

MPJE Review 2011

Eighth Semester

April 28, 2011

9:00-9:30	MPJE and study resources
9:30-10:00	Federal pharmacy law review including FDCA
10:00-10:30	Controlled Substance Overview
10:30-10:45	Break
10:45-11:00	FPA Presentation
11:00-11:30	Controlled Substances Exercise
11:30-12:00	Florida Practice Act
12:00-12:30	Florida Pharmacy Rules
12:30-1:00	Florida Controlled Substances Act
1:00-2:00	Lunch
2:00-3:00	MPJE Question Review
3:00-4:00	Florida Case Scenarios
4:00-5:00	Pharmacy Jeopardy

Section 1 - MPJE

Exam Overview

- Computer-adaptive examination
 - All questions answered in order, no going back
- Combines federal- and state-specific law
- Based on a national blueprint of pharmacy jurisprudence competencies
 - questions are tailored to the specific laws in each state.
- Consists of 90 multiple-choice test questions.
 - 75 questions used to calculate score.
 - 15 items serve as pretest questions, and do not affect the MPJE score. Those pretest questions are dispersed throughout the examination and cannot be identified by the candidate.
 - Must complete at least 80 questions for examination to be scored
- Two hour duration, no breaks given
- Passing score is 75. This is a scaled score, not a percentage
 - If fail, must wait at least 30 days to retake.
- Examination does not distinguish between State and Federal law. Accordingly, answer each question based on FL law.
- NSU approximately 90% pass rate

Competency Statements

Area 1 Pharmacy Practice (Approximately 84% of Test)

- **1.01.00 Identify the legal responsibilities of the pharmacist and other pharmacy personnel.**
 - 1.01.01 Identify the unique legal responsibilities of the pharmacist-in-charge (or equivalent), pharmacists, interns, and the owner of a pharmacy such as, the theft and/or loss of prescription

drugs; the destruction/disposal of prescription drugs; and the precedence of state, federal, or local requirements.

1.01.02 Identify the qualifications, scope of duties, and conditions for practice of pharmacy technicians and all other non-pharmacist personnel, including such topics as personnel ratios and duties.

- **1.02.00 Identify the requirements for the acquisition and distribution of pharmaceutical products, including samples.**

1.02.01 Identify the requirements for ordering or obtaining pharmaceuticals, including controlled substances, from a supplier of pharmaceuticals or other sources, including the content and maintenance of records of acquisition in pedigrees.

1.02.02 Identify the requirements for distributing a pharmaceutical product, including the content and maintenance of records of distribution. This addresses who may legally possess pharmaceutical products, (including drug samples), product labeling, packaging, repackaging, compounding, and sales to practitioners.

- **1.03.00 Identify the legal requirements that must be observed in the issuance of a prescription/drug order.**

1.03.01 Identify those pharmaceutical products for which a prescription/drug order is required and the limitations on their respective therapeutic uses.

1.03.02 Identify the scope of authority, scope of practice, and valid registration of all practitioners who are authorized under law to prescribe, dispense, or administer pharmaceutical products, including controlled substances. This addresses, but is not limited to federal and state registrations; methadone programs; office-based opioid treatment programs; regulations related to retired or deceased prescribers; Internet prescribing; limits on jurisdictional prescribing; and prescriber/patient relationships.

1.03.03 Identify the conditions under which the pharmacist participates in the administration of pharmaceutical products, or in the management of patients' drug therapy, which may include prescriptive authority, collaborative practice, consulting, counseling, and vaccine administration.

1.03.04 Identify the requirements for issuing a prescription/drug order, including content and format for written; telephonic voice transmission; electronic facsimile; computer and Internet; during emergency conditions and via tamper-resistant prescription forms.

1.03.05 Identify special requirements for the issuance of controlled substance prescriptions/drug orders, including content and format for written; telephonic voice transmission; electronic facsimile; computerized and Internet; during emergency conditions; conditions for changing a prescription; time limits for dispensing initial prescriptions/drug orders; and requirements for multiple Schedule II prescription orders.

1.03.06 Identify the limits of a practitioner's authority to authorize refills of a pharmaceutical product, including controlled substances.

- **1.04.00 Identify the procedures necessary to properly dispense a pharmaceutical product, including controlled substances, pursuant to a prescription/drug order.**

1.04.01 Identify responsibilities for determining whether prescriptions/drug orders were issued for a legitimate medical purpose and within all applicable legal restrictions, addressing such issues as corresponding responsibility; maximum quantities; and restricted distribution systems.

1.04.02 Identify the requirements for the transfer of existing prescription/drug order information from one pharmacist to another.

1.04.03 Identify the conditions under which a prescription/drug order may be filled or refilled. This includes but is not limited to emergency fills or refills; partial dispensing of controlled substances; declarations of disaster or emergency; patient identification; requirements for death with dignity; medical marijuana; and conscience/moral circumstances.

1.04.04 Identify the conditions under which prospective drug use review is conducted prior to dispensing a prescribed pharmaceutical product for appropriate patients. This includes the requirements for documentation, such as those for patient profiles.

1.04.05 Identify the conditions under which drug product selection is permitted or mandated; addressing consent of the patient and/or prescriber; passing on of cost savings; and documentation of the product dispensed.

1.04.06 Identify the requirements for the labeling of pharmaceutical products dispensed pursuant to a prescription/drug order, including such things as generic and therapeutic equivalency; formulary use; auxiliary labels; patient package inserts; Food and Drug Administration medication guides; and written drug information.

1.04.07 Identify the requirements for the appropriate packaging of pharmaceutical products dispensed pursuant to a prescription/drug order, including such things as child-resistant and customized patient medication packaging.

1.04.08 Identify the conditions under which a pharmaceutical product could not be dispensed, including conditions as in adulteration; misbranding; and dating.

1.04.09 Identify the requirements for compounding pharmaceutical products.

1.04.10 Identify the requirements for emergency kits, including such things as supplying; maintenance; access; security; and inventory.

1.04.11 Identify the regulations regarding the return and/or reuse of pharmaceutical products, addressing such issues as charitable programs; cancer or other repository programs; previously dispensed; and from “will call” areas of pharmacies.

1.04.12 Identify procedures and requirements for systems or processes whereby a non-pharmacist may obtain pharmaceutical products, addressing such issues as Pyxis (vending); after hour’s access; telepharmacies; and secure automated patient drug retrieval centers.

1.04.13 Identify procedures and requirements for establishing and operating central processing and central fill pharmacies, addressing, among other things, remote order verification.

- **1.05.00 Identify the conditions for making an offer to counsel or counseling appropriate patients, including the requirements for documentation.**

1.05.01 Identify the requirements to counsel or make an offer to counsel.

1.05.02 Identify the requirements to maintain documentation of counseling.

- **1.06.00 Identify the requirements for the distribution and/or dispensing of nonprescription pharmaceutical products, including controlled substances.**

1.06.01 Identify the requirements for the labeling of nonprescription pharmaceutical products.

1.06.02 Identify the requirements for the packaging and repackaging of nonprescription pharmaceutical products.

1.06.03 Identify the requirements for the distribution and/or dispensing of poisons, restricted, nonprescription pharmaceutical products, and other restricted materials or devices including but not limited to pseudoephedrine, dextromethorphan, emergency contraception, and behind the counter products as appropriate.

- **1.07.00 Identify the proper procedures for keeping records of information related to pharmacy practice, pharmaceutical products and patients, including requirements for protecting patient confidentiality.**

1.07.01 Identify the requirements pertaining to controlled substance inventories.

1.07.02 Identify the content, maintenance, storage, and reporting requirements for records required in the operation of a pharmacy, including, but not limited to, prescription filing systems; computer systems and backups; and prescription monitoring programs.

1.07.03 Identify requirements for protecting patient confidentiality, including Health Insurance Portability and Accountability Act requirements.

Area 2 Licensure, Registration, Certification, and Operational Requirements (Approximately 13% of Test)

- **2.01.00 Identify the qualifications, application procedure, necessary examinations, and internship requirements for licensure, registration, or certification of individuals engaged in the storage, distribution, and/or dispensing of pharmaceutical products (prescription and nonprescription).**

2.01.01 Identify the requirements for special or restricted licenses, registrations, authorizations, or certificates for pharmacists, pharmacist preceptors, pharmacy interns, pharmacy technicians, controlled substance registrants, and under specialty pharmacist licenses (nuclear, consultant, etc).

2.01.02 Identify the standards of practice for the practice of pharmacy, including, but not limited to quality assurance programs, including peer review; changing dosage forms; therapeutic substitution; error reporting; public health reporting requirements, such as notification of potential terrorist event, physical abuse, and treatment for tuberculosis; and issues of conscience and maintaining competency.

2.01.03 Identify notification requirements pertaining to their license to practice pharmacy.

2.01.04 Identify the requirements for the renewal or reinstatement of an individual's licensure, registration, or certification.

2.01.05 Identify the reasons for, classifications, and processes of, disciplinary actions that may be taken against a registered, licensed, certified, or permitted individual.

2.01.06 Identify the requirements for reporting to, and participating in, programs addressing the inability of an individual licensed, registered, or certified by the board to engage in the practice of pharmacy with reasonable skill and safety, by reason of impairment caused by the use of alcohol, drugs, chemicals, or other materials or mental, physical, or psychological conditions.

- **2.02.00 Identify the requirements and application procedure for the registration, licensure, certification, or permitting of a practice setting or business entity.**

2.02.01 Identify the requirements for registration, license, certification, or permitting of a practice setting, including but not limited to, in-state pharmacies; out-of-state pharmacies; specialty pharmacies; controlled substance registrants; wholesalers; distributors; manufacturers/repackagers; computer services providers; and Internet pharmacies.

2.02.02 Identify the operational and notification requirements for changes to the facility or changes in the application for licensure, registration, certification, or permit of a practice setting such as in remodeling; renaming; change of ownership; moving; and closing.

2.02.03 Identify the requirements for an inspection of a licensed, registered, certified, or permitted practice setting.

2.02.04 Identify the requirements for the renewal or reinstatement of a license, registration, certificate, or permit of a practice setting.

2.02.05 Identify the reasons for, classifications, and processes of disciplinary actions that may be taken against a registered, licensed, certified, or permitted practice setting.

- **2.03.00 Identify the operational requirements for a registered, licensed, certified, or permitted practice setting.**

2.03.01 Identify the requirements for the operation of a pharmacy or practice setting that are not directly related to the dispensing of pharmaceutical products. This includes, but is not limited to, issues related to space; equipment; advertising and signage; security, including temporary absences of the pharmacist; policies and procedures; libraries; and the display of licenses.

2.03.02 Identify the requirements for the possession, storage, and handling of pharmaceutical products, including controlled substances. This includes, but is not limited to, investigational new drugs; repackaged or resold drugs; sample pharmaceuticals; recalls; and outdated pharmaceutical products.

2.03.03 Identify the requirements for delivery of pharmaceutical products, including controlled substances. This includes, but is not limited to, issues related to identification of the person accepting delivery of a drug; use of the mail; contract delivery; use of couriers; use of pharmacy employees; use of kiosks, secure mail boxes, and script centers; use of vacuum tubes; and use of drive-up windows.

Area 3 Regulatory Structure and Terms (Approximately 3% of Test)

- **3.01.00 Identify the purpose of, and the terms and conditions found in, the laws and rules that regulate or affect the manufacture, storage, distribution, and dispensing of pharmaceutical products (prescription and nonprescription), including controlled substances.**

This includes such things as the Food, Drug, and Cosmetic Act(s) and Regulations; the Controlled Substances Act(s) and Regulations; OBRA 90's Title IV Requirements; Practice Acts and Rules; other statutes and regulations, including but not limited to, dispensing of methadone, child-resistant packaging, tamper-resistant packaging, drug paraphernalia, drug samples, pharmacist responsibilities in Medicare-certified skilled-nursing facilities; National Drug Code numbers; and schedules of controlled substances.

- **3.02.00 Identify the authority, responsibilities, and operation of the agencies or entities that enforce the laws and rules that regulate or affect the manufacture, storage, distribution, and dispensing of pharmaceutical products (prescription and nonprescription), including controlled substances.**

Test Scores – Nova Southeastern University

September 1 2010-December 31 2010

Total n=79
School average = 79
State average 79
National average 81
School passing rate 87
State passing rate 84
National passing rate 89

First time candidates n=75
School average = 79
State average 80
National average 81
School passing rate 88
State passing rate 87
National passing rate 91

Passing Rates (first time candidates)

2010 n=230	passing rate=87%
2009 n=227	passing rate 87%
2008 n=210	passing rate=95%
2007 n=213	passing rate=92%
2006 n=211	passing rate=88%

Download the full Pharmacy Practice Act, all rules of the Board of Pharmacy, the Pharmacist's Manual for Controlled Substances, and the FL Controlled Substance Act. Focus your studies on these laws. Use supplemental resources as needed.

Exam Resources

- Florida Pharmacy Act - FL Statutes 465
 - http://www.leg.state.fl.us/Statutes/index.cfm?App_mode=Display_Statute&URL=0400-0499/0465/0465.html
 - These laws will provide a general outline for your studying and the overall framework for pharmacy practice
- Florida Board of Pharmacy Rules - 64B16
 - <https://www.flrules.org/gateway/Division.asp?DivID=307>
 - Knowledge of these rules is essential, especially 64B16-27: Pharmacy Practice
- Pharmacist Manual / Controlled Substance Act (CSA)
 - http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.pdf

- A good number of questions involve controlled substance law. Study this manual comprehensively
- Florida Comprehensive Drug Abuse Prevention and Control Act (FL Controlled Substance Act)
 - http://www.leg.state.fl.us/statutes/index.cfm?App_mode=Display_Statute&URL=Ch0893/ch0893.htm
 - Try and identify differences between state and federal controlled substance law. Carefully study 893.04: Pharmacist and Practitioner. Focus on important words with precise legal meanings. Imagine different situations where these issues arise and how they would influence the law
- Miscellaneous Florida Laws
 - FL Statutes 456 deals with healthcare professionals generally in FL
 - FL Statutes 499 Florida's version of the FDCA
 - FL Statutes 120 Florida's Administrative Procedures Act
 - Not relevant for testing purposes
- Exam Study Books (based on Poor/Fair/Good/Very Good/Excellent rating scale)
 - **Florida Pharmacy Law Test by pharmacyexam.com**
 - 150 question compact disc (CD) with detailed answers.
 - Very Good resource, priced at \$50.00
 - **MPJE Florida / Help Pass Pharmacy Law by Stephen Strauss**
 - Very good resource, priced at \$161.65
 - **Guide to Federal Pharmacy Law** by Barry S Reiss and Gary D. Hall (7th Edition)
 - Based on the MPJE Competencies focus your studies on Section G and Section H. This book has exam-type questions for further review
 - Fair resource with a number of review questions and good study tips
 - **Florida State and Federal Pharmacy Law Guide** by Rxlaw.org
 - Good resource Priced at \$99.95
 - **Pronto Pass MPJE Review – Florida**
 - Poor resource priced at \$137.95
 - **Pharmacy Law: Textbook and Review** by Debra B, Feinberg 2008
 - Available electronically through NovaCat free of charge
 - 450 federal law review questions
 - Fair resource

How to Study & How to Test

- Remember this is FL. Always consider FL Law
- Consider every word in the question
- Look for unusual facts as triggers
- Focus your study time on State materials and controlled substances
- Read the MPJE competencies every day of your studying
- Do not memorize statute and regulation numbers (ie 64B16 - 28.100)
- Don't work about federal drug law names or years, only what they mean to present practice
- Get a good night sleep the night before
- Arrive at least 30 min early
- Be confident!

Section 2

Federal Pharmacy Law

Statutory Law

1890 Sherman Antitrust Act

- Outlaws agreements that restrain trade
 - attempts to monopolize, chain-store price discrimination, price fixing, predatory pricing, bundling products and services, deceptive trade practices, mergers which lessen competition

1938 Federal Food Drug and Cosmetic Act

- No adulterated or misbranded drugs in interstate commerce
 - Adulteration – (may be) gross, no follow-cGMP
 - Think inside the capsule
 - Misbranded – improperly labeled, not FDA registered establishment, no follow REMS/PPPA, improper advertising
 - Think outside the bottle
- Must disclose ingredients on label
- Drug must be proven safe before marketing
- Authorizes FDA inspection of manufacturers and distributors

1944 Public Health Service Act (PHSA)

- Biologic drugs (monoclonal/interleukins/etc) approved under a BLA (not an NDA)
- Biologics reviewed for purity, potency, and safety

1951 Durham-Humphrey Labeling Amendments to FDCA

- Allows refills of prescriptions
- Establishes Rx and OTC drug categories
 - OTC drugs must be labeled with adequate directions for use (drug facts label)
 - Pregnancy and breast-feeding warning
 - Calcium, Sodium, Magnesium, Potassium content
 - Domestic contact information to receive ADR report
 - OTC drugs approved under OTC monograph or NDA
 - Rx drugs labeled with adequate information for use (package insert)
 - Approved under NDA or grandfathered in pre-1938
 - Pregnancy Category
 - A safe in humans
 - B safe in animals / no data in humans
 - C unknown safety in humans
 - D unsafe in humans benefit may outweigh risk
 - X unsafe in humans, risk always outweighs benefit
 - Unit dose drugs labeling requirements
 - Generic name (or brand not both), strength, dosage form, expiration date (1 year or manufacturer if earlier), lot number, business name of packager, quantity, Rx Only and Habit Forming warning, if applicable
 - Directions for use not required on dose, but stored retrievably

1962 Kefauver-Harris Drug Efficacy Amendments to FDCA Act

- Drugs must be proven effective before marketing
- Creates NDA and SNDA
 - Phase I, Phase II, Phase III research
 - Studies require informed consent and IRB approval
- IND required to test new drug in humans
 - FDA has 30 days to issue “clinical hold” or else study can proceed
- Mandates Informed Consent in Clinical research
- Adverse Drug Reactions including clinical studies must be reported to FDA

- ADRs are reported using MedWatch Form
 - Manufacturers required to report. Healthcare professionals and patients report voluntarily.
- All drug labels to contain brand and generic name
- Advertising of drugs FDA-Rx, FTC-OTC
- Establishes cGMP requirements (Current Good Manufacturing Practices)
 - Each manufacturer must register each facility with the FDA and are required to be inspected every two years. If a facility is not registered than all drugs manufactured from the facility are misbranded. If the facility produce standards of strength, quality, or purity s a product the drug is deemed adulterated
 - Pharmacies that compound large amounts of drug not based on individual prescriptions must register with the FDA as a manufacturer and meet cGMP requirements. Pharmacies that compound drugs based on individual prescriptions are not considered manufacturers and do not need follow cGMP

1970 Controlled Substances Act (see following section)

1970 Poison Prevention Packaging Act

- Pharmacy must dispense drugs using child-resistant containers (with exceptions)
 - Exceptions found at <http://www.cpsc.gov/cpscpub/pubs/384.pdf>
- Enforced by the Consumer Product Safety Commission (CPSC)
- Use of reversible caps is acceptable
- Cannot reuse containers
- Patient may make blanket request for non-child resistant containers (oral request okay)
- Physician may request prescriptions be dispensed in non-child resistant containers
- Pharmacist can't unilaterally decide to dispense prescriptions in non-child resistant container
- Hospitals pharmacists exempt from requirement
- Manufacturers containers must be compliant
 - may market one size for in non-compliant packaging with labeling requirement

1982 Federal Anti-Tampering Act

- Illegal to tamper with over-the-counter drug products
- OTC Drugs must be sold in tamper-resistant packaging
 - Exceptions

1982 Orphan Drug Act

- Provides incentives for companies to develop drugs for rare (Orphan) diseases
 - Orphan disease defined as <200,00 patients or no reasonable expectation to recoup development costs
- Must still submit NDA and follow FDA rigorous drug approval process
- Orphan drug designates status not approval for marketing

1982 Federal False Claims Act

- Not allowed to falsely bill Medicare/Medicaid
- Allows whistleblowers to collect up to 25% of government award

1984 Hatch-Waxman Amendment to FDCA, aka Drug Price Competition and Patent-Term Restoration Act

- Establishes an abbreviated drug approval process for generic drugs (ANDA) based on bioequivalence
- Provides added patent term equal to drug development review period by FDA
- Establishes the Orange Book which lists all FDA approved drug products and cross-references generic drugs that can be substituted for brand drugs
 - AB rated drugs can be substituted
 - BX/BC/BE rated drugs are generic drugs that cannot be substituted

1986 National Childhood Vaccine Injury Act

- Many reports involving vaccines must be reported using VAERS form. Pharmacists in FL can vaccinate

1987 Prescription Drug Marketing Act

- Prohibits sale/trade/purchase of drug samples
 - Requires states such as FL to license drug wholesalers
 - Prohibits the sale/purchase/trade/or counterfeiting of any pharmaceutical coupon
 - No importation of drugs except by original Manufacturer
 - Patients cannot bring/order foreign drugs into this country
 - Allows use of starter packs
 - Requires prescription drugs to bear the legend Rx Only
 - Any drug without legend is considered misbranded
- 1990 The Omnibus Budget Reconciliation Act (OBRA 90)
- States required to mandate pharmacists to conduct prospective drug use reviews and counsel all Medicaid patients
- 1992 Prescription Drug User Fee Act
- Manufacturers must pay a user fee along with each drug that is marketed, facility that manufactures drugs, and each application for approval
 - Money is used to hire drug reviewers and facilitate the drug approval process
 - FDA promises that 90% of Priority drugs will be reviewed within 6 months and 90% of Standard (me too) drugs will be reviewed within 10 months
- 1994 Dietary Supplement Health and Education Act
- Allows dietary supplements to be categorized as food. Must be marketed to promote existing good health
 - Dietary supplements not required to be proven safe or effective, must follow cGMP, puts limitations on providing published information along with products, FTC regulates advertising
 - Products must be orally formulated only. Any disease claim makes the dietary supplement a drug and requires manufacturer to submit NDA
- 1996 FDA Export Reform and Enhancement Act
- Allows export of FDA approved drugs if labeled to meet other country requirements
 - Allows export of unapproved drugs if used for clinical investigation
 - API-active pharmaceutical ingredient may be imported only if part of an FDA approved application or will be used for compounding (no bulk manufacturing)
- 1996 Health Insurance Portability and Accountability Act (HIPAA)
- Pharmacies that bill electronically must limit disclosure of patient health information (PHI) to minimally necessary
 - Pharmacy employees may not use or disclose health information except for treatment, payment, regular health care operations
 - All pharmacy personnel must be trained about HIPAA
 - Pharmacy must have procedures and safeguards in place to ensure privacy
 - Pharmacy must appoint a responsible individual to ensure safeguards and procedures are followed
 - Patients must be notified of their rights and how information may be used
 - Patients typically sign away rights of HIPAA
 - Patients have rights to inspect and correct medical records
 - Only provide patient information to patient or legal representative (if minor, parent okay)
 - Patients may authorize friends and family to pick-up medication
 - May leave messages on answering machines as long as don't disclose PHI
 - Requires patients to authorize use of PHI for marketing
- 1997 FDA Modernization Act – Manufacturer friendly set of drug laws
- Allows for fast-track approval of life-saving drugs
 - Surrogate endpoints acceptable, must provide post-marketing confirmation study
 - Allows drug manufacturers to provide off-label sales information if requested by physician
 - Permits manufacturers to provide economic information and formulary support
 - Affirms pharmacist right to compound certain drugs based on individual prescriptions

- Allows drugs to receive an additional 6 month patent term if manufacturer submits data on pediatrics
- 2000 Drug Addiction Treatment Act (DATA 2000)
- Allows authorized physicians to treat drug addiction with buprenorphine (Subutex/Subuxone) in office-based practice whereby pharmacist dispense drugs
 - 30 patient limit (100 if meet special requirements)
 - Authorized physician unique provider number starting with X
 - Methadone may be prescribed for pain or opioid addiction
 - If used for opioid addiction, must be used as part of DEA registered program, three day exception rule
 - Methadone may be administered to addict incidental to surgery or acute medical care outside of program
 - Treatment requires completion of a number of FDA Forms (patient consent, responsibility statement, application for approval of use)
- 2003 Medicare Prescription Drug Improvement and Modernization Act (Medicare Part D)
- Provides prescription drug coverage to Medicare patients (>65 yo, disabled, ESRD) with copays and donut hole
 - Excludes weight loss, fertility, cosmetic, hair growth, bzd/barbiturates, OTC, cold and cough relief
 - Reimburses pharmacists for Medication Therapy Management of Medicare patients
 - Imposes on pharmacists and technicians to receive annual training on fraud, waste, and abuse and pharmacies to have written policies and procedures to address such
- 2005 Combat Methamphetamine Act
- Restricts pharmacy sales of pseudoephedrine (PSE)
 - 3.6 grams per person per day (#146, pseudoephedrine HCl 30 mg)
 - 9 grams of PSE per person per 30 day period (#366, pseudoephedrine HCl 30 mg)
 - Mail order 7.5 grams of PSE per person 30 day period (#305, pseudoephedrine HCl 30 mg)
 - All solid dosage forms of PSE must be sold in blister packs with no more than 2 doses/blister
 - All PSE is placed behind the counter
 - All purchasers must furnish picture ID
 - Retailers must maintain logbook of transactions
 - All pharmacy personnel selling PSE must have training and certification
 - No age limit on purchaser of PSE
- 2006 Dietary Supplement and Nonprescription Drug Consumer Protection Act
- Requires manufacturers to report serious ADRs to FDA for OTC and dietary supplements
- 2007 FDA Amendments Act – Drug laws focused on drug safety
- Establishes risk evaluation and mitigation strategies (REMS) for drugs with important health risks
 - Manufacturers to provide FDA approved medication guides, communication plans, elements to assure safe use, and implementation systems as determined by FDA
 - Requires all prescription drugs to have Side Effects Statement
 - Call your Doctor or FDA if Side Effects somewhere on bottle/cap/paper
 - Companies may pay review fee to FDA for review of DTCA prior to dissemination
- 2008 Ryan Haight Online Pharmacy Consumer Protection Act – Amendment to CSA
- Prohibits internet prescriptions for controlled substances without in-person medical evaluation
 - Online pharmacies must obtain modified DEA registration, have special website disclosure (statement of compliance) and DEA (monthly) reporting (if surpass threshold) requirements
- 2009 Family Smoking Prevention and Tobacco Act
- Grants limited authority to FDA involving tobacco (from ATF)
 - Bans flavored cigarettes
 - Requires cigarette companies to disclose all ingredients, prohibits youth-focused marketing
- 2010 Biologics Price Competition and Innovation Act
- Establishes a generic approval pathway for biologics (BLA)

Case Law

- Plan B OTC (Tummino v Torti, 2008)
 - Plan B Available Rx and OTC
 - OTC for patients 17 years of age and older with valid ID
- **Overtime Pay not Required** (De Jesus-Rentas v. Baxter Pharmacy, 2005)
 - Pharmacists are considered professionals and not entitled to overtime pay under the FLSA

Rules and Regulations

Drug Recalls involve a firm's voluntary removal or correction of a marketed product in violation of a law

- **Class I:** a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death.
- **Class II:** a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.
- **Class III:** a situation in which use of or exposure to a violative product is not likely to cause adverse health consequences.
- Each recall must have a 'Recall Strategy'
 - Depth of recall to three potential levels (consumer, retail, wholesale) and must have an effectiveness check to verify communication is successful
 - Firm responsible for promptly notifying each of its affected direct accounts about the recall.
 - Format, content, and extent should be commensurate with the hazard and strategy
 - Accomplished by telegrams, mailgrams, or first class letters conspicuously marked, in bold red type, on the letter and the envelope: "drug recall".
 - Letter and the envelope should be marked: "urgent" for class I and class II recalls.
 - Identify product, size, lot number(s), code(s) or serial number(s)
 - Explain concisely the recall
 - Provide specific instructions on what should be done with respect to the recalled products
 - Recalls can be initiated by manufacturer or government (FDA/State Board of Health)
 - Pharmacists do not have a duty to contact patients about a recalled drug if the drug has already been dispensed

Federal labeling requirements on select products or else considered misbranded

- Glandular preparations
 - No scientific evidence
- Isoproterenol
 - Severe paradoxical bronchoconstriction
- OTC sore throat lozenges/troches
 - If severe or persistent call physician, may be severe
- Ipecac
 - Call for professional advice before using
- Nonoxynol 9
 - Does not protect against HIV
- Phenindione
 - Causes agranulocytosis and hepatitis

- “Contains FD&C Yellow No. 5 (tartrazine) as a color additive”
 - Further warning statement required in precautions section of package insert
- “Contains FD&C Yellow No. 6 as a color additive”
- “Phenylketonurics: Contains Phenylalanine ____mg”
 - Aspartame containing drugs
- “Contains sulfite...”
- Systemic antibiotics, “to reduce the development of resistance, use only in proven or strongly suspected
- Alcohol and OTC internal analgesics/antipyretics
 - Advises consumers with a history of heavy alcohol use to consult a physician
 - 3 or more drinks per day
 - APA - Liver damage
 - NSAIDs - Internal bleeding
 - Combination - Liver damage and Stomach bleeding

Definitions

Misbranding

- Label is false or misleading
- Label missing
 - “Established Name” of the drug
 - Each active drug ingredient listed
 - Quantity of container ingredients
 - Adequate information for use (Rx drugs only)
 - name or location of manufacturer (packer or distributor)
 - Words, statements, information as required by law conspicuously and prominently displayed
 - Prescription drugs required to contain Rx only
- OTC labeling lacks adequate directions for use, adequate warnings, or address/phone number of manufacturer to report serious adverse effects
- Drug made in a nonregistered establishment
- Failure to include contact information to report adverse drug reactions
- Prescription drug promoted in violation of advertising provisions, lacking: established name of the drug, strength of the drug, brief summary requirement
- Drug is not in accordance with USP/NF specifications or offered for sale under the name of another drug
- Misrepresents to be a recognized drug
- Packed in violation of PPPA/FATA
- Not in compliance with REMS
- Health-endangering when used as prescribed

Adulteration

- Contains any filthy, putrid, or decomposed substance
- Contains an unapproved / unsafe color additive (from list)
- Exposed to any unsanitary condition where it may have been contaminated
- Involving substandard cGMPs
- Mixed or substituted with another product to reduce its strength
- Strength, quality, purity, not meeting compendia standards
 - If no standard exists, differing from strength, quality, purity indicated
 - Positron Emission Tomography compounded drug does not meet compounding standards
- Used in substitution of another substance
- Container is composed of any poisonous or deleterious substance which may render the contents injurious to health

Section 3 Federal Controlled Substance Law

Remember this is a closed-loop system. From manufacture of precursor chemicals thru dispensing to the patient, each controlled substance is documented and tightly controlled. Study the Pharmacist Manual (2010) closely for MPJE

Federal Controlled Substances Act

- Five schedules of drugs based on medical use, potential for abuse and dependence
- CII
 - No refills
 - No transfers
 - Sequential filling of multiple Rx's acceptable as long as each rx is written on a different blank, actual date of prescribing is written (no post-date), must contain information on earliest date to fill, and 90 limit max in total.
 - Oral Rx not permitted
 - Exceptions 1) emergency (amount limited to emergency, pharmacist writes Rx ("authorization for emergency dispensing) and attaches the original when it arrives, must get written Rx (or postmark) within 7 days) 2) Home infusion/IV if compounded for pain 3) Residents of LTCF 4) State licensed Hospice Facility
 - Partial fill allowed within 72 hours if unable to fill. Must mark on prescription face amount dispensed. If no complete order within 72 hrs must contact prescriber and void remaining amount.
 - LTCF partial fills permitted. Prescription valid for only 60 days from date written. Each partial fill, the pharmacist must document date of fill, quantity dispensed and remaining quantity and sign
 - Pharmacist may not change any essential element on Rx
 - May change address
 - Orders require Form 222 / CSOS
 - Each 222 is sequentially numbered in triplicate (issued in set of 7 or 14)
 - Completed in typewritten or permanent marking
 - One drug per line
 - Defective forms cannot be filled by supplier. Must void and re-executed
 - Very minor errors, like spelling errors not voidable
 - Stolen forms should be reported to DEA immediately
 - Also used to move CII from pharmacy to pharmacy or pharmacy to wholesaler
 - Remember closed-loop system.
- CIII-CV
 - Five refills in six months
 - 1 transfer permitted
 - If sharing a common (chain) database may transfer as many times as needed
 - May be written, oral or faxed
 - Partial fills permitted. Any amount may be filled as long as total quantity or six month duration is not violated.
 - Pharmacist may make any changes with consultation from prescriber
 - No special order form, although orders must be kept readily retrievable
- CV
 - Most are available without prescription and indicated as cough or antidiarrheal
 -
- SLCPS – Schedule Listed Chemical Products
 - These include agents such as ephedrine, pseudoephedrine, phenylpropanolamine

- Sellers must self-certify to DEA through the computer that 1) Employees have been trained 2) Records of the training are being maintained 3) sales limits are being enforced 4) Products are being stored behind the counter or in a locked cabinet AND 5) A written or electronic logbook is being maintained.
- List 1 Chemicals - drugs involved in the manufacture of a controlled substance
- List 2 Chemicals - solvents used in the manufacture of a controlled substance
- Electronic prescribing of Controlled Substances permitted
 - Pharmacy system must be suited
 - Prescriber system must be suited using double security measures
- Inventory requirements: see table
- Prescriptions may be filed in one of three methods
 - 1) Three separate files
 - i. CII
 - ii. CIII-CV
 - iii. Non-Controls
 - 2) Two separate files (CIII-CV Stamp)
 - i. CII
 - ii. CIII-CV + non-Controls → Red "C" Stamp ≥ 1 in lower right corner on controls
 - 3) Two separate files (CIII-CV stamp)
 - i. CII-CV → Red "C" Stamp for CIII-CV ≥ 1 in lower right corner
 - ii. Non-Controls
- Controlled substances may be stored in one of three methods in the pharmacy
 - 1) Stored in locked container
 - 2) Dispersed throughout the pharmacy
 - 3) Combination of 1 and 2
 - No special requirement for CII to be locked up, they can be dispersed among inventory
- Prescription Requirements (12 + refill /15 points)
 1. Date of issue
 2. Patient's full name
 3. Patients address
 4. Practitioner's name
 5. Practitioners address
 6. Practitioners DEA registration number
 7. Drug name
 8. Drug strength
 9. Dosage form
 10. Quantity prescribed
 - Number of refills (if any) authorized
 11. Directions for use
 12. Manual signature of prescriber

In Florida, Pharmacist must

 13. Initial the prescription
 14. Write date filled
 15. Note the prescription number
- Label Requirements: See FL law (9/11 points)
 - Hospitals do not need to follow label requirements
- Filled prescriptions for controlled substances permitted to be mailed (UPS/FedEx, USPS)
 - Package should be unmarked regarding contents
- Theft or significant loss
 - Notify DEA and local police
 - Complete DEA Form 106
- States determine who is entitled to prescribe controlled substances
 - In FL, midlevel practitioners not authorized to prescribe controlled substances

- Cannot delegate authority to another, although an agent can phone in prescription at request of registrant
- Military personnel authorized to prescribe controlled substances (Army, Navy, Marine Corps, Air Force, Coast Guard, Public Health Service, or Bureau of Prison) do not need a DEA registration number to prescribe in their official duty
 - Must provide Military Number in lieu of DEA number.
 - Prescriptions written in official duty may be filled by community pharmacy off base even without DEA number
- Hospital interns and residents so authorized to prescribe controlled substances do not need a DEA registration number to prescribe while in their scope of employment
 - Must provide Hospital DEA number and individual physician's internal hospital code
 - Prescriptions may be filled by outside community pharmacy using Hospital's DEA number
- Central fill of controlled substance prescriptions is permitted
 - Prescription information may be transmitted by fax or electronically to central fill pharmacy
 - Local pharmacy must write date, pharmacist transmitting, and "Central Fill" on face of prescription along with the central pharmacy's name, address and DEA number.
 - Central fill pharmacy fills the prescription and ships drug to local pharmacy for dispensing
 - Both pharmacies must be registered with DEA and store records for two years from date of last fill.

Executing 222 [Copy 1 is brown (supplier), Copy 2 is Green (DEA) and Copy 3 is Blue (Pharmacy)]

- Pharmacy places the order and retains Copy 3
 - Copy 1 and 2 mailed to supplier
- Supplier fills the order and retains Copy 1
 - Completes Copy 1 and 2
 - Copy 2 mailed to DEA
- Pharmacy completes Copy 3 upon receipt of order
 - Containers and date received
- Supplier can endorse form to another, if unable to complete order
- Each form must be signed and dated by a person authorized to sign or granted power of attorney

	CII	CIII-CV
Refills	No refills allowed	5 within 6 months
Transfer of prescription between pharmacies	No transfers permitted	1 allowed.
Transfer of bulk drugs between registrants (ie pharmacies)	Requires 222	Requires complete invoice
	Any pharmacy that transfers more than five percent of its inventory must register as distributor (Five Percent Rule)	
Oral Rx allowed	In case of emergency only	Yes
Facsimile Rx allowed	Fax may be received in preparation, but original hard-copy required to dispense	Yes
Partial Fills allowed	Generally no, exceptions: -Yes, if unable to provide (remainder required within 72 hrs). -Yes, for terminally ill patients and LTCF patients. Pharmacist must mark "Terminally Ill" or "LTCF Patient"	Yes, no restrictions as long as within total quantity and six month limitation
Maximum quantity	No limit - pharmacist judgment	No limit – pharmacist judgment

Expiration date	No expiration (FL law imposes 1 year expiration on all Rx)	Six months from date written
Inventory	Exact count	Estimated count unless container holds more than 1000 units which requires an exact count
Inventory Requirements	Initial inventory required, every two years thereafter. Must include Drug name, strength, dosage form, number of units/container, and number of containers (written, typewritten, or printed, kept on site and include inventory date and time: opening or close of business)	
Ordering	Form 222 / CSOS	No special form used
	All order forms must be readily retrievable and stored for 2 years onsite at place of business	
Theft or significant loss	Report to DEA Form 106	Report to DEA Form 106

DEA Form	Intent	Miscellany
41	Document disposal and destruction of scheduled drugs	
106	Unusual or excessive loss, disappearance, or theft	Necessity based on pharmacist judgment
222	Order CI and CII	Can be completed electronically - CSOS
224	New Application for Retail Pharmacy, Hospital/Clinic, Practitioner, Teaching Institution, or Mid-Level Practitioner	Pharmacies are registered not pharmacists
224a	Renewal Application for Retail Pharmacy, Hospital/Clinic, Practitioner, Teaching Institution, or Mid-Level Practitioner.	Renewal application due every three years
224b	Affidavit for Chain Renewal	Renew license for chain pharmacy operating under single registration
224C	Application for Modification of Registration for Online Pharmacies	
225	New Application for Manufacturer, Distributor, Researcher, Analytical Laboratory, Importer, Exporter	Manufacturers and distributors of controlled substances (Ortho, McKesson). Valid 12 months
363	New Application for Narcotic Treatment Programs	Methadone / Buprenorphine maintenance and detoxification programs
510	New Application for Domestic Chemical	Business involved with precursor chemicals used in the manufacture of controlled substances

Known brand, generic, and schedule of most common controlled substances

Schedule 1	Marijuana, ecstasy, PCP, heroin, LSD, Peyote, Salvia (in FL)
Schedule 2	Cocaine, Dilaudid, Demerol, Oxycontin, Sublimaze, Dexedrine, Ritalin, pentobarbital, MS Contin
Schedule 3	Buprenorphine, Vicodin, Anabolic Steroids, Codeine
Rule of 3	Generally, the quantities are evenly divisible by 3 (not typically morphine and opium) Codeine 90 mg dose (or ≤ 1.8 g / 100 ml), Hydrocodone 15 mg dose (or ≤ 300 mg/ 100 ml)
Schedule 4	Benzodiazepines, Sonata, Lunesta, Soma (in FL)
Schedule 5	Lyrica (requires Rx)
Rule of Five	Generally, the quantities are evenly divisible by 5 ≤ 200 mg codeine/ 100 ml, ≤ 100 mg opium/ 100 ml, ≤ 2.5 mg diphenoxylate

Section 4

FL Pharmacy Laws

Permits Types

Community pharmacy (Independent/Chain)

- Typical independent or chain drug store
 - Each store has its own permit
- Must have a prescription drug manager of record named
- May use automated filling systems
 - Policy and procedure manual required, final loading check by pharmacist, readily retrievable electronic record to identify all personnel involved with dispensing, mechanism to deal for product recalls, minimum dual verifications (barcode, electronic, RFID) and must be able to generate patient specific drug label
- May permit limited sterile compounding if properly equipped and is inspected by Board

Class I Institutional Pharmacy (Nursing Home)

- Typical nursing home
- Does not have a pharmacy on premises: no dispensing on premises
- Must have a consultant pharmacist of record named
 - Consultant must provide written, on-site consultation (drug regimen review) at least once a month
- May use automated filling systems
 - Pharmacist must perform prospective drug use review and approve each medication order prior to administration except for overrides (require retrospective review), requires electronic verification process or daily pharmacist audit
 - Consultant of record responsible to maintaining a record of each transaction or operation, controlling access to the system, and maintaining policies and procedures

Class II Institutional Pharmacy (Hospital)

- Typical hospital pharmacy
- Has pharmacy onsite
 - Drugs must be dispensed in unit-dose packages
 - Typically has a formulary system approved by medical staff
 - Required to have operating hours sufficient to provide adequate and quality services
 - Considered closed whenever pharmacist not present and on duty
 - Must lock the pharmacy to prevent access from non-pharmacists
- Must have consultant pharmacist of record named

Modified Class II Institutional Pharmacy

- Pharmacies that meet all the requirements for a Class II permit, except space and equipment requirements (typically primary alcoholism treatment centers, free-standing emergency rooms, rapid in/out surgical centers, certain county health programs, and correctional institutions)
- Must have consultant pharmacist of record named
 - Consultant must provide written, on-site consultation (drug regimen review) at least once a month
- All drugs dispensed must be for on-site use only
- Consultant pharmacist must provide written protocols and a policy and procedure manual

Modified Class II A, eg Methadone clinic, dialysis center

- Formulary limited to 15 drugs or less

- <10 Modified Class II registrations
- Must not have large stock bottles of controlled substances (>100 dosages)

Modified Class II B, eg Surgical Center

- No formulary limitations, drugs can be stored in bulk or unit-dose
- >90% of Modified Class II registrations

Modified Class II C

- No drugs can be stored in bulk
- None currently registered in FL

Special Pharmacy

Special-Limited Community

- Employees and dependents personal use, patients of a hospital under a continuation of a course of therapy, Patients in the emergency room

Special-Parenteral and Enteral

- sterile products and parenteral/enteral compounding functions

Special-Closed System Pharmacy

- dispenses medicinal drugs, utilizing closed delivery systems, to facilities where prescriptions are individually prepared for the ultimate consumer, including nursing homes, jails, ALF's

Special-Non Resident (Mail Service)

- pharmacy located outside this state delivering a dispensed medicinal drug in any manner into this state

Special-End Stage Renal Disease

- Provides dialysis products and supplies to persons with chronic kidney failure for self-administration at the person's home or specified address

Special-Parenteral/Enteral Extended Scope

- Pharmacies which compound patient specific enteral/parenteral preparations in conjunction with institutional pharmacy permits

Special-ALF

- Assisted Living Facilities providing a drug delivery system utilizing medicinal drugs provided in unit dose packaging
- Consultant of record must provide written, on-site consultation (drug regimen review) at least once a month

Internet Pharmacy

- In state or out of state pharmacy which uses the Internet to communicate to FL patients or fill prescriptions for FL patients
 - Must always maintain an active pharmacy and DEA registration if dispensing controls
- Required to register as an Internet Pharmacy in FL
- Pharmacy must be open, ie accessible at least six days a week and 40 hours a week, and maintain a toll-free telephone number that is listed on the label of each prescription bottle filled.
- Must designate a licensed prescription drug manager
 - PDM does not need be licensed in FL
 - PDM must notify state within 30 days of relinquishing responsibility
- Requirement of permit is to protect FL patients and ensure a legitimate and competent practice

Nonresident Pharmacy

- Any out of state pharmacy that ships, mails, delivers, or advertises it fills prescription medications to patients in FL must register as a nonresident pharmacy
 - Must always maintain an active pharmacy license and DEA registration if dispensing controls
- Pharmacy must be open, ie accessible at least six days a week and 40 hours a week, and maintain a toll-free telephone number that is listed on the label of each prescription bottle filled.
- Requirement of permit is to protect FL patients and ensure nonresident pharmacy is legitimate and competent
- Mail Order Pharmacies register as Special Pharmacy not non-resident pharmacy

Nuclear Pharmacy

- Requires the practice of a FL licensed nuclear pharmacist to be named Prescription Department Manager (PDM)
 - Must notify state within 10 days of relinquishing responsibility
- Must have a secured radioactive storage and decay area
 - The Hot lab, storage area, and compounding and dispensing area shall be a minimum of 150 square feet
- Must have full spectrum of supplies (syringes, gloves, protective labcoat) and equipment (hood, shield, scintillation counter, etc)
- Registered technicians employed only in a nuclear pharmacy may write new prescriptions from a prescriber's oral prescription

Permits Generally

- Permits are not transferrable; meaning can't just sign over the pharmacy. New owner must complete full application and be approved by BOP
- Must be 18 years of age
- Do not need to be pharmacist to own/permit a pharmacy
 - No Medicaid or other healthcare fraud or criminal activity
 - Fingerprint, application, and background check
- Must have sufficient drug information resources necessary to operate pharmacy
- Permits and licenses must be conspicuously displayed
- Individuals must be readily identifiable by license through name badges (Tech/Intern/RPh)
- May advertise drugs and prices
 - No controlled substance advertising
- Check expiration dates quarterly and remove expired drugs immediately
- Maintain Continuous Quality Improvement Program to deal with errors
 - Requires a written policy and procedure manual. Must take proactive steps towards improvement.
 - Must conduct reviews at least every three months (quarterly) and consider how staffing levels, workflow, and technology contributed to the error.
 - There must be a record/database of errors.
 - Each incident must be documented/summarized by the pharmacist that first become aware of the matter on the initial date notified and include a description of the event that is sufficient to permit categorization and analysis. Must also include a description of the remedial measures instituted. Reports must be maintained for two years. Reports are not discoverable in court. However summaries may be reviewed by State Department of Health as long as names and identities are stricken.
- Must hang sign regarding generic substitution (all pharmacies)
- Must substitute generic drugs unless 1) patient requests otherwise 2) prescriber mandates "Medically Necessary" or 3) drug is on negative formulary.
 - Must give patient right to refuse, inform patient of substitution and price difference
 - Must pass full savings on to patient
- Samples not allowed in community pharmacy. Samples only in Class II institutional pharmacy upon written request of prescriber
- Each pharmacy must name a PDM or Consultant of Record and must notify the board of any change in this status
- Each pharmacy is typically granted only a single permit
 - Hospitals may also have a permit for an on-site community pharmacy
 - Rare exceptions may be granted, ie Community Pharmacy also granted Special Parenteral/Enteral permit
- Drugs must only be stored in the pharmacy

- Hospitals may also store drugs as necessary to treat (Surgical Units/ER)
 - Must be delineated in
- Destruction of controlled substances require execution of DEA Form 41
 - witnessed and signed by the prescription department manager and D.E.A. agent, or a Department inspector (no DEA approval required)
 - witnessed by the prescription department manager for the permit, one other pharmacist, and a sworn law enforcement officer (Form must be mailed to DEA at least two weeks before proposed date and approved by them)
 - Also may use DEA registered reverse distributors

Nursing homes whereby controlled substances have been dispensed and not used must not be returned to the pharmacy. They must be locked and stored by the nursing home until destroyed.

 - witnessed and signed by the consultant pharmacist, director of nursing, and the administrator or his designee, which may include a licensed physician, pharmacists, mid-level practitioner, or nurse.

Pharmacy

- Must be open to inspection (Medicaid/Board of Pharmacy/State Health Department/Insurance companies)
- Must be open a minimum 40 hrs a week and five days a week
 - Sign in block letters at least one inch must state hours of operation in unobstructed view, either at front door or by pharmacy
 - May also close New Year's Day, Memorial Day, Fourth of July (Independence Day), Labor Day, Veterans' Day, Thanksgiving, Christmas and any bona fide religious holiday
- Must have working sink, running water, sufficient shelving to maintain a clean/organized practice, refrigeration for drugs, sanitation, a print or electronic drug information, a print or electronic copy of FL drug laws, and anything else typically relied upon for your particular practice.
- Must have a patient consultation area directly next to pharmacy
 - Must have a sign that indicates "Patient Consultation Area" or something equivalent
 - Note there is no size requirement for this sign
- No other business can advertise or display Rx, Apothecary, Pharmacy, etc.
- If pharmacist is "not present and on duty," pharmacy considered closed!
 - Whenever a pharmacy is closed, it must be locked so that no non-pharmacist can enter
 - Sign in block letters at least two inches, prominently displayed, that states exactly "Prescription Department Closed"
 - Not present and on duty means that the pharmacist is away from the pharmacy doing any non-job related activity
 - Pharmacist may leave to counsel patients, take a meal break and attend to personal hygiene, and do other job responsibilities (ie take out garbage, etc.)
- Sterile Compounding permitted
 - Require a policy and procedures manual, adequately skilled, educated, instructed, and trained personnel, must be USP Chapter 797 Compliant, requires a proper designated area, specified anteroom and clean room, appropriate environmental control devices, disposal containers, environmental controls, documented, ongoing QA control program.
 - Expiration dates: Low risk compounding (48 hrs room temp, 14 days cold, 45 days frozen). High risk compounding (24 hrs room temp, 3 days cold, 45 days frozen)
 - Chemotherapy compounding requires vertical laminar hood and adequate protections
- Central Fill Pharmacies are permitted in FL
 - Central fill pharmacies fill prescriptions for controlled substances on behalf of retail pharmacies with which they have a contractual agreement
 - All records must be maintained by both pharmacies for 2 year period
- Common databases are permitted in FL
 - All pharmacies accessing must be properly licensed and under common ownership
 - Database owner

- Owner must have written policy and procedure manual
- Must maintain records of all pharmacist activity
 - Each pharmacist must maintain right to exercise professional judgment
 - No pharmacist is responsible for errors of another pharmacist not under direct, personal supervision.
- Closing of a pharmacy must follow procedures
 - Prior to closing, must notify Board of Pharmacy of closing, return permit, and advise to where prescriptions will be transferred
 - Upon closing, must physically deliver the prescription files to a pharmacy operating within reasonable proximity and provide a means by which to advise the public of the new location of their prescription files, receiving pharmacy must keep files separate and not commingle
 - May transfer drug to another pharmacy transfer drug to other pharmacy
 - Provide Board date of transfer, name, address, DEA# of two pharmacies, complete inventory of controlled substances
- Tablet Imprints. Under both Federal and State law, all tablets dispensed must have a unique imprint/identifier that in conjunction with the product's size, shape, and color, permits the unique identification of the drug product and the manufacturer
 - Exemptions include compounded medications, radiopharmaceuticals, investigational drugs, and any product whose size or physical characteristics make imprinting unfeasible or impossible
- National Drug Codes (NDC) serve as a universal (unique) product identifier for human drugs
 - Every distinct drug, package has a unique ten digit, three segment number (11 digit HIPAA standard)
 - 1) Manufacturer or Labeler 2) Drug Product 3) Package Size
 - 4-4-2, 5-3-2, or 5-4-1 configurations
 - Use is currently voluntary, used by insurance and pharmacies to process claims
 - Not Required to be on a drug label
 - Presence of a NDC number does not denote FDA approval

Pharmacy and Recordkeeping

- Compounded prescriptions have specific recordkeeping requirements
 - Date of compounding, traceable control number, complete formula maintained in a readily accessible format, pharmacist / technician signature or initials, manufacturer of materials used, quantity in units of finished product, package size and number of units prepared and name of the patient who received the particular compounded product
- Pharmacy must maintain patient records and they must be immediately retrievable
 - Full name, address, and telephone number, age or date of birth, and gender, list of all new and refill prescriptions over preceding two years, pharmacist clinical comments
 - Must make reasonable efforts to obtain allergies, chronic diseases, and current medications
 - Hard copy or a computerized record must be maintained for at least two years,
- Pharmacy must record each prescription filled in a data processing unit
 - Have capacity to produce a daily hard-copy printout, shall be produced within 72 hours.
 - Each individual pharmacist who dispenses or refills a prescription drug order shall verify that the data indicated on the daily hard-copy printout is correct, by dating and signing such document within seven days from the date of dispensing
 - Maintain a log book in which each individual pharmacist shall sign a statement each day, attesting to the fact that the information entered into the data processing system that day has been reviewed by him or her and is correct as entered, stored for at least two years
 - Prescriptions must be stored for at least two years
 - May use an electronic imaging recordkeeping system is able to capture both sides of a prescription
- Pharmacy must maintain a back-up recordkeeping system

- Back-up system typically uses disk, tape or other electronic medium.
 - Must be backed-up on a regular basis, at least weekly
 - Must report to the Board in writing any significant loss of data within 10 days of discovery
- In case of emergency, ie Hurricane the pharmacy must have an auxiliary procedure to ensure proper refilling.
 - All of the appropriate data shall be retained for on-line data entry as soon as the system is available for use again.

Controlled Substance Recordkeeping

- Pharmacy must maintain a computerized record of controlled substance prescriptions dispensed
 - Hard copy printout summary of such record, covering the previous 60 day period, shall be made available within 72 hours following a request for it by authorized law enforcement
 - Date / Patient name and address (+ species) / Drug name and Quantity
- Biennial complete and accurate inventory
 - Date may vary by no more than 6 months from the biennial date that would otherwise apply
- Records of all controls lost, destroyed or stolen including name, quantity, and date
- All records must be readily retrievable from other business records and retained for at least two years

Pedigree Papers

- Each drug wholesaler of prescription drugs must provide a pedigree paper to the person who receives the drug

Pharmacist Responsibilities

- Must be licensed
 - 18 years of age, pass NAPLEX and MPJE, meet internship requirements
- Must be fit and competent to practice
 - Cannot be intoxicated or have any physical or mental impairment which threatens safety of patients
- Final check of prescriptions
 - Initial or sign the prescription face and write date filled
- Must conduct prospective drug use review (check suitability of prescription) for each prescription filled and take the necessary steps to ensure safe practice
- Must counsel patients on medication if requested
- Must be present and on duty while working
- Must make drug pricing readily available upon request
- May take a 30 min meal break while keeping pharmacy open
 - Most post prominently a sign in the pharmacy indicating the specific hours of the day during which meal breaks may be taken
 - Pharmacist remains directly and immediately available to patients during such meal breaks
 - Technicians remain under the direct and supervision of the pharmacist and the pharmacist must certify all prescriptions after the meal break
- Sign the daily prescription log affirming they are responsible for the prescriptions filled
- Use professional judgment and establish validity of all prescriptions and obtain "satisfactory patient information" if unknown
 - Mail order prescriptions exempt if covered by insurance
- Direct and immediate responsibility over all interns and technicians and accept full responsibility
 - May delegate responsibilities to technicians and interns while assuming ultimate supervision and complete responsibility while conducting continuing review of their work.
- Dispense a one-time 72 hr emergency refill if prescriber unavailable, including controlled substances
 - Essentially any drug other than a CII can be refilled. Pharmacist must create a record and contact the physician as soon as possible

- FL Pharmacist can prescribe from limited formulary, although practically speaking this is non-existent
 - No injectables, pregnant patients or nursing mothers, recommended dose and duration only (34 d max), must make a prescription, maintain patient profile and store for at least two years
 - Pharmacy interns or technicians cannot be delegated authority to prescribe
- Pharmacists can order fluoride treatments if patients do not have fluoride supplement in their water. Maximum one year of therapy. Must not switch fluoride brands.
- Responsible for compounding medications
 - Interpret and identify all incoming orders, mix or be physically present and give direction to the registered pharmacy technician
- Only pharmacist can use title pharmacist, druggist, etc
- May immunize for influenza with proper credentialing
 - Protocol with physician, board approved/certified 20 hrs minimum
 - Maintain \$200,000 of professional liability insurance
- Fill out of state/ out of country prescriptions only if 1) valid 2) licensed prescriber and 3) for chronic or recurrent condition
 - Acute diseases should be attended to in the state or country that it arises in
- Fill prescriptions for pain (narcotics) only if valid
 - If the pharmacist has any questions about said validity the pharmacist must 1) verify with doctor and 2) if patient is unknown, photocopy identification or document on back of prescription
- Consultant pharmacist or PharmD with required coursework may order lab tests
- Report to State Department of Health any concerns that a prescriber is involved in diversion

Patient Counseling

- In FL, every prescription, there must be an offer to counsel verbally and in writing (Note that anyone can make the offer, but only the pharmacist or intern can counsel)
 - For delivery, the offer shall be in writing and shall provide for toll-free telephone access to the pharmacist
- Counseling not required for inpatients of a hospital or institution where other licensed health care practitioners are authorized to administer the drug(s) and not required if refused

Continuing Education Requirements

- 30 hours ACPE approved CE every 2 years
 - First time to include 1 hr HIV/AIDS (FL), Each renewal 2 hours Medication Errors
 - 10 of 30 hours live seminar, video teleconference, or through an interactive computer-based application
 - If first renewal is <12 months after licensure no CE is required
 - Between 12 and 24 months 15 hours required
 - May acquire 5 credits attending all day Board meeting, 5 credits volunteer services to indigent, 5 credits / post graduate professional semester credit
 - Retain documents for 2 yrs after license renewed
- 3 hr special course required to order/evaluate lab tests

Dispense Pharmacist-only Narcotics in FL

- Schedule V only, Adult patient only, proof of identification required (even if patient known), bound volume must be maintained as a record
- Dose not to exceed 120 milligrams of codeine, 60 milligrams dihydrocodeine, 30 milligrams of ethyl morphine, or 240 milligrams of opium within 48 hr
 - No limit on prescription
- Pharmacist may withhold sale at discretion if believe purpose is abuse

Consultant pharmacists

- May hire other consultant to do work, although ultimate responsibility remains with consultant of record

- Consultant of record must notify board within 10 days of relinquishing responsibility
- Requires successful completion of a Consultant Pharmacist course of at least 12 hours sponsored by an accredited college of pharmacy located within the State of Florida, and approved by the Florida Board of Pharmacy
- Must undergo a 40 hr clerkship under the supervision of a consultant pharmacist preceptor within one year of completion of the course, must be completed over three (3) consecutive months, 60% of which shall occur on-site at an institution that holds a pharmacy permit.
- Consultant preceptor must be licensed consultant pharmacists for at least one year can precept no more than two pharmacist applicants at a time

Nuclear Pharmacist

- Must renew their license every two years
- Must receive at least 24 hrs approved continuing education credit for nuclear pharmacy every two years
 - Cannot be applied towards the required 30 general hours required of all pharmacists

Technicians

- 1:1 technician to pharmacist
 - May be 3:1 with approval from Board of Pharmacy
 - Request must include brief description of the workflow include operating hours of pharmacy, number of pharmacists/interns/and technicians.
- Must be registered
 - Complete application, pay fee, must be at least 17 years of age, provide proof of Board approved training program (proposed 160 hours within 6 months)
 - Disciplined pharmacist ineligible to be registered
- Must complete 20 hours of CE required biennially
 - 4 hours live, 2 hours med errors
- Pharmacy must have written job descriptions for technicians as well as policies and procedures.
 - Ensure each technician is knowledgeable and work requests do not exceed the written job description/policy/procedure. Must provide and document training for technicians.
- Technicians must wear a visible identification badge with name and title (Registered Pharmacy Technician) and identify themselves in all communications as technicians
- Registered pharmacy technicians **may**
 - data entry and label preparation
 - fill prescriptions including controlled substances
 - file/retrieve prescriptions, patient profiles, and other records
 - contact patient for information on patients' name, current medications, dosage, quantity, directions and date of last refill
 - contact prescriber for information on illegible dates, signature on prescription, quantity prescribed, "medical necessity" of drug, license and DEA number
 - initiate communication and accept prescription refills from prescriber('s office)
 - counting, weighing, measuring, pouring and compounding
 - compounding and reconstituting in the presence of pharmacist
- Registered pharmacy technician **may not**
 - Receive new prescriptions over the phone including change in any drug, strength, or dosage (*however, nuclear technicians may receive diagnostic orders*)
 - evaluate the appropriates of a prescription
 - conduct a final check of the drug
 - perform a prospective drug review (DUR) such as checking the suitability of drug allergies, therapeutic duplication, etc.
 - provide patient counseling
 - monitor prescription usage
 - override clinical alerts without contacting the pharmacist

Interns

- 1:1 Intern to pharmacist
- May give copies and transfers
- Must register with State, demonstrate proof of enrollment or graduation from accredited school of pharmacy

Prescribers

- In FL, the following may prescribe, limited to within scope of practice:
 - Dentists
 - Optometrists (Ocular drugs only)
 - Physicians (MD / DO)
 - Physician Assistants, Nurse Practitioners
 - Under supervision of a licensed physician, No controlled substances
 - Podiatrists
 - Veterinarians
- In FL, the following may theoretically prescribe with very limited authority, but practically should be viewed as unable to prescribe:
 - Chiropractors
 - Pharmacist
 - Naturopaths (pre 1959)
- In FL, the following are never able to prescribe:
 - Anesthesiologist Assistants, Doctors of Oriental Medicine, Nurses, Respiratory Therapists, Psychologists
- No "Office Use" of Controlled substances allowed
- May order "Office Use" of compounded prescriptions in amounts limited to anticipated use
- Must write prescription legibly

Prescriptions

- All Florida prescriptions expire in one year
 - CIII-CV expire in 6 months
- Prescriptions must contain the following (12 + refill /15 points)
 1. Date of issue
 2. Patient's full name
 3. Patients address
 4. Practitioner's name
 5. Practitioners address
 6. Practitioners DEA registration number
 7. Drug name
 8. Drug strength
 9. Dosage form
 10. Quantity prescribed
 - a. Number of refills (if any) authorized
 11. Directions for use
 12. Manual signature of prescriber

In Florida, Pharmacist must

 13. Initial the prescription
 14. Write date filled
 15. Write the prescription number
- FL maintains a Negative drug formulary- the following generic drugs cannot be substituted for a brand drug
 1. Digitoxin (*note this is NOT digoxin*)
 2. Conjugated Estrogen (*ie Premarin, Cenesta, Enjuvia*)
 3. Dicumarol (*note this is NOT warfarin*)

4. Solid Oral Dosages of Chlorpromazine (*Can substitute syrup, injection, and suppository*)
5. Controlled Release Theophylline (*Can substitute immediate release formulations*)
6. Oral Pancrelipase

Note that absence of levothyroxine, warfarin and digoxin.

- All dispensed outpatient prescriptions must be labeled with the following: (9/11)
 1. Name of pharmacy
 2. Address of pharmacy
 3. Date of dispensing.
 4. Serial (prescription) number.
 5. Name of the patient or, if the patient is an animal, the name of the owner and the species of animal.
 6. Name of the prescriber.
 7. Name of the drug dispensed (except where the prescribing practitioner specifically requests that the name is to be withheld).
 8. Directions for use.
 9. Expiration date (FL uses a 1 year beyond-use date or manufacturers expiration date if earlier)

Controlled Substances must also include:

10. Date of initial fill if a refill
 11. Cautionary statement (Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed
 - a. Unclaimed prescriptions may be stored in pharmacy and reused, subject to 1 year beyond-use date from date originally filled or manufacturer's expiration date
- Prescriptions can be compounded in FL
 - Must be in anticipation of prescriptions based on routine, regularly observed prescribing patterns, preparation pursuant to a prescription of drugs which is not commercially available, preparation of commercially available products from bulk when the prescribing practitioner has prescribed the compounded product on a per prescription basis and the patient has been made aware of the compounding
 - Centralized fill pharmacy may compound for another pharmacy
 - May compound for doctor "office use"
 - Florida permits a one-time 72 hr emergency refill if prescriber unavailable, including controlled substances
 - Essentially any drug other than a CII can be refilled. Pharmacist must create a record and contact the physician as soon as possible
 - Pharmacists and Interns may give copies and transfers to another pharmacy
 - Taking Transfer/Copy
 - Dispensing pharmacist must tell patient the prescription at other pharmacy is now cancelled, establish legitimate prescription with valid refill(s) (including pharmacy/pharmacist is licensed), record the prescription, the name of the copying pharmacy, the prescription number, the drug, the original amount dispensed, the date of original dispensing, and number of remaining refills.
 - Giving Transfer/Copying
 - Pharmacist must determine valid request, provide the prescription, the name of the pharmacy, the prescription number, the drug, the original amount dispensed, the date of original dispensing, and number of remaining refills. Pharmacist must record the transferring pharmacy name, pharmacist, and date of

- request and cancel the electronic prescription (or void written prescription).
 - If prescription is not dispensed within a reasonable time, the transferring pharmacy should contact the copying pharmacy and the prescription should be revalidated through the same process, as described above.
 - May dispense generic even if brand was originally filled
 - Unless prohibited by negative formulary or “Medically Necessary”
- Dispensed prescriptions may not be returned to stock and must never be redispensed. The pharmacist may wish to give credit or a refund but cannot combine any drug because the quality cannot be assured.
 - Unused unit-dose medications dispensed to inpatients and properly labeled may be returned to the pharmacy for redispensing.
 - Pharmacist must maintain appropriate records for any unused or returned medicinal drugs.
- Patient Medication Information Sources (3 types) that may need to be provided with each prescription dispensed
 - Medication Guide is considered part of the Drug labeling
 - If required and no provide drug is misbranded
 - Required for certain drugs the FDA determines has risks that need to be provided to patients
 - Currently about 200 drugs have a Medication Guide required
 - Patient Package Insert (PPI) is considered part of the drug labeling
 - Required for all estrogens and oral contraceptives
 - Outpatient: Required with each prescription
 - Inpatient: Provided before first dose and every 30 days thereafter
 - Consumer medication information (CMI) are the pharmacy leaflets provided by pharmacies with drugs
 - Required under law to be provided
 - Are not FDA reviewed/approved and not part of the drugs labeling

FL Board of Pharmacy

- Job is to protect the public (FL patients) not the pharmacists
- Composed of 9 members, appointed by the Governor, confirmed by the Senate
 - 7 licensed pharmacist members, state residents, representative of various practice settings, in practice for at least 4 years, at least 1 member must be at least 60 years of age
 - 1 community pharmacy representative
 - 1 Class II institutional Pharmacy
 - 5 members no setting requirement, various
 - 2 community members, state residents, not pharmacists, no connection to the profession, drug wholesales or pharmaceutical manufactures
- Probable cause panel investigates rule violations or complaints to determine if there is sufficient cause to bring before the full board. Meets as often as necessary
 - Composed of two members of the Board of Pharmacy, one of which must be a pharmacist (usually chair)
 - Double affirmative vote required to find probable cause exists that a violation has occurred

Florida Prescription Drug Monitoring Program of Controlled Substances

- Program is still in development
 - Attempts to minimize diversion of controlled substances
- Pharmacist dispensing of controls monitored as well as physician prescribing of controls

- Within 15 days of dispensing using ASAP Standards, pharmacy must report Doctors Name, DEA#, Date Rx written, Pharmacy's name, address, DEA#, Date Rx filled and method of payment, Full name, address and DOB of patient, name, national drug code, quantity, and strength of controlled substance.
- State Department of Health to issue Patient "Advisory Report" to pharmacist and physician upon request for Rx history
- Not reported: hospitals, nursing homes, ambulatory surgical centers, hospices, intermediate care facilities for the developmentally disabled, correctional facilities, emergency rooms, patients under the age of 16, one-time, 72-hour emergency refills, and patients directly administered controlled substances by a physician

Differences between Federal and FL Pharmacy Laws

	Florida State Law	Federal Law
Expiration date on CII's	Schedule II prescriptions expire 1 year from the date of the original prescription. Rule 64B16-27.211 Prescription Refills.	No expiration on Schedule II prescriptions is described.
Patient counseling requirements	A verbal and printed offer to counsel must be made for all outpatient prescriptions including new or refill prescriptions. If the drug is not delivered directly to the patient (or agent), the offer shall be in writing and provide for toll-free telephone access to the pharmacist. No such requirement for inpatient prescriptions. Rule 64B16-27.820 Patient Counseling.	OBRA-90 requires counseling be offered to all Medicaid patients only.
Carisoprodol Schedule	Carisoprodol is a schedule IV controlled substance 893.03 (4).(jjj). Carisoprodol.	Carisoprodol is not a controlled substance although DEA currently considering such
CII Emergency Prescriptions	limited to a 72-hour supply. 893.04.(1).(f).	amount adequate to treat the patient during the emergency period
Written format on controlled substance prescriptions	the date on controlled substance prescriptions must be written out in abbreviated month (Jan 1, 2011) and quantity must be provided in both numbers (30) and letters (thirty). Pharmacist may write the information in after verifying with prescriber. If prescriber is unavailable, then the pharmacist may dispense the controlled substance but <u>may</u> insist that the person to whom the controlled substance is dispensed provide valid photographic identification. If a prescription includes a numerical notation of the quantity of the controlled substance or date, but does not include the quantity or date written out in textual format, the pharmacist may dispense the controlled substance without verification by the prescriber of the quantity or date if the pharmacy previously dispensed another prescription for the person to whom the prescription was written 893.04(2).(d).	No requirement exists for how date should be written or for how quantity must be provided on controlled substance prescriptions
Legible	Yes. Prescription be legibly written or typed; that	No requirements

prescription law	the quantity of the drug must be written in numerical and textual format; that the date of the prescription must be written in textual letters (e.g. July 1, 2003); and that the practitioner must sign the prescription on the day it is issued. § 456.42	
Multiple drugs on same blank	Each blank must only have drugs from same class prescribed.	No restriction
Oral Prescriptions for CIII	Oral prescriptions for Schedule III medications are limited to a 30 day supply including refills	No restriction for oral Schedule III prescriptions are described
Checking prescriptions for Controlled Substances	The pharmacist must write his/her initials and the date filled on the face of all controlled substance prescriptions	There is no requirement that the initials of the pharmacist filling the prescription and the date filled be written on the face of the prescription
Tamper resistant pad requirements	All written Medicaid outpatient prescriptions must be written on counterfeit resistant pads Counterfeit resistant prescription pads for Schedule II, III, IV drugs are recommended, but not required. Counterfeit pads contain: <ul style="list-style-type: none"> – Preprinted physician's name, address, and category of licensure – Security features <ul style="list-style-type: none"> • background green or blue and resist reproduction. • The blank must be printed on watermarked paper. • The blank must resist erasures and alterations. • The word 'void' or 'illegal' to appear on any photocopy or reproduction 	All written Medicaid outpatient prescriptions must be written on tamper-resistant pads
Prescribers of Controlled Substances	Florida authorizes Dentists <ul style="list-style-type: none"> • Physicians (MD and DO) • Dentists • Podiatrists • Veterinarians Midlevel Practitioners NOT authorized. Note that theoretically an out of state DEA licensed midlevel practitioner may write a valid prescription in FL if "necessary for the continuation of treatment of a chronic or recurrent illness"	Federal law allows states to determine which practitioners can prescribe. Midlevel practitioners may be authorized under state law, but Florida prohibits.
Salvia Schedule	Schedule I	Not scheduled
Amount of CV Available without prescription	Lower	Higher

Table adapted in part from J. Fass PharmD, April 2011

Recordkeeping Requirements in Florida

Prescription record	Two years from date of last dispensing	893.04(1)(d), 64B16-28.140
Controlled substance inventory	Conducted every two years	893.07(1)(a)
Inventory records	Maintained for at least two years	893.07(4)(a)(b)
Pharmacy permits	Expire every odd years on Feb 28 th	
Immunization records	Maintain for at least five years	465.189(3)
Patient records for pharmacist-only drug orders	Two years	64B16-27.210
Patient records for prescription drugs dispensed	Two years from date of last entry	64B16-27.800
Pharmacy Continuous Quality Improvement Program summarizations	Two years	64B16-27.300
Clean rooms and laminar flow hoods certification of operational efficiency by an independent contractor or National Sanitation Foundation Standard 49	All records must be maintained at least every two years	64N16-27.797
High risk CSP- every six months Mediums and low risk CSP - annually		
Dispensing logbook	Two years	64B16-28.140
Starter Dose prescription Records	Two years	64B16-28.503
Class II Institutional Pharmacy reports / analysis generated as part of the quality assurance program	Two years	64B16-28.605
Class II Institutional Pharmacy transaction records from the automated medication system for all controlled substances dispensed or distributed	Two years	64B16-28.605
Class II Institutional Pharmacy reports / databases related to access to the system or any change in the access to the system or to medication in the system	Two years	64B16-28.605
Class II Institutional Pharmacy remote medication order records that identify the name, initials, or identification code of each person who performed a processing function for every medication order.	Two years	64B16-28.606
Automated pharmacy system transactions for Long Term Care, Hospice, and Prisons	Two years	64B16-28.607
Drug Samples records of distribution, destruction, or return to the manufacturer or distributor, thefts or significant losses of drug samples, and of all requests made under for drug samples.	Three years	499. 028
Wholesale records	The longer of two years following the disposition of the drug or three years	499.0121

	from the creation of the record	
Records and sales of ether by manufacturers, distributors, and dealers	Five years	499.66

Section 5

Exam Type Questions

Try and pinpoint the rule/law that shows why each correct answer is right and why each incorrect answer is wrong. Pick out 20 rules of law or MPJE Competencies that you think might be tested and write one or two questions for each.

- All community pharmacists and technicians must have annual training involving fraud, waste, and abuse?
 - True
 - False
- In order for 1 pharmacist to have 3 technicians to directly supervise, the pharmacist must:
 - Confirm each technician is receiving 30 CE credits every two years
 - Ensure that the technicians have graduated an ACPE-accredited program
 - Obtain written notification permitting such ratio from the prescription department manager or consultant pharmacist of record
 - Register each technician with the Board of Pharmacy by documenting the differing responsibilities that each technician will assume
 - None of the above
- Which of the following may keep drug samples?
 - Nova Community Pharmacy
 - Dr. Inova, MD
 - Nova Community Hospital
 - a and b only
 - None of the above
- A prescription may be written for Xanax, Soma, Lorcet and Vicodin on the same prescription blank?
 - Yes, multiple controlled substances may be written on the same prescription blank
 - Yes, as long as the pharmacist documents that therapy is valid and a patient-prescriber relationship exists
 - No. Lorcet and Vicodin are the same drug and this is considered therapeutic duplication.
 - No, different schedules of controlled substances require different prescription blanks
- What is the check digit in Dr. Matthew's DEA number AM123456_____
- An Ophthalmologist prescribes oxycodone 30 mg #180 for headache. The pharmacist should:
 - Fill the prescription if the pharmacist determines this is a valid prescription
 - Fill the prescription only if oxycodone is indicated for headache
 - Not fill the prescription as midlevel practitioners in FL cannot prescribe controlled substances
 - Not fill the prescription as Ophthalmology is the practice of medicine involving the eye
- Pharmacists are not entitled to overtime pay in excess of 40 hour work week because:
 - They are professionals exempt under the Federal Fair Labor Standards Act (FLSA)
 - They are contractually obligated to provide Medication Therapy Management (MTM) to all Medicare Part D patients
 - They are non-unionized in Florida
 - Pharmacists are entitled to overtime pay under the Learned Intermediary Doctrine

8. How long does an immunizing pharmacist in FL have to maintain patient records in FL?
- 1 year
 - 2 years
 - 3 years
 - 4 years
 - None of the above
9. Pharmacist receives a prescription for an off-label indication. The pharmacist should:
- Call the physician and request confirmation that the drug is being used off label
 - Use professional judgment and if the prescription is valid, fill the prescription
 - Contact the insurance company and determine if this is a covered indication
 - Search Medline and see if there are any randomized controlled trials using the written indication
 - Interview the patient and evaluate if this is an appropriate use of the drug
10. A young man enters your pharmacy and wants to purchase 90 tablets of Pseudoephedrine (PSE). You should instruct him:
- PSE is now a schedule I controlled substance and it is against the law to sell
 - The maximum allowable sale is 36 tablets
 - That a valid ID is required to purchase the product
 - That the age limit to purchase PSE is 18 years of age
11. If a controlled substance prescription is for an animal, which of the following is required on the prescription?
- Name of the physician
 - Species of animal
 - Name of the owner
 - All of the above
12. A dose-ranging study is conducted to establish the target dose for a large-scale randomized controlled efficacy study. This study is considered:
- Phase I
 - Phase II
 - Phase III
 - Phase IV
 - Preclinical
13. A pharmacist while verifying a prescription sneezes onto his sleeve. The technician screams yuck and then grabs the order from the pharmacist. The technician then pours out the bottle contents and refills the prescription vial; but instead of putting 25 mg tabs in the bottle (as is ordered), the technician counts 50 mg tabs erroneously. This prescription is
- Adulterated
 - Misbranded
 - Adulterate and Misbranded
 - Neither Adulterated or Misbranded
14. When transferring a prescription, the pharmacist must do all of the following except:
- Advise the patient that the prescription on file at the other pharmacy will be canceled
 - Determine that the prescription is still valid
 - Notify the doctor who wrote the prescription that it will be transferred
 - Notify the pharmacy where the prescription is currently filled that it will be canceled
15. You receive a prescription from Dr. John Smith for Cocaine 20 mg for "office use". Dr. Smith is a known ear, nose, and throat surgeon that needs the product for surgery later in the week. He is registered with the DEA

- a) You should fill the prescription and label the drug product for Office Use
 - b) You should fill the prescription and label the product for John Smith
 - c) You should not fill the prescription because Cocaine is a schedule I controlled substance
 - d) You should not fill the prescription, but instead request that Dr. Smith complete a DEA form 222 whereby your pharmacy acts as a supplier
16. Florida pharmacist may take meal breaks under which of the following conditions
- a) The pharmacist closes the pharmacy for business while allowing the technicians to continue to work
 - b) The pharmacist may leave the premises without closing the pharmacy as long as the meal break is 30 minutes or shorter
 - c) The pharmacist make take a meal break while keeping the pharmacy open as long as a sign is present indicating the specific hours a meal break may be taken
 - d) The pharmacist cannot take a meal break in FL
17. According to Florida law, a Pharmacist can prescribe (order) drugs from a very limited formulary under which of the following conditions?
- a) Maximum day supply of 34 days
 - b) Must maintain patient records for two years
 - c) Patient may not be pregnant or nursing
 - d) All of the above
18. Which of the following drugs is scheduled in FL but not under Federal Law
- a. Buprenorphine
 - b. Carisoprodol
 - c. Sodium oxybate
 - d. Sublimaze
 - e. They are all scheduled under Federal law
19. A home infusion pharmacy receives a fax for an IV Morphine Sulfate order. Which of the following statements is correct.
- a. The pharmacist should not fill the order unless the patient is in hospice
 - b. The pharmacist may pre fill the order but must receive the actual written order to dispense the drug
 - c. The pharmacist should wait to receive the actual written order before preparing the IV
 - d. The pharmacist should fill the order as the fax will serve as the actual prescription
20. A prescription is written for insulin with PRN refills on January 1. On July 1 the patient comes to the pharmacy to refill the prescription and informs the pharmacist that the prescribing physician in independent practice is away traveling to Haiti as part of Doctors Without Borders and unavailable for communication. The pharmacist should:
- a. Refill the prescription as valid refills remain
 - b. Refill the prescription as prescriptions in FL are valid for 1 year
 - c. Not refill the prescription as the physician is away from practice
 - d. Not refill the prescription as PRN refills for insulin are not permitted

21. Match the DEA Form with the Quote

- | | | |
|---------|-------|--|
| 1. 41 | i. | Yuck, this oxy smells like rotten chicken |
| 2. 106 | ii. | Yup, my technician stole my oxy |
| 3. 222 | iii. | I need to order ecstasy and oxy |
| 4. 224 | iv. | I want to sell oxy legally wearing my pharmacist smock |
| 5. 224a | v. | The hospital needs to renew their oxy license |
| 6. 224b | vi. | That chain def needs to renewed their oxy license |
| 7. 224C | vii. | oxy.com needs to modify their oxy license |
| 8. 225 | viii. | I want to make and wholesale oxy to my boyz to import and research |
| 9. 363 | ix. | Uh oh, I'm addicted to Oxy. Gonna open a clinic |
| 10. 510 | x. | Yeah I'll sell you some 3, 4-Methylenedioxyphenyl-2-propanone to make oxyo |

22. Match the Pharmacy name with the appropriate permit

- | | | |
|---|-------|----------------------------------|
| 1. Matt's Mail Order Pharmacy | i. | Community |
| 2. O'Matties Irish Nursing Home | ii. | Class I Institutional |
| 3. St. Matthew's Hospital Pharmacy Department | iii. | Class II Institutional |
| 4. DJ Matty Methadone and Dialysis Pharmacy | iv. | Modified Class IIa Institutional |
| 5. Matthew's Surgical Center Pharmacy | v. | Modified Class IIb Institutional |
| 6. Maddy Radioactive Rx Isotopes | vi. | Modified Class IIc Institutional |
| 7. Matthew Florida Correctional Pharmacy | vii. | Special Pharmacy Permit |
| 8. Wehttam's Parenteral and Enteral ESRD Pharmacy | viii. | Internet |
| 9. www.mattsrx.com | | |

Section 6

FL Case Scenarios

Section 7

Wrap-Up and Disclaimer

This is a working draft. The information contained herein is not guaranteed for accuracy. Please forgive any errors or omissions. The author requests that either during or after your studying you send comments to the on this review and/or the examination to Matthew Seamon at mseamon@nova.edu.

Good luck!