) drugs?
  - Never Changed
  - Drug
  - Strength
  - Earliest fill date
  - Patient name
  - Prescriber name/ signature
  -
Permitted – Prohibited Changes

• Which information may be changed on a prescription for controlled drugs?
  • Change with consultation
  • Patient's address
  • Directions for use
  • Prescriber's DEA#/Address
  • Issue date
  • Quantity / Drug Form / Drug Strength
  • Date written

---

eScrips

• How can a prescription get to the pharmacy?
  • Patient brings paper Rx
  • Fax of Rx
  • Telephone call (live or voice message)
  • Electronic Prescribing
eScrips – E Prescribing

• Electronic Prescribing
  • Electronic file sent from prescribers system directly to the pharmacy.
  • Process was devised as a method to add efficiency, cost reduction and improve patient safety.

Electronic Prescribing

• Prescriber must use a qualified ePrescribing System
  • System Requirements (Benefits)
    • The system must generate a complete list of the patient's active meds.
    • Allows selection of meds, printing of Rx, transmission of Rx and an alert system.
Electronic Prescribing

• Requirements (Benefits)
  • Provides info regarding lower cost meds, therapeutic alternatives.
  • Provides info regarding patient’s insurance formulary
  • Insurance requirements for specialized meds.

Benefits/Penalties E-Prescribing

• Benefit to prescriber
  • Secure system with a series of checks
    • Drug Interactions
    • Formulary
    • Record of prescribed meds
    • Troubleshooting of prescriptions done upfront
Benefits/Penalties E-Prescribing

- Financial Rewards/Penalties
  - Now, 1% bonus on total Medicare Part B payments for the year.
  - Now, 1% penalty on total Medicare Part B payments if NOT used.
  - Bonus reduced to 0.5% in 2013
  - Penalty increased to 1.5% in 2013 and 2% in 2014

Pharmacy Benefits E-Prescribing

- Financial Rewards/Penalties
  - None
Pharmacy Benefits E-Prescribing

- Efficiency
  - Clear transmission
  - No handwriting interpretation
  - Prescriber's information generally complete
  - Direct transmission for refill
  - Time saving in receipt and processing is significant
  - No forged or altered prescriptions
  - Future will allow transmission of information regarding compliance etc.

Patient Benefits E-Prescribing

- Improved safety
  - Reduced error risk
  - Reduced risk of drug interactions
- Reduced cost by improved drug selection
- Improved patient compliance
- Speed filling and refill request process
- Future will allow transmission of information regarding compliance etc.
E-Prescribing

- Controlled Drugs
- Until 2010 eScripts were only allowed for Non-Controlled prescriptions
- 2010 standards were released for application to Controlled drugs
- Have they been implemented?

http://www.practicefusion.com/pages/ePrescribing.html
Miscellaneous

• Florida
  • “Pain Clinics”
  • Pharmacies DEA license revoked
  • Independent pharmacies
  • Chain - first time ever
• West Virginia legal action
  • Wholesalers
  • Pharmacy level