Slide 1

Pharmacy Law, Ethics, and Regulatory Agencies

Chapter 2

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Slide 2

Learning Objectives

Lesson 2.1: Federal Laws Affecting the Pharmacy Technician and Functions of the FDA and DEA

1. List the history of federal drug laws in chronologic order.
2. Describe the implications of the Health Insurance Portability and Accountability Act (HIPAA).
3. Explain how the Patient Protection and Affordable Care Act (ACA) and the Drug Quality and Security Act (DQSA) have changed health care.
4. Discuss the following related to the Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA): (a) define the functions of the FDA and DEA; (b) describe the process for reporting any problems with a drug or any adverse reactions to the FDA; (c) explain the three classes of drug recalls defined by the FDA.

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Food and Drug Administration History

- History of the FDA is important in pharmacy
- FDA is under the direction of the Department of Health and Human Services
- FDA's main function: Enforce guidelines for manufacturers to ensure safety and effectiveness of medications

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1906 Pure Food and Drug Act

- Enacted to stop the sale of inaccurately labeled drugs
- Manufacturers were required to:
  - Provide truthful information on the label before a drug was sold
  - Prove the drug's effectiveness

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1914 Harrison Narcotics Act

- Enacted to curb recreational use of opium
  - No longer available without a prescription
  - Records required for prescriptions
  - Importation and distribution were restricted

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1938 Federal Food, Drug, and Cosmetic Act

(Slide 1 of 2)

- Enacted because the 1906 law was not worded strictly enough and did not include cosmetics
- Required drug companies to include directions to the consumer regarding use of a drug and also package inserts
- All addictive substances had to be labeled: "Warning: May be habit forming"

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1938 Federal Food, Drug, and Cosmetic Act
(Slide 2 of 2)

- Defined the exact labeling for products and defined misbranding and adulteration as illegal
- Requires the following:
  - Mandatory food labeling
  - Standards of identity
  - Information on imitation foods
  - Nutritional information for special dietary foods
- Provided the legal status for the FDA

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1951 Durham-Humphrey Amendment

- Required label on prescription drugs: "Caution: Federal law prohibits dispensing without a prescription."
- Required a doctor's order and supervision for certain drugs
- Made the initial distinction between legend drugs (by prescription only) and over-the-counter (OTC) medications that do not require a doctor's order (non-prescription drugs)

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1962 Kefauver-Harris Amendments

- Enacted in an attempt to ensure the safety and effectiveness of all new drugs on the market
- Burden put on manufacturers to ensure "good manufacturing practice" (GMP)
- Prevented the sale of thalidomide in the United States; children in Europe were born with birth defects after mothers used drug during pregnancy

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1970 Comprehensive Drug Abuse Prevention and Control Act

- Established the Drug Enforcement Administration (DEA) to enforce the laws covering controlled substances and their distribution
- Created stair-step categories of controlled substances (schedules I-V)

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1970 Poison Prevention Packaging Act

- Required all medications to be placed in containers with childproof caps or packaging
  - Includes both OTC and legend drugs
- Exceptions include:
  - Physician request for non-childproof cap
  - Certain legend medications
  - Hospitalized patients or patient request

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1972 Drug Listing Act: National Drug Code

- Every drug has a unique 10-digit number divided into three segments
  - Numbers identify the labeler, product, and trade package size
  - First set of numbers assigned by the US Food and Drug Administration (FDA)
  - Second set of numbers identifies product specifics
  - Third set of numbers identifies the specifics of the package size and types

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1983 Orphan Drug Act; 1987 Prescription Drug Marketing Act

- Orphan Drug Act: Eased restrictions (and thus costs) for development of new drugs for those with a rare disease (affecting 1 in 200,000 people)
- Prescription Drug Marketing Act
  - Helps prevent counterfeit drugs and ingredients from entering the supply chain
  - Limits diversion of pharmaceutical samples and prescription drugs

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1990 Omnibus Budget Reconciliation Act (OBRA '90)

- Deals specifically with practicing pharmacists
- Enacted because of reimbursement regulations for people who are covered by Medicaid or Medicare
- Requires pharmacists to counsel (at the time of purchase) all patients who receive new prescriptions
- Three important provisions:
  - Evaluation of drug therapy
  - Review of drug therapy
  - Drug utilization evaluation (DUE) board review

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1996 Health Insurance Portability and Accountability Act (HIPAA)

- Deals with patient's right to continuance of health insurance even when changing employers
- Change for pharmacies: Pharmacists and technicians have direct knowledge of a patient's medical information; the patient must sign a consent form to grant others access to this information
- All covered physicians were required to update their HIPAA policies/procedures and implement changes no later than September 23, 2013

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Patient Confidentiality

- Prevents privileged information about a customer from being disclosed without his or her consent
- Changes have been made throughout all medical facilities and medical information centers that limit access to patient information
- All individually identifiable health information is protected
- Pertains to information in any form or media

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Examples of What Technicians Cannot Do

- As a pharmacy technician, you may not:
  - Offer any personal or medical information pertaining to the patient to any entity not covered under HIPAA rules/regulations
  - Share any information with any family member or friend, coworker, manager, or any entity not covered under HIPAA rules/regulations

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Public Health Activities

- PHI may be disclosed to:
  - Public health authorities
  - Entities subject to FDA regulation
  - Those who have been exposed to a communicable disease
  - Employers regarding work-related illness/injury to comply with Occupational Safety and Health Administration (OSHA)

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Law Enforcement Purposes

- PHI may be disclosed to law enforcement officials:
  - As required by law (for example, court orders)
  - To identify or locate a suspect, fugitive, material witness, or missing person
  - To provide information about a victim
  - If criminal activity caused a victim's death

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2000 Drug Addiction Treatment Act (DATA 2000)

- Physicians can prescribe controlled substances to persons suffering from opioid addiction
  - Only for maintenance or detoxification treatments

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2003 Medicare Modernization Act

- Provides a drug discount card to those with low incomes who require assistance from a pharmacy company to obtain medications

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2005 Combat Methamphetamine Epidemic Act

- Addresses all areas of the manufacture and sale of pseudoephedrine (an ingredient used to make methamphetamine), as well as law enforcement
- Strict guidelines
  - Only a licensed pharmacist or technician may dispense, sell, or distribute this drug

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2010 Patient Protection and Affordable Care Act; 2013 Drug Quality and Security Act

- Patient Protection and Affordable Care Act (ACA)
  - Two important technician-related components:
    - Electronic health records (EHRs)
    - Medication therapy management (MTM)
- Drug Quality and Security Act (DQSA)
  - FDA tracking system for bulk compounding supplies

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Food and Drug Administration/ Drug Enforcement Administration

- FDA
  - Enforces guidelines for manufacturers to ensure safety and effectiveness of medications
    - Anything that contains any avoidable, poisonous, or harmful substance is considered unsafe
- DEA
  - Prevents illegal distribution and misuse of controlled substances
  - Issues licenses and enforces the nation's drug laws

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FDA Reporting Process and Adverse Reactions
(Slide 1 of 2)

- 1-800-FDA-1088: Toll-free number for reporting any defect in OTC medications and any other drug problems
- Should report: Any medication reaction that might cause disability, hospitalization, or death
- Patient's identity must be kept confidential

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FDA Reporting Process and Adverse Reactions
(Slide 2 of 2)

- MedWatch: FDA program that allows consumers and health care professionals to report any discrepancies or adverse reactions to medications

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Recalled Drugs

- Three classes of recalls:
  - Class 1: Products that could cause serious harm or prove fatal
  - Class 2: Products found to cause a temporary health problem or pose a slight threat of serious harm
  - Class 3: Products that may have a minor defect or other condition that would not harm the patient

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Learning Objectives

Lesson 2.2: Controlled Substances, Drug Warnings, Prescribing Medications, and Pharmacy Guidelines

(Slide 1 of 2)

5. Describe the proper handling of controlled substances, and explain the necessary forms and regulations used for controlled substances.
6. Discuss the following related to drug monographs: (a) list the basic information contained in a drug monograph; (b) explain the purpose of boxed warnings and MedGuides; and (c) list and explain the five pregnancy categories established by the FDA.
7. Discuss the following related to prescription guidelines: (a) list who can prescribe medications and medical devices; (b) describe prescription orders and prescription labels; and (c) perform the function of verifying a DEA number.

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Learning Objectives

Lesson 2.2: Controlled Substances, Drug Warnings, Prescribing Medications, and Pharmacy Guidelines

(Slide 2 of 2)

8. Describe special prescribing programs and explain the purpose of risk management programs for prescription drugs.
9. Explain the verification process for Internet pharmacies.
10. Explain the Occupational Safety and Health Administration (OSHA) guidelines as they pertain to pharmacy.
11. Explain the purpose of The Joint Commission.
12. Explain why pharmacy technicians must be knowledgeable about the law when performing nondiscretionary duties, and discuss the differences between morals and ethics.

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Controlled Substances

- Commonly known as narcotics and are addictive
  - Narcotics are derived from opium or opium-like substances
- Opium comes from the poppy seed plant and has analgesic effects and also affects mood and behavior
  - Opioids, such as codeine and morphine, are substances created from opium
- Each type of narcotic is assigned a rating that depends on its addictive and abuse potential

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Ratings of Scheduled (Controlled) Substances

- Five levels based on potential for abuse
  - C-I: Strongest potential for abuse; no medicinal use in the United States (for example, LSD, heroin)
  - C-II, C-III, C-IV, C-V: All medicinal narcotic drugs
  - C-V: Kept OTC in some states because of low potential abuse
  - C-II: Must be locked up because of high potential abuse
- U.S. Attorney General assigns the schedule for a drug

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Tamper-Proof Prescriptions

- New scripts have up to eight different tamper-proof security marks on them
  - Prevents forgery and fraud

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Registration Requirements for Maintaining Narcotics

- DEA has four main registration forms
  - Form 224: Needed by pharmacy to dispense controlled substances
    - Must be renewed every 3 years using Form 224a
  - Form 225: To manufacture or distribute controlled substances
  - Form 363: To run a narcotic treatment program or compound narcotics
  - Form 41: Returns to reverse distributor

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Refilling Controlled Substances

- Strict guidelines
  - Drugs rated C-III through C-V can be refilled a maximum of five times or within 6 months of the original order, whichever comes first
  - Record must be kept with pharmacist's initials and date drug was dispensed

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Ordering Controlled Substances
(Slide 1 of 3)

- Pharmacy obtains C-II substances from a distributor
- Form 222 must be filled out by the receiving pharmacy in pen, typewriter, or indelible pencil
- Top copy and middle copy with carbon paper are sent to the supplier or manufacturer

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Ordering Controlled Substances
(Slide 2 of 3)

- Top and middle copies with carbon paper are returned to distributor or wholesaler
- Filing electronically is also possible (but not for C-I or C-II drugs)
- Pharmacy retains bottom copy
  - Invoice and form are retained for 7 years

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Ordering Controlled Substances
(Slide 3 of 3)

- Drugs rated C-III, C-IV, or C-V
  - Ordered on normal invoice forms but must be filed and retained for DEA or board of pharmacy (BOP) inspection
  - Should be kept separate from other nonscheduled drugs
  - Forms kept for 2 years

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Record Keeping

- Three methods of filing controlled substances
  - In some states, the BOP may require a specific method
- Controlled substances must be logged out of pharmacy stock before being issued
  - Double-check the remaining stock

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Narcotic Inventory

- Narcotics are at high risk for drug diversion
- Perpetual inventory
- Pharmacist must validate all counts done by a technician
- Discrepancies are investigated by DEA

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Reverse Distributor

- All controlled substances that are unwanted, unusable, or outdated that are returned to the distributor
  - Prevents drug diversion

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Filling, Refilling, and Transferring Prescriptions for Controlled Drugs

- Original fill of C-II through C-V drugs: Written, oral, or fax
- Emergency C-II original fill: Oral order only in emergency situations
- Refills of C-II through C-V drugs
  - C-II: No refills
  - C-III and C-IV: Five times within 6 months
  - C-V: No restrictions

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Partial Filling of C-II Through C-V Drugs

- C-III, C-IV, and C-V: Must have remainder dispensed within 6 months
- C-II: Must have remainder dispensed within 72 hours
- Transfer of prescriptions C-II through C-V: May be transferred only once
- Some states require schedule V drugs to be dispensed by a pharmacist
- Controlled substances C-II through C-V may be mailed as long as contents are not identified on packaging

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Drug Monographs

- Contained in the *Physicians' Desk Reference* (PDR) in doctor's office and *Facts and Comparisons* in pharmacy
- Includes: Description, clinical pharmacology, indications and usage, contraindications, warnings, precautions, drug abuse and dependence, adverse reactions, dosage, and how supplied
- Boxed warning (also called Black Box Warning)
- MedGuides: Printouts required for certain medications

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Pregnancy Categories

- FDA established five categories to identify a drug's potential harm to a fetus or pregnant woman
  - Category X: Not to be used during pregnancy
  - Category A: No evidence of harm based on studies
  - Categories B-D: Various levels of risk

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Prescription Regulations

- Who can prescribe?
  - FDA and DEA have no authority to determine prescribers
- Prescribers are licensed by their individual state boards
- Standard practitioners in all 50 states are physicians, surgeons, doctors of osteopathy, dentists, podiatrists, veterinarians, and optometrists

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Who Can Receive a Prescription?

- Pharmacy technicians take in prescriptions, interpret them, and fill them
- Technicians cannot take phone orders
- Pharmacists give the final check, take verbal telephone orders, and transfer prescriptions to another pharmacy

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Prescription Labels and Prescription Orders

- The information on a prescription label differs from a prescription order
- Two necessary components are pharmacy information and patient information
- Special labeling sometimes is required because of adverse effects or the possibility of teratogenicity to an unborn fetus
- Labels include: Name, address, and phone number of the pharmacy; name of prescriber and date prescription was filled; prescription number and cautions

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Repackaging

- Medication taken from bulk packages and placed into blister packs or unit-dosing devices must include:
  - Drug name
  - Strength and dosage form
  - Manufacturer and lot number
  - Expiration date

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Drug Enforcement Administration Verification

- All prescribers must be registered with the DEA to write prescriptions for controlled substances
- Prescribers are given a nine-character identification code, which is different for each prescriber
- First two characters are letters: A or B, followed by the first letter of the prescriber's last name
- Next seven digits are composed of numbers added together

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Special Prescribing Programs

- Programs for opioid maintenance
  - Methadone maintenance treatment (MMT)
  - Suboxone and Subutex
- Risk management programs for prescription drugs
  - iPledge Program
  - Drug Abuse and Monitoring Programs
    - As of 2016, more than 45 states participating in the program

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Pharmacy Sites

- Brick and mortar stores
- Mail-order pharmacies
- E-pharmacies
  - National Association of Boards of Pharmacy (NABP) verifies these sites but does not regulate them
  - Potential for illegally ordered drugs
  - Voluntary accreditation: Through Verified Internet Pharmacy Practice Sites (VIPPS)

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Occupational Safety and Health Administration (OSHA)

- Safety Data Sheet (SDS) must be available for all chemicals
  - Includes information on storage requirements, handling, and what to do in case of a spill or contact with the eyes

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The Joint Commission

- Mission is to improve the safety and quality of care via accreditation of health care organizations
- Areas of concern include:
  - How look-alike, sound-alike drugs are identified
  - How communication, allergy notification, conflicting prescriptions, verbal orders, and other areas that may create an avenue for errors are handled

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Legal Standards

- State law: Differs by state
- Liabilities: Negligence or tort
- Mistakes are made for many reasons
- Consider purchasing malpractice insurance
- Laws change regularly

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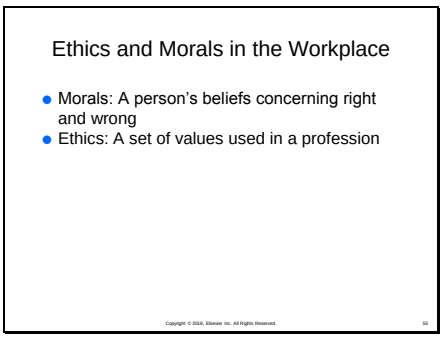

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