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Health

Connecticut and Federal Pharmacy Law

Course Objectives

- Understand the roles of the regulatory bodies overseeing pharmacy practice
- Describe the laws surrounding controlled substances
- Describe differences between federal and state drug laws

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Regulatory Bodies

Introduction

- Pharmacy laws & regulations
  - states require pharmacies & pharmacists to be licensed
  - many states require pharmacy technicians to be licensed or registered

- If state pharmacy law or federal law has stricter requirements, the more strict requirement must be followed

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Federal Regulatory Bodies

- **Drug Enforcement Administration (DEA)**
  - Enforces the controlled substances laws and regulations of the US, including the investigation and prosecution of major violators to these laws
  - Manages the drug intelligence program in cooperation with government agencies

State Regulatory Bodies

- **Connecticut Department of Consumer Protection (DCP)**
  - Multiple divisions, contains **Drug Control Division**
  - Regulates all persons and firms involved in the distribution of legal drugs, medical devices, and cosmetics in CT
  - Oversees **licensing** for **pharmacies**, **pharmacists**, **technicians**, manufacturers, wholesalers, controlled substance providers, and medical marijuana
  - Operates a prescription monitoring program for controlled substances

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Assessment Question

This organization enforces the laws related to controlled substances.

A. Federal Drug Administration (FDA)
B. Drug Enforcement Agency (DEA)
C. CT Department of Consumer Protection
D. CT Commission of Pharmacy

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Controlled Substances and the Law

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Controlled Substances Overview

- Controlled substances are those drugs that have the potential for misuse, abuse, diversion, or addiction

- Are subject to stricter controls through both federal and state laws
  - Must follow the stricter requirements if different

- Must register with DEA to handle or prescribe controlled substances
  - Creates a closed system of drug movement
  - Pharmacies, prescribers, distributors, manufactures, etc…
  - Receive DEA number

Controlled Substances Act

- Federal law regulates all facets of controlled substances
  - Manufacturing
  - Distribution
  - Dispensing
  - Storage & record keeping

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DEA

- Drug Enforcement Administration
- Pharmacies, prescribers, wholesalers, drug manufacturers, & others must be registered with DEA
- DEA numbers
  - physician: number starts with either letter A or B followed by first letter of physician's last name
  - Process for verification of DEA number

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DEA Forms

- DEA Form 222
  - Used for ordering Schedule II controlled substances
  - Alternatively, pharmacies may use online CSOS (http://www.deaecom.gov/)

- DEA Form 106
  - Reporting of Drug Losses

- CII records must be separate from CIII, CIV, & CV records

Scheduling

- Drugs classified as different schedules based on abuse/dependence potential
- Commercial containers must have “C-symbol” with roman numeral designating schedule
- States may have their own scheduling
  - Need to follow stricter scheduling
- C-I drugs are generally not available in the pharmacy
  - Occasionally used in investigational studies or clinical trials

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Scheduling

- Schedule I (CI)
  - most restrictive
  - high potential for abuse
  - generally not available in pharmacy
  - examples: heroin and LSD

- Schedule II (CII)
  - high potential for abuse or misuse
  - high risk of dependence
  - examples: Meperidine (Demerol), methadone, morphine, oxycodone (OxyIR, OxyContin), methylphenidate (Ritalin)

Scheduling

- Schedule III (CIII)
  - moderate potential for abuse, misuse & dependence
  - includes combination drug products
    - acetaminophen and codeine (Tylenol #3)

- Schedule IV (CIV)
  - low potential for abuse & limited risk of dependence
  - examples: Diazepam (Valium), lorazepam (Ativan), phenobarbital, & other sedatives and hypnotics

Scheduling

- Schedule V (CV)
  - lower potential for abuse, misuse, or dependence
  - examples: cough medications with limited amount of codeine, anti- diarrheal medications containing limited amount of opiate, such as diphenoxylate/atropine (Lomotil)
  - in some states, no prescription required
    - May be dispensed by a pharmacist without a prescription if specific requirements are met

Scheduling

Schedule	Potential for abuse	Accepted Medical Use	Examples (Federal)
I	++++	NO	Ecstasy, Heroin, LSD, Marijuana*, Mescaline, Methaqualone, Peyote
II	++++	YES	Amphetamine, Cocaine, Fentanyl, Hydromorphone, Methadone, Methylphenidate, Morphine, Oxycodone, PCP, Pentobarbital
III	+++	YES	Anabolic steroids, Benzphetamine, Buprenophine, Butabarbital, Dronabinaol, Ketamine, Nalorphine, Testosterone
IV	++	YES	Alprazolam, Chlordiazepoxide, Diazepam, Eszopiclone, Midazolam, Oxazepam, Phenobarbital, Phentermine, Tramadol, Zaleplon, Zolpidem
V	+	YES	Acetaminophen/codeine elixir, Ezogabine, Lacosamide, Lomotil, Pregabalin, Robitussin AC

*Considered C-II by state of Connecticut

Labeling of Controlled Meds

- Federal law:
  - Drug manufacturer's packaging labeled with C & appropriate Roman numeral
    - CII, CIII, CIV and CV

Dispensing (CT)

- For hospitals, infirmaries, clinics:
  - **C-II** orders are limited to **7 days**
    - Requires written order within **24 hours**
  - **C-III,IV,V** orders are limited to **30 days**
    - Requires written order within **72 hours**

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Records for Controlled Meds

- Must maintain complete & accurate records for controlled substances
  - Purchased, received, distributed, or dispensed
  - Initial & biennial inventories required

- Federal law requires pharmacy to
  - Keep controlled substance records for 2 years
  - Have records readily available for DEA inspection

Documentation

- Pharmacies must have accurate record of all controlled substances
  - Invoices, receipts, inventory records, transfer records
  - Must perform initial and biennial (every 2 years) inventories
    - Includes drugs stated for destruction or waste
- Required to be kept for inspection for **3 years** (CT)
  - DEA only requires 2 years
- CT requires **3 separate files** that are easily retrievable:
  - Non-controlled drug records
  - C-III, IV, V drug records
  - C-II drug records
- Hospitals require separate proof of use sheets if controlled substances are not directly administered to patients from pharmacy
  - Dispensed from floor stock (Pyxis machines)
- EPIC maintains all of this information

Storage (CT)

Hospital Pharmacy:

- C-II,III drugs must be kept in:
  - <150 units = a completely enclosed + locked wood or metal cabinet
  - 150-1000 units = an approved safe
  - >1000 units = enclosed masonry room (or equivalent) with vault steel door
- C-IV, V drugs must be kept in secure location in prescription compounding are or drug room

Purchasing C-II Drugs

- **DEA Form 222** required for sale or transfer of C-II drug
- Only those registered with DEA can obtain order forms
- Forms come in triplicate copies
  - Two go to supplier, third retained for purchaser records
- Must be prepared by registered purchaser
- Each form is specific to one supplier
- Contains 10 lines, only one item can be placed on each line
  - Different items (even if variation is slight) must be placed on a different line
- Purchaser can authorize other individuals to obtain/fill out these forms by creating a Power of Attorney

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DEA Form 222

BLANK DEA FORM-222
U.S. OFFICIAL ORDER FORM - SCHEDULES I & II

See Reverse of PURCHASER'S Copy of Instructions	No order form may be issued for Schedule I and II substances unless a completed application form has been received, (21 CFR 1305.04).	OMB APPROVAL No. 1117-0010
TO: *(Name of Supplier)*	STREET ADDRESS	
CITY and STATE	DATE	TO BE FILLED IN BY SUPPLIER SUPPLIERS DEA REGISTRATION No.

LINE No.	TO BE FILLED IN BY PURCHASER No. of Packages	Size of Package	Name of Item	National Drug Code	Packages Shipped	Date Shipped
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						

◀ LAST LINE COMPLETED *(MUST BE 10 OR LESS)*	SIGNATURE OR PURCHASER OR ATTORNEY OR AGENT
Date Issued / DEA Registration No.	Name and Address of Registrant
Schedules	Shaded areas are pre-printed by DEA prior to mailing to the registrant.
Registered as a / No. of this Order Form	

DEA Form-222
(Oct. 1992)

U.S. OFFICIAL ORDER FORMS - SCHEDULES I & II
DRUG ENFORCEMENT ADMINISTRATION
SUPPLIER'S Copy 1

Note: The graphic illustrated above is only a depiction of the DEA Form-222. It is not intended to be used as an actual order form.

Purchasing C-II Drugs

- **Controlled Substance Ordering System (CSOS)** is an electronic equivalent to DEA Form 222
  - Contains the same information
- Records are maintained electronically
- May also be used for C-III, IV, V drugs
  - Not at Yale
- No line item limits
- Offers faster and more accurate validation
  - Allows more rapid ordering and smaller inventories
- Purchaser must register for a CSOS digital certificate
- Purchaser must create record of the quantity and date received of each item when receiving a shipment

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Diversion

- If suspected, investigate diversion using available means
  - Use C-II Safe Compare Report
- DEA should be notified directly of any theft or significant loss of controlled substances
  - “Significant” is open to interpretation and location specific
- **DEA Form 106** (Report of Theft or Loss of Controlled Substances) must be completed
  - Formally documents quantity and circumstances of loss
  - Send original + copy to DEA Diversion Field Office
  - Pharmacy should keep a copy for its records
- Pharmacy is responsible only after signing for and taking custody of a shipment from a supplier

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Disposal

- Pharmacy transfers controlled substances to **reverse distributer** (registered with DEA) for destruction
- Reverse distributer issues a DEA Form 222 (or electronic equivalent) to the pharmacy for C-II
  - Submit **DEA Form 41** to DEA to document destruction
- Also used for returns and recalls
- On site destruction requires 2 employees to witness

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Prescription Monitoring Program

- Individual states have systems in place to monitor controlled substance prescribing and dispensing
- **CT Prescription Monitoring and Reporting System (CPMRS)**
  - Requires **weekly** reporting to DCP
- Information is shared with:
  - Regulatory and law enforcement agencies
  - Practitioners
  - Pharmacists
  - Public/private entities for statistical, research, or educational purposes
- Hospitals required to submit information for outpatients only

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CT Marijuana Laws

- Currently identified as a C-I drug federally, C-II in CT
  - Should follow stricter laws
- May only be dispensed from a licensed dispensary under a pharmacist
- Patients must have a valid CT registration certificate
- Only approved for specified debilitating medical conditions and for palliative use
- Yale policy:
  - If patient is in legal possession, “all formulations of medical marijuana must be removed from the facility immediately by an agent designated by the patient or if such removal is not possible it will be held as a patient belonging, although hospital does not assume responsibility for this medication. Pharmacy Services will not secure the medication within pharmacy.”

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