

# Legal Pitfalls of Working in Family Medicine

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# OBJECTIVES

- In-Office Use of Compounded Products
  - Pain Management
  - Dispensing Controlled Substances for Pain
  - DEA Registration
  - Telemedicine
  - Medical Directorships
- 


# **In-Office Use of Compounded Products**




# Office Use Compounding Definition

- See Fla. Admin Code R. 64B16-27.700(3)
  - “Office use” means the administration of a compounded drug to a patient by a practitioner in the practitioner’s office or by the practitioner in a health care facility or treatment setting
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# Office Use Compounding

- Pharmacist may dispense & deliver a quantity of a compounded drug for office use if:
    - The quantity of compounded drug does not exceed the amount a practitioner anticipates may be used in the office before the expiration date
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# Office Use Compounding


- Pharmacist may dispense & deliver a compounded drug if:
    - The quantity of compounded drug is reasonable considering the intended use & the nature of the practitioner's practice
    - The quantity of compounded drug is not greater than an amount the pharmacy is capable of compounding in compliance United States guidelines
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# Office Use Compounding

- Pharmacist may dispense & deliver a compounded drug if:
  - The pharmacy and the practitioner enter into a written agreement


# Written Agreement Shall Provide

- Compounded drug may only be administered to the patient listed on prescription
  - Compounded drug may not be dispensed to the patient or sold to anyone else
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# Written Agreement Shall Provide

- Practitioner must record on the patient's chart the lot number and beyond-use data
  - Practitioner must provide the patient with a means to report complaints or adverse reactions to facilitate recalls
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# Recordkeeping

- In addition to requiring a written agreement between the pharmacy and provider, the pharmacy must maintain readily-retrievable records for four years of all compounded drugs ordered for office use
- 


# Recordkeeping

- The records must include:
    - The name, address and phone number of the practitioner ordering the compounded drug and the date of the order
    - The name, strength and quantity of the compounded drug, including the number of containers and quantity in each
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# Recordkeeping

- The records must include:
    - Date the drug was compounded
    - Date the compounded drug was provided to the practitioner
    - Lot number and beyond-use date
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# Labeling

- The pharmacy must affix a label to the compounded drug that is provided for office use. The label must include:
    - Compounding pharmacy's name, address and phone number
    - List of active ingredients and their strengths
    - Pharmacy's lot number and beyond-use date
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# Labeling


- The label must include:
    - Quantity in the container
    - Appropriate ancillary instructions such as storage instructions, cautionary statements or hazardous drug warning labels
    - Statement “For Institutional or Office Use Only  
– Not for Resale”
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# **Pain Management**




# Pain Management Clinic Definition

- Pain management clinics are those that advertise in any medium for any type of pain-management services; or
  - Where in any month a majority of patients are prescribed certain controlled substances for the treatment of chronic non-malignant pain
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# **Pain Management Clinic Registration Requirements**

- Must be registered with Department of Health
  - If clinic ownership changes, new owner must register with Department of Health
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# **Pain Management Clinic Registration Requirements**


- Clinic must be fully owned by physician or group of physicians who are currently licensed
  - Clinic's designated physician must have clear and active license with no restrictions to practice and no current discipline
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# Pain Management Guidelines


- The Board has adopted these guidelines for evaluating the use of controlled substances for pain control




# Evaluate the Patient

- Physician must conduct and document a complete medical history and examination of patient
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# Treatment Plan


- Written treatment plan should state objectives used to determine treatment success
  - Shall indicate if any further diagnostic evaluations or treatments are planned
  - After treatment begins, physician shall adjust drug therapy if necessary
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# Informed Consent & Agreement for Treatment


- Physician must discuss the risks and benefits of controlled substance use with patient
  - Patient shall receive prescriptions from one physician and one pharmacy
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# Informed Consent & Agreement for Treatment

- If patient is high risk of abuse, physician shall employ a written agreement (pain contracts) outlining patient responsibilities:
    - Urine screening
    - Number & frequency of all prescription refills
    - Reasons for which drug therapy may be discontinued
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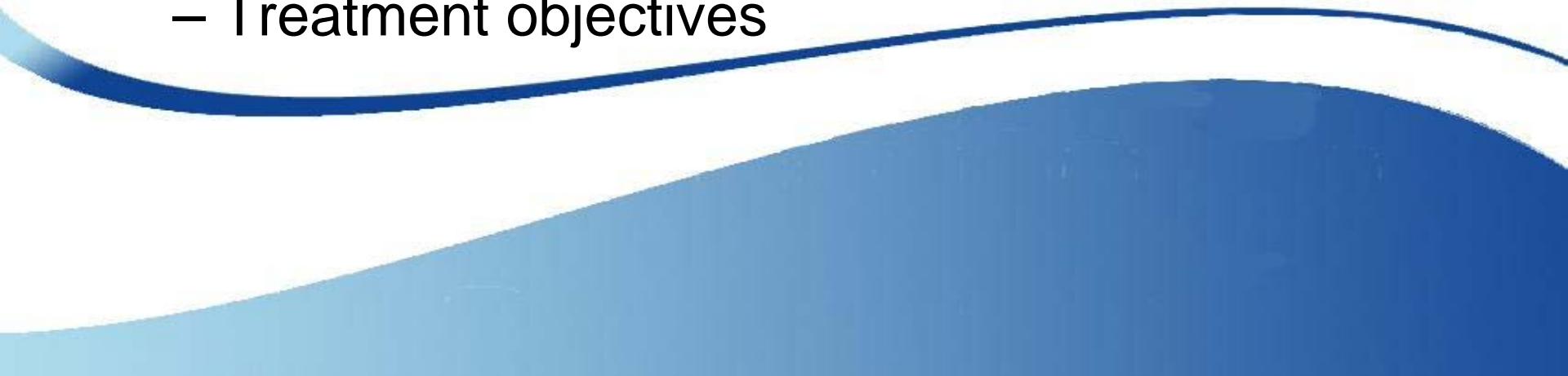
# Periodic Review

- Physician must review the course of treatment & new information about the etiology of the pain
  - If treatment goals are not being met, physician shall reevaluate the appropriateness of continued treatment
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# Consultation

- Physician shall be willing to refer the patients as necessary for additional evaluation and treatment in order to achieve treatment objectives
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# Medical Records

- The physician is required to keep accurate & complete records to include:
    - Complete medical history & physician evaluation
    - Diagnostic, therapeutic & laboratory results
    - Evaluation & consultation
    - Treatment objectives
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# Medical Records

- Records must include:
    - Discussion of risk and benefits
    - Treatments
    - Medications (date, type, dosage & quantity)
    - Instructions and agreements
    - Drug testing results
    - Periodic reviews
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# **Compliance with Controlled Substance Laws & Regulations**

- To prescribe, dispense or administer controlled substances, the physician must be licensed in the state and comply with applicable federal and state regulations
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# Controlled Substance Prescriptions


- Florida law requires that all prescriptions be legibly printed or typed
  - That the quantity of drug prescribed appear in textual and numeric formats
  - The data be written out in textual letters
- 

# Controlled Substance Prescription Must Include


- Date of issue
  - Patient's name and address
  - Practitioner's name, address and DEA registration number
  - Drug name
  - Drug strength
  - Dosage form
  - Directions for use
  - Number of refills (if any)
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**Standards for Dispensing  
Controlled Substances for Pain  
by the Florida Board of  
Pharmacy**




# Standards for Dispensing Controlled Substances

- Criteria that should cause a pharmacist to question legitimacy of a prescription:
    - Frequent loss of controlled substance prescriptions
    - Only controlled substance medications are prescribed for patient
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# Standards for Dispensing Controlled Substances

- Questionable Criteria:
    - One person presents controlled substance prescriptions with different patient names
    - Same controlled substance medication prescribed by 2 or more prescribers at same time
    - Patient pays cash & insists on brand name product
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# Standards for Dispensing Controlled Substances

- A pharmacist with reason to believe that a prescriber is involved with diversion must report the prescriber to the Florida Department of Health
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# Discipline

- The Board will not take disciplinary action against a physician for failing to adhere strictly to the provisions of their standards for the use of controlled substances in the treatment of pain if good cause is shown in such deviations
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# Discipline

- The Board will judge the validity of prescribing based on the physician's treatment of the patient and on available documentation, rather than on the quantity and chronicity of prescribing
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# Physician Liability for Overprescribing


- Penalties for violating the Florida statute on prescribing controlled substances are:
  - The minimum penalty for the first violation is a 6-month license suspension & a \$10,000 fine
  - The maximum penalty is total license revocation plus the fine

# Physician Liability for Overprescribing

- Penalties for violating statutes on prescribing controlled substances in other states:
    - Manslaughter
    - Attempted murder
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# Professionals Who Cannot Prescribe Controlled Substances

- Physician Assistants
  - Ambulance Service
  - Medical Psychologists
  - Nursing Homes
  - Nurse Practitioners
  - Registered Pharmacists
  - Telemedicine Providers
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# DEA Registration




# DEA Application Requirements

- Personal/Business Information
    - Individual Registration (Practitioner, MLP, Researcher)
      - Full Name, Address, Social Security Number, and Phone Number
    - Business Registration
      - Name of the Business, Address, Tax ID, and Phone Number
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# DEA Application Requirements

- Activity
    - Business activity and drug schedule information
    - In addition, some registrants will need to provide specific drug codes and/or chemical codes related to their operations
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# DEA Application Requirements

- State License(s)
    - It is mandatory to provide State medical and/or controlled substance licenses/registrations
    - Failure to provide valid & active state licenses will be cause to declare the application as defective and will be withdrawn
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# DEA Application Requirements


- Florida does not have a separate controlled substance prescription permit
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# DEA Application Requirements

- Background Information
  - Information pertaining to controlled substances in the applicant's background




# Renewal of Applications


- According to the Office of Diversion Control
    - New applications are processed within 4 to 6 weeks
    - Renewal applications are processed within approximately 4 weeks
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# DEA'S Locum Tenens Policy

- Controlled Substance Act requires a separate registration for each place of business or practice where controlled substances are manufactured, distributed or dispensed
  - DEA issues a registration based upon the authority to handle controlled substances granted by the state in which the practitioner practices
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# DEA'S Locum Tenens Policy

- Separate registrations for separate locations
    - A separate registration is required for each principle place of business or practice at one general physical location where controlled substances are manufactured, distributed, imported or dispensed by a person
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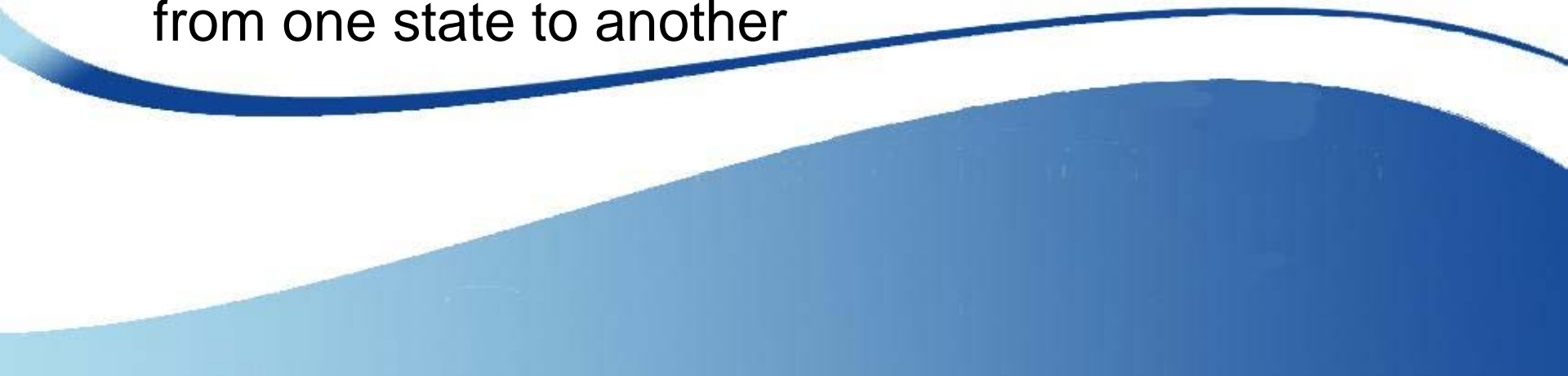
# DEA'S Locum Tenens Policy

- Practitioners who register at one location in a state, but practice at other locations within the same state are not required to register with DEA at any other location in that state at which they only prescribe controlled substances
  - If they maintain supplies, administer or directly dispense controlled substances at a location, practitioners must register that location
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# Multiple State DEA Registration

- Practitioners that wish to administer, dispense or prescribe controlled substances in multiple states have the following options regarding a DEA registration:
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# Multiple State DEA Registration

- Will need to obtain a separate DEA registration in each state if they plan to administer, dispense or prescribe controlled substances
  - Practitioner working solely in a hospital/clinic setting may use the hospital's DEA registration if the hospital agrees
  - Practitioners must transfer existing DEA registration from one state to another
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# **Telemedicine in Florida**



# Current Telemedicine Rules in Florida


- Adopted more than 10 years ago
  - Have not kept up with changing attitude of the public on telemedicine
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# Florida Senate Health Policy Committee


- Senate committee plans to vote on a telemedicine bill February 18, 2014
  - Committee's bill:
    - Allows regulatory board to negotiate compacts for telemedicine
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# Florida Senate Health Policy Committee

- Committee's bill:
    - Defines 11 terms for a telemedicine industry, including what is meant by advanced communications technology, a “distant site” an “in-person” consultation and a telemedicine provider
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# Florida Senate Health Policy Committee


- Committee's bill:
    - Allow insurers to limit telemedicine coverage to those providers with in the insurer's provider network
    - Mandate the standard of care
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# Florida Senate Health Policy Committee


- Bill issues:
    - Whether reimbursements for a telemedicine visit will be the same as a face-to-face consultation
    - Confusion concerning the nexus of licensing and interstate compacts
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# Florida Board of Medicine

- Rule Provisions

- Telemedicine establishes a physician-patient relationship
  - All regulations regarding patient confidentiality & record keeping are applicable
  - Exempts out medical advice given by emergency responders
  - Does not apply to physicians or PAs providing emergency medical care
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# Florida Board of Medicine

- Rule 64B8-0.014, FAC – Standards for Telemedicine Prescribing Practice
    - Feb. 6, 2014 the Board's Telemedicine Committee approved draft language in proposed rule
    - Matter tabled to address language regarding refills & to look at all existing prescribing rules
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# **Medical Directorships**



# Medical Director Legal Responsibilities

- Ensure signs identifying the medical director are posted in a visible location in clinic
  - Ensure all practitioners providing services or supplies to patients maintain current, active & unencumbered Florida license
  - Review patient referral contracts or agreements executed by the clinic
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# Medical Director Legal Responsibilities


- Ensure that clinic's practitioners have active appropriate licensure for the level of care they are providing
  - Serve as the clinic's medical records owner
  - Ensure the clinic's compliance with all record keeping, physician office surgery, and adverse incident reporting requirements
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# Medical Director Legal Responsibilities

- Conduct systematic reviews of the clinic's claims submissions and billings in order to ensure that the billings and claims submissions are not fraudulent

# Medical Director Legal Pitfalls

- Medical directors must have full and unencumbered license
  - Compensation agreements based on physician referrals could violate federal Anti-Kickback Statute, Florida Patient Brokering Act or Federal Stark Law
  - Medical malpractice liability
  - Requirements physicians must meet when supervising personnel and providers
- 



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