MPJE Review 2017
PHRC 7803

9:00-12:00 Introduction to MPJE and Study Resources
Federal Law Overview
12:00-1:00 Lunch
1:00-4:00 FL State Law
MPJE Question Review and Florida Case Scenarios

2017 Hot Topics

- Sterile Compounding / Permit (SSCP)
- Hours of Operation (20 hours)
- Immunizations
- Scope of Practice – Midlevel Practitioners (Narcotics 7d max)
- CII Controlled substances (Partial Fills fine, remainder within 72h)
- Naloxone Standing Orders / Epinephrine / Collaborative Practices
- Practitioner Recovery Network
- Drug Disposal
- Non-Resident Pharmacies/Permits
- Pedigree Papers (1/3/4/6 with Board Approval)
- Prescription Department Manager (one pharmacy unless approved)
- Technician Ratios
- Violations of Board Rules

Section 1 - MPJE

Exam Overview

- Computer-adaptive examination using selected response test questions
  - All questions answered in order, no going back
  - Rich in situational questions
- Online registration
  - $250.00 per examination
  - Partial refund available for cancelled or withdrawn examination is $165.00 (not missed)
  - Reschedule appointments available $50.00 per reschedule
  - Re-sitting fee is $100.00
- Administered at Pearson VUE testing centers.
  - Two forms of identification required
    - One picture ID with signature
  - Palm Vein Scan and Photograph at testing site
  - Erasable note board and pen will be provided
- 3 hour Appointment Time
  - **2.5 hours to complete, no breaks given**
    - You may take a break but that time will be deducted from your examination total
- 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 120 multiple-choice test questions.
    - 100 questions used to calculate score (operational)
    - 20 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 answer questions in order
    - Once an answer is confirmed, there is no opportunity to return to the question
    - Must complete at least 107 questions to be scored
    - Question Types
        - Multiple Choice
        - Select All That Apply
        - Ordered Response
- 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.
- This is an examination of the law. Not how a particular insurance company contracts and not how your pharmacist practices.
- "Test of Confidence"
- Avoid misconduct. Avoid any inkling of misconduct. Avoid any perception of misconduct

Competency Statements

Area 1 Pharmacy Practice (Approximately 83% of Test) = 100 total, 83 scored

1.1 Legal responsibilities of the pharmacist and other pharmacy personnel

1.1.1 Unique legal responsibilities of the pharmacist-in-charge (or equivalent), pharmacists, interns, and pharmacy owners

•Responsibilities for inventory, loss and/or theft of prescription drugs, the destruction/disposal of prescription drugs and the precedence of Local, State, or Federal requirements

1.1.2 Qualifications, scope of duties, and conditions for Practice relating to pharmacy technicians and all other non-pharmacist personnel

• Personnel ratios, duties, tasks, roles, and functions of non-pharmacist personnel

1.2 Requirements for the acquisition and distribution of pharmaceutical products, including samples

1.2.1 Requirements and record keeping in relation to the ordering, acquiring, and maintenance of all pharmaceutical products and bulk drug substances/excipients

•Legitimate suppliers, pedigrees and the maintenance of acquisition records

1.2.2 Requirements for distributing pharmaceutical products and preparations, including the content and maintenance of distribution records

•Legal possession of pharmaceutical products (including drug samples), labeling, packaging, repackaging, compounding, and sales to practitioners

1.3 Legal requirements that must be observed in the issuance of a prescription/drug order

1.3.1 Prescription/order requirements for pharmaceutical products and the limitations on their respective therapeutic uses

• Products, preparations, their uses and limitations applicable to all prescribed orders for both human and veterinary uses

1.3.2 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

•Federal and State registrations, methadone programs, office-based opioid treatment programs, regulations related to retired or deceased prescribers, Internet prescribing, limits on jurisdictional prescribing

1.3.3 Conditions under which the pharmacist participates in the administration of pharmaceutical products, or in the management of patients' drug therapy

• Prescriptive authority, collaborative practice, consulting, counseling, medication administration (including immunization, vaccines), ordering labs, medication therapy management, and disease state management

1.3.4 Requirements for issuing a prescription/order

•Content and format for written, telephonic voice transmission, electronic facsimile, computer and Internet, during emergency conditions, and tamper-resistant prescription forms.

1.3.5 Requirements for the issuance of controlled substance prescriptions/orders

•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 orders

1.3.6 Limits of a practitioner's authority to authorize refills of a pharmaceutical product, including controlled substances

1.4 Procedures necessary to properly dispense a pharmaceutical product, including controlled substances, pursuant to a prescription/drug order

1.4.1 Responsibilities for determining whether prescriptions/orders were issued for a legitimate medical purpose and within all applicable legal restrictions

•Corresponding responsibility, maximum quantities, restricted distribution systems, red flags/automated alerts, controlled substances, valid patient / prescriber relationship, and due diligence to ensure validity of the order

1.4.2 Requirements for the transfer of existing prescription/order information from one pharmacist to another

1.4.3 Conditions under which a prescription/order may be filled or refilled

•Emergency fills or refills, partial dispensing of a controlled substance, disaster or emergency protocol, patient identification, requirement for death with dignity, medical marijuana, and conscience /moral circumstances

1.4.4 Conditions under which prospective drug use review is conducted prior to dispensing

•Patient-specific therapy and requirements for patient-specific documentation

1.4.5 Conditions under which product selection is permitted or mandated

•Consent of the patient and/or prescriber, passing-on of cost savings, and appropriate documentation

1.4.6 Requirements for the labeling of pharmaceutical products and preparations dispensed pursuant to a prescription/order

•Generic and therapeutic equivalency, formulary use, auxiliary labels, patient package inserts, FDA medication guides, and written drug information

1.4.7 Packaging requirements of pharmaceutical products, preparations, and devices to be dispensed pursuant to a prescription/order

•Child-resistant and customized patient medication packaging

1.4.8 Conditions under which a pharmaceutical product, preparation, or device may not be dispensed

• Adulteration, misbranding, and dating

1.4.9 Requirements for compounding pharmaceutical products

• Environmental controls, release checks and testing, beyond use date (BUD), initial and ongoing Training

1.4.10 Requirements for emergency kits

•Supplying, maintenance, access, security, and inventory

1.4.11 Conditions regarding the return and/or reuse of pharmaceutical products, preparations, bulk drug substances/excipients, and devices

•Charitable programs, cancer or other repository programs, previously dispensed, and from “”will call”” areas of pharmacies

1.4.12 Procedures and requirements for systems or processes whereby a non-pharmacist may obtain pharmaceutical products, preparations, bulk drug substances/excipients, and devices

•Pyxis (vending), after hour’s access, telepharmacies, and secure automated patient drug retrieval centers

1.4.13 Procedures and requirements for establishing and operating central processing and central fill pharmacies

•*Remote order verification*

1.4.14 Requirements for reporting to PMP, accessing information in a PMP and the maintenance of security and confidentiality of information accessed in PMPs

1.4.15 Requirements when informed consent must be obtained from the patient and/or a duty to warn must be executed

•*Collaborative practice and investigational drug therapy*

1.5 Conditions for making an offer to counsel or counseling appropriate patients, including the requirements for documentation

1.5.1 Requirements to counsel or to make an offer to counsel

1.5.2 Required documentation necessary for counseling MPJE

1.6 Requirements for the distribution and/or dispensing of non-prescription pharmaceutical products, including controlled substances

1.6.1 Requirements for the labeling of non-prescription pharmaceutical products and devices

1.6.2 Requirements for the packaging and repackaging of non-prescription pharmaceutical products and devices

1.6.3 Requirements for the distribution and/or dispensing of poisons, restricted, non-prescription pharmaceutical products, and other restricted materials or devices

• *Pseudoephedrine, dextromethorphan, emergency contraception, and behind the counter products as appropriate*

1.7 Procedures for keeping records of information related to pharmacy practice, pharmaceutical products and patients, including requirements for protecting patient confidentiality

1.7.1 Requirements pertaining to controlled substance inventories

1.7.2 Content, maintenance, storage, and reporting requirements for records required in the operation of a pharmacy

•*Prescription filing systems, computer systems and backups, and prescription monitoring programs*

1.7.3 Requirements for protecting patient confidentiality and confidential health records

• *HIPAA requirements and conditions for access and use of information*

1.8 Requirements for handling hazardous materials such as described in USP <800>

1.8.1 Requirements for appropriate disposal of hazardous materials

1.8.2 Requirements for training regarding hazardous materials

• *Reverse distributors, quarantine procedures, comprehensive safety programs, Material Safety Data Sheets*

1.8.3 Environmental controls addressing the proper storage, handling, and disposal of hazardous materials

• *Ventilation controls, personal protective equipment, work practices, and reporting*

1.8.4 Methods for the compounding, dispensing and administration of hazardous materials

• *All hazardous materials including sterile and non-sterile compounding*

Area 2 – Licensure, Registration, Certification, and Operational Requirements (15%) 18 total, 15 scored

2.1 Qualifications, application procedure, necessary examinations, and internship for licensure, registration, or certification of individuals engaged in the storage, distribution, and/or dispensing of pharmaceutical products (prescription and non-prescription)

2.1.1 Requirements for special or restricted licenses, registration, authorization, or certificates

• *Pharmacists, pharmacist preceptors, pharmacy interns, pharmacy technicians, controlled substance registrants, and under specialty pharmacist licenses (Nuclear, Consultant etc.)*

2.1.2 Standards of practice related to the practice of pharmacy

• *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*

2.1.3 Requirements for classifications and processes of disciplinary actions that may be taken against a registered, licensed, certified, or permitted individual

2.1.4 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

• *Impairment caused by the use of alcohol, drugs, chemicals, or other materials, or mental, physical, or psychological conditions*

2.2 Requirements and application procedure for the registration, licensure, certification, or permitting of a practice setting or business entity

2.2.1 Requirements for registration, license, certification, or permitting of a practice setting

• In-state pharmacies, out-of-state pharmacies, specialty pharmacies, controlled substance registrants, wholesalers, distributors, manufacturers/repackagers, computer services providers, and internet pharmacies

2.2.2 Requirements for an inspection of a licensed, registered, certified, or permitted practice setting

2.2.3 Requirements for the renewal or reinstatement of a license, registration, certificate, or permit of a practice setting MPJE

2.2.4 Classifications and processes of disciplinary actions that may be taken against a registered, licensed, certified, or permitted practice setting

2.3 Operational requirements for a registered, licensed, certified, or permitted practice setting

2.3.1 Requirements for the operation of a pharmacy or practice setting that is not directly related to the dispensing of pharmaceutical products

•Issues related to space, equipment, advertising and signage, security (including temporary absences of the pharmacist), policies and procedures, libraries and references (including veterinary), and the display of licenses

2.3.2 Requirements for the possession, storage, and handling of pharmaceutical products, preparations, bulk drug substances/excipients, and devices, including controlled substances

•Investigational new drugs, repackaged or resold drugs, sample pharmaceuticals, recalls, and outdated pharmaceutical products

2.3.3 Requirements for delivery of pharmaceutical products, preparations, bulk drug substances/excipients, and devices, including controlled substances

• 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, script centers, use of vacuum tubes, and use of drive-up windows

Area 3 – General Regulatory Processes (2%) 3 total, 2 scored

3.1 Application of regulations

3.1.1 Laws and rules that regulate or affect the manufacture, storage, distribution, and dispensing of pharmaceutical products, preparations, bulk drug substances/excipients, and devices, (prescription and non-prescription), including controlled substances

• 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, NDC numbers, and schedules of controlled substances

Test Scores – Nova Southeastern University

Passing Rates= All Attempts (first time attempts)
2016 = 77% (75%)
2015 = 93% (94%)
2014 = 93% (92%)
2013 = 98%
2012 = 98%

Exam Resources

- Florida Pharmacy Act - FL Statute 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 (~30%) involve controlled substance law. Study this manual comprehensively. Know this.
- Florida Comprehensive Drug Abuse Prevention and Control Act (FL Controlled Substance Act) FL Statute 893
  - 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 (adulteration, misbranding etc)
  - FL Statutes 120 Florida's Administrative Procedures Act
    - 120 Not relevant for testing purposes

- PreMPJE http://www.prempje.com/

- Exam Study Guides (based on Poor/Fair/Good/Excellent rating scale)
  - MPJE Florida / Help Pass Pharmacy Law by Stephen Strauss
    - Good resource, priced at $161.65
  - Florida Pharmacy Law Test by pharmacyexam.com
    - 150 question compact disc (CD) with detailed answers.
    - Good resource, priced at $50.00
  - Guide to Federal Pharmacy Law by Barry S Reiss and Gary D. Hall (7th Edition)
    - Looking at 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

        - Fair-Good resource Priced at $99.95
        - Comprehensive inclusion of relevant statutes; excessive information not adequately distilled
        - Number of test questions available
    - 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 (Most Important Section In this Packet)

- **Focus your study time on State materials and controlled substances**
    - **Study One week, intensely**
- Remember this is a FL exam. Always rely on FL Law.
- Read the MPJE competencies every day of your studying
- Know brand and generics and schedule of controlled substances
- Know labeling and prescription requirements
- Consider every word in the question
- Look for unusual facts as triggers
- Know the law and THEN use common sense to answer the question. (Use Common Sense)
- If you don't KNOW the answer then think Policy – what would a smart law be to help provide information and access to patients while providing them the necessary safeguards (Think Policy)
- Do not get distracted with practice or insurance. This is a law test. Answer based on law, not what you see or are told (Law Test, Not Insurance Contract)
- Do not memorize statute and regulation numbers (ie 64B16 - 28.100), fees, or specific disciplinary measures
- Do not memorize legislation years or names (FDCA 1938), understand only what they mean to practice
- Get a good night sleep the night before
- Arrive at least 30 min early.
- **Be confident! This is a test of confidence! Chose the "smartest" answer confidently and then move on.**

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 are all illegal

1938 Federal Food Drug and Cosmetic Act

- No adulterated or misbranded drugs in interstate commerce
    - Adulteration – (may be)gross/filthly/putrid, no follow-cGMP
        - Think inside the pill
    - 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
        - Currently require information on "Pregnancy", "Lactation", and "Females and Males of Reproductive Potential"
            - *Note Pregnancy Ratings no longer in use (ie ABCDX)*
    - 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
    - 505(b)(2) Paper NDA may be used where there is *extensive* data to support a use. No clinical data is required.
- 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 fails to comply wuith 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

    - **All drugs** to be dispensed/sold in child-proof resistant containers with **exceptions**:
        - PANS-E/Pains-E "don't be a Pans-E, use child proof containers" **except**:
            - Provera, Prednisone / Amorphous cholestyramine/ isosorbide diNitrate/sublingual nitroglycerine, sexy birth controls/ Erythromycin, Effervescent aspirin, Effervescent acetaminophen
- Patient may make blanket request for non-child resistant containers (oral request okay)
- Physician may request individual prescriptions be dispensed in non-child resistant containers
    - Cannot make blanket requests for all prescriptions for a patient
- Pharmacist can't unilaterally decide to dispense prescriptions in non-child resistant container
- Enforced by the Consumer Product Safety Commission (CPSC)
- Use of reversible caps is acceptable
- Cannot reuse plastic containers (glass is okay, must use new tops each fill)
- 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-if breached provides evidence of tampering
    - Label must indicate tamper-resistant features
    - Exceptions include dermatologicals, dentifrice, insulin, and lozenge products

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 cannot be substituted

1986 National Childhood Vaccine Injury Act

- Many reports involving vaccines must be reported using VAERS form. (any conditions on the Reportable Events Table, those listed in the manufacturer's package insert, and clinically significant or unexpected events). Pharmacists in FL can vaccinate selectively

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
        - FDA inspectors exercise enforcement discretion for personal use
            - the product must be for personal use (a 90-day supply or less, and not for resale);

    - intended for a serious condition for which effective treatment may not be available domestically
    - no commercialization or promotion to U.S. residents
    - drug poses no unreasonable risk; and
    - patient affirms in writing it is for the patient's own use and provides doctor's contact information
    - FDA will not routinely search personal baggage
- Importation of Active Pharmaceutical Ingredients (bulk substances) legal only if:
    - Intended for compounding and meets the requirements of 503A FDCA or
    - Has an approved drug application (NDA/ANDA/NADA/ANADA/IND) or
    - Used in an approved OTC monograph drug
- 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 for reimbursement

1992 Prescription Drug User Fee Act

- Manufacturers must pay a user fee along with each drug that is marketed, facility that manufacturers drugs, and each application for approval (reauthorized every five years)
    - 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 amount "minimally necessary"
- Pharmacy employees may not use or disclose health information except for treatment, payment, regular health care operations
    - May provide to patients upon request (verbal okay)
- 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
    - 100 patient limit per physician year one (275 patients thereafter)
- Authorized physician unique provider number staring with X
- Treatment requires completion of a number of FDA Forms (patient consent, responsibility statement, application for approval of use)

Methadone is used for pain and opioid addiction

        - Pain use is treated like any CII narcotic.
        - Methadone 40 mg tabs/disks indicated for addiction only. Not approved for pain
    - If used for opioid addiction, patient MUST be used as part of DEA registered program (DEA Form 363)
        - Three day exception rule - methadone may be administered to addict by physician while making arrangements. Also may be ordered in a hospital incidental to surgery or acute medical care outside of program

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 (+ 2008 Methamphetamine Production Prevention Act)

- Restricts pharmacy sales of pseudoephedrine (PSE)
    - 3.6 grams per person per day (#146, pseudoephdrine HCl 30 mg)
    - 9 grams of PSE per person per 30 day period (#366, pseudoephdrine HCl 30 mg)
    - Mail order 7.5 grams of PSE per person 30 day period (#305, pseudoephdrine HCl 30 mg)
    - See http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/appendix/appdx_g.htm for quantity limits
- 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, or secured in pharmacy
- All purchasers must furnish picture ID (see exception immediately below)
- Retailers must maintain logbook of transactions at least two years
    - Products packaged for individual sale that contain less than 60 mg of pseudoephedrine are exempt from the logbook and ID requirements – ie Travel Size
- All pharmacy personnel selling PSE must have training and self-certification
- **In FL, Must be at least 18 years of age to buy PSE, must show ID, and sign log**
- In FL, Must be 18 years of age to purchase **Dextromethorphan** – still available OTC, no quantity limits

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 survey's not sufficient to fill a prescription
- Online pharmacies must obtain modified DEA registration, have special website disclosure (statement of compliance) and DEA (monthly) reporting (if surpass threshold) requirements
    - Statement of Compliance: *In accordance with the Controlled Substances Act and the DEA regulations, this online pharmacy has made the notifications to the DEA Administrator required by 21 U.S.C. § 831 and 21 C.F.R. § 1304.40."*

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);

2012 Generic Drug User Fee Act (GDUFA) – charges Fees for Generic Drug manufacturers for ANDA and to market generally

2012 Food and Drug Administration Safety and Innovation Act (FDASIA)

- Improves FDA's inspection authority and the drug supply by expediting inspections
- Creates incentives to encourage the development of products for antibiotic-resistant infections
- Expands the scope of products that qualify for accelerated approval, creates a new "breakthrough therapy" program - drugs that treats a serious or life-threatening condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement on a clinically significant endpoint(s) over available therapies gives Fast Track review benefits
- Legislatively address the current drug shortage problem by broadening the scope of the early notification requirement, manufacturers are required to report discontinuances to FDA regardless of cause, mandates reporting of shortages of biological products, and requires FDA to issue a non-compliance letter to manufacturers who fail to comply with the drug shortage notification

2013 Drug Quality and Security Act / 2014 Compounding Quality Act (**503B**)

- Permits registration of large-scale compounding pharmacies, called "Outsourcing Facility"
    - Must be under the direct supervision of a pharmacist; must meet cGMPS
    - Does not have to be registered with a state as a licensed pharmacy
- Products must be labeled "compounded drug" and "not for resale"
    - Must include Name, Address, and Phone # of outsourcing facility
    - Must report products compounded to FDA
- Facility must report adverse events
- Open to FDA Inspection

2013 Drug Supply Chain Security Act

- Dispensers must:
    - confirm that trading partners (manufacturers, repackagers, wholesale distributors, dispensers, and third-party logistics providers) are authorized under federal law
    - maintain lot-level product tracing information—namely, transaction information, history, and statements—for 6 years
    - establish systems for verification and handling of suspect or illegitimate products

2016 Comprehensive Addition and Recovery Act (CARA)

- nurse practitioners and physician's assistants to administer, prescribe, and dispense narcotics in office-based opioid treatment programs
    - increases the patient limit for office-based treatment from 30 to 100 (first year) and 275 thereafter

- Expand the availability of naloxone to law enforcement agencies and other first responders

Social Security Act

- Skilled nursing facilities must provide “pharmaceutical services” including procedures that assure the accurate acquiring, receiving, dispensing, and administering of all drugs and biologicals to meet the needs of each resident
    - must be provided in a timely manner that avoids discomfort or endangers the patients health and safety
- Facilities must employ or obtain the services of a licensed pharmacist who - Provides consultation on all aspects of the provision of pharmacy services in the facility
- Must have policies on drug related issues
- A licensed pharmacist must review each resident’s medication regimen at least once a month

Case Law

- Plan B OTC (Tummino v. Hamburg/FDA 2013)
    - Plan B now available OTC without any-point of sale or age restrictions. Sell like any OTC
    - Note FL has no law that requires pharmacists to dispense contraception or any other drug against their religious/moral opposition.
- Overtime Pay not Required (De Jesus-Rentas v. Baxter Pharmacy, 2005)
    - Pharmacists are considered professionals, not entitled to overtime pay under the FLSA

Federal 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 Phenlalanine ___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
- Phytondione (Vitamin K) oral and injectable are prescription-only.
- Epinephrine injection requires prescription/ Inhaler OTC (being phased out CFC)
- Isotretinoin - iPledge program utilized, required registration for wholesalers, prescribers, pharmacies dispensing and *all male and female* patients, 30 day supply only, females must use two methods of birth control, one month prior to one month after therapy, two negative pregnancy tests prior to initiation of therapy
- Thalidomide – STEPS program developed to minimize fetal exposure of drug, restricted distribution, restrictions involve *men and women*, prescribers must be in program as well

Definitions

Misbranding (FL 499.007)

- 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
- Lacking precautionary statement for drugs subject to deterioration

Adulteration (FL 499.006)

- 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

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

Section 3
Federal Controlled Substance Law

Federal Controlled Substances Act

- Five schedules of drugs based on medical use, potential for abuse and dependence
- CI
    - High potential for abuse, have no currently accepted medical use in treatment in the United States, and there is a lack of accepted safety for use of the drug or other substance under medical supervision.
    - May not be prescribed, administered, or dispensed for medical use.
        - May order/use for research and investigational use
    - Order using DEA 222 / CSOS
- 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 day limit max in total.
    - Oral Rx not permitted
        - Exceptions 1) emergency (immediate administration of the drug is necessary for proper treatment of patient, no alternative treatment is available, and it's not possible for the prescriber to provide a written Rx, 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)
            - Central fill not permitted for emergency situations
    - Facsimile Rx not permitted
        - Exceptions 1) Home infusion/IV if narcotic compounded for pain 2) Residents of LTCF 3) State licensed Hospice Facility
    - Partial fill allowed within 72 hours. 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 (eg Drug, Patient, Signature)
  - May change address, quantity, strength, directions with authorization, always use proper judgment
  - Note the DEA has issued conflicting guidance as to what constitutes "Essential Element"
- 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.
  - Form 222 can also be used by pharmacy to ship drug to Reverse Distributor (pharmacy acting as supplier, maintains Copy 1) who disposes of drug using Form 41

- CIII-CIV
  - Five refills in six months from date written
  - 1 transfer permitted
    - If sharing a common (chain) database may transfer as many times as needed
  - In FL, Pharmacist and Interns can transfer controlled substance prescriptions
  - Prescriptions may be written, verbal, or electronic
  - Partial fills permitted. Any amount may be filled as long as total quantity or six month duration is not violated. Note: Partial Fills are not considered Refills!
  - Pharmacist may make any changes with consultation from prescriber
  - No special order form, although orders must be kept readily retrievable
- CV
  - No limit on refills (Florida 6 month expiration)
  - 1 transfer permitted
    - If sharing a common (chain) database may transfer as many times as needed
  - Most are available without prescription and indicated as cough or antidiarrheal
  - Lyrica (pregabalin) requires prescription
  - cough preparations with less than 200 milligrams of codeine or per 100 milliliters (Robitussin AC), Lomotil, Motofen, Lyrica, Parepectolin
  - Dispensing non-prescription drug must be done by PHARMACIST
    - 8 oz max opium containing product / 4 oz codeine per **48 hours**
    - Purchaser must be 18 years old; furnish ID if not known, document transaction in bound record-book
      - Include name and address of the purchaser, the name and quantity of controlled substance purchased, the date of each purchase, and the name or initials of the pharmacist who dispensed the drug
    - Central fill pharmacies may not dispense CV's at the retail level to a purchaser
  - Prescriptions may be written, verbal, or electronic
  - Partial fills permitted. Any amount may be filled as long as total quantity or six month duration is not violated. Note: Partial Fills are not considered Refills!
  - Pharmacist may make any changes with consultation from prescriber
  - No special order form, although orders must be kept readily retrievable
- SLCPS – Schedule listed Chemical products: used in manufacture of Meth
  - Ephedrine, pseudoephedrine, phenlypropanolamine
    - 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
  - Ephedrine, Pseudoephedrine, Ergonovine, Iodine, Sasfrole, Piperidine
- List 2 Chemicals - solvents used in the manufacture of a controlled substance
  - Acetone, HCl, K/NA-Permanganate
- Electronic prescribing of Controlled Substances permitted; including CII
  - Pharmacy system must be suited
  - Prescriber system must be suited using double security measures
- Inventory requirements: see table
  - CII – exact
  - CIII-CV – estimated unless container holds more than 1000 units which requires an exact count
- Prescriptions may be <u>filed</u> 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 <u>stored</u> 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 requirement for CII's to be locked up; they can be dispersed among inventory. Goal is to make it difficult to steal all at once!
- Prescription Requirements: Default to FL law (11/15 points)
- Label Requirements: Default to FL law (9/11 points)
  - Hospitals do not need to follow label requirements as these are orders not prescriptions
- Filled prescriptions for controlled substances are permitted to be mailed via common carrier (UPS/FedEx, USPS)
  - Package should be unmarked regarding contents
  - Pharmacist cannot mail Controlled Substances prescriptions out of the United States. This is considered illegal Export.
- Theft or <u>significant</u> loss
  - Notify DEA and local police
  - Complete DEA Form 106
- Pharmacy may use reverse distributor to dispose controlled substances
  - For schedule II controlled substances, the reverse distributor must issue an official order form (DEA Form 222) or the electronic equivalent to the pharmacy.
  - For schedules III-V controlled substances pharmacy must maintain a record of distribution that lists the drug name, dosage form, strength, quantity, and date transferred.
  - The DEA registered reverse distributor who will destroy the controlled substances is responsible for submitting a DEA Form 41 (Registrants Inventory of Drugs Surrendered) to the DEA when the controlled substances have been destroyed. A DEA Form 41 should not be used to record the transfer of controlled substances between the pharmacy and the reverse distributor disposing of the drugs.
- Breakage, damage, spillage of **<u>recoverable</u>** or **destruction** of controlled substances must be reported to DEA on a DEA Form 41 (Registrants Inventory of Drugs Surrendered).

- Drug may also be disposed of through shipment to a reverse distributor
- Any drug spilled/broken/damaged **non-recoverable**, pharmacist must document the circumstances of the breakage in their inventory records. Two individuals who witnessed the breakage must sign the inventory records, indicating what they witnessed.

- States determine who is entitled to prescribe controlled substances
  - In FL, midlevel practitioners are newly authorized to prescribe controlled substances (PA and ARNP)
  - Optometrists can prescribe Tylenol with Codeine #3 only
  - Require DEA and state registration
  - Cannot delegate authority to another, although an agent can phone in prescription at request of registrant (ie receptionist) including emergency prescriptions of CII
- 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 Service 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 and counseling
  - Both pharmacies must be registered with DEA and store records for FOUR years from date of last fill.
  - May NOT fill prescriptions Schedule II in EMERGENCY SITUATIONS; use local pharmacy only [21CFR1306.11]
- DEA Registered Pharmacy may keep an Emergency Kit, containing controlled substances in a LTCF that is not registered with the DEA.
  - Security safeguards must be in place
  - Must maintain inventory and records

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 from registrant (wide leeway in who/how many are granted power of attorneys)

Calculating DEA Number- e.g. BS1212125 (Be prepared to do this on exam)

- ✓ A valid DEA number consists of 2 letters, 6 digits, and 1 check digit.
- ✓ The first letter is a code identifying the type of registrant (currently in use: **A/B/F/G/M)**
  - M for midlevel practitioner only
- ✓ The second letter is the first letter of the registrant's last name.

  Step 1: add the first, third, and fifth digits of the DEA number (1+1+1)

  Step 2: add the second, fourth, and sixth digits of the DEA number (2+2+2)

Step 3: multiply the result of Step 2 by two (6 x 2)
Step 4: add the result of Step 1 to the result of Step 3 (3+12)
Then, the last digit of this sum must be the same as the last digit of the DEA number.

	CII	CIII-CV
Refills	No refills allowed	5 within 6 months from date written (CV-unlimited refills)
Transfer of prescription between pharmacies	No transfers permitted	1 allowed (may transfer additional times to the maximum if within same common database)
Transfer of bulk drugs between registrants (ie pharmacies)	Requires 222	Requires complete invoice
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 (see exception) • Narcotic compounded for direct administration to patient • LTCF/Hospice Patients	Facsimile acceptable under Federal Law – check State Law (**Florida no permit**)
Electronic Rx Allowed	Yes, if meet applicable security requirements	Yes, if meet applicable security requirements
Partial Fills allowed	Yes: (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. Drug name, strength, dosage form, number of units in each 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, Standard Invoice okay
	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
Any pharmacy that transfers more than five percent of its inventory must register as distributor (*Five Percent Rule*)		

DEA Form	Intent	Additional
41	Document disposal and destruction of scheduled drugs	Not used for breakage or spillage if drug is non-recoverable
106	Unusual or excessive loss, disappearance, or theft	What constitutes unusual or excessive loss is 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 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, heroin, LSD, Peyote, Salvia, *Peyote (allowed in Native American Church ceremony)*
Schedule 2	Dilaudid, Demerol, Oxycontin, Sublimaze, Dexedrine, Ritalin, **Vicodin** (hydrocodone with APA), Pentobarbital, MS Contin, Codeine straight, Amphetanine, Tylox, Codeine, Hydrocodone straight, *Cocaine, PCP*
Schedule 3	Buprenorphine, Anabolic Steroids – Oxandrin, Testosterone, ketamine, Didrex, Suboxone, **Tylenol w/ Codeine**, Fiorinal, ***(Fioricet is non-controlled, but scheduled III in Florida)***
Rule of three	*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, **Tramadol**
Schedule 5	Lyrica (requires Rx), Robitussin AC, Phenergan with Codeine
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
Florida State Pharmacy Laws

Permits Types

Community pharmacy (Independent/Chain)

- Pharmacy where medicinal drugs are compounded, dispensed, stored, sold, filled or dispensed on an outpatient basis.
- Typical independent or chain drug store
  - Each store must have its own permit
- Must have a prescription drug manager of record named
  - May only be manager of one pharmacy at a time (exceptions may be granted)
  - Must notify state within 10 days of relinquishing responsibility
- 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 do limited sterile compounding if properly equipped and is inspected by Board

Class I Institutional Pharmacy (Nursing Home)

- "A pharmacy in which all medicinal drugs are administered from individual prescription containers to the individual patient and in which medicinal drugs are not dispensed on the premises"
- Typical nursing home
- Does not have a pharmacy on premises: no dispensing on premises permitted
- Drugs must be securely stored available only to appropriate licensed staff
- 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
- May contract with a pharmacy to provide "starter doses" until the other contracted pharmacy can dispense/deliver the meds.
- May have an emergency medication kit for residents
  - Drugs selection determined by Medical Director, Director of Nursing and Pharmacist. Must have written policies and procedures for use. Kit must be sealed and all contents labeled. If seal is broken must reseal by next business day. Inventory log must be atttached to kit.
  - Doctors prescribe emergency medicine which is administered by nurse/physician. Pharmacy (Consultant) oversees recordkeeping and inventory, ensures valid prescription subsequentyly written and restocks inventory.
    - Facility may have controls but does not have to be DEA-registered
  - ICD/FF Intermediate Care Facility for Developmentally Disabled

        - Up to five controlled drugs may be included (with up to three doses of each for 60 beds or less (and an additional three doses for each 60 beds subsequent)
        - Nurse or pharmacist may inventory, replace, and reseal

Class II Institutional Pharmacy (Hospital)

- "A pharmacy that employs the services of a registered pharmacist or pharmacists who, in practicing institutional pharmacy, provide dispensing and consulting services on the premises to patients of that institution, for use on the premises of that institution"
- 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 no present and on duty
        - Must lock the pharmacy to prevent access from non-pharmacists
- Must have consultant pharmacist of record named
- ER Prescribers may dispense drugs for outpatient use.
    - Smallest duration necessary or 24 hrs.
    - Only if drug is warranted and community pharmacy services are not available
    - Records must be made by prescriber and maintained by Consultant Pharmacist
    - Drug must be properly labeled
        - Controlled Substances okay to dispense
- May apply for a Special Pharmacy – Limited Community license to dispense remaining multi-dose medications used in the hospital (topical, creams, insulin, eye drops, etc) at discharge *(saves the patients money re-ordering these medications)*
- Cancer Drug Donation Program (499.029 for more information) Hospital pharmacy may accept donated cancer drugs and supplies from eligible donors, inspects the donated cancer drugs and supplies for authenticity and dispenses the cancer drugs and supplies to eligible patients.
    - Hospital must complete and submit a Notice of Participation form
    - May charge the recipient of the drug or supply a handling fee of no more than 300 percent of the Medicaid dispensing fee or no more than $15, whichever is less for each cancer drug or supply dispensed
    - Drugs must remain in their original sealed container or in a tamper-evident unit-dose packaging. Never in actual possession of patient
    - May not be accepted or dispensed if there is less than six months remaining until the expiration date.
    - Controlled substances are not eligible for donation.
    - Eligible patients uninsured and do not qualify for third-party insurance coverage, Medicaid, or any other state or federal assistance programs

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

- Pharmacy services provided to employees and dependents for personal use, patients of a hospital (Institutional Class II permit) under a continuation of a course of therapy, Patients in the emergency room
- Hospital pharmacy practicing under a continuation of a course of therapy using multi-dose medicinal drugs (see above section on Class II Pharmacies)

Special-Parenteral and Enteral

- provides parenteral (IV), enteral, and cytotoxic pharmacy services to outpatients

Special-Parenteral/Enteral Extended Scope

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

Special-Closed System Pharmacy

- Not open to the public.
- Prescriptions are individually prepared for dispensing utilizing closed delivery systems to facilities where prescriptions are individually prepared for the ultimate consumer, including nursing homes, jails, Assisted Living Facilities (ALF's), Intermediate Care Facility/Mentally Retarded (ICF-MR's) or other custodial care facilities
- May share location with an establishment that hold community permit

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-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
    - Subject to FL State BOP inspection

Special Sterile Compounding Permit (SSCP)

- special permit, which is required before any permitted pharmacy may engage in the preparation of compounding sterile products.
- not required for 1) Stand-alone Special Parenteral/Enteral pharmacies; 2) Special Parenteral/Enteral Extended Scope pharmacies; 3) pharmacies that only perform non-sterile compounding; and 4) non-resident pharmacies
- Available also for "Outsourcing Facilities;" update with board if register as Outsourcing Facility
- requires Special Pharmacies to be under the professional supervision of the PDM or Consultant Pharmacist of Record licensed in the State of Florida. A Florida licensed pharmacist shall perform compounding and dispensing of medicinal drugs
- Compounding must be in strict compliance with the State Standards (64B16-27.700 and 27.797) of Good Manufacturing Practices
- If also compound, dispense patient-specific prescriptions, must register as a Hospital (Institutional Class II) or Community Pharmacy as well

Internet Pharmacy Permit

- 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, with a toll-free telephone number that is listed on the label of each prescription bottle filled (doesn't need to be 24/7/365)
- 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 Permit (**Mail Order**)

- 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. Notify Board within 30 days if change name, corporate officer, or PDM pharmacist.
        - If mail only one-time delivery to FL, exempt from registration
            - All Non-Sterile Products shipped to FL must register Nonresident Sterile
    - If also providing sterile products in FL, must ALSO register as nonresident Sterile Compounding Pharmacy (see below)
- Pharmacy must be open, ie accessible at least six days a week and 40 hours a week, with a toll-free telephone number that is listed on the label of each prescription bottle filled (doesn't need to be 24/7/365)
- Requirement of permit is to protect FL patients and ensure nonresident pharmacy is legitimate and competent
- Mail Order Pharmacies out of state must register as non-resident pharmacies.
- Nonresident Sterile Compounding Permit required to ship, mail, deliver, or dispense any sterile products into the state
    - Also applies to FDA Licensed Outsourcing Facility; they must have permit

Nonresident Sterile Compounding Permits

- May ship/compound ONLY FOR PATIENT SPECIFIC PRESCRIPTIONS
    - If non-resident state does not inspect, the non-resident pharmacy may request an inspection from FL BOP or may contract with an approved entity to conduct the inspection, with the cost to the non-resident permitee
    - Must comply with FL and non-resident state sterile compounding requirements

OUTSOURCING PHARMACY- OUT OF STATE Nonresident Sterile Compounding Permits

- Out of state pharmacies (Outsourcing Facilities) may register with the Florida Board of Pharmacy as a non-resident SCP

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 (*surprisingly tested*)
- 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

Animal Shelter Pharmacy (not tested)

- Provides for purchase of sodium pento-barbital and sodium pento-barbital with lidocaine for animal euthanasia

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
    - Renewable every two years
- Community pharmacy permit required in FL, to dispense controlled substances listed in Schedule II or Schedule III [repermitting required in 2012]
- Must be 18 years of age
- Pharmacist / Non-Pharmacist may own/permit a pharmacy
    - No Medicaid or other healthcare fraud or criminal activity
        - Fingerprint, application, and background check
- Inspection must occur before a permit is issued
    - written policies and procedures for preventing controlled substance dispensing based on fraudulent representations or invalid practitioner-patient relationships must be provided
    - Permit must be issued before DEA will register
- 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 permitted
    - No advertise ephedrine (salts/isomers) drugs for stimulation, mental alertness, weight loss, appetite control, energy, non-FDA approved indications
- Check expiration dates every four months (three times a year) 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 four 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)
- Medicaid provider pharmacies required to post two signs, *Important Notice to Medicaid Recipients*, and *Aviso Importante a Recipientes de Medicaid* in a conspicuous location that is visible to recipients. The signs inform recipients of a toll-free number that can be called if the prescription is denied and the pharmacy failed to provide the denial information and an Important Information About Your Florida Medicaid Prescription Drug Benefits
- 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
        - Handwritten Rx-medically necessary handwritten
        - Verbal Rx-expressly indicates medically necessary
        - Electronic Rx-overt act indicates medically necessary
- 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 area
    - Hospitals may also store drugs in areas deemed necessary to treat (Surgical Units/ER)
        - Must be delineated in policies and procedures manual
    - Nursing homes may store secure, available only to appropriate licensed staff
- Destruction of controlled substances require execution of DEA Form 41
    - witnessed and signed by the prescription department manager and Department inspector (no DEA prior approval required) OR two licensed individuals (MD/DO, RN, RPh, Law Enforcement)
        - Form must be mailed to DEA at least two weeks before proposed date and approved by them
    - Also may use DEA registered reverse distributors using form 222/41 respectively

    <u>Nursing homes</u> whereby controlled substances have been dispensed and not used must not be returned to the pharmacy. They must locked and stored by the nursing home until destroyed (64B16-28.303 Destruction of Controlled Substances)
    - Permittee to complete DEA Form 41witnessed and signed by the consultant pharmacist/PDM along with DEA Agent or Inspector
    - May also be destroyed by at least two persons who are either a licensed pharmacist, physician, nurse, or sworn law enforcement officer → Requires DEA Form 41 and letter describing destruction to DEA at least two weeks prior. DEA must grant approval prior to destruction
- Each applicant with a 5% or greater financial interest in the pharmacy seeking a permit must submit a signed affidavit disclosing any 5% or greater interest in any permitted pharmacy in the past 5 years that has closed voluntarily or involuntarily, has voluntarily relinquished its permit, has had its permit suspended or revoked, or has had an injunction issued against it by a regulatory agency.
- Applications must include written policies and procedures for preventing controlled substance dispensing based on fraudulent representations or invalid practitioner-patient relationships.

<u>Miscellaneous Permits Issued in FL [NOT TESTED]</u>

- The following must have a permit to operate in FL:
    (a) A prescription drug manufacturer;
    (b) A prescription drug repackager;
    (c) A nonresident prescription drug manufacturer;
    (d) A prescription drug wholesale distributor;
    (e) An out-of-state prescription drug wholesale distributor;
    (f) A retail pharmacy drug wholesale distributor;
    (g) A restricted prescription drug distributor;
    (h) A complimentary drug distributor;
    (i) A freight forwarder;
    (j) A veterinary prescription drug retail establishment;
    (k) A veterinary prescription drug wholesale distributor;
    (l) A limited prescription drug veterinary wholesale distributor;
    (m) A medical oxygen retail establishment;
    (n) A compressed medical gas wholesale distributor;
    (o) A compressed medical gas manufacturer;
    (p) An over-the-counter drug manufacturer;
    (q) A device manufacturer;
    (r) A cosmetic manufacturer;
    (s) A third party logistics provider; or

(t) A health care clinic establishment.

Pharmacy

- Must be open to inspection (Medicaid/Board of Pharmacy/State Health Department/Insurance companies)
    - May not view patient's prescription records or other confidential data without a warrant
    - May not take any physical materials (evidence) without consent or a subpoena
    - State Pharmacy Inspections twice during the first year of operation
        - Minimum of 1 inspection per year thereafter
        - Passed inspection for three years without discipline inspected every two years
        - If fail inspection or disciplined during previous 2 years inspected annually until passed inspections for most current three years
- Audit Rights (see 465.1885)
    - 7 day advanced calendar notice
        - Not allowed during first three days of the month without Pharmacist's consent
    - Limited to 24 months after claim is submitted
    - Audit that requires professional judgment must be conducted by a pharmacist
    - Audit may be reviewed, corrected by pharmacy
- Regulation of Daily Operating Hours (64B16-28.1081 Regulation of Daily Operating Hours)
    - Pharmacy must be open a minimum 20 hrs a week
        - If not yet open, must tell Board no commencing operation, within 14 days of receiving permit and then tell Board within 2 days of opening. Sign must be hung before opening block letters one inch noting not yet open, no prescriptions filled.
    - Required to have a sign in block letters at least one inch must state hours of operation in unobstructed view, either at front door or by pharmacy providing hours
        - If pharmacy is open less than 40 hours per week must post specific hours of operation, information on afterhours access and have policies for transferring a prescription and emergency refills.
- 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, quarantine area for defective drugs, and anything else typically relied upon for your particular practice. Must be clean and orderly
- 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
- Must place notice in customer area and link on website to AHCA health information
- 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.)
- FL allows compassionate use/ investigational use of a non-approved drug for a patient who has given informed consent and has documentation from the prescribing physician has a terminal illness, that is expected death within 1 year/

Sterile Compounding permitted USP 797 (64B16.27.797)

- This section incorporates USP 797 Guidelines into law (Pharmaceutical Compounding Sterile-Sterile Preparations). Also USP 71 (sterility tests), USP 85 (Bacterial Endotoxins Test) and USP 731 (Loss on Drying) are now FL Law.

- ABC Required: Anteroom (ISO 8 or better [lower]), Buffer Room (ISO 7 or better)/Compounding Room (ISO 5 or better involving uni-directional HEPA-filtered air). Lower the ISO, the more sterile the area.
    - Facilities must be tested twice a year minimum for sterility and air particle count
    - Chemotherapy must be compounded in a dedicated hood in a negative pressure room or biological safety hood. Needleless, splash free devices should be used to minimize exposure of drug molecules to the environment.
    - Ceiling Tiles inlaid with polymer and caulking if not ISO Class 7 or better
- Expiration dates (Beyond Use Dating is the terminology now used that you can't begin infusing anything Beyond the Date of expiration): Low risk compounding (48 hrs room temp, 14 days cold , 45 days frozen). Medium Risk (30 hrs room temp, 9 days cold, 45 days frozen) High risk compounding (24 hrs room temp, 3 days cold , 45 days frozen)
- A site can extend date beyond these standard times if you have your own data to prove your technique is effective for that period of time – cannot use literature to extend date – only your own proof of effectiveness.
    - Low risk- aseptic manipulations entirely within ISO 5 or better hoods; combining 3 or less sterile products into a single bag/vial. Technically, you have 3 entries into the vial or bag – not 3 separate products. So if you need to enter the IV bag twice to place the entire dose of reconstituted drug, then you only have one more entry before you move to medium risk
    - Medium risk – combining more than three (3) commercial sterile drug products and those requiring complex manipulations and/or preparation methods. Must use ISO 5 or less - same technicality – it really is 3 entries into the IV container, not 3 separate drug products
    - High risk- non-sterile ingredients, lack effective antimicrobial preservatives, sterile surfaces. Must use ISO 5 or less
    - Immediate use in emergency (ie Code) discard in 1 hour if administration has not begun (good for 24 hours once hung)
- 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.
    - All compounding personnel are required to demonstrate competency by completing a media-filled test that represents low-level compounding annually the testing becomes more demanding if a pharmacist or technician is going to prepare high risk products – more frequent tests (I think twice a year), different tests (sterilizing a non-sterile product) for high risk
    - Employee or student cannot work in IV room until they have passed all of their tests, including the media-filled test which takes 2 weeks
    - Must complete aseptic hand-washing and wear (don) appropriate garb
        - Must remove personal outer garments, cosmetics, jewelry, piercings, and artificial nails before entering buffer area
        - In order: shoe covers/head and facial hair covers/face masks/hand wash/gown and sleeve/antispectic hand wash/sterile powder-free gloves. Must use sterile isopropyl alcohol
    - 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.
    - All compounding personnel are required to demonstrate competency by completing a media-filled test that represents low-level compounding annually
    - Must complete aseptic hand-washing and wear (don) appropriate garb

- Must remove personal outer garments, cosmetics, jewelry, piercings, and artificial nails before entering buffer area

Chemotherapy compounding requires vertical laminar hood with negative pressure and adequate protections including splash free devices

- Central Fill Pharmacies are permitted in FL (64B16-28.450)
  - Patient drops off prescription at local pharmacy who then transmits to Central Fill Pharmacy (fax/electronic transmission). This central fill pharmacy then fills the prescription and mails to local pharmacy who then dispenses to patient.
  - Central fill pharmacies may fill prescriptions for controlled substances on behalf of retail pharmacies with which they have a contractual agreement (no emergency CII)
  - 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 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.
  - IF ONLY process drugs for other pharmacies and do not compound, dispense, store or sell drugs, THEN do not require sink, running water, refrigeration, patient consultation area, signs, and daily operating hours
- 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
  - Close-out inventory, including controlled-substances
  - Permit NOT transferable
    - Change of ownership of business entity (corporation, etc) does not necessitate new permit unless identity of business entity changes
- 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 HIPPAA 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
- Only Pharmacy may sell poisons (see 859.04 for list)
  - Must be labeled with pharmacy name and address and the word "Poison"
    - Must make seller aware of poisonous characteristics and ensure legitimate use if unusual quantity

- Sale of syringes in FL is based on city/county ordinances which vary from requiring Rx to OTC. However, must never sell syringes to a minor without a prescription under FL law.

Pharmacy and Recordkeeping (64B16-28.140)

- Prescriptions must be stored for at least four years
    - May use an electronic imaging recordkeeping system is able to capture both sides of a prescription
- Pharmacy must record each prescription filled in a data processing unit
    - Maintain record for at least four years
    - Have capacity to produce a daily hard-copy printout within 72 hours.
    - Each individual pharmacist who dispenses or refills drugs 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
    - Each pharmacy must 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 four years
        - Must date and sign in the same manner as signing a check or legal document
- 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 four 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 Four years
- Pharmacy must maintain a back-up recordkeeping system
    - Back-up system on 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.
- **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
- The prescription department manager and the permit holder are responsible for the proper maintenance of such records and responsible that such data processing system can produce the records outlined in this section and that such system is in compliance with this subsection
- Medicaid / Medicare recordkeeping 10 years

Controlled Substance Recordkeeping (Florida law now requires records maintained for 4 years)

- 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 four years

- Summary Record of previous 60 days of controlled substance dispensing shall be available within 72 hours of request by any authorized law enforcement official (volume, identity, prescriber, and patient name)

Dispensing Controlled Substances in FL for Pain (64B16-27.831)

- If there are any concerns about the use/abuse/legitimacy of a controlled substance prescription, the pharmacist SHALL:
    - Verify Rx with prescriber. If not able to verify and believes Rx to be valid should dispense 72 hr supply
    - Require Picture ID and make copy or document ID. If no ID still must confirm identity
    - * note should always obtain ID when dispensing prescriptions for controlled substances in FL if patient is not known*

Dispensing Practitioners

- In FL, physicians and other prescribers may register as dispensing practitioners, allowing them to dispense drugs on premises similar to a veterinarian.
- May not dispense CII or CIII drugs (may dispense CIV's and CV's)
    - May dispense associated with surgical procedure, 'approved' clinical trial, methadone per 3 day rule
- Must comply with same pharmacy rules, including open to inspection
- Must allow patients options to fill elsewhere
- Use of drug samples is not included in this section and does NOT require registration as dispensing practitioner

Pedigree Papers

- Each drug wholesaler of prescription drugs must provide a pedigree paper to the person who receives the drug
    - Pharmacy and Wholesaler maintain copies
        - Often wholesaler maintains pharmacy's copies as well – which is fine
    - No pedigree papers for veterinary drugs and drop shipments

FL Medical Marijuana – Low THC Cannabis permitted for Compassionate Use – not tested

AKA Charlottes Web law. Named after young girl with Refractory Seizures

- >10% CBD, ≤0.8% THC permitted for patients in state registry
- Physician orders (not prescribes); must maintain treatment plan. Patient must be State Resident.
- Pharmacists NOT involved in dispensing/selling/growing

FL Medical Marijuana – Constitutional Amendment (passed Nov 2016) – not tested

- Titled: Use of Marijuana for Debilitating Medical Conditions

Pharmacist Responsibilities [Major concept on exam is differentiating responsibilities between pharmacist/interns and technicians]

- Must be licensed
    - 18 years of age, pass NAPLEX and MPJE, meet internship requirements
    - License renewal every two years
        - If licensed in FL for 50 years or more, lifetime license issued, no fee required
- Must be fit and competent to practice
    - Cannot be intoxicated or have any physical or mental impairment which threatens safety of patients
- Must report any fraudulent prescriptions to law enforcement. Must also report any significant loss of controlled substances to local law enforcement within 24 hrs
- 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
    - Must 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 immediate 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.
        - May monitor use technology to assist
- 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 "within a reasonable time"
    - One vial of insulin okay, in lieu of 30d supply
    - Pharmacy interns or technicians cannot be delegated authority to prescribe
    - State of Emergency by Executive Order of Florida Governor (ie Hurricane) pharmacist may dispense 30 day emergency prescription refill supply
- 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, shingles pneumococcal and ***all vaccinations listed by the CDC schedule including international travel vaccines*** with proper credentialing including Meningococcal B
    - **Under protocol with physician only** (conditions, categories, terms, scope, etc)
    - Interns can also also immunize 1:1 supervision of a pharmacist
    - Complete board approved/certified 20 hrs minimum education including CPR training, epinephrine, reimbursement procedures, reporting to VAERS
        - Pharmacist may administer epinephrine if necessary per protocol
        - 3 hr CE course biannually
    - Maintain $200,000 of professional liability insurance
    - Maintain record for **5 years**
    - *Other immunizations may be authorized under Florida State of Emergency (ie hurricane, epidemic)*
- May dispense **epinephrine** auto-injectors to authorized entity (restaurant, camp, theme parks, sports arenas)
- May dispense **naloxone auto inject** or intranasal under "Standing Order" similar to vaccinations. Must have prescriber protocol
- May enter into Collaborative Practice Agreements with a prescriber (ie change dose in Coumadin clinic, initiate therapy in a diabetes clinic)
- Fill out of state/ out of jurisdiction (country) prescriptions only if 1) valid order 2) licensed prescriber in that state/jurisdiction and 3) for chronic or recurrent condition only.
    - Acute diseases should be attended to in the state or country that it arises in

- Must comply with Standards of Practice for Filling Controlled Substances (see 64B16-27.831), that is to use sound professional judgment
    - Goal is for the pharmacist to dispense valid prescriptions. Habit of failing to fill valid prescriptions out of fear is a violation of the rules
    - There must exist a valid doctor patient relationship and a legitimate medical purpose
    - 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
    - May reject the filling of a controlled substance prescription only after pharmacist:
        - First tries and communicate and rectify the concern with the patient and the prescriber's office OR
        - Checks the PDMP Database (e-Forsce)
    - Must report to Department of Health if suspect physician is involved with illegal diversion
    - Communication between pharmacist and patient should not be overheard by others
- Must report to State Department of Health any concerns that a prescriber is involved in diversion
- Must report any fraudulent attempts to obtain scheduled drugs within one business day or first degree misdemeanor
- Ensure patient-physician relationship still exists and prescription is valid
    - If a <u>physician dies</u> after the original prescription is written and refills remain, they should be viewed as valid refills and refilled accordingly
- Consultant pharmacist or PharmD with required coursework may order lab tests
    - Consultant must receive 3 hours of continuing education relating to laboratory and clinical testing as established by the Board
- <u>Prescription Department Manager</u> is responsible for Number of locations – limits, CQI Programs, Recordkeeping, Automation (QA/Security/Recordkeeping), Closing, Inspection, Compliance with the full law. Named on permit application, and fingerprinted. Notify board within 10 days if changed.
    - Rule: can only be PDM for one location only, unless otherwise approved by Board (if show close proximity and limited workload)
- Duty to Notify Patients in person about adverse incidents that result in SERIOUS HARM to the patient. Does not constitute an admission or acknowledgment of guilt (456.0575)
- Must comply with USP<800> when handling hazardous materials (NOT implemented under July 1st 2018)
    - Establishes standards for handling hazardous drugs (HD) to promote patient safety, worker safety, and environmental protection
        - Antineoplastic and other HDs are listed with the National Institute for Occupational Safety and Health (NIOSH)
    - Compounding, dispensing, storage, handling, disposal, training interns and technicians regarding quarantine, Material Safety Data Sheets, use of reverse distributors, etc.

<u>Patient Counseling</u>

- In FL, for every prescription, there must be an offer to counsel <u>verbally and in writing</u>. (Note that anyone can make the offer, but only the pharmacist or intern under the direct and immediate personal supervision 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
- If a person picks up a prescription for another you must still offer to counsel!

<u>Continuing Education Requirements (all pharmacists)</u>

- **30 hours ACPE approved CE every two years** (30 CE credits = 3 CEU)
    - First time renewal to include 1 hr HIV/AIDS (FL), Each renewal <u>2 hours Medication Errors</u>

    - 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 (in Risk Management) attending all day Board meeting, 5 credits volunteer services to indigent, 5 credits / post graduate professional semester credit
    - Retain documents for 2 years after license renewed
- Pharmacist must complete a mandatory 2-hour CE on Controlled Substances each cycle (counts toward the 30 hours)
- 3 hr special course required to order lab tests
    - In order to order lab tests, pharmacist must collaborate with a physician under a "Prescriber Care Plan"
        - individualized assessment of a patient and orders for specific drugs, laboratory tests, and other pharmaceutical services intended to be dispensed or executed by a pharmacist
    - "Drug Therapy Management" is any act or service by a pharmacist in compliance with orders in a Prescriber Care Plan
- Board of Pharmacy may require disciplinary coursework for misfilles
    - Laws and Rules must be at least 12 hrs / Med Errors (QRE) must be at least 8 hrs
- No need to maintain hard copies of CE completion, but instead must report CE through Board portal. Board of Pharmacy no longer conducting audits for CE credits as they are instead reviewed in electronic tracking system

FL Pharmacist can order/dispense from limited formulary without a prescription (Pharmacist only class of drugs), although practically speaking this is non-existent (outdated)

- No injectables, pregnant patients or nursing mothers, recommended dose and duration only (34 d max), must create a prescription, maintain patient profile and store for at least FOUR years including chief complaint (in patients own words). Formulary in Appendix (see 64B16-27.220)
- Records must be protected under HIPAA

Dispense Pharmacist-only Narcotics

- Schedule V only, Adult patient only (18 years of age minimum), 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 hrs
- Pharmacist may withhold sale at discretion if believe purpose is abuse

Impaired Practitioners (Drugs/Alcohol/Mental/Physical (DAMP) condition) (see 456.076)

- Florida has an impaired practitioner programs for pharmacists (+pharmacy students) (and other licensed healthcare providers)
- Complaints involving DAMP impairment will not be subject to disciplinary action (ie loss of licensure) if the Probable Cause Panel/Board of Pharmacy (PCP/BOP) determines the pharmacist, working with a state-approved impairment consultant:
    - Acknowledges the impairment
    - Voluntarily enrolls in an approved-treatment program
    - Withdrawals or limits scope of practice as determined by consultant
    - Makes available pertinent medical records to consultant
- Upon fulfilling the requirements of the program, the pharmacist may return back to practice unrestricted as long as no other complaints have been filed.
    - No practice while in program
- Pharmacist pays own expenses
- If there is no complaint a pharmacist may still join the program without oversight by PCP or BOP. Must withdraw from practice
- If pharmacist does not comply with the program, such facts will be disclosed to the board for action (ie suspension, etc…)

- Reports to Department of Health will undergo a probable cause panel to establish preliminary requisite

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
- Must obtain 24 CE credits every two years approved for consultant in addition to the 30 required of all pharmacusts (54 credits total)

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
    - Must complete 200 hour approved didactic coursework
    - Must complete 500 hours on the job training

Interns

- Unlimited number per pharmacist allowed
    - *~~1:1~~ ratio eliminated 2012*
- May give copies and transfers
    - Interns may transfer controlled substance prescriptions in FL
    - (remember technicians may not transfer ANY prescriptions)
- Must register with State, demonstrate proof of enrollment or graduation from accredited school of pharmacy
- Must be currently enrolled and attending an accredited pharmacy school
- May immunize adults under the direct and immediate supervision of a certified immunizing pharmacist (1:1 Ratio on immunizations)
    - Must complete 20 hours board approved coursework
    - Registration fee waived for interns

Technicians

- **1:1 technician to pharmacist ratio DEFAULT**
    - However, this ratio may be increased with written approval from Board of Pharmacy
        - Request must include brief description of the workflow include operating hours of pharmacy, number of pharmacists/interns/and technicians.
        - *The maximum Pharmacist:Technician ratio with approval was ~~1:3~~. However, as of July 1, 2014 this maximum allowable ratio was removed from the law, allowing the board to increase the maximum ratio*
        - **Up to 3:1 ratio allowed for sterile compounding**
        - **Up to 4:1 ratio allowed for dispensing**
        - **Up to 6:1 ratio allowed if not involving with sterile compounding or dispensing**
- 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

    - Interns can work as technicians without registering
    - Do not have to register while in technician school
- 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 in pharmacy, signed by the technicians.
    - Ensure each technician is knowledgeable and work requests do not exceed the written job description/policy/procedure.
    - includes information on 12 items defined in rule (this manual must be maintained at the pharmacy)
    - Prescription Department Manager must maintain documentation of appropriate training, such as certification, attendance logs, and quiz scores
- Technicians must wear a visible identification badge with name and title (Registered Pharmacy Technician) and identity themselves in all communications as technicians
- Pharmacists may delegate certain tasks to technicians (Registered Technicians including Technicians In Training). Pharmacist must have Direct Supervision meaning can provide personal assistance. This includes the use of Technology (ie video or audio)

Pharmacy technicians **MAY** (64B16-27.420):

- Data entry;
- Labeling of preparations and prescriptions;
- Retrieval of prescription files, patient files and profiles, and other similar records pertaining to the practice of pharmacy;
- The counting, weighing, measuring, and pouring of prescription medication or stock legend drugs and controlled substances, including the filling of an automated medication system;
- The initiation of communication to confirm the patient's name, medication, strength, quantity, directions, number of refills, and date of last refill;
- The initiation of communication with a prescribing practitioner or their agents to obtain clarification on missing or illegible dates, prescriber name, brand or generic preference, quantity, license numbers or DEA registration numbers;
- The acceptance of authorization to dispense medications pursuant to a prescribing practitioner's authorization to fill an existing prescription that has no refills remaining (refill authorization);
- The receiving, in a permitted nuclear pharmacy, of diagnostic orders only;
- Assisting in preparing parenteral and bulk solutions or assisting in any act involving sterile compounding
- Organizing of or participating in continuous quality improvement related events, meetings, or presentations;
- Participation in a monitoring program to remove deteriorated pharmaceuticals to a quarantine area; and
- While under the direct supervision of the pharmacist, performance of any other mechanical, technical or administrative tasks which do not themselves constitute practice of the profession of pharmacy.
- A registered pharmacy technician, under the supervision of a pharmacist, may initiate or receive communications with a practitioner or his or her agent, on behalf of a patient, regarding refill authorization request

Pharmacy technicians **MAY NOT** (64B16-27.420):

- Receive new non written prescriptions or receive any change in the medication, strength, or directions of an existing prescription;
- Interpret a prescription or medication order for therapeutic acceptability and appropriateness;
- Conduct final verification of dosage and directions;

- Engage in prospective drug review;
- Monitor prescription usage;
- Override clinical alerts without first notifying the pharmacist;
- Transfer a prescription;
- Prepare a copy of a prescription or read a prescription to any person for purposes of providing reference concerning treatment of the person or animal for whom the prescription was written;
- Engage in patient counseling;
- Receive therapy or blood product procedures in a permitted nuclear pharmacy; or Engage in any other act that requires the exercise of a pharmacist's professional judgment.

Prescribers

- In FL, the following may prescribe, limited to **scope of practice**:
  - Dentists (DDS, DMD)
  - Physicians (MD / DO)
  - Podiatrists (DPM)
  - Veterinarians (DVM)
  - Optometrists (OD) (OcularTopical and Systemic drugs per formular (see Formulary 463.0055) – some analgesics, antibiotics, antivirals, and antiglaucomas
    - Only control allowed is Tylenol 3 with Codeine). Must have complete additional training to prescribe oral medications (ie 20 hour course)

  Physician Assistants (PA), Nurse Practitioners (ARNP)
    - Effective January 1st 2017 may prescribe controlled substances
      - 7 day max CII narcotics
- Physicians cannot self-prescribe controlled substances in FL (Medical Rule); may prescribe for family friend within scope of practice. Must document in chart. Should never pre-sign prescription blanks
- In FL, the following (may prescribe under statute but very narrowly construed and thus 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 to be prescribed or dispensed
- May order "Office Use" of compounded prescriptions in amounts limited to anticipated use (see 64B16-27.000 Definition of Compounding). Must be labeled For Office Use – Not For Resale
- Must write prescription legibly (Unique FL law)

Prescriptions

- Florida prescriptions expire in one year
  - CIII-CV expire in 6 months per Controlled Substance Law
- **Prescriptions** must be legible and contain the following (11 + refills /15 points)
  1. Date of issue (month spelled out)
  2. Patient's full name
  3. Patients address
  4. Practitioner's name (species if controlled substance for an animal)
  5. Practitioners address
  6. Drug name
  7. Drug strength
  8. Dosage form
  9. Quantity prescribed (in numeric and textual form)
     - Number of refills (if any) authorized

10. Directions for use
11. Manual signature of prescriber

Controlled prescriptions in Florida, Pharmacist must

12. Practitioners DEA registration
13. Initial the prescription
14. Write date filled
15. Note the prescription number

- Different prescriptions required for different drug classes/scheduled. Cannot prescribe drugs from different schedules on same prescription blank
- Controlled substance prescriptions require counterfeit-resistant, vendor-approved blanks
  - Veterinary drugs exempt from requirement to use counterfeit-resistant pads
- 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
  - ✓ Any drug that has all A-rated generics are not permitted to be included on FL's Negative Drug Formulary

  Note that absence of levothyroxine, warfarin and digoxin which have been removed over the years
- All prescriptions must be based upon a valid practitioner-patient relationship that includes a documented patient evaluation, including history and a physical examination adequate to establish the diagnosis for which any drug is prescribed and any other requirement. This is interpreted as physician must be in active practice, accessible conventional communications. *Important note, Florida law has no rules defining valid prescription*.
- All dispensed outpatient prescriptions must be **LABELED/LABELING** with the following (9/11) items - [See 64B16-28.108]
  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 to be withheld).
  8. Directions for use.
  9. Expiration date (FL uses a 1 year beyond-use date (discard aftyer date / do not use after date) from date filled or manufacturers expiration date if earlier)

  * note what is NOT REQUIRED on the label – patient address, date prescription was written, address of prescriber, quantity, dosage form, number of refills remaining, formulation, telephone number of the pharmacy.

<u>Controlled Substances must also include:</u>

10. Date of initial fill if a refill
11. Cautionary statement required under Federal Law (Caution: **Federal law prohibits the transfer of this drug to any person other than the patient for whom it was**

prescribed) [CII-CIV Only]

Repackaged drugs must be labeled with (R-E-P-A-C-K 6 Requirement)

1. Brand or generic name.
2. Strength.
3. Dosage form.
4. Name of the manufacturer.
5. Expiration date.
6. Lot number:
    a. Manufacturer's lot number, or
    b. Number assigned by the dispenser or repackager which references the manufacturer's lot number.

- Prepacking in Class II pharmacy / Community pharmacy must follow documented procedures as set up be Consultant Pharmacist on Record / Prescription Department Manager

- Prescriptions may be **COMPOUNDED** in FL pharmacy – *differentiate from manufacturers who need manufacturing license in State and FDA approval to market products*
    - 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
        - Labeling requirements:
            - The name, address, and phone number of the compounding pharmacy;
            - The name and strength of the preparation of a list of active ingredients and strengths;
            - The pharmacy's lot number and beyond-use-date;
            - The quantity or amount in the container; (note non-compounded drugs are exempt from labeling quantity)
            - The appropriate ancillary instructions such as storage instructions, cautionary statements, or hazardous drug warning labels were appropriate; and
            - The statement "For Institutional or Office Use Only – Not for Resale," or if the drug is provided to a veterinarian the statement "Compounded Drug."
        - Recordkeeping requirements (4 years)
            - The name, address and phone number of the practitioner ordering the compounded drug for office use and the date of the order;
            - The name, strength, and quantity of the compounded drug provided, including the number of containers and quantity in each;
            - The date the drug was compounded;
            - The date the compounded drug was provided to the practitioner;
            - The lot number and beyond use date.
    - Non-Sterile Compounding 'Good Manufacturing Practices' as defined by USP 795. USP 795 is NOT law
    - Central fill pharmacy may compound for another pharmacy with agreement
    - May compound limited amounts for doctor's "Office Use" (see 64B16-27.700)
- 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 as law is written. Pharmacist must create a record and contact the physician as soon as possible
- Standards for the Prescription of Obesity Drugs (64B8-9.012): All Prescriptions for weight loss drugs must be in writing signed by the prescribing physician. Initial prescriptions may not be called into the pharmacy. Refills may be phoned in. Physician must meet personally with patient and may only prescribe FDA approved drugs. *Note this is a a medical rule, not a pharmacy rule so unlikely to be tested on MPJE.*
- 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).
    - Interns may give/take transfers for Controlled Substances under State and Federal law
    - 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 comingle 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.
- 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
- Patient Medication Information Sources (3 types) provided with prescriptions dispensed
    - Medication Guide is considered part of the Drug labeling
        - 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
        - If required and do not provide, drug is misbranded
    - 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
        - Other products may Voluntarily seek approval to provide these to patients.
        - Approved by the FDA

- Brochures/Pamphlets/Leaflets/ Consumer medication information (CMI) is the pharmacy drug information provided by pharmacies with dispensed drugs
    - Required under law to be provided for every prescription dispensed
    - Are not FDA reviewed/approved and not part of the drugs labeling
        - If no provide, no liable for misbranding
- Students may carry epinephrine auto injectors in FL school with written authorization from physician and parent/guardian. School nurse must be informed and work with student to develop an overall emergency health plan annually.

FL Board of Pharmacy

- Job is to protect the public (FL patients) not the pharmacists or the profession
- 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
        - 2 Community pharmacy representative
        - 2 Class II institutional Pharmacy /Modified Class II
        - 3 members open requirement
    - 2 community members, state residents, not pharmacists, no connection to the profession, drug wholesales or pharmaceutical manufactures
- Members serve 4 year terms
- May discipline pharmacists who deviate from law/rule
    - Sanctions may include fine, suspension, revocation
    - Defaulting on student loans subjects the graduate to suspension of pharmacist license
    - Failing any drug test subjects the pharmacist to suspension or restriction of the license to practice
- 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 (positive) vote required to find probable cause exists that a violation has occurred

<u>Florida Prescription Drug Monitoring Program of Controlled Substances</u>

- Dispensing CII-CIV drugs are reported to the States Prescription Drug Monitoring Program
- Pharmacist dispensing of controls monitored; as well as physician prescribing of controls
    - Attempts to minimize diversion of controlled substances
- Program called E-FORCSE
    - Within 7 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 – summary of reported information for a patient
- Not reported: hospitals, nursing homes, correctional facilities, ambulatory surgical centers, hospices, intermediate care facilities for the developmentally disabled, correctional facilities, emergency rooms, patients under the age of 16, one-time doses, 72-hour emergency refills, and patients directly administered controlled substances by a physician
- Compounded drugs are included (ie reportable) in database
- It is illegal in FL for a person to possess prescription drugs without a valid prescription. Florida law recognizes that there are limited instances where the possession of prescription drugs without a valid prescription is warranted. The department is authorized to issue letters of exemption in such cases for certain qualified persons for lawful research, teaching, or testing, and not for resale.

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 generally on Schedule II prescriptions. 60 days from date issued for LTC patients and Terminal Illness 21 CFR 1306.13
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 Medicaid patients only.
CII Emergency Prescriptions – Verbal	limited to a 72-hour supply. 893.04.(1).(f).	limited to 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 may 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 prescription law	Yes. Prescription be legibly written or typed; that 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	No requirements
Multiple drugs on same blank	Each blank must only have drugs from same class prescribed.	No restriction
Oral Prescriptions for	Oral prescriptions for Schedule III medications are limited to a 30 day supply including refills	No restriction for oral Schedule III prescriptions

CIII		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	Counterfeit resistant prescription pads for Schedule II, III, IV drugs are required [veterinary prescriptions are exempt] Counterfeit pads contain: – Preprinted physician's name, address, and category of licensure – Security features • 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 893.065	All written Medicaid outpatient prescriptions must be written on tamper-resistant pads
Prescribers of Controlled Substances	Florida authorizes Dentists • Physicians (MD and DO) • Dentists • Podiatrists • Veterinarians Midlevel Practitioners NOT authorized. • Optometrist can only prescribe Tylenol #3 Codeine 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 (NP/PA) may be authorized under state law, but Florida prohibits.
Salvia Schedule	Schedule I	Not scheduled
Amount of CV Available without prescription	Lower	Higher

Recordkeeping Requirements in Florida

Prescription record	Four years from date of last dispensing	465.022 12 (b)
Controlled substance inventory	Conducted every two years	893.07(1)(a)
Inventory records	Maintained for at least four years	893.07(4)(a)(b)
Pharmacy permits	Expire every odd years on Feb 28th	
Immunization records	Maintain for at least five years	465.189(3)
Patient records for pharmacist-only drug	Four years	64B16-27.210

orders		
Patient records for prescription drugs dispensed	Four years from date of last entry	465.022 12 (b)
Compounded drugs ordered by practitioners for office use	Four years	64B16-27.700
Pharmacy Continuous Quality Improvement Program summarizations	Four years	64B16-27.300
Dispensing logbook	Four years	64B16-28.140
Starter Dose prescription Records	Four years	64B16-28.503
Class II Institutional Pharmacy reports / analysis generated as part of the quality assurance program	Four years	64B16-28.605
Class II Institutional Pharmacy transaction records from the automated medication system for all controlled substances dispensed or distributed	Four 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 medications	Four 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.	Four years	64B16-28.606
Automated pharmacy system transactions for Long Term Care, Hospice, and Prisons	Four 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 from the creation of the record	499.0121
Prescription drug distributions	Four years	465.022
Records and sales of ether by manufacturers, distributors, and dealers	Five years	499.66

VIOLATION	MINIMUM, INCLUDING FIRST TIME OR SINGLE COUNT VIOLATIONS	MAXIMUM, INCLUDING MULTIPLE OR REPEATED VIOLATIONS OF THE SAME PROVISION
(a) Obtaining a license or permit by misrepresentation, fraud, or error.		

1. By negligent misrepresentation on original application or renewal.	$1,000 fine and 12 hour Laws and Rules course or MPJE and 3 hour ethics course.	$5,000 fine and one (1) year suspension, to Revocation.
2. By fraudulent misrepresentation on original application or renewal.	$10,000 fine for each count and Revocation.	$10,000 fine for each count and Revocation.
3. By error of the Department or Board on original application or renewal.	Revocation	Revocation
(b) Procuring or attempting to procure a license or permit for another person by false representation.	$10,000 fine for each count and Revocation.	$10,000 fine for each count and Revocation.
(c) Permitting any unlicensed persons, including owner or operator of pharmacy, to practice pharmacy.	$2,500 fine and 12 hour Laws & Rules course or Multistate Pharmacy Jurisprudence Exam (MPJE).	$5,000 to $10,000 fine and one (1) year suspension followed by one (1) year probation, to Revocation.
(d) Being unfit or incompetent to practice pharmacy by reason of habitual intoxication, medicinal drug abuse, or physical or mental condition that threatens public safety.	$250 fine, indefinite suspension with PRN review and board appearance.	Revocation
(e) Violating laws governing the practice of pharmacy.		
1. Chapter 465, F.S.: **FLORIDA PHARMACT ACT**		
a. Failure to supervise registered pharmacy technician.	$250 fine and one (1) year probation and 12 hour Laws and Rules course or MPJE.	$1000 fine and one (1) year suspension followed by one (1) year probation, to Revocation.
b. Operating a pharmacy that is not registered.	$500 fine per month to maximum of $5,000 (penalty will require permittee to renew permit or cease practice).	$10,000 fine (penalty will require permittee to renew permit or cease practice), to Revocation.
c. Operating a pharmacy where an unlicensed, unregistered, or unsupervised person practices	$5,000 fine and one (1) year probation.	$10,000 fine and one (1) year suspension followed by one (1) year probation, to

pharmacy.		Revocation.
d. Making a false or fraudulent statement to the board.	$10,000 fine.	$10,000 fine and Revocation.
e. Practicing pharmacy as an inactive licensee.	Fine based on length of time in practice while inactive; $500 fine per month.	$10,000 fine and two (2) years suspension, to Revocation.
f. Selling or dispensing drugs without a prescription.		
(I) Non-scheduled legend drugs.	$1,500 fine.	$5,000 fine and one (1) year probation, to Revocation.
(II) Scheduled (controlled substances) legend drugs.	$5,000 fine and (1) year probation.	$10,000 fine and one (1) year suspension followed by one (1) year probation, to Revocation.
g. Selling samples or complimentary drugs.		
(I) Non-scheduled legend drugs.	$1,500 fine and (1) year probation.	$5,000 fine and one (1) year probation, to Revocation.
(II) Scheduled (controlled substances) legend drugs.	$5,000 fine and one (1) year probation.	$10,000 fine and one (1) year suspension followed by one (1) year probation, to Revocation.
h. Failure to notify the board of, or failure to have, a prescription department manager or a supervising, a responsible, or a consultant pharmacist.		
(I) Failure to notify.	Fine based on length of time prior to notifying board. $500 per month.	$7,500 maximum (penalty requires notification or ceasing practice).
(II) Failure to have prescription department manager or a supervising, a responsible, or a consultant pharmacist of record.	Fine based on length of time practicing without designated pharmacist, $750 fine per month and one (1) year probation.	$2,000 fine per month, to Revocation.
i. Failure to comply with substitution of	$500 fine and 12 hour Laws &	$2,500 fine, 12 hour Laws & Rules course or MPJE, and

legend drug requirements.	Rules course or MPJE.	one (1) year probation.
j. Failure to follow negative formulary requirements.	$1,000 fine and 12 hour Laws & Rules course or MPJE.	$2,500 fine, 12 hour Laws & Rules course or MPJE, and one (1) year probation.
k. Failure to follow emergency prescription requirements.	$500 fine.	$1,000 fine and one (1) year probation.
l. Engage in prohibited rebate scheme.	$1,500 fine and 12 hour Laws & Rules course or MPJE.	$5,000 fine, 12 hour Laws & Rules course or MPJE, and one (1) year probation, to Revocation.
m. Failure to comply with pharmacist dispensing requirements.		
(I) Failure to follow procedure, but dispense drug appearing on formulary.	$500 fine.	$1000 fine and one (1) year probation to suspension of right to dispense.
(II) Dispensing drug not on the formulary.	$1,500 fine and 12 hour Laws & Rules course or MPJE.	$5,000 fine and one (1) year probation to $10,000 fine and Revocation.
n. Failure to timely report fraudulent obtaining or attempted obtaining of controlled substances from a pharmacy.		
(I) Failure to timely report.	$500 fine.	$1,000 fine and one (1) year probation.
(II) Failure to report.	$1,000 fine and one (1) year probation.	$5,000 fine and one (1) year suspension followed by one (1) year probation, to Revocation.
o. Violation of facsimile prescription requirements	$500 fine.	$1,000 fine and one (1) year probation.
p. Violation of requirements for administration of vaccines and epinephrine autoinjection.		
(I) Failure to enter into a written protocol.	$2,500 fine and 12 hour Laws & Rules course or MPJE.	$5,000 fine and one (1) year probation.

(II) Failure to maintain proper insurance.	$500 fine and suspension until insured.	$1,000 fine, suspension until insured, followed by one (1) year probation.
(III) Failure to maintain and make available patient records.	$500 fine.	$1,000 fine and one (1) year probation.
(IV) Uncertified administration of vaccine.	$5,000 fine and suspension until certified.	$7,500 fine and suspension until certified, followed by one (1) year probation, to Revocation.
(V) Failure to submit copy of protocol or written agreement to the board.	$500 fine.	$1,000 fine and one (1) year probation.
2. Chapter 499, F.S.:		
a. Adulteration or misbranding of a drug.		
(I) Adulteration of a drug.	$1000 fine and 12 hour Laws & Rules course or MPJE.	$5,000 fine and one (1) year suspension followed by one (1) year probation, to Revocation.
(II) Receipt or delivery of any drug that is adulterated or misbranded.	$1000 fine and 12 hour Laws & Rules course or MPJE.	$5,000 fine and one (1) year probation, to Revocation.
(III) Incomplete or inaccurate labeling.	$250 fine and 12 hour Laws & Rules course or MPJE.	$2,500 fine and one (1) year probation.
(IV) Fraudulent misbranding of legend drugs.	$10,000 fine and one (1) year suspension followed by one (1) year probation.	$10,000 fine and two (2) years suspension followed by two (2) years probation, to Revocation.
b. Failure to obtain a permit or registration, or operating without a valid permit when it is required.	$500 fine per month to maximum of $5,000 (penalty will require permittee to renew permit or cease practice).	$10,000 fine (penalty will require permittee to renew permit or cease practice), to Revocation.
c. Prescription drug pedigree violations.	$500 fine and 12 hour Laws & Rules course or MPJE.	$5,000 fine and one (1) year probation, to Revocation.
d. Recordkeeping requirement.	$500 fine and 12 hour Laws & Rules course or MPJE.	$5,000 fine and one (1) year probation, to Revocation.
e. Storage of drugs.	$500 fine and 12 hour Laws &	$5,000 fine and one (1) year

	Rules course or MPJE.	probation, to Revocation.
3. Chapter 893, F.S. **CONTROLLED SUBSTANCES**		
a. Filling a written or oral prescription for controlled substances that does not meet the requirements of Chapter 893, F.S.	$1,500 fine.	$5,000 fine and one (1) year probation, to Revocation.
b. Failing to retain prescription records for two (2) years.	$1,000 fine.	$5,000 fine and one (1) year probation, to Revocation.
c. Failing to appropriately label.	$250 fine and 12 hour Laws & Rules course or MPJE.	$2,500 fine and (1) year probation.
d. Dispensing a Schedule II drug inappropriately with a non-written prescription.	$5,000 fine and one (1) year probation.	$10,000 fine and one (1) year suspension followed by one (1) year probation, to Revocation.
e. Inappropriate refilling of Schedule III, IV, or V drugs.	$1,750 fine and one (1) year probation.	$5,000 fine and one (1) year suspension.
f. Receiving controlled substances without an appropriate order form.	$2,500 fine.	$5,000 fine and one (1) year probation, to Revocation.
g. Possession of controlled substances outside the regular course of business, occupation, profession, employment, or duty.	$2,500 fine and one (1) year probation.	$5,000 fine and one (1) year suspension followed by one (1) year probation, to Revocation.
h. Failure to take a biennial inventory.	$1,000 fine.	$2,500 fine and one (1) year probation.
i. Failure to maintain a complete and accurate record of controlled substances.	$1,000 fine and one (1) year probation.	$5,000 fine and two (2) years probation, to Revocation.
j. Dispensing Schedule V controlled substances in other than good faith	$5,000 fine and one (1) year probation.	$10,000 fine and one (1) year suspension followed by one (1) year probation, to Revocation.
k. Inappropriate selling of Schedule V controlled substance.	$1,500 fine and one (1) year probation.	$5,000 fine and one (1) year suspension.
l. Unlawful possession of controlled	$5,000 fine and two (2) years	$10,000 fine and one (1)

substance.	probation.	year suspension followed by two (2) years probation, to Revocation.
4. Violation of Federal Drug Abuse Act 21 U.S.C. 821 et seq. (Manufacture, Distribution, and Dispensing of Controlled Substances.)	$500 fine and one (1) year probation.	$2,000 fine up to $10,000 and one (1) year suspension followed by two (2) years probation, to Revocation.
5. Violation of **Food and Drug Act** 21 U.S.C. 301 – 392.	$2,500 fine and one (1) year suspension.	$7,500 fine and two (2) years suspension followed by two (2) years probation, to Revocation.
(f) Criminal conviction related to Pharmacy.		
1. Misdemeanor.	$1,000 fine.	$5,000 fine, one (1) year probation, to Revocation.
2. Felony.	$5,000 fine and one (1) year suspension followed by two (2) years probation.	$10,000 fine and two (2) years suspension followed by three (3) years probation, to Revocation.
(g) Using in the compounding of a prescription, or furnishing upon prescription, an ingredient or article different in any manner from the ingredient or article prescribed, except as authorized in Section 465.019(6), F.S. or Section 465.025, F.S. or, compounding, dispensing or distributing legend drugs outside professional practice of pharmacy.	$250 fine without ingestion or harm, to $500 with ingestion, and complete approved CE course in the prevention of medication errors of no less than eight (8) hours.	$500 fine without ingestion or harm, to $1,000 with ingestion, complete approved CE course in the prevention of medication errors of no less than eight (8) hours, and two (2) years probation, to Revocation.
(h) Filing a false report or failing to file a report required by law.		
1. Knowing violation.	$10,000 fine and one (1) year probation.	$10,000 fine and one (1) year suspension followed by two (2) years probation, to Revocation.
2. Negligent violation.	Reprimand.	One (1) year probation and

		$1,000 fine.
(i) Failure to make prescription price information available.	$250 fine and 12 hour Laws & Rules course or MPJE.	$1,000 fine and one (1) year probation.
(j) Improperly placing returned drugs into the stock of a pharmacy.	$1,500 fine.	$3,000 fine and one (1) year probation.
(k) Violating a rule or order of the Board or Department.		
1. **Rules of Board of Pharmacy**.		
a. Rules 64B16-28.101 to 64B16-28.1035, F.A.C. • Display license and id • Oral rx and copies • Refill expired drugs • Pharmacy interns • Padlock; Sign: "Prescription Department Closed • Daily Operating Hours • Single permit location • Change ownership	$500 fine and 12 hour Laws & Rules course or MPJE.	One (1) year probation and $2,000 fine.
b. Sink and running water, sufficient space, refrigeration, sanitation, equipment.	Suspension until compliance.	$2,000 fine and Revocation.
c. Knowingly purchase, sell, possess, or distribute counterfeit drugs.	$5,000 fine, one (1) year suspension followed by one (1) year probation to Revocation.	$10,000 fine and Revocation.
d. Failure to remove outdated pharmaceuticals, or dispensing of same.	$500 fine for possession, $1,000 fine for dispensing.	$2,500 – $5,000 fine and two (2) years probation, to Revocation.
e. Violation of destruction of controlled substances.	$500 fine and 12 hour Laws & Rules course or MPJE.	$5,000 fine and two (2) years probation, to Revocation.
f. Serving as consultant pharmacist without being licensed as a consultant pharmacist.	$500 per month up to $5,000 fine. (fine based upon the length of time the person is serving as a consultant without being licensed as a	$7,500 fine and one (1) year suspension followed by two (2) years probation, to Revocation.

	consultant pharmacist.)	
g. Violation of requirements for records maintained in a data processing system.	$1,000 fine and 12 hour Laws & Rules course or MPJE plus 8 hours CE course in record keeping.	$5,000 fine and two (2) years probation, to Revocation.
h. Failure to properly store legend drugs.	$1,000 fine and 12 hour Laws & Rules course or MPJE.	$5,000 fine and one (1) year probation, to Revocation.
i. Practicing nuclear pharmacy without being licensed as a nuclear pharmacist.	$500 per month up to $5,000 fine. (fine based upon the length of time the person is practicing without being licensed as a nuclear pharmacist.)	$10,000 fine and one (1) year suspension, to Revocation.
j. Failure to follow technical requirements for nuclear pharmacy.	One (1) year probation and $1,000 fine, to $2,500 fine and six (6) months suspension followed by one (1) year probation.	$5,000 fine and one (1) year suspension followed by two (2) years probation, to Revocation.
k. Failure to properly transfer prescription files and medicinal drugs when closing pharmacy.	Revocation.	Revocation.
l. Failure to complete the required continuing education during the biennial licensure period.		
(I) Failure to complete less than ten (10) hours.	$500 fine and suspension until completed.	$1,500 fine and suspension until completed.
(II) Failure to complete ten (10) or more hours.	$1,000 fine. In addition, licensees shall take two (2) additional hours of continuing education for each of the continuing education deficiencies. Said hours shall not count for continuing education renewal requirements for the next biennium.	$2,500 fine and suspension until deficiency and penalty units are completed. In addition, licensees shall take two (2) additional hours of continuing education for each of the continuing education deficiencies. Said hours shall not count for continuing education renewal requirements for

		the next biennium.
m. Failure to retain continuing education records.	$250 fine.	$1,500 fine and suspension of license until undocumented courses are completed and documentation is submitted to the Department.
n. Failure to practice in accordance with established practice standards.		
(I) Pharmacist.	$500 to $1,000 fine and 12 hour Laws & Rules course or MPJE to one (1) year probation.	$2,500 to $10,000 fine and one (1) year suspension followed by two (2) years probation, to Revocation.
(II) Pharmacy Intern.	$250 to $500 fine and 12 hour Laws & Rules course or MPJE	$1,000 to $5,000 fine and one (1) year suspension followed by two (2) years probation, to Revocation.
(III) Permittee.	$500 to $1,000 fine and 12 hour Laws & Rules course or MPJE to one (1) year probation.	$2,500 to $10,000 fine and one (1) year suspension followed by two (2) years probation, to Revocation.
o. Failure to have or maintain current policies and procedures for automated pharmacy system or central fill pharmacy.	$500 to $1000 fine and 12 hour Laws & Rules course or MPJE.	$2,500 to $5,000 fine and suspension of license/permit until current policies and procedures are in place, to Revocation.
p. Failure to have or maintain standards for an institutional pharmacy.	$500 fine and 12 hour Laws & Rules course or MJPE.	$2,500 to $5,000 fine and suspension of license until policies and procedures are in place, to Revocation.
q. Failure to have or maintain standards for a special pharmacy.	$500 fine and 12 hour Laws & Rules course or MJPE.	$2,500 to $5,000 fine and suspension of license until policies and procedures are in place, to Revocation.
r. Failure to maintain standards for animal control shelters.	$500 fine and 12 hour Laws & Rules course or MJPE.	$2,500 to $5,000 fine and suspension of license until policies and procedures are

		in place, to Revocation.
s. Failure to comply with Board's rule on patient counseling.	$250 fine without ingestion or harm, to $500 with ingestion, and complete approved CE course in the prevention of medication errors of no less than eight (8) hours.	$500 fine without ingestion or harm, to $1,000 with ingestion, complete approved CE course in the prevention of medication errors of no less than eight (8) hours, and two (2) years probation, to Revocation.
t. Standards of practice for compounding CSPs.		
(I) No harm.	$500 fine, 12 hour Laws & Rules course, and course governing sterile compounds, to $2,000 fine and one (1) year probation.	$2,500 to $10,000 fine and one (1) year suspension followed by two (2) years probation, to Revocation.
(II) Harm.	$2,000 fine, one (1) year probation, and 12 hour Laws & Rules course, to Revocation.	Revocation.
2. Violation of orders of the Board or Department.	$2,500 fine and one (1) year probation, to suspension until compliance with order.	$5,000 fine and one (1) year probation, to suspension until compliance with order, to Revocation.
(l) License disciplined by another jurisdiction for an offense that would constitute a violation of this chapter.	Same penalty as imposed in other jurisdiction or as closely as possible to penalties set forth in Florida Statutes.	Same penalty as imposed in other jurisdiction or as closely as possible to penalties set forth in Florida Statutes to $10,000 fine and Revocation.
(m) Failing to report to the Department any Chapter 458 or 459, F.S., licensee violation.	$500 fine and 12 hour Laws & Rules course or MJPE.	$1,500 fine and 12 hour Laws & Rules course or MJPE.
(n) Abandoning or allowing permit to become null and void after notice of disciplinary proceedings.	Revocation.	Revocation.
(o) Failing to notify the Board of	$500 fine and 12 hour Laws &	$2,000 fine and two (2)

commencement or cessation of practice due to discipline in another jurisdiction.	Rules course or MJPE	years probation
(p) Using or releasing patient records improperly.	$1,000 fine and 12 hour Laws & Rules course or MJPE.	$2,500 fine and one (1) year probation.
(q) Knowingly, or with reason to believe, dispensing based on purported prescription where patient-prescriber relationship is invalid.		
(I) Reason to believe.	$2,000 fine, 12 hour Laws & Rules course or MJPE, and one (1) year probation.	$2,500 to $10,000 fine and one (1) year suspension followed by two (2) years probation, to Revocation.
(II) Knowingly.	Revocation.	Revocation.
(r) Committing an error or omission during prescription drug processing.	$250 fine without ingestion or harm, to $500 with ingestion, and complete approved CE course in the prevention of medication errors of no less than eight (8) hours.	$500 fine without ingestion or harm, to $1,000 with ingestion, complete approved CE course in the prevention of medication errors of no less than eight (8) hours, and two (2) years probation, to Revocation.
(s) Guilty of a felony involving moral turpitude.	$1,000 fine and 12 hour Laws & Rules course or MJPE.	$5,000 fine and one (1) year probation, to Revocation.
(t) Guilty of a crime related to health care fraud.	Revocation and a fine of $10,000, or in the case of application for licensure, denial of license.	Revocation and a fine of $10,000, or in the case of application for licensure, denial of license.
(u) Violating Section 456.072, F.S.		
1. Making misleading, deceptive, or fraudulent representation in or related to the practice of the licensee's profession.	$10,000 fine and one (1) year probation.	Revocation, and a fine of $10,000.
2. Intentionally violating any rule adopted by the Board or the Department.	$2,500 fine and two (2) years probation.	$5,000 to $10,000 fine and one (1) year suspension followed by two (2) years probation, to Revocation.

3. Being convicted or found guilty of, or entering a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to the practice of, or the ability to practice, a licensee's profession.		
a. Misdemeanor.	$1,000 fine and suspension until compliant.	$2,500 fine and suspension until compliant, followed by one (1) year probation, to Revocation.
b. Felony.	$3,000 fine and one (1) year probation.	$5,000 to $10,000 fine and one (1) year suspension followed by two (2) years probation, to Revocation.
4. Failing to comply with the educational course requirements for human immunodeficiency virus and acquired immune deficiency syndrome, or medical errors.	$500 fine.	$1,000 fine.
5. Having a license or the authority to practice the regulated profession revoked, suspended, or otherwise acted against, including the denial of licensure, by the licensing authority of any jurisdiction, including its agencies or subdivisions, for a violation that would constitute a violation under Florida law. The licensing authority's acceptance of a relinquishment of licensure, stipulation, consent order, or other settlement, offered in response to or in anticipation of the filing of charges against the license, shall be construed as action against the license.	Same penalty as imposed in other jurisdiction or as closely as possible to penalties for similar violation.	Same penalty as imposed in other jurisdiction or as closely as possible to penalties for similar violation, to $10,000 fine and Revocation.
6. Having been found liable in a civil proceeding for knowingly filing a false report or complaint with the Department against another licensee.	$3,000 fine.	$5,000 to $10,000 fine and one (1) year suspension followed by two (2) years probation, to Revocation.

7. Attempting to obtain, obtaining, or renewing a license to practice a profession by bribery, by fraudulent misrepresentation, or through an error of the Department or the Board.	$10,000 fine and Revocation or denial of license application.	$10,000 fine and Revocation or denial of license application.
8. Except as provided in Section 465.016, F.S., failing to report to the Department any person who the licensee knows is in violation of this part, the chapter regulating the alleged violator, or the rules of the Department or the Board.	$500 fine and 12 hour Laws & Rules course or MJPE.	$1,500 fine and 12 hours Laws & Rules or MJPE, to one (1) year suspension or Revocation.
9. Aiding, assisting, procuring, employing, or advising any unlicensed person or entity to practice a profession contrary to this part, the chapter regulating the profession, or the rules of the Department or the Board.	$2,000 fine and 12 hour Laws & Rules course or MJPE, to one (1) year probation.	$2,500 to $10,000 fine and one (1) year suspension followed by two (2) years probation, to Revocation.
10. Failing to perform any statutory or legal obligation placed upon a licensee, including failure to repay student loans or perform scholarship service obligations.		
a. Generally.	$2,000 fine.	$2,500 to $10,000 fine and one (1) year suspension followed by two (2) years probation, to Revocation.
b. Student loans or scholarship service.	The minimum disciplinary action imposed shall be a suspension of the license until new payment terms are agreed upon or the scholarship obligation is resumed, followed by probation for the duration of the student loan or remaining scholarship obligation period, and a fine equal to 10 percent of the	Suspension of the license until new payment terms are agreed upon or the scholarship obligation is resumed, followed by probation for the duration of the student loan or remaining scholarship obligation period, and a fine equal to 10 percent of the defaulted loan amount, to Revocation with a minimum

	defaulted loan amount.	total fine of $10,000.
11. Making or filing a report which the licensee knows to be false, intentionally or negligently failing to file a report or record required by state or federal law, or willfully impeding or obstructing another person to do so. Such reports or records shall include only those that are signed in the capacity of a licensee.		
a. Knowingly filing a false report or willful obstruction.	$10,000 fine and two (2) years probation.	$10,000 fine and one (1) year suspension followed by two (2) years probation, to Revocation.
b. Negligently failing to file a report or record.	$2,500 fine.	$5,000 fine and one (1) year probation, to Revocation.
12. Making deceptive, untrue, or fraudulent representations in or related to the practice of a profession or employing a trick or a scheme in or related to the practice of a profession.	$10,000 fine and two (2) years probation.	$10,000 fine and one (1) year suspension followed by two (2) years probation, to Revocation.
13. Exercising influence on the patient or client for the purpose of financial gain of the licensee or a third party.	$3,000 fine and two (2) years probation.	$5,000 to $10,000 fine and one (1) year suspension followed by two (2) years probation, to Revocation.
14. Practicing or offering to practice beyond the scope permitted by law or accepting and performing professional responsibilities the licensee knows, or has reason to know, the licensee is not competent to perform.	$2,000 fine and two (2) years probation.	$5,000 to $10,000 fine and one (1) year suspension followed by two (2) years probation, to Revocation.
15. Delegating or contracting for the performance of professional responsibilities by a person when the licensee delegating or contracting for performance of such responsibilities knows, or has reason to know, such person is not qualified by training, experience, and authorization when	$2,000 fine and two (2) years probation.	$5,000 to $10,000 fine and one (1) year suspension followed by two (2) years probation, to Revocation.

required to perform them.		
16. Violating any provision of Chapter 456, F.S., the applicable professional practice act, a rule of the Department or the Board, or a lawful order of the Department or the Board, or failing to comply with a lawfully issued subpoena of the Department.	$1,000 fine and 12 hour Laws & Rules course or MPJE, to one (1) year probation.	$5,000 to $10,000 fine and one (1) year suspension followed by one (1) year probation, to Revocation.
17. Improperly interfering with an investigation or inspection authorized by statute, or with any disciplinary proceeding.	$2,500 fine and two (2) years probation.	$5,000 to $10,000 fine and one (1) year suspension followed by two (2) years probation, to Revocation.
18. Engaging or attempting to engage in sexual misconduct as defined and prohibited in Section 456.063(1), F.S.	$10,000 fine and Revocation.	$10,000 fine and Revocation.
19. Being unable to practice with reasonable skill and safety by reason of illness or use of alcohol, drugs, narcotics, chemicals, or as a result of any mental or physical condition (board has authority to issue order to compel examination).	$500 fine, suspension until safe to practice with reasonable skill and safety, and appearance before the board.	$2,500 fine and Revocation.
20. Failing to report to the Board, or the Department if there is no Board, in writing within 30 days after the licensee has been convicted or found guilty of, or entered a plea of nolo contendere to, regardless of adjudication, a crime in any jurisdiction.	$1,000 fine.	$5,000 to $10,000 fine and one (1) year suspension followed by two (2) years probation, to Revocation.
21. Testing positive for any drug, as defined in Section 112.0455, F.S., on any confirmed preemployment or employer ordered drug screening when the practitioner does not have a lawful prescription and legitimate medical reason for using such drug.	$500 fine, suspension until safe to practice with reasonable skill and safety and appearance before the board.	$2,500 fine and Revocation.

22. Being terminated from, or failing to successfully complete, an impaired practitioners treatment program.	Suspension until successful completion or receipt of written confirmation of compliance with ongoing treatment and a fine of up to $1,000.	Revocation.
23. Being convicted of, or entering a plea of guilty or nolo contendere to, any misdemeanor or felony, regardless of adjudication, under 18 U.S.C. s. 669, ss. 285-287, s. 371, s. 1001, s. 1035, s. 1341, s. 1343, s. 1347, s. 1349, or s. 1518, or 42 U.S.C. ss. 1320a-7b, relating to the Medicaid program.	Revocation and a fine of $10,000, or in the case of application for licensure, denial of license.	Revocation and a fine of $10,000, or in the case of application for licensure, denial of license.
24. Failing to remit the sum owed to the state for overpayment from the Medicaid program pursuant to a final order, judgment, or settlement.	$500 to $5,000 fine and one (1) year probation.	$2,500 to $5,000 fine and suspension until amount owed is remitted, followed by two (2) years probation, to Revocation.
25. Being terminated from the state Medicaid program pursuant to Section 409.913, F.S., any other state Medicaid program, or the federal Medicare program, as a result of fraud and abuse unless eligibility to participate in the program from which the practitioner was terminated has been restored.	$10,000 fine and one (1) year probation, to one (1) year suspension followed by one (1) year probation.	$10,000 fine and two (2) years suspension followed by two (2) years probation, to Revocation.
26. Being convicted of, or entering a plea of guilty or nolo contendere to, any misdemeanor or felony, regardless of adjudication, a crime in any jurisdiction which relates to health care fraud.	Revocation and a fine of $10,000, or in the case of application for licensure, denial of license.	Revocation and a fine of $10,000, or in the case of application for licensure, denial of license.
27. Willfully failing to comply with Section 627.64194 or 641.513, F.S., with such frequency as to indicate a general business practice.	Reprimand and a fine of $250.	$500 fine and one (1) year probation, to Revocation.
(v) Violation of Section 828.055, F.S. by a permitted county or municipal animal control agency or humane society.		

1. Using drugs for animal euthanasia for an improper use.	Reprimand and a fine of $250.	$500 fine and one (1) year suspension followed by one (1) year probation, to Revocation.
2. Failing to take reasonable precautions against misuse, theft, loss, or diversion.	Reprimand and a fine of $250.	$500 fine and one (1) year suspension followed by one (1) year probation, to Revocation.
3. Failing to detect or to report a significant loss, theft, or inventory shortage of drugs.	Reprimand, $500 fine, and one (1) year probation.	$1,000 fine and one (1) year suspension followed by two (2) years probation, to Revocation.
4. Failing to follow the rules of the Board regarding proper storage and handling of drugs.	Reprimand and a fine of $250.	$500 fine and one (1) year suspension followed by one (1) year probation, to Revocation.
5. Violating any provision of Section 828.055, Chapter 465, Chapter 499, F.S., or any rule adopted under those chapters.	Reprimand and a fine of $250.	$500 fine and one (1) year suspension followed by one (1) year probation, to Revocation.

893.04 Pharmacist and practitioner.—

(1) A pharmacist, in good faith and in the course of professional practice only, may dispense controlled substances upon a written or oral prescription of a practitioner, under the following conditions:

(a) Oral prescriptions must be promptly reduced to writing by the pharmacist or recorded electronically if permitted by federal law.

(b) The written prescription must be dated and signed by the prescribing practitioner on the day when issued.

(c) There shall appear on the face of the prescription or written record thereof for the controlled substance the following information:

1. The full name and address of the person for whom, or the owner of the animal for which, the controlled substance is dispensed.
2. The full name and address of the prescribing practitioner and the practitioner's federal controlled substance registry number shall be printed thereon.
3. If the prescription is for an animal, the species of animal for which the controlled substance is prescribed.
4. The name of the controlled substance prescribed and the strength, quantity, and directions for use thereof.
5. The number of the prescription, as recorded in the prescription files of the pharmacy in which it is filled.

6. The initials of the pharmacist filling the prescription and the date filled.
(d) The prescription shall be retained on file by the proprietor of the pharmacy in which it is filled for a period of 2 years.
(e) Affixed to the original container in which a controlled substance is delivered upon a prescription or authorized refill thereof, as hereinafter provided, there shall be a label bearing the following information:
1. The name and address of the pharmacy from which such controlled substance was dispensed.
2. The date on which the prescription for such controlled substance was filled.
3. The number of such prescription, as recorded in the prescription files of the pharmacy in which it is filled.
4. The name of the prescribing practitioner.
5. The name of the patient for whom, or of the owner and species of the animal for which, the controlled substance is prescribed.
6. The directions for the use of the controlled substance prescribed in the prescription.
7. A clear, concise warning that it is a crime to transfer the controlled substance to any person other than the patient for whom prescribed.
(f) A prescription for a controlled substance listed in Schedule II may be dispensed only upon a written prescription of a practitioner, except that in an emergency situation, as defined by regulation of the Department of Health, such controlled substance may be dispensed upon oral prescription but is limited to a 72-hour supply. A prescription for a controlled substance listed in Schedule II may not be refilled.
(g) A prescription for a controlled substance listed in Schedule III, Schedule IV, or Schedule V may not be filled or refilled more than five times within a period of 6 months after the date on which the prescription was written unless the prescription is renewed by a practitioner.
(2)(a) A pharmacist may not dispense a controlled substance listed in Schedule II, Schedule III, or Schedule IV to any patient or patient's agent without first determining, in the exercise of her or his professional judgment, that the prescription is valid. The pharmacist may dispense the controlled substance, in the exercise of her or his professional judgment, when the pharmacist or pharmacist's agent has obtained satisfactory patient information from the patient or the patient's agent.
(b) Any pharmacist who dispenses by mail a controlled substance listed in Schedule II, Schedule III, or Schedule IV is exempt from the requirement to obtain suitable identification for the prescription dispensed by mail if the pharmacist has obtained the patient's identification through the patient's prescription benefit plan.
(c) Any controlled substance listed in Schedule III or Schedule IV may be dispensed by a pharmacist upon an oral prescription if, before filling the prescription, the pharmacist reduces it to writing or records the prescription electronically if permitted by federal law. Such prescriptions must contain the date of the oral authorization.
(d) Each prescription written by a practitioner in this state for a controlled substance listed in Schedule II, Schedule III, or Schedule IV must include a written and a numerical notation of the quantity of the controlled substance prescribed and a notation of the date in numerical, month/day/year format, or with the abbreviated month written out, or the month written out in whole. A pharmacist may, upon verification by the prescriber, document any information required by this paragraph. If the prescriber is not available to verify a prescription, the pharmacist may dispense the controlled substance, but may 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.
(e) A pharmacist may not dispense more than a 30-day supply of a controlled substance listed in Schedule III upon an oral prescription issued in this state.
(f) A pharmacist may not knowingly dispense a prescription that has been forged for a controlled substance listed in Schedule II, Schedule III, or Schedule IV.
(3) Notwithstanding subsection (1), a pharmacist may dispense a one-time emergency refill of up to a 72-hour supply of the prescribed medication for any medicinal drug other than a medicinal drug listed in Schedule II, or up to one vial of insulin to treat diabetes mellitus, in compliance with s. 465.0275.
(4) The legal owner of any stock of controlled substances in a pharmacy, upon discontinuance of dealing in controlled substances, may sell said stock to a manufacturer, wholesaler, or pharmacy. Such controlled substances may be sold only upon an order form, when such an order form is required for sale by the drug abuse laws of the United States or this state, or regulations pursuant thereto.
History.—s. 4, ch. 73-331; s. 2, ch. 75-18; s. 12, ch. 79-12; s. 2, ch. 90-2; s. 1436, ch. 97-102; s. 301, ch. 99-8; s. 2, ch. 2007-156; s. 5, ch. 2009-202; s. 5, ch. 2014-113; s. 6, ch. 2016-145; s. 35, ch. 2016-230.

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.

From MPJE Blueprint

Multiple-choice Item Format
How many total CPE hours are required to be completed upon the second renewal of a pharmacists license in this jurisdiction?
A. 15
B. 20
C. 25
D. 30
E. 40

Multiple-response Item Format
Which of the following medications are classified as Schedule II controlled substances in this jurisdiction? (Select **ALL** that apply.)
☐A. Strattera
☐B. Lisdexamfetamine
☐C. Meprobamate
☐D. Amphetamine
☐E. Dexmethylphenidate

Ordered-response Item Format
Place the following in the order in which they would expire according to federal regulations, starting with the earliest.(**ALL** options must be used.)

Unordered Options	Ordered Response

A partially filled methylphenidate prescription for a patient not in an LTCF	
A phoned-in, emergency oxycodone prescription	
A written bupropion prescription	
An electronic alprazolam prescription	
A partially filled morphine prescription for a patient in an LTCF	

1. In order for 1 pharmacist to have 6 technicians to directly supervise, the pharmacist must:
   a) Confirm each technician is receiving 30 CE credits every two years
   b) Ensure that the technicians have graduated an ACPE-accredited program and have a 4-year undergraduate degree
   c) Obtain written notification permitting such ratio from the prescription department manager or consultant pharmacist of record
   d) *Ensure they are not involved in dispensing or sterile compounding
   e) None of the above. The maximum allowable ratio is 1:3.

2. Which of the following may prescribe Oxycodone in Florida for back surgery (select all that apply)?
   a) *Nurse Practitioner
   b) *Physician Assistant
   c) *Physician
   d) *Veterinarian
   e) Chiropracter

3. A prescription may be written for Xanax, Soma, Lorcet and Vicodin on the same prescription blank?
   a) Yes, multiple controlled substances may be written on the same prescription blank
   b) Yes, as long as the pharmacist documents that therapy is valid and a patient-prescriber relationship exists
   c) No. Lorcet and Vicodin are the same drug and this is considered therapeutic duplication.
   d) *No, different schedules of controlled substances require different prescription blanks

4. What is the check digit in Dr. Matthew's DEA number AM123456_____(*3)

5. An Ophthalmologist prescribes oxycodone 30 mg #180 for headache. The pharmacist should:
   a) *Fill the prescription if the pharmacist determines this is a valid prescription
   b) Fill the prescription only if oxycodone is indicated for headache
   c) Not fill the prescription as midlevel practitioners in FL cannot prescribe controlled substances
   d) Not fill the prescription as Ophthalmology is the practice of medicine involving the eye

6. How long does an immunizing pharmacist in FL have to maintain patient records in FL?
   a) 1 year
   b) 2 years
   c) 3 years
   d) 4 years
   e) *None of the above

7. A young man enters your pharmacy and wants to purchase 90 tablets of Pseudoephedrine (PSE). You should instruct him:
   a) PSE is now a schedule I controlled substance and it is against the law to sell
   b) The maximum allowable sale is 36 tablets
   c) That a valid driver's license is required to purchase the product

d) *That the age limit to purchase PSE is 18 years of age

8. If a controlled substance prescription is for an animal, which of the following is required on the prescription?
   a) Name of the physician
   b) Species of animal
   c) Name of the owner
   d) *All of the above

9. A young woman requests that her elderly mother receive all prescriptions (blanket request) in a non child resistant containers. The pharmacist should:
   a) comply with the request as the woman is looking out for her mother
   b) *comply with the request as long as the woman is the official caregiver of the elderly woman
   c) not comply with the request because a blanket request for non child resistant containers is illegal
   d) not comply with the request because only the prescribing physician can make blanket requests for dispensing in non-child resistant containers

10. A pharmacist while verifying a prescription medication spills coffee in the Stock Container of HCTZ (25 mg). The technician empties the bottle in order to clean it out, mixing it with another bottle of HCTZ (50 mg) by accident; The technician then fills a prescription for HCTZ 25 mg using both tablets. The prescription is:
    a) Adulterated
    b) Misbranded
    c) *Adulterate and Misbranded
    d) Neither Adulterated or Misbranded

11. When transferring a prescription, the pharmacist must do all of the following except:
    a) Advise the patient that the prescription on file at the other pharmacy will be canceled
    b) Determine that the prescription is still valid
    c) *Notify the doctor who wrote the prescription that it will be transferred
    d) Notify the pharmacy where the prescription is currently filled that it will be canceled

12. 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

13. A hospital pharmacy technician properly garbed adds sterile water as a diluent in a vial of a tobramycin under ISO 5 conditions for immediate use. The product when stored at room temperature should be labeled with a beyond use date of:
    a) *1 hour
    b) 48 hours
    c) 14 days
    d) 45 days

14. As owner of a community pharmacy you decide to open a new business, a nursing home. You apply for a Class I institutional Pharmacy permit, along with the other required permits. The Board of Pharmacy should rule:
    a) A pharmacist cannot own both a community pharmacy and Class I institutional pharmacy and reject the application

b) The application may be approved as long as a pharmacist owner applying is named the pharmacist consultant of record
c) The application is rejected because there is a significant conflict of interest and potential for illegal kickbacks because the community pharmacy will provide drugs to the nursing home
d) *None of the above

15. A woman calls your institutional pharmacy wanting to return a prescription for oxycodone for her father in a LTCF that died earlier that day. What should the pharmacist do?
a) Accept the return since the patient was in a LTCF
b) Accept the return since the drug is a CII
c) Not accept the return since the patient died
d) *Not accept the return because the drug was dispensed
e) two of the above answers are correct

16. The Pharmacist makes a final check on a prescription for Ativan and the technician files the medication in alphabetical order while it awaits to be picked up by the patient. Three weeks later you find out the patient died, the medication was never picked up, and the medication is still filed away in alphabetical order. What should the pharmacist do with the unclaimed prescription?
a) Destroy the medication using DEA Form 41
b) Return the drug to a reverse distributor because it cannot be returned to stock or else the drug will be misbranded
c) Dispense to the doctor for "office use" to use for another patient subject to six month expiration from date originally written
d) Contact the State Medical Examiner, confirm patient death and then return to stock using the manufacturer's expiration date
e) *Return to stock subject to a 12 month beyond-use date from date originally filled

17. You open a pharmacy on Wall Street and decide to use a central fill pharmacy upstate to fill the prescriptions. Which of the following pharmacies is required to counsel the patient on a prescription for lorazepam.
a) The central fill pharmacy only
b) The central pharmacy and Wall Street Pharmacy
c) *Wall Street Pharmacy only
d) Neither pharmacy is required to counsel the patient
e) Central fill pharmacies cannot fill prescriptions for controlled substances

18. The registrant of a DEA license in a community pharmacy wishes to have his wife order stock of methadone for pain patients. Choose the best response:
a) The wife may order methadone only if it in tablet form
b) The wife may order methadone only if she a licensed pharmacist
c) The wife may order methadone only if she has a valid DEA registration
d) *The wife may order methadone only if she has been granted power of attorney

19. A pharmacist receives a prescription for Magic Mouthwash. The pharmacist compounds the drug using Milk of Magnesia (OTC), Diphenhydramine (OTC), Lidocaine (Rx) and Nystatin (Rx). Which of the following labels would be correct
a) Magic Mouthwash
b) Lidocaine and Nystatin
c) *Milk of Magnesia, Diphenhydramine, Lidocaine, and Nystatin
d) Magic Mouthwash, Lidocaine and Nystatin

20. How many years is a community pharmacy permit good for?
a) *2 years
b) 3 years

c) 4 years
d) Indefinitely as long as it continues to pass inspection

21. A Nursing Home patient needs diazepam injection to treat a seizure. The nurse on staff accesses the Emergency Medicine Kit. Which of the following is correct?
    a) The Nurse must be registered with the DEA to administer the injection.
    b) *The seal must be resealed within the next business day.
    c) The pharmacy on-site must have a written prescription for diazepam from the hospital director before the seal can be broken.
    d) The consultant pharmacist of record must report the drug usage to the DEA using a Form 41 within seven business days.
    e) a and b only
    f) a and b and c only

22. Which of the following is required on the drug label for a drug
    a) Address of the pharmacy
    b) Prescription (Serial) Number
    c) Expiration Date/Beyond Use Date
    d) Date of dispensing
    e) Quantity of the drug dispensed
    f) *a through d only

23. Which of the following can a registered technician do, under the direct and immediate supervision of a pharmacist
    a) *Enter an order
    b) Counsel a patient on a prescription drug refill
    c) *Conduct CII inventory
    d) Interpret a prescription order for appropriateness
    e) *Initiate communications with a prescriber for omitted quantity of a prescription order
    f) Independently override clinical alerts

24. Place the following in order of the number of refills permissible, starting with the least.(ALL options must be used)

Unordered Options	Ordered Response
Soma	
Vicodin	
Byetta	
Lyrica	

25. Place the following in the order in how long they must be maintained, starting with the shortest duration.(**ALL** options must be used.)

Unordered Options	Ordered Response
DEA Ordering Records	
FL Prescription Records	
FL immunization Records	
Pseudoephedrine Sales Records	
Continuous Quality Improvement Program Records	

Section 6
Wrap-Up and Disclaimer

This is a working draft for instructional use only. No actual exam content was used in the preparation of this review. The information contained herein is not guaranteed for accuracy and contains discrepancies. No representations or warranties are given on the material attached. Note, the law is subject to extensive interpretation and Board rulings prevail. Please forgive any errors or omissions. Nothing in this document should be considered legal advice or establishing any attorney-client relationship. The author requests that either during or after your studying you send comments on the relevance and quality of this review (no Exam Content) and/or the examination to Matthew Seamon at mseamon@nova.edu.

Good luck!
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