

PHMT A050N: PHARMACY LAW AND ETHICS

Item	Value
Curriculum Committee Approval Date	12/04/2024
Top Code	122100 - Pharmacy Technology
Units	0 Total Units
Hours	27 Total Hours (Lecture Hours 27)
Total Outside of Class Hours	0
Course Credit Status	Noncredit (N)
Material Fee	No
Basic Skills	Not Basic Skills (N)
Repeatable	Yes; Repeat Limit 99
Open Entry/Open Exit	No
Grading Policy	P/NP/SP Non-Credit (D), • Letter Non-Credit (L)

Course Description

This noncredit course introduces students to the legal and ethical principles governing pharmacy practice. Students will learn to navigate federal and state regulations, with a focus on controlled substances, prescription requirements, and patient safety. Legal standards and ethical guidelines to real-world scenarios and how they relate to professional integrity and compliance are included. This course is part of the Certificate of Completion – Pharmacy Technician. Not Transferable.

Course Level Student Learning Outcome(s)

1. Apply federal and state pharmacy laws to ensure the safe and legal dispensing of medications, including controlled substances, by identifying valid prescriptions and following proper documentation procedures.

Course Objectives

- 1. Identify and apply relevant federal and state laws to pharmacy practice scenarios.
- 2. Explain the legal implications of handling controlled substances.
- 3. Demonstrate proper procedures for dispensing medications according to prescriptions.
- 4. Uphold ethical principles in all aspects of patient care.
- 5. Navigate professional situations with integrity and respect.

Lecture Content

Introduction to Pharmacy Law and Ethics Importance of legal and ethical principles in pharmacy practice Legal framework of pharmacy practice (federal and state laws) Federal Pharmacy Law (PTCE references in parentheses) Key federal laws (Food, Drug Cosmetic Act [FDC Act], Federal Food, Drug, and Cosmetic Act Amendments, Controlled Substances Act [CSA]) and their impact on pharmacy practice (PTCE 1.1, 1.2, 1.3) Regulatory agencies (FDA, DEA, USP) and their roles in pharmacy oversight The Federal Controlled Substances Act (CSA) Classification of controlled substances (Schedules II-V) and their regulations (PTCE 3.1, 3.2) Overview of the Controlled Substances Act (CSA) Federal Requirements for Controlled Substance Prescriptions (PTCE 4.1) Valid

prescriptions must include all required components to ensure compliance
 Prescriber Information: Name, address, telephone number, DEA, NPI, State license number Patient information: Name, DOB, telephone number, address Medication information: Medication name, strength, amount, direction, refill DAW Valid prescriber signature Date of the prescription Methods to verify a prescriber DEA number Regulation for Telephone orders, facsimiles, and E-Prescribing Regulations for refills authorization and expiration of scheduled II and scheduled III-V prescriptions (PTCE 4.4) Regulation for partial filling of controlled substance prescriptions Regulation for transferring prescriptions of scheduled II and scheduled III V Federal Requirements (FDA and DEA) for Controlled Substances ion: line-through; Ordering and transferring controlled substances DEA Form 222 is utilized for ordering Schedule II substances and only be done by licensed pharmacists. Schedule III to V substances can be ordered directly from wholesaler or drug companies. Receiving and storing controlled substances Receiving and storing procedures to ensure compliance Storage of Schedule II V Mandate for monitoring and documentation Overview of DEA requirements for record keeping, documentation, and record retention Federal Requirements for Damaged or Outdated and Returned Controlled Substances Overview of reverse distribution and its part of the regulation framework to minimize the risk of controlled substance misuse and to promote public safety. Procedure for reporting damaged or outdated controlled substances and DEA Form 41 Procedure for returning controlled substances and DEA Form 222 Labeling requirements for returning controlled substances. Take-back program organized by DEA Diversion Prevention Strategies Identifying and reporting potential controlled substance diversion Use of DEA form 106 Importance of preventing misuse and abuses of controlled substances Federal Requirements for Non-Controlled Substance Requirement for non-controlled prescriptions Refilling and transferring Federal labeling requirements Importance of accurate labeling for patient safety. Procedures for dispensing non-controlled substance for patient safety. Non-controlled substances can be ordered directly through wholesale. Procedures for receiving shipment orders. Documentation and record-keeping requirements Returning medications to supplier guidelines and record-keeping for returns. Take-back programs in community, pharmacy, and nation initiatives. Guidelines for reporting and documenting of loss and theft of non-controlled substances. Federal Requirements for Handling and Disposal of Nonhazardous, Hazardous, Pharmaceutical Substances and Waste Classification of hazardous drugs Procedures and requirements of handling Personal Protective Equipment (PPE) Procedures of handling accidental exposure Use of Material Safety Data Sheets (MSDS). Overview of Resource Conservation and Recovery Act (RCRA) Identify the type of waste. Determine the appropriate disposal method. Overview of non-hazardous substances and procedures of handling Secure area to prevent theft or misuse Proper temperature and environmental controls to maintain drug integrity Procedures of disposal non-hazardous substance Regular trash Mixing with an undesirable substance for precaution OSHA Requirements for Prevention and Treatment of Hazardous Substances Exposure OSHA and its role to enforce practices that foster a safe and healthy workplace for employees. Guideline for prevention and treatment of substance exposure Handwashing procedures Disposal of sharps Eyewash station Pill kit Employer responsibilities under the OSHA law Employee Right to Know Overview FDA Recall Requirements Three types of drug recalls Class I Class II Class III FDA recall requirements and steps involved for: Medications Devices Supplies Supplements Patient safety is prioritized in all procedures Federal Requirements for Restricted Drug Programs and Related Medication Processing Requirement of Pseudoephedrine purchasing Age restrictions Identification Sales limit Logbook requirements Secure storages Medications under Risk Evaluation and Mitigation Strategies (REMS) Purpose to implement

strategies to educate patients and healthcare providers, promoting safe usage. Procedures to dispense medication under REMS program Patient Confidentiality Professional Conduct Protecting patient privacy and safeguarding patient information (PTCE 6.1, 6.2) Patient Confidentiality Laws (HIPAA) Exceptions to patient confidentiality and when disclosure may be necessary. OBRA-90 requirement for consultation Overview of OBRA-90 including consultation and medication management therapy OBRA-90 significantly impacts the roles of pharmacy technicians, emphasizing their importance in supporting pharmacists and enhancing patient care. The importance of offering mandatory patient counseling Federal Requirements for Availability of Medications Prescription medications are only available with prescriptions from license providers. Customer can purchase Over The Counter (OTC) without prescriptions Overview of Other Federal Requirements FDA requirements for consumer medication information and Medication guides Methods to electronically verify a prescriber s DEA . Overview process to determine the state, federal, and local laws and regulations that apply to one s practice site. Introduction to State Pharmacy Law Variations and similarities in state pharmacy laws across the US State pharmacy boards and their responsibilities for licensing and regulation Key Areas of State Pharmacy Regulations Overview Pharmacy Technician licensing requirements California license requirement CE required for license renewals State Requirements regarding Roles and Responsibilities Pharmacists Pharmacy Technicians Other employees State Requirement for Pharmacy operations and Dispensing Practices Facility and space requirement Prescription file storage Reference materials Cleanliness Pharmacy Technician Code of Ethics Ethical principles guiding professional conduct (competence, integrity, patient care) (PTCE 7.1) Building positive relationships with patients, pharmacists, and other healthcare professionals Conflict resolution strategies in the pharmacy setting Review Case Studies Applying legal and ethical principles through interactive case studies in pharmacy practice scenarios

Method(s) of Instruction

- Enhanced NC Lect (NC1)

Instructional Techniques

Lecture and direct instruction Digital presentations Classroom discussions Individual and group projects and/or presentations Oral pair and group work Instructor written and oral feedback Problem solving activities Case studies Role-reversal exercises Reading assignments Videos

Reading Assignments

Students will spend approximately 1 hour per week reading from the assigned textbook and additional instructional material provided by the instructor.

Writing Assignments

Students will write a one-page essay or create a presentation on the ethical implications of handling controlled substances. They will describe a real-world pharmacy scenario (based on a case study) involving controlled substances, and explain how they would apply ethical principles and legal standards to ensure compliance with federal law and patient safety.

Out-of-class Assignments

Students will research three federal pharmacy laws (e.g., the Controlled Substances Act, the Food, Drug Cosmetic Act, and the OBRA-90). They will create note cards that explain each law, its purpose, and its

application to pharmacy practice. Students will share their findings with the class.

Demonstration of Critical Thinking

Students will be presented with a potential ethical problem or legal issue in pharmacy dispensing and will be asked to write a short description of the legal and ethical issues in the situation and how they might resolve them.

Required Writing, Problem Solving, Skills Demonstration

Students will write a one-page essay or create a presentation on the ethical implications of handling controlled substances. They will describe a real-world pharmacy scenario (based on a case study) involving controlled substances, and explain how they would apply ethical principles and legal standards to ensure compliance with federal law and patient safety.

Eligible Disciplines

Pharmacy technology: Any bachelor's degree and two years of professional experience, or any associate degree and six years of professional experience.

Textbooks Resources

1. Required Bonnie S. Bachenheimer. Manual for Pharmacy Technicians, 5th ed. ASHP Publications, 2019 Rationale: Industry standard manual for the field. Has not been updated more recently.