Florida Pharmacy Disciplinary Laws and Rules Course

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Course Description

This course provides a comprehensive examination of Federal and Florida laws governing pharmacy practice, with emphasis on controlled substances regulation, recordkeeping, security, and diversion prevention. Participants will explore the Controlled Substances Act, Drug Enforcement Administration (DEA) requirements, and Florida Statutes Chapters 465, 499, and 893, as well as applicable Florida Administrative Code rules. The course highlights prescription requirements, ordering and inventory controls, theft and loss reporting, prescription drug monitoring programs, and emergency exceptions. Through real-world examples and case-based discussions, participants will develop practical skills in legal compliance, professional judgment, and patient safety. Emphasis is placed on the pharmacist's corresponding responsibility, ethical decision-making, and regulatory enforcement processes. This course prepares participants to navigate inspections, audits, and disciplinary actions while ensuring lawful, safe, and effective pharmacy operations in diverse practice settings.

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Learning Objectives

Upon successful completion of this course, pharmacists will be able to:

- Interpret and apply Federal and Florida pharmacy laws and administrative rules to pharmacy practice.
- Identify legal requirements for prescribing, dispensing, labeling, and recordkeeping of controlled substances.
- Explain the pharmacist's corresponding responsibility under the Controlled Substances Act.
- Demonstrate compliance with DEA registration, ordering, inventory, and security requirements.
- Recognize and respond appropriately to controlled substance theft, loss, or diversion.
- Analyze exceptions for emergency dispensing, electronic prescriptions, and telepharmacy.
- Apply Florida-specific statutes and rules to real-world pharmacy practice scenarios.
- Prepare for regulatory inspections, audits, and professional disciplinary processes.

ACCREDITATION

iCARE Pharmacy Services, Inc. is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants are unable to receive continuing education for discipline coursework.

iCARE Pharmacy Services, Inc. is approved by the Florida Board of Pharmacy as a provider of continuing pharmacy education. Approval number 20 -

DISCLOSURES

Author have no relevant conflict of interests nor financial relationships. All persons in a position to control the content of this activity have declared that no conflict of interest exists for this activity.

TARGET AUDIENCE

Pharmacists and Technicians who are disciplined by the Florida Board of Pharmacy.

CANCELLATION POLICY

Participants must submit cancellations in writing. Participants will receive a credit for a future CPE activity.

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Chapter 1: The Impact of Federal Laws on Pharmacy Practice

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Chapter 1: Federal Laws Impacting Pharmacy Practice

Federal laws play a crucial role in shaping pharmacy practice in the United States by promoting patient safety, protecting health information, preventing fraud, and improving access to medications. Several major federal laws—including the Drug Quality and Security Act (DQSA), Health Insurance Portability and Accountability Act (HIPAA), the Medicare Modernization Act (MMA), the National Institute for Occupational Safety and Health (NIOSH), Omnibus Budget Reconciliation Act of 1990 (OBRA '90), and the Tamper-Resistant Prescription Law - have significantly influenced the responsibilities and professional standards of pharmacists.

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1.1 The **Drug Quality and Security Act (DQSA)** of 2013 enhanced oversight of drug compounding and established a national system for tracking prescription drugs throughout the supply chain. This law improves medication safety by reducing the risk of contaminated or counterfeit drugs and affects pharmacy inventory management and compounding practices (U.S. Food & Drug Administration [FDA], 2023).

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DQSA Background:

The DQSA was enacted in response to the **2012 fungal meningitis outbreak** linked to contaminated compounded drugs from the New England Compounding Center, which resulted in 64 deaths and over 750 infections. This incident highlighted significant gaps in the regulation of compounded drugs and the need for improved oversight. The act was signed into law by President Obama on **November 27, 2013.**

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Provisions The DQSA consists of two main titles:

Title I: Compounding Quality Act (CQA):

Regulation of Compounding: The act amends the Federal Food, Drug, and Cosmetic Act to provide the FDA with greater authority to regulate compounding pharmacies. It establishes a framework for **outsourcing facilities** that can produce compounded drugs under specific conditions, in cluding registration and reporting requirements.

Safety Measures: It requires these facilities to report biannually on compounded drugs and submit adverse event reports, ensuring better monitoring of drug safety.

Prohibitions: The act prohibits the resale of compounded drugs labeled "not for resale" and addresses misleading advertising practices.

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Title II: Drug Supply Chain Security Act (DSCSA):

Traceability: This title establishes requirements for tracing prescription drug products through the supply chain, aiming to prevent counterfeit drugs from entering the market. It mandates the creation of an electronic, interoperable system for tracking and tracing prescription drugs over a ten-year timeline.

Documentation Standards: The act requires manufacturers, wholesalers, and dispensers to provide transaction documentation during the transfer of drug ownership, enhancing accountability and safety in the distribution process.

Impact

The DQSA aims to improve the safety and quality of compounded drugs and e nhance the security of the drug supply chain. By establishing clear regulations a nd oversight mechanisms, the act seeks to protect patients from unsafe medications and ensure that compounded drugs meet necessary quality standards.

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1.2 The **Health Insurance Portability and Accountability Act (HIPAA)** of 1996 established national standards for the protection of patient health information. In pharmacy practice, HIPAA governs how pharmacists handle prescriptions, patient profiles, and insurance records. Pharmacists must ensure that protected health information is only shared for legitimate purposes and that safeguards are in place to prevent unauthorized access. Compliance with HIPAA is essential, as violations may result in significant legal penalties (U.S. Department of Health & Human Services [HHS], 2013).

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Covered Entities: The following types of individuals and organizations are subject to the Privacy Rule and considered covered entities:

Healthcare providers: Every healthcare provider, regardless of size of practice, who electronically transmits health information in connection with certain transactions. These transactions include:

- Claims
- Benefit eligibility inquiries
- Referral authorization requests
- Other transactions for which HHS has established standards under the HIPAA Transactions Rule.

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Health plans include:

- Health, dental, vision, and prescription drug insurers
- Health maintenance organizations (HMOs)
- Medicare, Medicaid, Medicare+Choice, and Medicare supplement insurers
- Long-term care insurers (excluding nursing home fixed-indemnity policies)
- Employer-sponsored group health plans
- Government- and church-sponsored health plans
- Multi-employer health plans

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To comply with the HIPAA Security Rule, all covered entities must:

- Ensure the confidentiality, integrity, and availability of all e-PHI
- Detect and safeguard against anticipated threats to the security of the information
- Protect against anticipated impermissible uses or disclosures that are not allowed by the rule
- Certify compliance by their workforce
- Covered entities should rely on professional ethics and best judgment when considering requests for these permissive uses and disclosures. The HHS Office for Civil Rights enforces HIPAA rules, and all complaints should be reported to that office. HIPAA violations may result in civil monetary or criminal penalties.

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Exception: A group health plan with fewer than 50 participants administered solely by the establishing and maintaining employer, is not covered.

Healthcare clearinghouses: Entities processing nonstandard information received from another entity into a standard format or vice versa. Healthcare clearinghouses receive identifiable health information when providing processing services to a health plan or healthcare provider as a business associate.

Business associates: *A non-member of a covered entity's workforce using individually identifiable health information to perform functions for a covered entity*. These functions, activities, or services include:

- Claims processing
- Data analysis
- Utilization review

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1.3 The **Medicare Modernization Act (MMA)** of 2003 introduced Medicare Part D, greatly expanding prescription drug coverage for Medicare beneficiaries. This law increased pharmacists' responsibilities related to insurance billing, formulary management, and patient education. The MMA also established Medication Therapy Management (MTM) services, allowing pharmacists to play a more active role in optimizing medication therapy and improving patient outcomes (Centers for Medicare & Medicaid Services [CMS], 2023).

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The Medicare Modernization Act (MMA), enacted in 2003, significantly reformed Medicare by introducing a voluntary prescription drug benefit (Medicare Part D) and enhancing the overall Medicare program.

Overview of the MMA:

The **Medicare Prescription Drug, Improvement, and Modernization Act** (MMA) was signed into law on **December 8, 2003**, by President George W. Bush. This act represented the most substantial overhaul of the Medicare program since its inception in 1965. The primary goal of the MMA was to provide a **voluntary prescription drug benefit** to Medicare beneficiaries, addressing the rising costs of prescription medications that many seniors faced.

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Key Provisions

Introduction of Medicare Part D: The MMA established **Medicare Part D** which offers a prescription drug benefit to eligible Medicare beneficiaries. This program began on **January 1, 2006**, and allows beneficiaries to enroll in private insurance plans that provide coverage for prescription drugs.

Cost Structure: Under Part D, beneficiaries pay a monthly premium, an annual deductible, and a percentage of their drug costs. Initially, beneficiaries faced a coverage gap known as the "Donut Hole," where they had to pay a higher share of their drug costs until they reached a certain spending limit.

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Key Provisions cont.

Enhanced Benefits: The MMA aimed to provide more coverage options and enhanced benefits, including negotiated prices for drugs and catastrophic coverage limits for high cost beneficiaries. It also Included provisions for premium subsidies for low-income individuals.

Integration with Medicare Advantage: The act allowed for the integration of prescription drug coverage with Medicare Advantage plans, providing beneficiaries with more comprehensive health care options.

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Impact and Legacy

The MMA has had a lasting impact on Medicare, significantly increasing access to prescription drugs for millions of seniors. However, it has also faced criticism regarding its complexity, the coverage gap, and the reliance on private insurance companies to provide drug coverage. Subsequent legislation, including the Affordable Care Act, has made adjustments to the MMA, particularly in addressing the coverage gap.

In summary, the Medicare Modernization Act was a landmark piece of legislation that transformed Medicare by introducing a crucial prescription drug benefit, thereby improving access to necessary medications for many older Americans.

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1.4 The **National Institute for Occupational Safety and Health (NIOSH)** is a U.S. federal agency focused on protecting workers' health and safety. Established in 1970 under the Occupational Safety and Health Act, NIOSH operates as part of the Centers for Disease Control and Prevention (CDC). Its main role is research, not enforcement. NIOSH studies workplace hazards such as chemical exposures, noise, heat, and infectious diseases, and develops recommendations to prevent injuries and illnesses. The institute also supports training, provides guidance during emergencies, and collaborates with industries and academic institutions. Through research and prevention strategies, NIOSH helps improve workplace safety nationwide.

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The National Institute for Occupational Safety and Health (NIOSH) is the federal institute responsible for conducting research and making recommendations for the prevention of work-related injury and illness. NIOSH is part of the Centers for Disease Control and Prevention (CDC), in the Department of Health and Human Services (DHHS).

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1.5 The **Omnibus Budget Reconciliation Act of 1990 (OBRA)** Section 4401 was enacted by Federal lawmakers to ensure fiscally responsible spending of Federal funding while concurrently ensuring safe and effective therapeutic outcomes for Medicaid patients. OBRA '90 includes three key drug utilization review (DUR) components that impact the practice of pharmacy: prospective drug utilization review, record-keeping requirements, and a requirement to offer counsel.

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OBRA '90 further outlines specific information that the pharmacist, while exercising professional judgment, should discuss with the patient when the offer to counsel is accepted, such as:

- Name of the drug (brand name, generic, or other descriptive information);
- Intended use and expected action;
- Route, dosage form, dosage, and administration schedule;
- Common severe side effects or adverse effects or interactions and therapeutic contraindications that may be encountered, including how to avoid them and the action required if they occur;
- Techniques for self-monitoring of drug therapy;
- Proper storage;
- Potential drug-drug[2] interactions or drug-disease contraindications;
- Prescription refill information; and
- Action to be taken in the event of a missed dose.

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OBRA '90 - As a condition of participation and to receive continued Federal funding for State Medicaid programs, OBRA '90 and regulations adopted by CMS require States to establish standards regarding implementation of patient counseling requirements. Although the original Federal requirements of OBRA '90 were intended to apply only to Medicaid beneficiaries, States established unique patient counseling regulations for both Medicaid and non-Medicaid beneficiaries. As a result, all patients are entitled to the benefits associated with patient counseling standards of care

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1.5 The **Occupational Safety and Health Administration (OSHA)** is a United States government agency established in 1970 under the Occupational Safety and Health Act. Its main purpose is to ensure safe and healthy working conditions for employees by setting and enforcing workplace safety and health standards. OSHA applies to most private-sector employers and workers, as well as some public-sector employees.

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OSHA's purpose is to reduce workplace injuries, illnesses, and fatalities by identifying hazards, requiring employers to follow safety regulations, and promoting best practices. The agency conducts workplace inspections, investigates accidents and complaints, and can issue citations or fines to employers who violate safety standards. In addition, OSHA provides training, education, and resources to help both employers and employees understand their rights and responsibilities. By encouraging hazard prevention, employee participation, and continuous improvement in safety programs, OSHA plays a critical role in protecting workers and improving overall workplace health and productivity across the United States.

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1.6 The **Omnibus Budget Reconciliation Act of 1990 (OBRA '90)** marked a turning point in pharmacy practice by formally expanding the clinical role of pharmacists. This law requires pharmacists to conduct prospective drug use reviews and offer patient counseling for Medicaid patients. These requirements help identify potential drug interactions, inappropriate dosing, and therapeutic duplication, thereby improving patient safety. Although OBRA '90 specifically applies to Medicaid, its standards have become common practice for all patients (U.S. Congress, 1990).

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1.7 The **Tamper-Resistant Prescription Law** was enacted to reduce prescription fraud and abuse in the Medicaid program. It requires written prescriptions to include specific security features that prevent copying, alteration, or counterfeiting. Pharmacists must verify that prescriptions meet these requirements and collaborate with prescribers when issues arise, reinforcing their role in fraud prevention (CMS, 2008).

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Tamper-resistant prescription laws are designed to prevent prescription fraud and abuse by requiring specific security features on prescription pads used for Medicaid patients and controlled substances.

Overview of Tamper-Resistant Prescription Laws

Tamper-resistant prescription laws were implemented to combat prescription drug abuse and fraud. These laws require the written prescriptions for certain medications, particularly those covered by Medicaid, be executed on tamper-resistant prescription pads.

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The key features of these laws include:

Implementation Timeline:
The Medicaid Tamper-Resistant Prescription Law was enacted as part of the U.S. Troop Readiness, Veterans'
Care, Katrina Recovery, and Iraq Accountability Appropriations Act of 2007. The law's first phase went into effect on April 1, 2008, requiring at least one tamper resistant feature on prescription pads. By October 1, 2008, all Medicaid prescriptions were required to have multiple security features.

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Security Features: Prescription pads must include features from three categories to be considered tamper-resistant:

Copy Resistance: Features that prevent unauthorized copying of completed or blank prescription forms (e.g., pantographs that display "Void" when copied).

Erasure Resistance: Features that prevent the alteration of information on the prescription (e.g., special inks that change color when tampered with).

Counterfeit Resistance: Features that prevent the use of counterfeit prescription forms (e.g., embedded security threads or barcodes).

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State Variations: While federal laws set minimum requirements, individual states may have additional regulations regarding tamper-resistant prescriptions. Some states may use different terminology, such as "counterfeit-resistant prescriptions".

Enforcement and Compliance: Pharmacies are required to verify that prescriptions are compliant with tamper resistant laws. If a prescription does not meet the requirements, pharmacies may obtain verbal or faxed confirmation from the prescriber to fill the prescription temporarily.

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Implications for Healthcare Providers and Patients

Healthcare Providers: Physicians must ensure they use compliant prescription pads when prescribing medications covered by Medicaid. Failure to comply can lead to issues with reimbursement and potential legal consequences.

Patients: Patients receiving prescriptions for controlled substances should be aware that their prescriptions must be written on tamper-resistant pads to be valid for Medicaid reimbursement.
These laws aim to enhance the security of prescription medications and reduce the risk of prescription fraud, ultimately protecting both patients and healthcare providers.

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1.7 The **Food and Drug Administration (FDA)** plays a vital role in pharmacy by ensuring the safety, effectiveness, and quality of medications. The FDA evaluates and approves prescription and over-the-counter drugs before they reach the market and monitors them for safety through post-marketing surveillance. It regulates drug manufacturing, labeling, storage, and distribution to maintain quality standards. The FDA also oversees compounding guidelines, drug recalls, and warnings related to adverse effects. By enforcing federal regulations and providing evidence-based guidance, the FDA helps pharmacists dispense medications safely, counsel patients accurately, and protect public health.

Test Your Knowledge

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Question 1:
Which requirement was introduced by the Omnibus Budget Reconciliation Act of 1990 (OBRA '90) to enhance patient safety in pharmacy practice?

A. Mandatory use of tamper-resistant prescription pads for all controlled substances
B. Prospective drug use reviews and patient counseling for Medicaid patients
C. Establishment of Medicare Part D prescription drug coverage
D. National tracking of prescription drugs through the supply chain

Correct Answer:
B. Prospective drug use reviews and patient counseling for Medicaid patients

Question 2:
Which federal law established a national system for tracking prescription drugs and increased oversight of drug compounding?

A. Health Insurance Portability and Accountability Act (HIPAA)
B. Medicare Modernization Act (MMA)
C. Drug Quality and Security Act (DQSA)
D. Tamper-Resistant Prescription Law

Correct Answer:
C. Drug Quality and Security Act (DQSA)

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Chapter 2: Drug Enforcement Administration (DEA) and Controlled Substances Act (CSA)

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Chapter 2: DEA and Controlled Substances

2.1 Drug Enforcement Administration (DEA)

The DEA is a federal agency under the U.S. Department of Justice responsible for enforcing the Controlled Substances Act (CSA). It regulates the manufacturing, distribution, prescribing, and dispensing of controlled substances (Schedules I–V) to prevent diversion and abuse. Pharmacists must comply with DEA registration requirements, maintain controlled substance inventories, follow proper storage and recordkeeping, and report thefts or losses. For example, a community pharmacist dispensing oxycodone (Schedule II) must verify the prescriber's DEA registration number, document dispensing records accurately, and ensure secure storage to remain compliant with federal law.

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The Drug Enforcement Administration was established on July 1, 1973,[3] by Reorganization Plan No. 2 of 1973, signed by President Richard Nixon on July 28. It proposed the creation of a single federal agency to enforce the federal drug laws as well as consolidate and coordinate the government drug control activities. Congress accepted the proposal, as they were concerned with the growing availability of drugs. As a result, the Bureau of Narcotics and Dangerous Drugs (BNDD), the Office of Drug Abuse Law Enforcement (ODALE); approximately 600 Special Agents of the Bureau of Customs, Customs Agency Service, and other federal offices merged to create the DEA.

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The DEA is the primary federal agency charged with implementing and enforcing the Controlled Substances Act (CSA), which is Title II of a larger Federal Act called the Comprehensive Drug Abuse Prevention and Control Act of 1970. The DEA is responsible for drugs listed in the CSA's five drug Schedules, categories that rank drugs by their potential for harm, and whether they have a medical use. The CSA seeks to ensure legitimate access to controlled pharmaceuticals, while preventing illicit use of controlled drugs.

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2.2 The Federal Controlled Substances Act (CSA)

The CSA (Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. §§ 801–971) regulates the manufacture, distribution, and dispensing of controlled substances to prevent abuse and diversion. It classifies drugs into schedules, sets recordkeeping, labeling, and security requirements, and provides penalties for violations.

Example: A pharmacist must comply with CSA requirements when dispensing oxycodone (Schedule II), maintaining accurate records, and storing it securely to prevent diversion.

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The Controlled Substances Act (CSA) regulates the manufacture, use, importation, possession, and distribution of certain drugs and substances deemed to pose a risk of abuse and dependence.

Overview of the CSA

The **Controlled Substances Act** was enacted in 1970 as part of the Comprehensive Drug Abuse Prevention and Control Act. It establishes a legal framework for regulating controlled substances in the United States. The Act categorizes drugs into five schedules (IV) based on their potential for abuse, medical utility, and safety or dependence liability

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Pharmacist's Manual

The DEA publishes the **Pharmacist's Manual**, which provides guidance for pharmacists on CSA compliance, dispensing requirements, recordkeeping, and security standards. It is an essential reference for understanding federal obligations.

Example: A pharmacist consulting the manual confirms that refills of Schedule III–V drugs are limited to five within six months.

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CSA Definitions

The CSA defines terms such as "controlled substance," "dispense," "practitioner," and "pharmacy" to clarify regulatory responsibilities (21 U.S.C. §802).

Example: "Dispense" includes the pharmacist's final act of delivering a medication pursuant to a prescription; counting tablets alone does not constitute dispensing.

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Protecting Patient Access to Emergency Medications Act of 2017
This act amended federal law to allow certain practitioners and pharmacies to dispense controlled substances in emergencies without a prescription under defined conditions.

Example: A pharmacist may dispense emergency doses of an opioid antagonist to a first responder in an overdose scenario.

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Application of the CSA to Dispensing

To apply for a controlled substance registration, one must complete the appropriate application forms, provide necessary documentation, and pay any applicable fees.

Pharmacists must dispense controlled substances according to CSA rules, including valid prescriptions, recordkeeping, labeling, and security measures (21 CFR Part 1306).

Example: Dispensing a Schedule II opioid requires a written or electronic prescription signed by a DEA-registered prescriber; no refills are allowed.

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Required Information for Labels of Controlled Substances

DEA requires controlled substance labels to include the pharmacy name, address, prescription number, patient name, drug name/strength, directions, and warning statements (21 CFR §1306.22).

Example: A pharmacist labels hydrocodone with patient info, dosage instructions, and "Caution: Federal law prohibits the transfer of this drug to any person other than the patient prescribed."

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United States Postal Service Mailing Requirements for Controlled Substances

Controlled substances may be mailed following DEA and USPS regulations, including secure packaging, labeling, and authorized sender/receiver verification (21 CFR §1317).

Example: A mail-order pharmacy ships a Schedule III antidepressant in a sealed, labeled envelope using traceable shipping methods.

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2.3 Controlled Substance Schedules

The CSA classifies drugs into five schedules (I–V) based on medical use, abuse potential, and dependence risk (21 U.S.C. §812).

Example: Fentanyl is Schedule II; its high abuse potential and accepted medical use dictate strict handling and prescribing rules.

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Schedule I Controlled Substances

Schedule I substances have no accepted medical use and high abuse potential. They are illegal to prescribe or dispense in the U.S. (e.g., heroin, LSD).

Example: A pharmacist may not dispense Schedule I substances; only DEA-licensed research facilities can handle them.

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Schedule II Controlled Substances
Schedule II drugs have accepted medical use but high abuse potential, no refills permitted, and strict documentation (e.g., oxycodone, morphine).

Example: A patient receives a written prescription for morphine; the pharmacist files it and dispenses only the exact quantity.

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Schedule III Controlled Substances

Schedule III drugs have moderate abuse potential and accepted medical use. Refills limited to five within six months (e.g., hydrocodone combination products).

Example: A patient may refill a hydrocodone-acetaminophen prescription up to five times in six months.

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Schedule IV Controlled Substances

Schedule IV drugs have lower abuse potential; prescriptions may be refilled up to five times in six months (e.g., alprazolam).

Example: A pharmacist verifies prescription refills and documents each dispensing of alprazolam.

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Schedule V Controlled Substances
Schedule V drugs have the lowest abuse potential, often available OTC in some states (e.g., cough syrups with codeine).

Example: A pharmacist may dispense a Schedule V cough syrup without a new prescription under state law limits.

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Rescheduling
The DEA can add, remove, or transfer drugs between schedules based on abuse, safety, and medical use evidence (21 U.S.C. §811).

Example: In 2014, hydrocodone combination products were moved from Schedule III to II, tightening dispensing and prescribing rules.

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Registration
Pharmacies, prescribers, and manufacturers must register with the DEA to handle controlled substances (21 U.S.C. §822).

Example: A community pharmacy completes DEA Form 224 to legally dispense controlled drugs.

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To register a new pharmacy with the DEA, one must complete the application process, which includes submitting the required forms and ensuring compliance with controlled substance regulations.

Steps for DEA Registration

Determine Eligibility: Ensure that your pharmacy meets the necessary requirements to register with the DEA. This includes having a valid state pharmacy license and complying with federal and state laws regarding controlled substances.

Complete the Application: One can apply for a new DEA registration online or via a paper application. The application form is available on the DEA's official website. For online applications, visit the DEA Diversion Control Division's registration page.

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Submit Required Information: The application will require details such as the pharmacy's name, address, and the type of services provided. Ensure that all information is accurate and complete to avoid delays in processing.

Pay the Registration Fee: There is a fee associated with the registration process, which varies depending on the type of registration (e.g., retail pharmacy, hospital, etc.). Make sure to check the current fee structure on the DEA website.

Await Processing: After submission, the DEA will process your application. One may receive electronic notifications regarding the status of your application. Ensure that the email address associated with your registration is current and active.

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Receive Your DEA Registration: Once approved, you will receive your DEA registration certificate, which allows your pharmacy to handle controlled substances legally.

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Important Considerations

Separate Registrations: Each pharmacy location must have its own DEA registration. If you plan to operate multiple locations, you will need to register each one separately.

Compliance: Ensure ongoing compliance with DEA regulations, including proper record
keeping and reporting of controlled substances.
For more detailed information and to access the application form, visit the DEA's official registration page. This will guide you through the necessary steps to successfully register your new pharmacy with the DEA.

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New Pharmacy Registrations
New pharmacies apply to the DEA using Form 224, demonstrating compliance with security, recordkeeping, and personnel requirements.

Example: A new retail pharmacy receives DEA approval before ordering Schedule II opioids.

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DEA Form 224 is an **application for registration under the Controlled Substances Act**. It is primarily used by pharmacies and other entities to apply for a new registration with the DEA to dispense controlled substances. This form is essential for any pharmacy before beginning operations involving controlled substances.

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Persons Required to Be Registered
Pharmacists, prescribers, manufacturers, distributors, researchers, and certain institutional staff must hold DEA registration to handle controlled substances.

Example: A hospital pharmacist managing Schedule II medications must be registered with the DEA.

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Separate Registration for Separate Locations

DEA regulations require distinct registrations for each physical site handling-controlled substances.

Example: A pharmacy chain operating multiple stores must register each location separately.

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On-Line Pharmacies

Internet pharmacies must comply with DEA regulations and maintain verification and reporting for controlled substances dispensed online.

Example: A telepharmacy verifies prescriber credentials before shipping Schedule III medications.

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DEA Number

The DEA issues a unique number to registered practitioners and pharmacies for controlled substance prescribing and dispensing verification.

DEA numbers should be verified using the following procedure:

- Be sure it has 2 letters and 7 numbers (e.g., AA1234567)
- Add the first, third and fifth digits and record as SUM 1
- Add the second, fourth and sixth digits. Multiply the results by 2. Record as SUM 2
- Add SUM 1 and SUM 2 to obtain SUM 3
- The seventh digit will be the second digit of SUM3 for validation. If not, the DEA number is not valid.

Example: Pharmacists verify a prescriber's DEA number before filling a Schedule II prescription.

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Renewal of Pharmacy Registration
DEA registrations must be renewed every three years using Form 224a. Failure to renew results in termination of registration.

Example: A pharmacy renews its DEA registration online before expiration to continue dispensing controlled substances legally.

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Chapter 2: DEA and Controlled Substances

Prescriptions

A prescription is a lawful order from a practitioner for a patient-specific medication. Prescriptions for controlled substances must comply with DEA regulations, state law, and professional standards. Proper documentation, validity, and patient-specific instructions ensure safe and legal dispensing.

Example: A physician writes a prescription for hydrocodone with patient information, directions, and DEA number.

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Chapter 2: DEA and Controlled Substances

Required Information for Prescriptions

DEA rules (21 CFR §1306.05) require the practitioner's name, address, DEA number, patient's name/address, drug name, strength, quantity, directions, and date of issuance.

Example: A pharmacist rejects a prescription missing the DEA number for a Schedule II opioid.

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Chapter 2: DEA and Controlled Substances

Persons Entitled to Issue Prescriptions

Only practitioners authorized by law (physicians, dentists, nurse practitioners, physician assistants) with a valid DEA registration may issue controlled substance prescriptions (21 U.S.C. §829).

Example: A dentist prescribes a Schedule III analgesic after a tooth extraction.

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Chapter 2: DEA and Controlled Substances

Purpose of Issue; Corresponding Responsibility
Controlled substance prescriptions must be issued for a **legitimate medical purpose**. Pharmacists share corresponding responsibility to verify validity (21 CFR §1306.04).

Example: A pharmacist questions an unusually high opioid dose and contacts the prescriber before dispensing.

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Chapter 2: DEA and Controlled Substances

Verification of Practitioner Registration by DEA Number
Pharmacists must verify the DEA number to confirm the prescriber is registered for the appropriate drug schedule.

Example: Checking DEA number AB1234567 for a Schedule II prescription before dispensing oxycodone. Is this legitimate?

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Chapter 2: DEA and Controlled Substances

Manner of Issuance

Prescriptions may be issued **written, oral, electronic, or faxed** following CSA rules.

Example: A physician faxes a Schedule II narcotic for hospice care to a pharmacy.

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Chapter 2: DEA and Controlled Substances

Specific Prescription Requirements for Schedule II Controlled Substances

Schedule II prescriptions must be **written or electronic**, signed by the prescriber, include no refills, and provide all required patient/prescriber info (21 CFR §1306.12).

Example: A patient receives a 30-day supply of morphine, no refills permitted; pharmacist logs prescription.

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Chapter 2: DEA and Controlled Substances

Specific Prescription Requirements for Schedules III, IV, and V Controlled Substances

These may be oral, written, or electronic and may be refilled up to five times in six months (21 CFR §1306.13).

Example: A patient receives a Schedule III hydrocodone combination product prescription with refills authorized.

Selected Exceptions Under the Controlled Substances Act

a. Exceptions for Schedule II Facsimile Prescriptions

Faxed Schedule II prescriptions are allowed in hospice, LTCF, or for compounded sterile products. **Example:** Faxed oxycodone prescription sent from a hospice physician to a pharmacy.

b. Emergency Dispensing

Schedule II drugs may be dispensed on oral emergency prescriptions with limited quantity, followed by a written prescription within seven days (21 CFR §1306.11). **Example:** Patient in severe pain receives an emergency phone-order for morphine.

c. Electronic Prescriptions

Electronic prescribing is permitted if DEA-compliant software is used. **Example:** A physician sends a secure e-prescription for hydrocodone.

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Chapter 2: DEA and Controlled Substances

Nonprescription Dispensing
Schedule V substances may be dispensed OTC under state rules (21 U.S.C. §829).

Example: Cough syrup with codeine dispensed without a prescription to an adult with ID and log entry.

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Chapter 2: DEA and Controlled Substances

Ordering Schedules I and II Controlled Substances on DEA Form 222 is required for each order of Schedule I/II drugs (21 CFR §1305.03).

Example: A pharmacy orders morphine tablets using Form 222.

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Chapter 2: DEA and Controlled Substances

Tracking Receipt on DEA Form 222
Pharmacies must document receipt and reconcile order forms.

Example: Received morphine shipment is logged with date, quantity, and supplier.

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Chapter 2: DEA and Controlled Substances

Transfers
Controlled substances can only be transferred to DEA-registered entities.

Example: A hospital transfers excess Schedule III meds to another registered pharmacy.

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Chapter 2: DEA and Controlled Substances

Supplier Acceptance of DEA Form 222
Suppliers review accuracy before filling orders; incomplete forms are rejected.

Example: Wrong quantity on Form 222 requires correction.

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Chapter 2: DEA and Controlled Substances

Cancellation and Voiding an Official Order Form
Forms can be canceled by the purchaser or supplier and documented.

Example: Pharmacy voids Form 222 after order duplication.

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Chapter 2: DEA and Controlled Substances

Lost or Stolen Order Forms
Loss must be reported to the DEA immediately (21 CFR §1311).

Example: Missing Form 222 triggers DEA notification and investigation.

DEA FORM 224

- All entities that prepare, handle, or distribute controlled substances must register with the DEA using DEA Form 224. The form is available online at https://www.deadiversion.usdoj.gov/drugreg/reg_apps/224/224_instruct.htm

DEA FORM 222

- A purchaser must make a copy of the original DEA Form 222 for their records and submit the original to the supplier
- The form must include the name and address of the supplier, as well as the name and address of the purchaser
- When transferring controlled substances between laboratories, the receiving party must also have a DEA Form 222

DEA FORM 106

- The **DEA Form 106** is used to report the **theft or loss of controlled substances**. Here are the key points:
- It must be completed electronically via the Theft/Loss Reporting Online (TLR) system
- Registrants must provide the National Drug Code numbers for the substances involved
- All forms must be submitted electronically; paper copies are no longer accepted
- Any person or facility registered with the DEA that experiences loss or theft of controlled substances is required to complete this form
- Refer to the DEA website for more detailed instructions.

DEA FORM 41

- Title 21 Code of Federal Regulations; PART 1317 — DISPOSAL sets forth the rules for the delivery, collection, and destruction of damaged, expired, returned, recalled, unused, or otherwise unwanted controlled substances that are lawfully possessed by registrants (subpart A) and non-registrants (subpart B).
- Promptly destroy that controlled substance in accordance with https://www.ecfr.gov/current/title-21/chapter-II/part-1317/subpart-C using an on-site method of destruction;
- Promptly deliver the controlled substance to a reverse distributor's registered location by common or contract carrier pick-up or by reverse distributor pick-up at the registrant's registered location;
- DEA Form 41 shall include the names and signatures of the **two** employees who witnessed the destruction. 21 C.F.R. **§** 1317.95(d)

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Chapter 2: DEA and Controlled Substances

Ordering Schedules III-V Controlled Substances
No Form 222 needed; standard invoices and records suffice (21 CFR §1304).

Example: Ordering acetaminophen with codeine tablets through normal purchasing channels.

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Chapter 2: DEA and Controlled Substances

Electronic Ordering - Controlled Substance Ordering System (CSOS)
DEA-authorized electronic orders replace paper forms for Schedule I-II drugs.

The **DEA Electronic Ordering System (CSOS)** allows for secure electronic tra nsmission of controlled substance orders without the need for the tradition al paper DEA Form 222.

Benefits: CSOS reduces ordering errors, allows for more line items on a single order, and speeds up transactions, leading to cost savings.

Process: Users must enroll with the DEA to obtain a CSOS digital certificate, which is required for electronic orders.

Example: A pharmacy submits CSOS order for oxycodone via secure software.

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Chapter 2: DEA and Controlled Substances

Inventory: Initial Inventory
Pharmacies must take exact counts of all controlled substances on opening day.

Example: New pharmacy counts and logs all Schedule II–V drugs.

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Chapter 2: DEA and Controlled Substances

Biennial Inventory
Every two years, pharmacies must take a complete inventory (21 CFR §1304.11).

Example: Inventory includes Schedule II, III, IV, V drugs, with exact counts for Schedule II.

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Chapter 2: DEA and Controlled Substances

Newly Scheduled Controlled Substance Inventory
Substances newly classified as controlled must be inventoried on the effective date.

Example: Newly scheduled hydrocodone products are added to pharmacy inventory on Day 1 of scheduling.

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Chapter 2: DEA and Controlled Substances

Required Records

DEA regulations (21 CFR §1304.03) mandate that pharmacies maintain records of controlled substances' receipt, dispensing, and inventory. These include invoices, DEA Form 222, prescriptions, and inventory logs.

Example: A pharmacist maintains paper/electronic records of all Schedule II-V drugs, ensuring compliance for DEA inspection.

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Chapter 2: DEA and Controlled Substances

Prescription Records

Prescriptions must be retained for **two years** (21 CFR §1304.04). Schedule II prescriptions require separate files; III–V may be kept together.

Example: Schedule II oxycodone prescriptions are filed separately, while hydrocodone combination prescriptions (Schedule III) are in a second file.

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Chapter 2: DEA and Controlled Substances

Electronic Prescriptions

Electronic prescriptions for controlled substances must be DEA-compliant, encrypted, and stored securely (21 CFR §1311).

Example: A pharmacy securely archives electronic Schedule II prescriptions for later reference and auditing.

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Chapter 2: DEA and Controlled Substances

Offsite Records

Pharmacies may store older records offsite with prior DEA notification; they must be retrievable within **two business days** (21 CFR §1311).

Example: A pharmacy stores prescriptions older than two years in an offsite secure facility.

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Chapter 2: DEA and Controlled Substances

Separate Records
Schedule II records must be kept separate from other prescriptions. Schedule III–V can be separate or centrally stored under specific rules (21 CFR §1304.04).

Example: Controlled substance prescriptions are filed by schedule for easy DEA inspection.

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Chapter 2: DEA and Controlled Substances

Records of Receipt and Dispersal
Pharmacies must document all controlled substance purchases and dispensing, including invoices and DEA Form 222 for Schedule I-II drugs (21 CFR §1304).

Example: When receiving morphine, the pharmacist logs quantity, supplier, and date; dispensed doses are recorded daily.

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Chapter 2: DEA and Controlled Substances

Security Requirements
Controlled substances must be stored in **secure, locked cabinets** or dispersed throughout non-controlled stock (21 CFR §1301.71).

Example: Schedule II narcotics are stored in a locked cabinet accessible only to authorized personnel.

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Chapter 2: DEA and Controlled Substances

Diversion Prevention
Pharmacies must implement policies and procedures to prevent theft or misuse (21 CFR §1301.71).

Example: Restricted access areas, background checks, and inventory reconciliation help prevent diversion of opioids.

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Chapter 2: DEA and Controlled Substances

The Prescription Drug Marketing Act of 1987 (PDMA)

PDMA regulates drug distribution, requiring proper labeling, pedigree, and prohibiting resale of samples to ensure safety and authenticity (21 U.S.C. §353).

Example: A pharmacy refuses to purchase discounted samples from an unlicensed wholesaler.

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Chapter 2: DEA and Controlled Substances

Employee Screening
DEA requires pharmacies to **screen employees handling controlled substances** for criminal history or substance abuse risk.

Example: A pharmacy conducts background checks and drug screening for all new pharmacy technicians.

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Chapter 2: DEA and Controlled Substances

Controlled Substance Theft or Significant Loss
The DEA mandates reporting theft or significant loss of controlled substances **within one business day** using DEA Form 106 (21 CFR §1301.76).

Example: A pharmacy discovers missing fentanyl patches and immediately files Form 106.

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Chapter 2: DEA and Controlled Substances

Controlled Substance Registrant Protection Act (CSRPA)
CSRPA (18 U.S.C. §670) provides federal penalties for robbery, burglary, or theft from pharmacies handling controlled substances.

Example: Armed robbery targeting oxycodone is prosecuted under federal law.

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Chapter 2: DEA and Controlled Substances

The **Prescription Drug Marketing Act (PDMA)** was signed into law on April 22, 1988, as a response to growing concerns about the safety of prescription drugs in the United States.

The act aims to protect consumers by establishing safeguards in the drug distribution system and preventing the introduction of counterfeit, adulterated, misbranded, subpotent, or expired drugs into the market.

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Chapter 2: DEA and Controlled Substances

Key Provisions

Reimportation Restrictions: The PDMA prohibits the reimportation of prescription drugs produced in the U.S., except for emergency medical care.

Drug Samples: The act restricts the sale, purchase, or trade of prescription drug samples and requires that samples be distributed only to licensed practitioners upon written request.

Authorized Distributors: Manufacturers must maintain a list of authorized distributors of record, and unauthorized distributors must inform their wholesale customers of all previous sales of the product before selling it to them.

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Chapter 2: DEA and Controlled Substances

Civil and Criminal Penalties: The act establishes penalties for violations, ensuring compliance with its provisions.

Consumer Protection: The PDMA aims to protect consumers from the risks associated with counterfeit and substandard drugs by ensuring that only safe and effective medications are available in the market.

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Chapter 2: DEA and Controlled Substances

Breakage and Spillage
Breakage or spillage of controlled substances must be documented and destroyed under DEA supervision; losses are reported if significant (21 CFR §1307.21).

Example: A spilled morphine solution is recorded and destroyed with two witnesses present, and minor losses logged internally.

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Chapter 2: DEA and Controlled Substances

Transfer or Disposal of Controlled Substances

Pharmacies must follow DEA rules when transferring or disposing of controlled substances, including use of Form 222 for Schedule I-II drugs and DEA-approved reverse distributors (21 CFR §1317).

Example: Expired oxycodone tablets are sent to a DEA-registered reverse distributor for destruction.

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Chapter 2: DEA and Controlled Substances

Methamphetamine Control
Methamphetamine precursors (pseudoephedrine, ephedrine) are regulated under the Combat Methamphetamine Epidemic Act (21 U.S.C. §§ 830–831). Pharmacies must limit sales, maintain logs, and verify purchaser ID.

Example: A pharmacy logs pseudoephedrine purchases and restricts sale to 3.6 g per day per federal law.

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Chapter 2: DEA and Controlled Substances

The **Combat Methamphetamine Epidemic Act** of 2005 (CME A) is a federal law aimed at regulating the sale of pseudo-ephedrine and other precursor chemicals used in the illicit production of methamphetamine.

Purpose of the Act

The CMEA was enacted to combat the growing problem of methamphetamine production and abuse in the United States. It regulates the sale of over-the counter medications containing pseudoephedrine, a common ingredient in cold and allergy medications that can be used to manufacture methamphetamine.

Chapter 2: DEA and Controlled Substances

Key Provisions

Sales Restrictions: The act limits the amount of pseudoephedrine that an individual can purchase to **3.6 grams per day** and **9 grams per month**. This is to prevent individuals from buying large quantities for illicit use.

Behind-the-Counter Sales:
Products containing pseudoephedrine must be kept behind the counter or in locked cabinets, making them less accessible to potential abusers.

Identification Requirements: Customers must present a valid photo ID when purchasing these products, and retailers are required to maintain a log of sales for at least two years.

Chapter 2: DEA and Controlled Substances

Employee Training: Retailers must train employees on how to recognize suspicious transactions and comply with the law's requirements.

Reporting Suspicious Transactions: Retailers are required to report any suspicious purchases to law enforcement, which helps in monitoring potential illegal activities related to methamphetamine production.

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Chapter 2: DEA and Controlled Substances

Employee Screening
DEA requires pharmacies to **screen employees handling controlled substances** for criminal history or substance abuse risk.

Example: A pharmacy conducts background checks and drug screening for all new pharmacy technicians.

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Chapter 2: DEA and Controlled Substances

The **DEA employee screening procedures** are outlined in **21 CFR § 1301.90**.

Key points include:

- Employers must inquire about **felonies and misdemeanors** within the past five years and any current charges for criminal offenses.
- Questions about **drug use** (narcotics, amphetamines, barbiturates) in the past three years are also part of the screening process.
- Employers must obtain written authorization to check court and law enforcement records for potential charges or convictions.
- The screening process is essential for assessing the likelihood of an employee committing a drug security breach.

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Chapter 2: DEA and Controlled Substances

Controlled Substance Theft or Significant Loss
The DEA mandates reporting theft or significant loss of controlled substances **within one business day** using DEA Form 106 (21 CFR §1301.76).

Example: A pharmacy discovers missing fentanyl patches and immediately files Form 106.

Test Your Knowledge

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Question 1:
Which action is required of a pharmacist under the **Controlled Substances Act (CSA)** when dispensing a **Schedule II medication**?
A. Allowing up to five refills within six months
B. Accepting an oral prescription without follow-up documentation
C. Verifying the prescriber's DEA registration and dispensing with no refills
D. Filing the prescription with Schedule III–V records

Correct Answer:
C. Verifying the prescriber's DEA registration and dispensing with no refills

Question 2:
Which DEA form must a pharmacy use to **report theft or significant loss** of controlled substances?
A. DEA Form 222
B. DEA Form 224
C. DEA Form 106
D. DEA Form 224a

Correct Answer:
C. DEA Form 106

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Chapter 3: Florida Statues

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Chapter 3: Florida Statutes

3.1 Florida Statutes Chapter 120: Administrative Procedure Act

Florida Statutes Chapter 120, the Administrative Procedure Act, governs how state agencies create rules and conduct hearings. It ensures transparency, fairness, and due process in administrative actions. For pharmacists, this law applies when challenging disciplinary actions taken by the Florida Board of Pharmacy. For example, a pharmacist accused of violating pharmacy law has the right to an administrative hearing before penalties are imposed. Chapter 120 protects licensees' rights while ensuring regulatory agencies follow lawful and consistent procedures.

Chapter 465, Florida Statutes & Chapter 64B16, Florida Administrative Code

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Chapter 3: Florida Statutes

Definitions §465.003, F.S. Rule 64B16-26.100, F.A.C.

Explanation:

Section 465.003 establishes the legal definitions that form the foundation of the Florida Pharmacy Act. These definitions precisely identify who may practice pharmacy and what activities constitute the practice of pharmacy in Florida. Terms such as *pharmacist*, *pharmacy*, *dispensing*, *prescription*, and *practice of pharmacy* define the scope of professional authority and responsibility. Rule 64B16-26.100 supports uniform application of these definitions across all Board of Pharmacy rules and enforcement actions. Clear definitions prevent misinterpretation, protect public safety, and ensure that only qualified individuals perform pharmacy-related functions.

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Chapter 3: Florida Statutes

Example:
A pharmacy technician may count tablets, but because *dispensing* is defined as a professional function under §465.003, the pharmacist must perform the final verification before the medication is released to the patient.

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Chapter 3: Florida Statutes

Florida Statute 465 pertains to the regulation of pharmacies and pharmacists in Florida. It includes various sections covering:

Licensure: Requirements for obtaining a pharmacist license and the renewal process.

Standards of Practice: Guidelines for pharmacy operations and practices.

Violations and Penalties: Procedures for violations of pharmacy regulations and the penalties for such violations.

Community Pharmacies: Regulations for community pharmacies, including permits and dispensing requirements.

Automated Pharmacy Systems: Regulations for automated systems used in pharmacies.

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Chapter 3: Florida Statutes

The Florida Board of Pharmacy §465.004, F.S. Chapter 64B16, F.A.C.

Explanation:
Section 465.004 establishes the Florida Board of Pharmacy as the regulatory authority responsible for overseeing the practice of pharmacy in the state. The Board's primary role is to protect the health, safety, and welfare of the public. It accomplishes this by adopting administrative rules, issuing licenses and permits, conducting inspections, and enforcing disciplinary actions when violations occur. Chapter 64B16 of the Florida Administrative Code contains the detailed rules created by the Board to implement the Pharmacy Act. These rules provide guidance on daily pharmacy operations, professional conduct, and regulatory compliance.

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Chapter 3: Florida Statutes

The Florida Board of Pharmacy §465.004, F.S. Chapter 64B16, F.A.C.

Example:
If a pharmacy fails a routine inspection due to improper drug storage or recordkeeping, the Florida Board of Pharmacy may impose fines, require corrective action, or discipline the permit holder under its authority in §465.004 and Chapter 64B16.

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Chapter 3: Florida Statutes

The Florida Board of Pharmacy §465.004, F.S. Chapter 64B16, F.A.C.

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Chapter 3: Florida Statutes

The Florida Board of Pharmacy §465.004, F.S. Chapter 64B16, F.A.C.

Example:
If a pharmacy fails a routine inspection due to improper drug storage or recordkeeping, the Florida Board of Pharmacy may impose fines, require corrective action, or discipline the permit holder under its authority in §465.004 and Chapter 64B16.

Chapter 3: Florida Statutes

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Pharmacist Licensure §465.006–§465.015, F.S.
Rules 64B16-26.300, 64B16-26.500, 64B16-26.700, F.A.C.

Explanation:
These statutes and rules outline the qualifications required to become and remain a licensed pharmacist in Florida. Requirements include graduation from an accredited college of pharmacy, completion of an approved internship, successful passage of required examinations, and ongoing continuing education. Licensure ensures that pharmacists possess the necessary knowledge, skills, and ethical standards to safely provide pharmaceutical care. Continuing education requirements promote lifelong learning and help pharmacists stay current with evolving laws, therapies, and professional standards.

Chapter 3: Florida Statutes

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Pharmacist Licensure §465.006–§465.015, F.S.
Rules 64B16-26.300, 64B16-26.500, 64B16-26.700, F.A.C.

Example:
A pharmacist who fails to complete the required continuing education hours under Rule 64B16-26.500 may be unable to renew their license and could face disciplinary action or temporary loss of the ability to practice.

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Chapter 3: Florida Statutes

Unlawful Acts and Consequences §465.016, F.S.
Rules 64B16-30.001, 64B16-30.003, F.A.C.

Explanation:
Section 465.016 identifies acts that are considered unlawful and detrimental to public safety, such as practicing pharmacy without a license, dispensing medications without a valid prescription, falsifying records, or violating controlled substance laws. The corresponding administrative rules provide disciplinary guidelines and specify penalties. Consequences may include fines, probation, license suspension or revocation, mandatory education, and referral for criminal prosecution when appropriate. These enforcement mechanisms serve as both punishment and deterrence.

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Chapter 3: Florida Statutes

Unlawful Acts and Consequences §465.016, F.S. Rules 64B16-30.001, 64B16-30.003, F.A.C.

Example:
A pharmacist who knowingly dispenses a controlled substance without a valid prescription may face license suspension or revocation, monetary penalties, and possible criminal charges under §465.016 and related rules.

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Chapter 3: Florida Statutes

Pharmacy Permits §465.019–§465.023, F.S.
Rules 64B16-28.100, 64B16-28.108, 64B16-28.300, F.A.C.

Explanation:
These provisions require any facility that dispenses prescription medications in Florida to obtain and maintain an appropriate pharmacy permit. Different permit types exist depending on the pharmacy's services and location, such as community, institutional, special, or nonresident pharmacies. Permits ensure that pharmacies meet minimum standards for facilities, staffing, equipment, and operations. Permit compliance allows the Board to monitor pharmacies and enforce safe medication practices.

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Chapter 3: Florida Statutes

Pharmacy Permits §465.019–§465.023, F.S.
Rules 64B16-28.100, 64B16-28.108, 64B16-28.300, F.A.C.

Example:
A pharmacy located outside Florida that dispenses medications to Florida residents must obtain a nonresident pharmacy permit under Rule 64B16-28.300 before legally shipping prescriptions into the state.

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Chapter 3: Florida Statutes

Pharmacy Standards §465.022–§465.023, F.S.
Rules 64B16-27.100, 64B16-27.300, 64B16-27.400, F.A.C.

Explanation:
These statutes and rules establish minimum operational standards for pharmacies to ensure safe and effective medication use. They address prescription processing, labeling, record retention, drug storage, security, and pharmacist supervision. Pharmacy standards help ensure consistency across practice settings and reduce the risk of medication errors, diversion, or patient harm. Compliance is routinely evaluated through inspections and audits.

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Chapter 3: Florida Statutes

Pharmacy Standards §465.022–§465.023, F.S.
Rules 64B16-27.100, 64B16-27.300, 64B16-27.400, F.A.C.

Example:
If a pharmacy fails to properly secure controlled substances as required under Rule 64B16-27.400, the pharmacy may be cited during an inspection and required to implement corrective measures or face disciplinary action.

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Chapter 3: Florida Statutes

3.2 Florida Statutes Chapter 395: Hospital Licensing and Regulation (TJC)

Joint Commission standards are the basis of an objective evaluation process that can help health care organizations measure, assess, and improve performance. The standards focus on important patient, individual, or resident care and organization functions that are essential to providing safe, high quality care.

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Chapter 3: Florida Statutes

The **Joint Commission (TJC)** sets nationally recognized standards for healthcare quality and patient safety, and these standards are widely adopted by healthcare facilities in **Florida** as a benchmark for accreditation. While TJC is a private accrediting body, its standards align closely with Florida regulatory requirements found in the **Florida Statutes (FS)** and **Florida Administrative Code (FAC)**. For example, **FS 395** (Hospital Licensing and Regulation) and **FAC 59A-3** require hospitals to maintain organized medical staff, quality assurance programs, patient safety protocols, and infection control measures—core elements also emphasized by TJC. Florida allows hospitals accredited by TJC to be "deemed" as meeting certain state licensure requirements, streamlining regulatory oversight. TJC standards focus on leadership accountability, patient rights, performance improvement, and safe clinical practices, reinforcing state expectations for high-quality care. Together, TJC accreditation and compliance with FS and FAC support consistent, safe, and effective healthcare delivery across Florida healthcare facilities.

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Chapter 3: Florida Statutes

3.3 Florida Statutes Chapter 456: Health Professions and Occupations

Florida Statutes Chapter 456 provides the general regulatory framework for licensed health professionals, including pharmacists. It establishes requirements for licensure, renewal, continuing education, and disciplinary procedures applicable across multiple healthcare professions. Chapter 456 also outlines patient rights, professional misconduct, and reporting obligations. For example, a pharmacist who fails to report a colleague's impairment or practices with an expired license may be disciplined under Chapter 456. This statute ensures professional accountability and consistent regulation among Florida's healthcare professions to protect public health and safety.

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Chapter 3: Florida Statutes

3.4 Florida Statutes Chapter 499: Florida Drug and Cosmetic Act

Florida Statutes Chapter 499 regulates the manufacturing, distribution, storage, and sale of drugs, devices, and cosmetics in Florida. The law aims to protect consumers from adulterated, misbranded, or counterfeit products by requiring proper permits and inspections. Pharmacies must ensure that drugs are obtained from authorized sources and stored according to legal standards. For example, a pharmacy that purchases medications from an unlicensed wholesaler or sells expired prescription drugs may face penalties under Chapter 499. This statute safeguards the integrity of Florida's drug supply.

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Chapter 3: Florida Statutes

3.5 Florida Controlled Substances Law Chapter 893, Florida Statutes

Standards and Schedules §893.02, §893.03, F.S.
Definition:
Florida's controlled substance standards and schedules classify drugs into Schedules I–V based on their accepted medical use, potential for abuse, and risk of dependence. Schedule I substances have a high potential for abuse and no accepted medical use, while Schedule V substances have the lowest abuse potential. These schedules regulate how substances may be prescribed, dispensed, stored, and documented to protect public health.

Example:
Oxycodone is classified as a Schedule II controlled substance, meaning it requires a written or electronic prescription with no refills permitted. A pharmacist may not dispense additional quantities without a new prescription.

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Chapter 3: Florida Statutes

3.5 Florida Controlled Substances Law Chapter 893, Florida Statutes
Pharmacist and Practitioner §893.02(13), §893.02(21), F.S.

Definition:
Under Chapter 893, a pharmacist is a licensed professional authorized to dispense controlled substances pursuant to a valid prescription, while a practitioner is a licensed healthcare provider (such as a physician, dentist, or veterinarian) authorized to prescribe, administer, or dispense controlled substances within the scope of their professional practice. Both are responsible for complying with state and federal controlled substance laws.

Example:
A licensed physician may prescribe hydrocodone for acute pain, and a pharmacist may dispense it only after verifying the prescription is legitimate and issued for a valid medical purpose.

Chapter 3: Florida Statutes

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Florida Statute 893 pertains to drug abuse prevention and control in Florida.

Key points include

Pharmacist and Practitioner Requirements: Oral prescriptions must be reduced to writing promptly, and prescriptions for controlled substances must include specific details such as the prescribing practitioner's name and address.

Controlled Substance Regulations: The statute outlines the regulatio ns for the use, possession, and distribution of controlled substances, including the requirements for prescriptions and dispensing.

Comprehensive Drug Abuse Prevention: The statute aims to comprehensively address drug abuse prevention and control in the state, covering various aspects such as prescription drug monitoring and public records exemptions.

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Chapter 3: Florida Statutes

The **Controlled Substance Ordering System (CSOS)** is a secure electronic system that allows DEA registered pharmaceutical drug manufacturers, distributors, pharmacies, hospitals, and other entities to transmit controlled substance orders electronically. This system replaces the need for supporting paper documents like the DEA Form 222. CSOS is designed to provide services to DEA registrants and is the only platform for electronic ordering of Schedule I and II controlled substances. It offers benefits such as faster transactions, accurate orders, and reduced costs due to decreased paperwork. The system is modernized to align with DEA's current requirements and improve the enrollment, modification, and revocation processes.

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Chapter 3: Florida Statutes

A controlled substance inventory is a comprehensive record of all controlled substances on hand, required to be maintained accurately and in compliance with federal regulations.

Key Requirements for Controlled Substance Inventory

1.Accurate Recording Keeping:

Each inventory must contain a complete and accurate record of all controlled substances on hand at the time the inventory is taken. This includes substances in possession or under the control of the registrant, such as those returned by customers or stored in warehouses.

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2. Initial and Biennial Inventories

Initial Inventory: Required when a registrant first engages in the manufacture, distribution, or dispensing of controlled substances. If no substances are on hand, this must be recorded as the initial inventory.

Biennial Inventory: A new inventory must be taken at least every two years following the initial inventory date. This can be done on any date within two years of the previous inventory.

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3. Separate Inventories:
Separate inventories are required for each registered location and for different schedules of controlled substances (Schedule I-II and Schedule III-V). Must be taken at Beginning of Business (BOB) or Close of Business (COB) 21 C.F.R. §1304.04(a)

4. Documentation:
The inventory must be documented in written, typewritten, or printed form. If an oral recording device is used, it must be promptly transcribed.

5. Retention of Records:
Inventory records must be maintained at the registered location for at least three years for inspection and copying purposes.

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Chapter 3: Florida Statutes

Best Practices for Conducting Inventory

Physical Count: Conduct an actual physical count of all controlled substance s on hand, including those that have expired and are awaiting destruction. 21 C.F.R. § 1304.04(a)

Use of Forms: Utilize specific forms for conducting inventories, such as Form 6 for annual/biennial inventories
and ensure that the date and business status (beginning or close of business) are noted.

Security Measures: Implement security measures to safeguard controlled substances, including background checks for employees with access and conducting biennial inventory reviews with separate counts by two staff members.

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Chapter 3: Florida Statutes

Best Practices for Conducting Inventory for Newly Scheduled Inventory

When a controlled substance is newly scheduled or reschedule, a physical inventory must be taken immediately.

The inventory must be taken at the Beginning of Business or Close of Business

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Chapter 3: Florida Statutes

INVENTORY LISTS

- Names of controlled substances
- Each finished form of substance (e.g. 50 milligram tablet)
- The number of dosage units of each finished form in the commercial container (e.g. 100 tablet bottle)
- The number of commercial containers of each finished form (e.g. three 100 tablet bottles)
- Disposition of the controlled substances

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Chapter 3: Florida Statutes

INVENTORY LISTS

The records and reports required by the Controlled Substances Act (CSA) are essential for maintaining the integrity of the controlled substances market. These records must be maintained by registrants and include detailed inform ation about the stocks of controlled substances on hand, the manufacturing, receipt, sale, delivery, or disposal of substances, and any theft or significant loss. The records must be maintained separately from all other records and readily retrievable for inspection and copying by authorized federal officers.

For practitioners, it is crucial to keep accurate records of all controlled substances on hand, including samples, and to report any theft or significant loss to the appropriate authorities. Practitioners who dispense controlled substances for maintenance or detoxification must maintain the same records as any other dispensing practitioner.

Chapter 3: Florida Statutes

General Record Keeping Requirements that apply to all controlled substance records required to be kept:

- Must be complete and accurate 21 C.F.R. § 1304.21(a)
- Must be stored at the registered location 21 C.F.R. § 1304.21(b)
- Must be kept for two years 21 C.F.R. § 1304.04(a)
- Must be readily retrievable 21 C.F.R. § 1304.04(f)(2)

SCHEDULE RECORDS

- Schedule II controlled substance records shall be maintained separately from all other records
- Schedules III-V controlled substance records must be kept separate from all other records or readily retrievable

SECURITY

- Registrants are required to provide effective controls and procedures to guard against theft and diversion of controlled substances. 21 C.F.R. § 1301.71(a)
- Registrant cannot employ anyone who has a felony drug conviction who will have access to controlled substance, without a DEA approved employment waiver. 21 C.F.R. § 1301.76(a)
- Practitioners are required to store stocks of CII-V controlled substances in a securely locked, substantially constructed cabinet. 21 C.F.R. § 1301.75(b)

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Chapter 3: Florida Statutes

The Florida Prescription Drug Monitoring Program (PDMP) §893.055, F.S.

Definition:
The Florida Prescription Drug Monitoring Program, known as E-FORCSE®, (Electronic-Florida Online Reporting of Controlled Substance Evaluation Program) is a statewide electronic database that tracks the prescribing and dispensing of controlled substances listed in Schedules II–V. PDMP was created by the 2009 Florida Legislature in an initiative to encourage safer prescribing of controlled substances and to reduce drug abuse and diversion within the state of Florida. The PDMP helps identify potential prescription drug abuse, diversion, and "doctor shopping." Pharmacists and prescribers are required to report dispensing data and may be required to consult the database before prescribing or dispensing certain controlled substances.

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Chapter 3: Florida Statutes

The Florida Prescription Drug Monitoring Program (PDMP) §893.055, F.S.

Example:
Before dispensing a Schedule II opioid, a pharmacist checks E-FORCSE® and discovers the patient recently filled similar prescriptions at multiple pharmacies, prompting the pharmacist to contact the prescriber before dispensing.

Important Information for Data Submitters (Pharmacies and Dispensing Health Care Practitioners)

Dispensers of controlled substances are required to report to the PDMP each time a controlled substance in schedules II, III, IV, and V are dispensed to a patient, as soon thereafter as possible but no later than close of business the day after the prescription is dispensed.

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Chapter 3: Florida Statutes

The Florida Prescription Drug Monitoring Program (PDMP) §893.055, F.S.

Important Information for Data Requestors (Prescribers and Pharmacists)

Each prescriber and dispenser or his or her designee has a duty to consult the PDMP system to review a patient's controlled substance dispensing history each time a controlled substance is prescribed or dispensed to a patient age 16 or older unless a statutory exemption applies.
Statutory exemptions include:

- If the patient is less than 16 years of age
- Drug being prescribed is a nonopioid schedule V
- System is not operational
- Requestor has technological or electrical failure
- Failure to consult in the PDMP may result in a non-disciplinary citation by the regulatory board.

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Chapter 3: Florida Statutes

Prohibited Acts §893.13, §893.135, F.S.

Definition:
Prohibited acts under Chapter 893 include the unauthorized possession, sale, manufacture, delivery, or trafficking of controlled substances. These statutes also prohibit prescription fraud, forged prescriptions, and dispensing or prescribing controlled substances without a legitimate medical purpose. Violations can result in severe criminal penalties, including fines and imprisonment.

Example:
A person who alters a prescription to increase the quantity of a controlled substance commits prescription fraud and may face felony charges under §893.13.

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Chapter 3: Florida Statutes

3.6 Miscellaneous Florida Statute

Emergency-Preparedness

Florida law (Chapter 252, Florida Statutes) requires that pharmacies and health facilities create emergency preparedness plans to maintain critical healthcare functions during disasters such as hurricanes. This includes continuity of pharmacy operations, emergency refill protocols, secure drug storage, and communication plans. Emergency-preparedness statutes align with broader public health rules mandating readiness for pandemics, hurricanes, and other crises. Florida's health agencies also implement annual drills and updates to these plans.

Example: A pharmacy on Florida's Gulf Coast prepares for hurricane season by securing extra inventory and ensuring access to backup power so patients can obtain life-sustaining medications during storm disruptions.

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Chapter 3: Florida Statutes

Emergency Treatment for Suspected Opioid Overdose *(FS §381.887)*
Florida law allows authorized practitioners and pharmacists to dispense *emergency opioid antagonists* (e.g., naloxone) through prescriptions, standing orders, or pharmacist orders to patients and caregivers. Civilians, first responders, and practitioners are afforded legal immunity when administering naloxone in good-faith emergencies. These laws aim to reduce opioid overdose deaths. Recent federal and state efforts to increase naloxone distribution and improve pharmacy access are ongoing, even as opioid addiction treatment access remains uneven nationally. A 2025 study found that many pharmacies still lack addiction treatment medications like buprenorphine—a related controlled substance—highlighting ongoing barriers to opioid crisis care.

Example: A pharmacist dispenses naloxone nasal spray without a practitioner visit for a patient's family member concerned about opioid overdose risk.

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Chapter 3: Florida Statutes

Expedited Partner Therapy (EPT)

Expedited Partner Therapy allows a healthcare provider to prescribe or dispense antibiotics to the *sexual partners* of patients diagnosed with certain STIs without requiring the partner's in-person evaluation. Florida supports EPT for conditions like chlamydia and gonorrhea. This practice reduces reinfection rates and public health burdens by treating partners who might not otherwise seek care.

Example: A physician diagnoses a patient with chlamydia and provides prescriptions for both the patient and their partner, even though the partner has not been examined.

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Chapter 3: Florida Statutes

Mid-Level Practitioners

Under Florida law, *mid-level practitioners* (e.g., nurse practitioners, physician assistants) may prescribe medications, including controlled substances within delegated authority and collaborative protocols with physicians. Their prescriptive privileges are governed by licensure, supervisory relationships, and DEA/Florida controlled substance rules.

Example: A nurse practitioner prescribes an antibiotic for a urinary tract infection within an established physician protocol.

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Chapter 3: Florida Statutes

Nursing Home Residents' Rights *(FS §400.022)*

Florida laws guarantee nursing home residents rights to dignity, privacy, informed consent, timely medical care, and access to their prescribed medications. Facilities must respect these rights and ensure safe medication management. Violations can lead to investigations, fines, or corrective action by the Agency for Health Care Administration (AHCA).

Example: A resident requests a pharmacist explain potential side effects of a new medication; the nursing home must facilitate this consultation.

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Chapter 3: Florida Statutes

Obesity Drugs

Florida does not yet have a single statute solely for *obesity drugs*, but treatment (including GLP-1 medications such as semaglutide) falls under pharmacy scope and controlled substances law when applicable. Pharmacists must dispense these medications under a valid prescription and ensure proper counseling, storage, and billing compliance. In 2025 and 2026, legislative proposals (e.g., SB 860) have emerged nationally and in Florida that could *restrict compounded obesity treatments*, reflecting growing concerns about access and regulation of obesity and GLP-1 therapies. These discussions also raise debate over drug pricing and supply safety. For example, recent pharmacy community chatter shows concern over potential law changes that would limit compounded GLP-1 access.

Example: A patient presents a prescription for a GLP-1 weight-loss injection. The pharmacist verifies its legitimacy and dispenses with counseling on side effects and insurance prior authorization requirements.

Chapter 3: Florida Statutes

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Prior Authorization

Prior authorization requires insurers or pharmacy benefit managers to approve certain medications *before* payment and dispensing. It ensures clinical appropriateness and cost control but can delay patient access. Florida's Prescription Drug Reform Act addresses transparency and oversight of PBMs, which affects prior authorization practices and data reporting.

Example: A pharmacist contacts an insurer to obtain prior approval before dispensing a high-cost biologic medication for rheumatoid arthritis.

Test Your Knowledge

Question 1:
Under **Chapter 465, Florida Statutes**, which activity is considered part of the **practice of pharmacy** and therefore requires pharmacist involvement?
A. Counting tablets for a prescription
B. Stocking over-the-counter medications
C. Final verification of a prescription before release to the patient
D. Delivering filled prescriptions to patients
Correct Answer:
C. Final verification of a prescription before release to the patient

Question 2:
Which statement best describes the purpose of the **Florida Prescription Drug Monitoring Program (E-FORCSE®)** under §893.055, F.S.?
A. To authorize pharmacists to prescribe controlled substances
B. To track the manufacturing of controlled substances in Florida
C. To monitor prescribing and dispensing of Schedule II–V controlled substances to reduce abuse and diversion
D. To replace the requirement for written prescriptions for Schedule II medications
Correct Answer:
C. To monitor prescribing and dispensing of Schedule II–V controlled substances to reduce abuse and diversion

Question 3:
Which authority is responsible for adopting administrative rules, issuing pharmacy licenses and permits, and enforcing disciplinary actions in Florida?
A. Florida Department of Health
B. Florida Legislature
C. Florida Board of Pharmacy
D. Agency for Health Care Administration (AHCA)
Correct Answer:
C. Florida Board of Pharmacy

iCARE PHARMACY SERVICES

Chapter 4: Florida Administrative Codes

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Chapter 4: Florida Administrative Codes

4.1 Florida Board of Pharmacy

The **Florida Board of Pharmacy (64B16, F.A.C.)** is the regulatory body authorized to adopt rules, oversee licensure, enforce practice standards, and discipline pharmacists and pharmacies in Florida. It enacts and enforces the administrative rules that implement the Florida Pharmacy Act (Chapter 465, F.S.). The Board's rules govern all aspects of pharmacy practice, including conduct, standards, permits, and disciplinary guidelines. For example, the Board's disciplinary guidelines outline penalties for practicing without a permit or violating laws. The Board's authority ensures public safety and consistent standards across all licensed pharmacy professionals and permittees in Florida.

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Chapter 4: Florida Administrative Codes

Licensure Issues

Florida Administrative Code rules under **64B16-26, F.A.C.** set requirements for pharmacist licensure, renewal, and qualifications. These rules define educational prerequisites, internship requirements, examination criteria, and continuing education expectations. For example, Rule 64B16-26.6012 allows Board-ordered disciplinary continuing education, including a 12-hour Laws & Rules course, to fulfill requirements after a violation. Licensure rules also include renewal timelines and CE mandates to ensure pharmacists remain competent. A pharmacist who fails to meet the CE requirements or complete a Board-approved internship may be denied renewal or subject to disciplinary action.

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Chapter 4: Florida Administrative Codes

Pharmacy Practice Standards

Pharmacy practice standards in **Rules 64B16-27.800, 64B16-27.820, and 64B16-27.830, F.A.C.**, define minimum operational expectations. Rule 64B16-27.800 requires pharmacies to maintain patient records with demographic and medication history details.

Rule 64B16-27.820 mandates patient counseling for new and refill prescriptions. Rule 64B16-27.831 outlines-controlled substance prescription validation and continuing education requirements, including use of the PDMP and professional judgment in validating prescriptions. For example, a pharmacist must offer counseling and document patient allergies and medication history before dispensing to ensure safe therapeutic outcomes.

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Chapter 4: Florida Administrative Codes

Standards for Pharmacy Permits

Rules in **64B16-28, F.A.C.** establish requirements for pharmacy permits before dispensing medications. Rule 64B16-28.451 allows pharmacies under common ownership to perform prescription drug processing using a shared database, with required policies and recordkeeping.

Permit standards govern facility requirements, database controls, quality assurance, and patient confidentiality. For example, a pharmacy operating under a prescription drug processing permit must maintain a secure electronic system that tracks which pharmacist or technician performed each processing function.

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Chapter 4: Florida Administrative Codes

Disciplinary Guidelines

Rules 64B16-30.001 and 64B16-30.003, F.A.C., set disciplinary guidelines and citation procedures for pharmacists, interns, and permittees. Rule 64B16-30.001 outlines ranges of penalties for violations (e.g., incompetence, operating without a permit, or failing to maintain standards). For example, practicing on an inactive license may result in fines and renewal orders under Rule 64B16-30.003. Disciplinary guidelines help ensure fair, consistent sanctions and corrective actions for regulatory violations.

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Chapter 4: Florida Administrative Codes

Nonresident Pharmacies

Rule 64B16-32.001, F.A.C., requires out-of-state pharmacies to obtain a nonresident pharmacy permit before shipping or delivering medications into Florida. This permit does not authorize shipment of compounded sterile products unless specific requirements are met.

Applicants must submit a Florida-approved application and comply with relevant statutory requirements. For example, a mail-order pharmacy in another state must secure a nonresident permit before legally dispensing prescriptions to Florida patients.

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Chapter 4: Florida Administrative Codes

Prescriber Rules Related to Pharmacy Practice – Weight Loss/Obesity & Telemedicine

Florida law requires prescribers to issue valid prescriptions meeting statutory elements; though not in 64B16, electronic prescribing is enforced by related Florida statutes requiring practitioners to transmit prescriptions electronically unless exceptions apply (e.g., hospice patients). Telemedicine laws allow practitioners to evaluate patients via telehealth, but controlled substances generally cannot be prescribed via telehealth except under specific conditions (e.g., psychiatric disorders). For example, a prescriber must generate an electronic prescription for a weight-loss medication unless an exception applies, and cannot prescribe a Schedule II via telehealth without qualifying circumstances.

Test Your Knowledge

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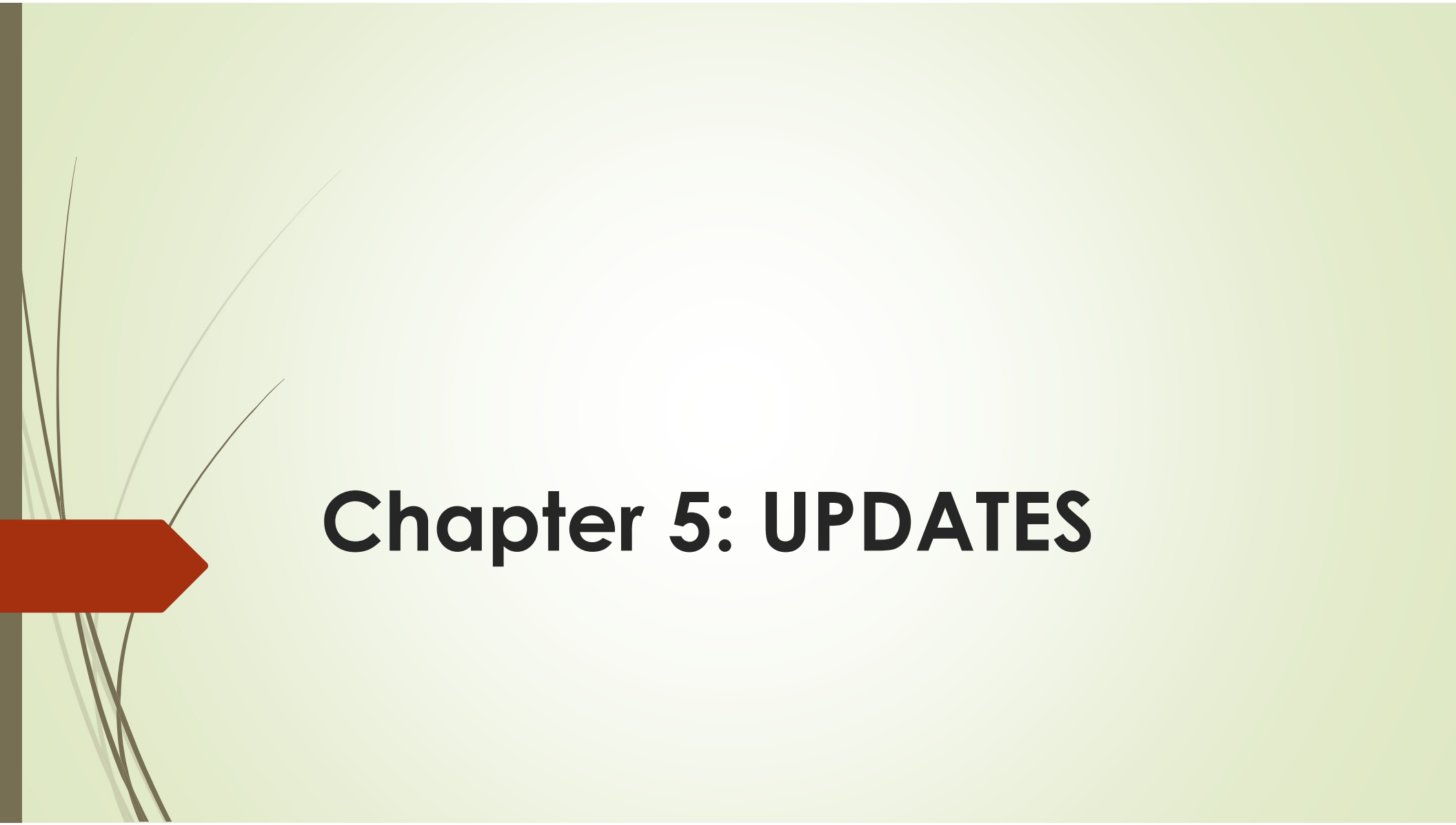
Question 1:
Which responsibility falls under the authority of the **Florida Board of Pharmacy** as established in **Rule Chapter 64B16, F.A.C.**?
A. Enacting criminal penalties for controlled substance trafficking
B. Adopting administrative rules and disciplining pharmacists and pharmacies
C. Approving medical school curricula for prescribers
D. Regulating hospital accreditation standards

Correct Answer:
B. Adopting administrative rules and disciplining pharmacists and pharmacies

Question 2:
Under **Rule 64B16-27.820, F.A.C.**, which action is required of a pharmacist when dispensing prescriptions?
A. Counseling only for controlled substances
B. Counseling only for new prescriptions
C. Offering patient counseling for both new and refill prescriptions
D. Counseling only if requested by the prescriber

Correct Answer:
C. Offering patient counseling for both new and refill prescriptions


Chapter 5: UPDATES

Chapter 5: The Biennial Inventory

- **893.07 Records**

(1) Every person who engages in the manufacture, compounding, mixing, cultivating, growing, or by any other process producing or preparing, or in the dispensing, importation, or, as a wholesaler, distribution, of controlled substances shall:

(a) On January 1, 1974, or as soon thereafter as any person first engages in such activity, and every second year thereafter, make a complete and accurate record of all stocks of controlled substances on hand. The inventory may be prepared on the regular physical inventory date which is nearest to, and does not vary by more than 6 months from, the biennial date that would otherwise apply. As additional substances are designated for control under this chapter, they shall be inventoried as provided for in this subsection.

(b) On and after January 1, 1974, maintain, on a current basis, a complete and accurate record of each substance manufactured, received, sold, delivered, or otherwise disposed of by him or her, except that this subsection shall not require the maintenance of a perpetual inventory.

Chapter 5: The Biennial Inventory

Compliance with the provisions of federal law pertaining to the keeping of records of controlled substances shall be deemed a compliance with the requirements of this subsection.

(2) The record of controlled substances received shall in every case show:

(a) The date of receipt.

(b) The name and address of the person from whom received.

(c) The kind and quantity of controlled substances received.

Chapter 5: The Biennial Inventory

(3) The record of all controlled substances sold, administered, dispensed, or otherwise disposed of shall show:

(a) The date of selling, administering, or dispensing.

(b) The correct name and address of the person to whom or for whose use, or the owner and species of animal for which, sold, administered, or dispensed.

(c) The kind and quantity of controlled substances sold, administered, or dispensed.

Chapter 5: The Biennial Inventory

(4) Every inventory or record required by this chapter, including prescription records, shall be maintained:

(a) Separately from all other records of the registrant, or

(b) Alternatively, in the case of Schedule III, IV, or V controlled substances, in such form that information required by this chapter is readily retrievable from the ordinary business records of the registrant.

Chapter 5: The Biennial Inventory

From the Pharmacists Manual on Controlled substances-

All required records concerning controlled substances must be maintained for at least two years for inspection and copying by duly authorized DEA officials. 21 U.S.C. 827(b) and 21 CFR 1304.04(a). Records and inventories of schedule II controlled substances must be maintained separately from all other records of the registrant. 21 CFR 1304.04(h)(1). All records and inventories of schedules III, IV, and V controlled substances must be maintained either separately from all other records or in such a form that the information required is readily retrievable from the ordinary business.

Chapter 5: The Biennial Inventory

From the Code of Federal Regulations

General requirements. Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken, and shall be maintained in written, typewritten, or printed form at the registered location. An inventory taken by use of an oral recording device must be promptly transcribed. Controlled substances shall be deemed to be "on hand" if they are in the possession of or under the control of the registrant, including substances returned by a customer, ordered by a customer but not yet invoiced, stored in a warehouse on behalf of the registrant, and substances in the possession of employees of the registrant and intended for distribution as complimentary samples.

Chapter 5: The Biennial Inventory

A separate inventory shall be made for each registered location and each independent activity registered, except as provided in paragraph (e)(4) of this section. In the event controlled substances in the possession or under the control of the registrant are stored at a location for which he/she is not registered, the substances shall be included in the inventory of the registered location to which they are subject to control or to which the person possessing the substance is responsible. **The inventory may be taken either as of opening of business or as of the close of business on the inventory date and it shall be indicated on the inventory.**

Chapter 5: DEA Report of Significant Loss

From 465-.015

It is unlawful for any pharmacist to knowingly fail to report to the sheriff or other chief law enforcement agency of the county where the pharmacy is located within 24 hours after learning of any instance in which a person obtained or attempted to obtain a controlled substance, as defined in s. 893.02, or at the close of business on the next business day, whichever is later, that the pharmacist knew or believed was obtained or attempted to be obtained through fraudulent methods or representations from the pharmacy at which the pharmacist practiced pharmacy. Any pharmacist who knowingly fails to make such a report within 24 hours after learning of the fraud or attempted fraud or at the close of business on the next business day, whichever is later, commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

Chapter 5: DEA Report of Significant Loss

A sufficient report of the fraudulent obtaining of controlled substances under this subsection must contain, at a minimum, a copy of the prescription used or presented and a narrative, including all information available to the pharmacist concerning the transaction, such as the name and telephone number of the prescribing physician; the name, description, and any personal identification information pertaining to the person who presented the prescription; and all other material information, such as photographic or video surveillance of the transaction.

Chapter 5: Sheriff / Local Police Requirements

From 465.015

It is unlawful for any pharmacist to knowingly fail to report to the sheriff or other chief law enforcement agency of the county where the pharmacy is located within 24 hours after learning of any instance in which a person obtained or attempted to obtain a controlled substance, as defined in s. 893.02, or at the close of business on the next business day, whichever is later, that the pharmacist knew or believed was obtained or attempted to be obtained through fraudulent methods or representations from the pharmacy at which the pharmacist practiced pharmacy. Any pharmacist who knowingly fails to make such a report within 24 hours after learning of the fraud or attempted fraud or at the close of business on the next business day, whichever is later, commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083. A sufficient report of the fraudulent obtaining of controlled substances under this subsection must contain, at a minimum, a copy of the prescription used or presented and a narrative, including all information available to the pharmacist concerning the transaction, such as the name and telephone number of the prescribing physician; the name, description, and any personal identification information pertaining to the person who presented the prescription; and all other material information, such as photographic or video surveillance of the transaction.

Chapter 5: Pitfalls of Inaccurate DEA Documentation or Late CSOS

Inaccurate documentation, late receipt of controlled substances, and failures in saving electronic Controlled Substance Ordering System (CSOS) records are significant compliance violations that can lead to severe penalties.

Key pitfalls regarding DEA paper and CSOS receipt include:

1. Inaccurate Documentation (Paper and Electronic)

- Missing Information: Records that are incomplete, lack key information, or contain mathematical errors can result in suspension of licenses and DEA-imposed penalties.

Chapter 5: Pitfalls of Inaccurate DEA Documentation or Late CSOS

- Discrepancies: Inability to produce required records, such as biennial inventory, or having logs that do not match physical inventory or patient records, constitutes an automatic fail in a DEA inspection

- Inaccurate CSOS Data: If a CSOS certificate or order is inaccurate, it must be addressed, and all electronic Schedule II orders must be maintained in an electronic format for two years.

Chapter 5: Pitfalls of Inaccurate DEA Documentation or Late CSOS

2. Late or Failed CSOS Electronic Receipt/Record Saving

- Failure to Save/Record: Records must be "readily retrievable". Failure to save CSOS records (including unaccepted or defective orders) or not maintaining them for the required two-year period can lead to fines up to $18,759 per violation.
- Electronic Receipt Issues: Failure to record the exact date and quantity of Schedule II, III-V substances received can cause a failed audit, especially if the records are not immediately available.
- System Vulnerabilities: Criminals may hack CSOS systems or authentication credentials, and failing to maintain secure CSOS credentials can be a major source of non-compliance.

Chapter 5: Pitfalls of Inaccurate DEA Documentation or Late CSOS

3. Consequences of Mismanagement

- Financial Penalties: DEA fines can escalate quickly, with potential penalties of over $18,000 for each individual missing line-item or documentation error.
- Legal Action: Violation of these regulations can lead to a letter of admonition, suspension/revocation of registration, or criminal charges.
- Operational Disruption: A failed DEA inspection can lead to an Immediate Suspension Order (ISO), which halts all controlled substance activity.

For optimal compliance, pharmacists must ensure that all records are accurately maintained, easily read, and retrievable, and to avoid sharing CSOS certificates.

Chapter 5: Mid-Level Practitioners

Qualified Advanced Practice Registered Nurses (APRNs/NPs) in Florida with an autonomous practice license can prescribe controlled substances (CS), provided they have met specific educational requirements, hold a master's or doctoral degree in a clinical specialty, and follow the Florida Board of Nursing formulary. Autonomous NPs are limited to a 7-day supply for Schedule II controlled substances, unless it is a psychiatric medication prescribed by a psychiatric nurse.

Chapter 5: Mid-Level Practitioners

Key Details on Controlled Substance (CS) Prescribing for Autonomous APRNs in Florida:

- Authority: Under HB 607 (2020), qualified APRNs can practice independently, including prescribing, without a physician supervision protocol.
- Requirements: To prescribe controlled substances, the APRN must have a master's or doctoral degree in a clinical nursing specialty, and comply with continuing education requirements.
- Registration: Autonomous NPs must register with the state and meet specific experience requirements (3,000+ hours in the last 5 years).

Chapter 5: Mid-Level Practitioners

Limitations:

- Schedule II: Limited to a 7-day supply, except for psychiatric mental health controlled substances, as noted in the Florida Statute 464.012.
- Formulary: APRNs must adhere to a formulary established by a committee that lists controlled substances they cannot prescribe or that have restricted uses, as outlined in Florida HB 423.
- Scope: Autonomous practice is generally restricted to primary care (family medicine, general pediatrics, general internal medicine).

Physician Assistants (PAs): While PAs have increased autonomy, their authority to prescribe controlled substances is generally still tied to a supervision agreement or, as noted in CS/HB 607, restricted to specialized rules

Chapter 5: Board Rule and Statutes

In Florida, a Board rule (agency rule) must have specific legislative reference. Under Florida's Administrative Procedure Act Chapter 120.54, an agency must have both a specific statutory grant of rulemaking authority and a specific law to be implemented, meaning rules cannot be adopted without legal authority.

Key requirements include:

- Rulemaking Authority: The rule must be authorized by a statute, not just generally related to a purpose.
- Specific Reference: The notice of proposed rule development must include the specific legal authority (statutory citation) for the rule,

Chapter 5: Board Rule and Statutes

- Implementation: The rule must directly implement or interpret a specific statutory power or duty.
- School Boards: School board rules must be based on statutory authority.

While Chapter 120.54 generally mandates this for state agencies, specific statutory references are essential for validation, particularly if a rule is challenged as an invalid exercise of delegated authority.

iCARE PHARMACY SERVICES

Chapter 6: Supplemental Laws and Rules Material

Supplemental Handouts

Handout 1: Board of Pharmacy Update

Handout 2: DEA Update

Handout 3: Drug Supply Chain Security Act

Handout 4: Ethics in Pharmacy

Handout 5: PDM Roles and Responsibilities

Handout 6: Pharmacy Discipline Process

References

Center for Disease Control and Prevention (CDC)

Centers for Medicare & Medicaid Services (CMS)

Drug Quality and Security Act (DQSA)

Florida Board of Pharmacy Statutes (F.S.) and Administrative Codes (F.A.C.)

Health Insurance Portability and Accountability Act (HIPAA)

Omnibus Budget Reconciliation Act of 1990 (OBRA '90)

U.S. Code of Federal Regulations (CFR)

U.S. Department of Health & Human Services (HHS)

U.S. Food & Drug Administration (FDA)

US Drug Enforcement Administration Diversion Control Division (DEA)