Federal and Florida Laws Related to the Prescribing of Controlled Substances

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I. Federal Laws on Prescribing Controlled Substances

Federal Laws on Prescribing Controlled Substances

- The Controlled Substances Act (21 U.S.C. §§801-890) governs licit and illicit drugs at the federal level.
- The U.S. Drug Enforcement Agency (DEA) enforces the Act.
- Drugs are categorized in five classes (Schedules I-V) (21 C.F.R. §§1808.11-1308.15) depending on the potential for addiction and abuse.
  - Schedule I drugs include heroin, LSD, and ecstasy.
  - Schedule V drugs have the lowest potential for abuse.

Federal Laws on Prescribing Controlled Substances

- C-II Rx do not have an expiration under federal law.
  - Florida prescriptions must be filled within 1 year
  - No refills for C-II under federal law
- C-III Rx expire 6 months following prescription date.
  - Within the 6 months, prescriptions may be refilled 5 times.
  - Physicians who prescribe controlled substances are required to have a certificate with the DEA.
  - General Rule:
  - Practitioners dispensing controlled substances for maintenance tx or detoxification must be separately registered for that purpose (21 U.S.C. §823(g))

II. Florida Laws and Rules on Prescribing Controlled Substances

A. Controlled Substance Prescribing

Controlled Substance Prescribing

I. "Chronic nonmalignant pain":
   - unrelated to cancer
   - persists more than 90d after surgery or beyond the usual course of the disease or injury causing the pain

II. Physicians prescribing controlled substances (opioids) for chronic nonmalignant pain must:
   - Identify yourself as a controlled substance providing practitioner on your Department of Health profile.
   - Satisfy medical records requirements:
     - Show that a physical examination was conducted before tx.
     - Document current and past tx for pain, including Rx from a previous physician.
     - Show a review of previous medical records.
       - The physician must request them if the physician does not have them.
     - The records must be individualized and not based on a consistent template.
       - Do the charts indicate a common diagnosis?

Controlled Substance Prescribing

- A photocopy of a government-issued photo ID (usually a driver's license).
  - Beware of out-of-state IDs
  - Beware of pts claiming no IDs
- Drugs prescribed.

- Write a tx plan with objectives for each pt.
- Sign a controlled substance agreement with the pt outlining the pt's responsibilities.
- Discuss abuse and addiction risks with pt.
- Meet with the pt at no more than 3 month intervals.
  - Assess tx.
  - Monitor risk of addiction.
  - Evaluate potential drug-related aberrant behavior.
  - Unless the physician is board-certified or -eligible in pain management (e.g. through the AOA), pts with drug abuse sx must be immediately referred to:
    - a board-certified pain management physician
    - an addiction medicine specialist, or
    - a mental health facility as it relates to drug abuse or addiction

Controlled Substance Prescribing

- While waiting for consultant's report, the physician must document the medical justification for continuing the prescription.
- After getting the report, the physician must incorporate the recommendations in treating the pt.

III. Exceptions:

- You may treat a cancer pt for pain by prescribing schedule II, III, or IV drugs and not have to register as a controlled substance providing practitioner and abide by the other requirements.
- If the pain is connected to an injury and is following its usual course, same thing.
- Prescribing for something other than chronic nonmalignant pain.
  - For example, Xanax for anxiety.

B. Pain-Management Clinics

Pain-Management Clinics

REGISTRATION

- Any medical practice location that advertises pain-management services must register as a pain-management clinic.
- Any clinic that – in any month – prescribes opioids, benzodiazepines, barbiturates, or carisoprodol for treating chronic nonmalignant pain for most of its pts, must register as a pain-management clinic with DOH.
- Each clinic must register separately, even if the owner or management or business name is the same.
- MDs/DOs usually must own the clinic.

Exception. If most clinic physicians primarily do surgeries, the clinic does not have to register.

Pain-Management Clinics

PHYSICIAN RESPONSIBILITIES

D.O.s providing professional services in pain management clinics are required:

- To notify the Board of Osteopathic Medicine within 10d of beginning or ending practice in a pain management clinic; and
- To comply with the clinic's physical and operational requirements, infection prevention and control requirements, health and safety requirements, quality assurance requirements, and data collection and reporting requirements.
  - Each D.O. individual is responsible for ensuring the clinic's compliance with:
    - physical and operational requirements.
    - infection prevention and control requirements.
    - health and safety requirements.
- Pain-management clinics must designate a physician (MD/DO) to be responsible for making sure the clinic complies with the clinic's registration and operational requirements.

C. Training Requirements for Physicians Practicing in Pain-Management Clinics

Training Requirements for Physicians Practicing in Pain-Management Clinics

Alternatives:

- Complete pain management fellowship accredited by American Osteopathic Association (AOA)
- Complete pain medicine residency accredited by AOA
- Have staff privileges at a Florida-licensed hospital to practice pain medicine or perform pain medicine procedures.

III. Current Florida Statistics Regarding Morbidity and Mortality of Controlled Substance-Related Deaths

Current Statistics

In 2014, the following document was published based on 2013 statistics: Drugs Identified in Deceased Persons by Florida Medical Examiners: 2013 Interim Report.

Here are some findings from the first half of 2013:

- 2,363 people died in Florida with at least one Rx drug in their system.
- 975 people died because of Rx drugs.
  - 568 people died from benzodiazepines.
    - 302 died from ethyl alcohol.
    - 291 died from cocaine.
    - 279 died from oxycodone.
    - 268 died from morphine.
    - 221 died from methadone.
    - 158 died from hydrocodone.
- Rx drugs were more prevalent than illicit drugs and caused more drug-related deaths.

Current Statistics

The 2013 Interim Report showed general improvement over 2012 (for the same period):

- Oxycodone deaths fell by 16.2%.
- Hydrocodone deaths were down 29.5%.
- Heroin deaths were down 6.8%
- Cocaine deaths were down 7.0%
- But deaths due to fentanyl increased 23.2%.

IV. Pharmacology of Opiate Drugs

Pharmacology

- Opioids are extremely effective pain relievers.
- They often encourage physical dependence.
- Opioids are sometimes called narcotics painkillers. They include:
  - codeine
  - fentanyl
  - hydrocodone
  - methadone
  - morphine
  - oxycodone
- Oxycontin is of particular concern because it is long acting and extended release.
- Effects of opiates greatly vary among different people.
  - Dr. Art Lipman, in "The Pharmacology of Opiate Drugs and Basic Principals," says morphine has no safe maximum dose.
  - Schedule II drugs include oxycontin, oxycodone, and morphine
    - High potential for abuse.
  - Schedule III drugs include butabarital and amphetamines.
  - Schedule IV drugs include valium.
    - Low risk of abuse.

V. Proper Prescribing of Opiate Drugs

Proper Prescribing of Opiate Drugs

Be familiar with Risk Evaluation and Mitigation Strategies (REMS)

- Required by FDA
- REMS are drug manufacturers' recommendations re proper use of opioids (and other high risk medications), for example medication guides
- Two REMS are for classes of opioid analgesics
  - Long-acting, extended release
    - REMS says that physicians are encouraged to take certain steps
  - Transmucosal immediate-relief fentanyl

Be sensitive to psychological issues.

- Ask about mood and family support structure.
- Chronic pain is often associated with psychiatric comorbidity.
- Low back pain is commonly associated with depression.
- 30% - 60% of chronic pain pts suffer from anxiety.
- Is the pt currently on anti-depressants?
- Was the pt on anti-depressants before? Which ones?
- What are the potential interactions between such anti-depressants and pain medication?

Proper Prescribing of Opiate Drugs

At the first appointment and at every appointment thereafter, get a urine sample from the pt for testing.

- Withhold initial Rx until you get results.
- Regular drug testing should be part of your contract with the pt.

Be attuned to signs of aberrant behavior.

- Has the pt claimed to have lost an Rx?
- Does the pt request early refills?
- Does the pt call the front office unnecessarily?

Consider screening questionnaires for each visit. The first two are especially important:

- Have you considered reducing your drug use?
- Have you been annoyed at people criticizing your drug use?
- Do you feel guilty about your drug use?

VI. Physician Liability for Overprescribing Controlled Substances

Physician Liability for Overprescribing Controlled Substances

The penalties for violating the Florida statute on prescribing controlled substances are severe:

- The minimum penalty for the first violation is a 6-month license suspension and a $10,000 fine.
- The maximum penalty is total license revocation plus the fine.
- The minimum penalty for a second violation is a 1-year suspension, probation, and a $10,000 fine.

Conclusion

- Questions?

Thanks for coming.

APPENDIX

Florida Statutes and Regulations on Prescribing Controlled Substances

Florida Statutes and Regulations

- Fla. Admin. Code Ann. r. 64B15-13.001 — Continuing Education for Biennial Renewal
- Fla. Stat. § 456.44 — Controlled Substance Prescribing
  - Fla. Stat. § 456.44(1) — Definitions
  - Fla. Stat. § 456.44(2) — Registration
  - Fla. Stat. § 456.44(3) — Standard of Practice
- Fla. Stat. § 459.0137 — Pain-Management Clinics
  - Fla. Stat. § 459.0137(1) — Registration
  - Fla. Stat. § 459.0137(2) — Physician Responsibilities
  - Fla. Stat. § 459.0137(3) — Inspection
  - Fla. Stat. § 459.0137(5) — Penalties; Enforcement
- Fla. Admin. Code Ann. r. 64B15-14.005 — Standards for the Use of Controlled Substances for Treatment of Pain
- Fla. Admin. Code Ann. r. 64B15-14.0051 — Training Requirements for Physicians Practicing in Pain -Management Clinics
- Fla. Admin. Code Ann. r. 64B15-14.0052 — Requirement for Pain Management Clinic Registration; Inspection or Accreditation.
- Fla. Admin. Code Ann. r. 64B15-19.002 — Violations and Penalties

Fla. Admin. Code Ann. r. 64B15-13.001
Continuing Education for Biennial Renewal

(1) (a) Every person licensed pursuant to Chapter 459, F.S., except … physician assistants …, shall be required to complete forty (40) hours of continuing medical education courses approved by the Board in the twenty-four (24) months preceding each biennial renewal period …. Five of the continuing medical education hours for renewal shall include … one hour Florida Laws and Rules [and] one hour on the federal and state laws related to the prescribing of controlled substances ….

(3) (b) The continuing medical education … with regard to … Florida Laws and Rules [and] controlled substances… shall be obtained by the completion of live, participatory attendance courses…..

(e) For purposes of this rule, a one (1) hour course on the federal and state laws related to the prescribing of controlled substances shall include: a review of the applicable federal and state laws and rules; review of the current Florida statistics regarding morbidity and mortality of controlled substance related deaths; pharmacology of opiate drugs; proper prescribing of opiate drugs; and a review of physician liability for overprescribing controlled substances.

Fla. Stat. § 456.44(1) Controlled Substance Prescribing

DEFINITIONS.—

(a) "Addiction medicine specialist" means … an osteopathic physician who holds a certificate of added qualification in Addiction Medicine through the American Osteopathic Association.

(b) "Adverse incident" means any incident set forth in s. 458.351(4)(a)-(e) or s. 459.026(4)(a)-(e).

(c) "Board-certified pain management physician" means a physician who possesses board certification in pain medicine by the American Board of Pain Medicine, board certification by the American Board of Interventional Pain Physicians, or board certification or subcertification in pain management or pain medicine by a specialty board recognized by the American Association of Physician Specialists or the American Board of Medical Specialties or an osteopathic physician who holds a certificate in Pain Management by the American Osteopathic Association.

(d) "Board eligible" means successful completion of an anesthesia, physical medicine and rehabilitation, rheumatology, or neurology residency program approved by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association for a period of 6 years from successful completion of such residency program.

(e) "Chronic nonmalignant pain" means pain unrelated to cancer which persists beyond the usual course of disease or the injury that is the cause of the pain or more than 90 days after surgery.

(f) "Mental health addiction facility" means a facility licensed under chapter 394 or chapter 397.

Fla. Stat. § 456.44(2) Controlled Substance Prescribing

REGISTRATION. -- …

Effective January 1, 2012, a physician licensed under … chapter 459 … who prescribes any controlled substance, listed in Schedule II, Schedule III, or Schedule IV as defined in s. 893.03, for the treatment of chronic nonmalignant pain, must:

(a) Designate himself or herself as a controlled substance prescribing practitioner on the physician's practitioner profile.

(b) Comply with the requirements of this section and applicable board rules.

Fla. Stat. § 456.44(3) Controlled Substance Prescribing

STANDARDS OF PRACTICE.—The standards of practice in this section do not supersede the level of care, skill, and treatment recognized in general law related to health care licensure.

(a) A complete medical history and a physical examination must be conducted before beginning any treatment and must be documented in the medical record. The exact components of the physical examination shall be left to the judgment of the clinician who is expected to perform a physical examination proportionate to the diagnosis that justifies a treatment. The medical record must, at a minimum, document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, a review of previous medical records, previous diagnostic studies, and history of alcohol and substance abuse. The medical record shall also document the presence of one or more recognized medical indications for the use of a controlled substance. Each registrant must develop a written plan for assessing each patient's risk of aberrant drug-related behavior, which may include patient drug testing. Registrants must assess each patient's risk for aberrant drug-related behavior and monitor that risk on an ongoing basis in accordance with the plan.

Fla. Stat. § 456.44(3) Controlled Substance Prescribing

(b) Each registrant must develop a written individualized treatment plan for each patient. The treatment plan shall state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and shall indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician shall adjust drug therapy to the individual medical needs of each patient. Other treatment modalities, including a rehabilitation program, shall be considered depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment. The interdisciplinary nature of the treatment plan shall be documented.

Fla. Stat. § 456.44(3) Controlled Substance Prescribing

(c) The physician shall discuss the risks and benefits of the use of controlled substances, including the risks of abuse and addiction, as well as physical dependence and its consequences, with the patient, persons designated by the patient, or the patient's surrogate or guardian if the patient is incompetent. The physician shall use a written controlled substance agreement between the physician and the patient outlining the patient's responsibilities, including, but not limited to:

1. Number and frequency of controlled substance Rx and refills.
2. Patient compliance and reasons for which drug therapy may be discontinued, such as a violation of the agreement.
3. An agreement that controlled substances for the treatment of chronic nonmalignant pain shall be prescribed by a single treating physician unless otherwise authorized by the treating physician and documented in the medical record.

Fla. Stat. § 456.44(3) Controlled Substance Prescribing

(d) The patient shall be seen by the physician at regular intervals, not to exceed 3 months, to assess the efficacy of treatment, ensure that controlled substance therapy remains indicated, evaluate the patient's progress toward treatment objectives, consider adverse drug effects, and review the etiology of the pain. Continuation or modification of therapy shall depend on the physician's evaluation of the patient's progress. If treatment goals are not being achieved, despite medication adjustments, the physician shall reevaluate the appropriateness of continued treatment. The physician shall monitor patient compliance in medication usage, related treatment plans, controlled substance agreements, and indications of substance abuse or diversion at a minimum of 3-month intervals.

(e) The physician shall refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention shall be given to those patients who are at risk for misusing their medications and those whose living arrangements pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder requires extra care, monitoring, and documentation and requires consultation with or referral to an addiction medicine specialist or psychiatrist.

Fla. Stat. § 456.44(3) Controlled Substance Prescribing

(f) A physician registered under this section must maintain accurate, current, and complete records that are accessible and readily available for review and comply with the requirements of this section, the applicable practice act, and applicable board rules. The medical records must include, but are not limited to:

1. The complete medical history and a physical examination, including history of drug abuse or dependence.
2. Diagnostic, therapeutic, and laboratory results.
3. Evaluations and consultations.
4. Treatment objectives.
5. Discussion of risks and benefits.
6. Treatments.
7. Medications, including date, type, dosage, and quantity prescribed.
8. Instructions and agreements.
9. Periodic reviews.
10. Results of any drug testing.
11. A photocopy of the patient's government-issued photo identification.
12. If a written prescription for a controlled substance is given to the patient, a duplicate of the prescription.
13. The physician's full name presented in a legible manner.

Fla. Stat. § 456.44(3) Controlled Substance Prescribing

(g) Patients with signs or symptoms of substance abuse shall be immediately referred to a board-certified pain management physician, an addiction medicine specialist, or a mental health addiction facility as it pertains to drug abuse or addiction unless the physician is board-certified or board-eligible in pain management. Throughout the period of time before receiving the consultant's report, a prescribing physician shall clearly and completely document medical justification for continued treatment with controlled substances and those steps taken to ensure medically appropriate use of controlled substances by the patient. Upon receipt of the consultant's written report, the prescribing physician shall incorporate the consultant's recommendations for continuing, modifying, or discontinuing controlled substance therapy. The resulting changes in treatment shall be specifically documented in the patient's medical record. Evidence or behavioral indications of diversion shall be followed by discontinuation of controlled substance therapy, and the patient shall be discharged, and all results of testing and actions taken by the physician shall be documented in the patient's medical record.

Fla. Stat. § 456.44(3) Controlled Substance Prescribing

This subsection [on standards of practice] does not apply to … a board-certified physician who has surgical privileges at a hospital or ambulatory surgery center and primarily provides surgical services. This subsection does not apply to a board-eligible or board-certified medical specialist who has also completed a fellowship in pain medicine approved by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association, or who is board eligible or board certified in pain medicine by the American Board of Pain Medicine or a board approved by the American Board of Medical Specialties or the American Osteopathic Association and performs interventional pain procedures of the type routinely billed using surgical codes. This subsection does not apply to a physician who prescribes medically necessary controlled substances for a patient during an inpatient stay in a hospital licensed under chapter 395.

Fla. Stat. § 459.0137(1) Pain-Management Clinics

(a) 1. As used in this section, the term …

a. "Board eligible" means successful completion of an anesthesia, physical medicine and rehabilitation, rheumatology, or neurology residency program approved by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association for a period of 6 years from successful completion of such residency program.

b. "Chronic nonmalignant pain" means pain unrelated to cancer which persists beyond the usual course of disease or the injury that is the cause of the pain or more than 90 days after surgery.

c. "Pain-management clinic" or "clinic" means any publicly or privately owned facility:

(I) That advertises in any medium for any type of pain-management services; or

(II) Where in any month a majority of patients are prescribed opioids, benzodiazepines, barbiturates, or carisoprodol for the treatment of chronic nonmalignant pain.

2. Each pain-management clinic must register with the department unless:

a. That clinic is licensed as a [hospital];

b. The majority of the physicians who provide services in the clinic primarily provide surgical services;

c. The clinic is owned by a publicly held corporation whose shares are traded on a national exchange or on the over-the-counter market and whose total assets at the end of the corporation's most recent fiscal quarter exceeded $50 million;

Fla. Stat. § 459.0137(1) Pain-Management Clinics

d. The clinic is affiliated with an accredited medical school at which training is provided for medical students, residents, or fellows;

e. The clinic does not prescribe controlled substances for the treatment of pain;

f. The clinic is owned by a corporate entity exempt from federal taxation under 26 U.S.C. s. 501(c)(3);

g. The clinic is wholly owned and operated by one or more board-eligible or board-certified anesthesiologists, physiatrists, rheumatologists, or neurologists; or

h. The clinic is wholly owned and operated by a physician multispecialty practice where one or more board-eligible or board-certified medical specialists who have also completed fellowships in pain medicine approved by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association, or who are also board-certified in pain medicine by the American Board of Pain Medicine or a board approved by the American Board of Medical Specialties, the American Association of Physician Specialists, or the American Osteopathic Association and perform interventional pain procedures of the type routinely billed using surgical codes.

Fla. Stat. § 459.0137(1) Pain-Management Clinics

(b) Each clinic location shall be registered separately regardless of whether the clinic is operated under the same business name or management as another clinic.

(c) As a part of registration, a clinic must designate an osteopathic physician who is responsible for complying with all requirements related to registration and operation of the clinic in compliance with this section. Within 10 days after termination of a designated osteopathic physician, the clinic must notify the department of the identity of another designated physician for that clinic. The designated physician shall have a full, active, and unencumbered license under chapter 458 or this chapter and shall practice at the clinic location for which the physician has assumed responsibility. Failing to have a licensed designated osteopathic physician practicing at the location of the registered clinic may be the basis for a summary suspension of the clinic registration certificate as described in s. 456.073(8) for a license or s. 120.60(6).

(d) The department shall deny registration to any clinic that is not fully owned by a physician licensed under chapter 458 or this chapter or a group of physicians, each of whom is licensed under chapter 458 or this chapter; or that is not a health care clinic ….

Fla. Stat. § 459.0137(1) Pain-Management Clinics

(e) The department shall deny registration to any pain-management clinic owned by or with any contractual or employment relationship with a physician:

1. Whose Drug Enforcement Administration number has ever been revoked.
2. Whose application for a license to prescribe, dispense, or administer a controlled substance has been denied by any jurisdiction.
3. Who has been convicted of or pleaded guilty or nolo contendere to, regardless of adjudication, an offense that constitutes a felony for receipt of illicit and diverted drugs, including a controlled substance listed in Schedule I, Schedule II, Schedule III, Schedule IV, or Schedule V of s. 893.03, in this state, any other state, or the United States.

(f) If the department finds that a pain-management clinic does not meet the requirement of paragraph (d) or is owned, directly or indirectly, by a person meeting any criteria listed in paragraph (e), the department shall revoke the certificate of registration previously issued by the department. As determined by rule, the department may grant an exemption to denying a registration or revoking a previously issued registration if more than 10 years have elapsed since adjudication. As used in this subsection, the term “convicted” includes an adjudication of guilt following a plea of guilty or nolo contendere or the forfeiture of a bond when charged with a crime.

Fla. Stat. § 459.0137(1) Pain-Management Clinics

(g) The department may revoke the clinic's certificate of registration and prohibit all physicians associated with that pain-management clinic from practicing at that clinic location based upon an annual inspection and evaluation of the factors described in subsection (3).

(h) If the registration of a pain-management clinic is revoked or suspended, the designated physician of the pain-management clinic, the owner or lessor of the pain-management clinic property, the manager, and the proprietor shall cease to operate the facility as a pain-management clinic as of the effective date of the suspension or revocation.

(i) If a pain-management clinic registration is revoked or suspended, the designated physician of the pain-management clinic, the owner or lessor of the clinic property, the manager, or the proprietor is responsible for removing all signs and symbols identifying the premises as a pain-management clinic.

(j) Upon the effective date of the suspension or revocation, the designated physician of the pain-management clinic shall advise the department of the disposition of the medicinal drugs located on the premises. The disposition is subject to the supervision and approval of the department. Medicinal drugs that are purchased or held by a pain-management clinic that is not registered may be deemed adulterated pursuant to s. 499.006.

Fla. Stat. § 459.0137(1) Pain-Management Clinics

(k) If the clinic's registration is revoked, any person named in the registration documents of the pain-management clinic, including persons owning or operating the pain-management clinic, may not, as an individual or as a part of a group, make application for a permit to operate a pain-management clinic for 5 years after the date the registration is revoked.

(l) The period of suspension for the registration of a pain-management clinic shall be prescribed by the department, but may not exceed 1 year.

(m) A change of ownership of a registered pain-management clinic requires submission of a new registration application.

Fla. Stat. § 459.0137(2) Pain-Management Clinics

PHYSICIAN RESPONSIBILITIES. --
These responsibilities apply to any osteopathic physician who provides professional services in a pain-management clinic that is required to be registered in subsection (1).

(a) An osteopathic physician may not practice medicine in a pain-management clinic, as described in subsection (4), if the pain-management clinic is not registered with the department as required by this section. Any physician who qualifies to practice medicine in a pain-management clinic pursuant to rules adopted by the Board of Osteopathic Medicine as of July 1, 2012, may continue to practice medicine in a pain-management clinic as long as the physician continues to meet the qualifications set forth in the board rules. An osteopathic physician who violates this paragraph is subject to disciplinary action by his or her appropriate medical regulatory board.

(b) A person may not dispense any medication on the premises of a registered pain-management clinic unless he or she is a [D.O. or M.D.].

Fla. Stat. § 459.0137(2) Pain-Management Clinics

(c) An osteopathic physician, a physician assistant, or an advanced registered nurse practitioner must perform a physical examination of a patient on the same day that the physician prescribes a controlled substance to a patient at a pain-management clinic. If the osteopathic physician prescribes more than a 72-hour dose of controlled substances for the treatment of chronic nonmalignant pain, the osteopathic physician must document in the patient's record the reason for prescribing that quantity.

(d) An osteopathic physician authorized to prescribe controlled substances who practices at a pain-management clinic is responsible for maintaining the control and security of his or her prescription blanks and any other method used for prescribing controlled substance pain medication. The osteopathic physician shall comply with the requirements for counterfeit-resistant prescription blanks in s. 893.065 and the rules adopted pursuant to that section. The osteopathic physician shall notify, in writing, the department within 24 hours following any theft or loss of a prescription blank or breach of any other method for prescribing pain medication.

(e) The designated osteopathic physician of a pain-management clinic shall notify the applicable board in writing of the date of termination of employment within 10 days after terminating his or her employment with a pain-management clinic that is required to be registered under subsection (1). Each osteopathic physician practicing in a pain-management clinic shall advise the Board of Osteopathic Medicine in writing within 10 calendar days after beginning or ending his or her practice at a pain-management clinic.

Fla. Stat. § 459.0137(2) Pain-Management Clinics

(f) Each osteopathic physician practicing in a pain-management clinic is responsible for ensuring compliance with the following facility and physical operations requirements:

1. A pain-management clinic shall be located and operated at a publicly accessible fixed location and must:
   a. Display a sign that can be viewed by the public that contains the clinic name, hours of operations, and a street address.
   b. Have a publicly listed telephone number and a dedicated phone number to send and receive faxes with a fax machine that shall be operational 24 hours per day.
   c. Have emergency lighting and communications.
   d. Have a reception and waiting area.
   e. Provide a restroom.
   f. Have an administrative area including room for storage of medical records, supplies, and equipment.
   g. Have private patient examination rooms.
   h. Have treatment rooms, if treatment is being provided to the patient.
   i. Display a printed sign located in a conspicuous place in the waiting room viewable by the public with the name and contact information of the clinic-designated physician and the names of all physicians practicing in the clinic.
   j. If the clinic stores and dispenses prescription drugs, comply with ss. 499.0121 and 893.07.

Fla. Stat. § 459.0137(2) Pain-Management Clinics

2. This section does not excuse an osteopathic physician from providing any treatment or performing any medical duty without the proper equipment and materials as required by the standard of care. This section does not supersede the level of care, skill, and treatment recognized in general law related to health care licensure.

(g) Each osteopathic physician practicing in a pain-management clinic is responsible for ensuring compliance with the following infection control requirements.

1. The clinic shall maintain equipment and supplies to support infection prevention and control activities.
2. The clinic shall identify infection risks based on the following:
   a. Geographic location, community, and population served.
   b. The care, treatment, and services it provides.
   c. An analysis of its infection surveillance and control data.
3. The clinic shall maintain written infection prevention policies and procedures that address the following:
   a. Prioritized risks.
   b. Limiting unprotected exposure to pathogens.
   c. Limiting the transmission of infections associated with procedures performed in the clinic.
   d. Limiting the transmission of infections associated with the clinic's use of medical equipment, devices, and supplies.

Fla. Stat. § 459.0137(2) Pain-Management Clinics

(h) Each osteopathic physician practicing in a pain-management clinic is responsible for ensuring compliance with the following health and safety requirements.

1. The clinic, including its grounds, buildings, furniture, appliances, and equipment shall be structurally sound, in good repair, clean, and free from health and safety hazards.
2. The clinic shall have evacuation procedures in the event of an emergency which shall include provisions for the evacuation of disabled patients and employees.
3. The clinic shall have a written facility-specific disaster plan which sets forth actions that will be taken in the event of clinic closure due to unforeseen disasters and shall include provisions for the protection of medical records and any controlled substances.
4. Each clinic shall have at least one employee on the premises during patient care hours who is certified in Basic Life Support and is trained in reacting to accidents and medical emergencies until emergency medical personnel arrive.

Fla. Stat. § 459.0137(2) Pain-Management Clinics

(i) The designated physician is responsible for ensuring compliance with the following quality assurance requirements. Each pain-management clinic shall have an ongoing quality assurance program that objectively and systematically monitors and evaluates the quality and appropriateness of patient care, evaluates methods to improve patient care, identifies and corrects deficiencies within the facility, alerts the designated physician to identify and resolve recurring problems, and provides for opportunities to improve the facility's performance and to enhance and improve the quality of care provided to the public. The designated physician shall establish a quality assurance program that includes the following components:

1. The identification, investigation, and analysis of the frequency and causes of adverse incidents to patients.
2. The identification of trends or patterns of incidents.
3. The development of measures to correct, reduce, minimize, or eliminate the risk of adverse incidents to patients.
4. The documentation of these functions and periodic review no less than quarterly of such information by the designated physician.

Fla. Stat. § 459.0137(2) Pain-Management Clinics

(j) The designated physician is responsible for ensuring compliance with the following data collection and reporting requirements:

1. The designated physician for each pain-management clinic shall report all adverse incidents to the department ….
2. The designated physician shall also report to the Board of Osteopathic Medicine, in writing, on a quarterly basis, the following data:
   - (a) The number of new and repeat patients seen and treated at the clinic who are prescribed controlled substance medications for the treatment of chronic, nonmalignant pain.
   - (b) The number of patients discharged due to drug abuse.
   - (c) The number of patients discharged due to drug diversion.
   - (d) The number of patients treated at the pain clinic whose domicile is located somewhere other than in this state. A patient's domicile is the patient's fixed or permanent home to which he or she intends to return even though he or she may temporarily reside elsewhere.

Fla. Stat. § 459.0137(3) Pain-Management Clinics

INSPECTION. --

(a) The department shall inspect the pain-management clinic annually, including a review of the patient records, to ensure that it complies with this section and the rules of the Board of Osteopathic Medicine adopted pursuant to subsection (4) unless the clinic is accredited by a nationally recognized accrediting agency approved by the Board of Osteopathic Medicine.

(b) During an onsite inspection, the department shall make a reasonable attempt to discuss each violation with the owner or designated physician of the pain-management clinic before issuing a formal written notification.

(c) Any action taken to correct a violation shall be documented in writing by the owner or designated physician of the pain-management clinic and verified by follow-up visits by departmental personnel.

Fla. Stat. § 459.0137(5) Pain-Management Clinics

PENALTIES; ENFORCEMENT: --

(a) The department may impose an administrative fine on the clinic of up to $5,000 per violation for violating the requirements of this section; chapter 499, the Florida Drug and Cosmetic Act; 21 U.S.C. ss. 301-392, the Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq., the Comprehensive Drug Abuse Prevention and Control Act; chapter 893, the Florida Comprehensive Drug Abuse Prevention and Control Act; or the rules of the department. In determining whether a penalty is to be imposed, and in fixing the amount of the fine, the department shall consider the following factors:

1. The gravity of the violation, including the probability that death or serious physical or emotional harm to a patient has resulted, or could have resulted, from the pain-management clinic's actions or the actions of the osteopathic physician, the severity of the action or potential harm, and the extent to which the provisions of the applicable laws or rules were violated.
2. What actions, if any, the owner or designated osteopathic physician took to correct the violations.
3. Whether there were any previous violations at the pain-management clinic.
4. The financial benefits that the pain-management clinic derived from committing or continuing to commit the violation.

Fla. Stat. § 459.0137(5) Pain-Management Clinics

(b) Each day a violation continues after the date fixed for termination of the violation as ordered by the department constitutes an additional, separate, and distinct violation.

(c) The department may impose a fine and, in the case of an owner-operated pain-management clinic, revoke or deny a pain-management clinic's registration, if the clinic's designated osteopathic physician knowingly and intentionally misrepresents actions taken to correct a violation.

(d) An owner or designated osteopathic physician of a pain-management clinic who concurrently operates an unregistered pain-management clinic is subject to an administrative fine of $5,000 per day.

(e) If the owner of a pain-management clinic that requires registration fails to apply to register the clinic upon a change of ownership and operates the clinic under the new ownership, the owner is subject to a fine of $5,000.

Fla. Admin. Code Ann. r. 64B15-14.005 Standards for the Use of Controlled Substances for Treatment of Pain

(1) Pain management principles.

(a) The Board of Osteopathic Medicine recognizes that principles of quality medical practice dictate that the people of the State of Florida have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. The Board encourages osteopathic physicians to view effective pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially important for patients who experience pain as a result of terminal illness. All osteopathic physicians should become knowledgeable about effective methods of pain treatment as well as statutory requirements for prescribing controlled substances.

(b) Inadequate pain control may result from an osteopathic physician's lack of knowledge about pain management or an inadequate understanding of addiction. Fears of investigation or sanction by federal, state, and local regulatory agencies may also result in inappropriate or inadequate treatment of chronic pain patients. Osteopathic physicians should not fear disciplinary action from the Board or other state regulatory or enforcement agencies for prescribing, dispensing, or administering controlled substances including opioid analgesics, for a legitimate medical purpose and that is supported by appropriate documentation establishing a valid medical need and treatment plan. Accordingly, these guidelines have been developed to clarify the Board's position on pain control, specifically as related to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management.

Fla. Admin. Code Ann. r. 64B15-14.005 Standards for the Use of Controlled Substances for Treatment of Pain

(c) The Board recognizes that controlled substances, including opioid analgesics, may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. Osteopathic physicians are referred to the U.S. Agency for Health Care Policy and Research Clinical Practice Guidelines for a sound approach to the management of acute and cancer-related pain. The medical management of pain including intractable pain should be based on current knowledge and research and includes the use of both pharmacologic and non-pharmacologic modalities. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity and duration of the pain. Osteopathic physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not synonymous with addiction.

(d) The Board of Osteopathic Medicine is obligated under the laws of the State of Florida to protect the public health and safety. The Board recognizes that inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Osteopathic physicians should be diligent in preventing the diversion of drugs for illegitimate purposes.

(e) The Board will consider prescribing, ordering, administering, or dispensing controlled substances for pain to be for a legitimate medical purpose if based on accepted scientific knowledge of the treatment of pain or if based on sound clinical grounds. All such prescribing must be based on clear documentation of unrelieved pain and in compliance with applicable state or federal law.

Fla. Admin. Code Ann. r. 64B15-14.005 Standards for the Use of Controlled Substances for Treatment of Pain

(f) Each case of prescribing for pain will be evaluated on an individual basis. The Board will not take disciplinary action against an osteopathic physician for failing to adhere strictly to the provisions of these guidelines, if good cause is shown for such deviation. The osteopathic physician's conduct will be evaluated to a great extent by the treatment outcome, taking into account whether the drug used is medically and/or pharmacologically recognized to be appropriate for the diagnosis, the patient's individual needs including any improvement in functioning, and recognizing that some types of pain cannot be completely relieved.

(g) The Board will judge the validity of prescribing based on the osteopathic physician's treatment of the patient and on available documentation, rather than on the quantity and chronicity of prescribing. The goal is to control the patient's pain for its duration while effectively addressing other aspects of the patient's functioning, including physical, psychological, social, and work-related factors. The following guidelines are not intended to define complete or best practice, but rather to communicate what the Board considers to be within the boundaries of professional practice.

(2) Definitions.

(a) Acute Pain. For the purpose of this rule, "acute pain" is defined as the normal, predicted physiological response to an adverse chemical, thermal, or mechanical stimulus and is associated with surgery, trauma, and acute illness. It is generally time-limited and is responsive to opioid therapy, among other therapies.

Fla. Admin. Code Ann. r. 64B15-14.005 Standards for the Use of Controlled Substances for Treatment of Pain

(b) Addiction. For the purpose of this rule, "addiction" is defined as a neurobehavioral syndrome with genetic and environmental influences that results in psychological dependence on the use of substances for their psychic effects and is characterized by compulsive use despite harm. Addiction may also be referred to by terms such as "drug dependence" and "psychological dependence." Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and should not be considered addiction.

(c) Analgesic Tolerance. For the purpose of this rule, "analgesic tolerance" is defined as the need to increase the dose of opioid to achieve the same level of analgesia. Analgesic tolerance may or may not be evident during opioid treatment and does not equate with addiction.

(d) Chronic Pain. For the purpose of this rule, "chronic pain" is defined as a pain state which is persistent.

(e) Pain. For the purpose of this rule, "pain" is defined as an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

(f) Physical Dependence. For the purpose of this rule, "physical dependence" on a controlled substance is defined as a physiologic state of neuro-adaptation which is characterized by the emergence of a withdrawal syndrome if drug use is stopped or decreased abruptly, or if an antagonist is administered. Physical dependence is an expected result of opioid use. Physical dependence, by itself, does not equate with addiction.

Fla. Admin. Code Ann. r. 64B15-14.005 Standards for the Use of Controlled Substances for Treatment of Pain

(g) Pseudoaddiction. For the purpose of this rule, "pseudoaddiction" is defined as a pattern of drug-seeking behavior of pain patients who are receiving inadequate pain management that can be mistaken for addiction.

(h) Substance Abuse. For the purpose of this rule, "substance abuse" is defined as the use of any substances for non-therapeutic purposes or use of medication for purposes other than those for which it is prescribed.

(i) Tolerance. For the purpose of this rule, "tolerance" is defined as a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce the same effect, or a reduced effect is observed with a constant dose.

(3) Guidelines. The Board has adopted the following guidelines when evaluating the use of controlled substances for pain control:

(a) Evaluation of the Patient. A complete medical history and physical examination must be conducted and documented in the medical record. The medical record shall document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also shall document the presence of one or more recognized medical indications for the use of a controlled substance.

Fla. Admin. Code Ann. r. 64B15-14.005 Standards for the Use of Controlled Substances for Treatment of Pain

(b) Treatment Plan. The written treatment plan shall state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and shall indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the osteopathic physician shall adjust drug therapy, if necessary, to the individual medical needs of each patient. Other treatment modalities, including osteopathic manipulative treatment and applications, or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

(c) Informed Consent and Agreement for Treatment. The osteopathic physician shall discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient, or with the patient's surrogate or guardian if the patient is incompetent. The patient shall receive prescriptions from one osteopathic physician and one pharmacy where possible. If the patient is determined to be at high risk for medication abuse or have a history of substance abuse, the osteopathic physician shall employ the use of a written agreement between physician and patient outlining patient responsibilities, including, but not limited to:

1. Urine/serum medication levels screening when requested;
2. Number and frequency of all prescription refills; and
3. Reasons for which drug therapy may be discontinued (i.e., violation of agreement).

Fla. Admin. Code Ann. r. 64B15-14.005 Standards for the Use of Controlled Substances for Treatment of Pain

(d) Periodic Review. Based on the individual circumstances of the patient, the osteopathic physician shall review the course of treatment and any new information about the etiology of the pain. Continuation or modification of therapy shall depend on the osteopathic physician's evaluation of progress toward stated treatment objectives such as improvement in patient's pain intensity and improved physical and/or psychosocial function, i.e., ability to work, need of health care resources, activities of daily living, and quality of social life. If treatment goals are not being achieved, despite medication adjustments, the osteopathic physician shall reevaluate the appropriateness of continued treatment. The osteopathic physician shall monitor patient compliance in medication usage and related treatment plans.

(e) Consultation. The osteopathic physician shall be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention must be given to those pain patients who are at risk for misusing their medications and those whose living arrangements pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder may require extra care, monitoring, documentation, and consultation with or referral to an expert in the management of such patients.

Fla. Admin. Code Ann. r. 64B15-14.005 Standards for the Use of Controlled Substances for Treatment of Pain

(f) Medical Records. The osteopathic physician is required to keep accurate and complete records to include, but not be limited to:

1. The complete medical history and a physical examination, including history of drug abuse or dependence, as appropriate;
2. Diagnostic, therapeutic, and laboratory results;
3. Evaluations and consultations;
4. Treatment objectives;
5. Discussion of risks and benefits;
6. Treatments;
7. Medications (including date, type, dosage, and quantity prescribed);
8. Instructions and agreements;
9. Drug testing results; and

Fla. Admin. Code Ann. r. 64B15-14.005 Standards for the Use of Controlled Substances for Treatment of Pain

10. Periodic reviews. Records must remain current, maintained in an accessible manner, readily available for review, and must be in full compliance with Rule 64B15-15.004, F.A.C. [Standards for the Use of Controlled Substances for Treatment of Pain], and Section 459.015(1)(o), F.S. ["Failing to keep legible, as defined by department rule in consultation with the board, medical records that identify the licensed osteopathic physician or the osteopathic physician extender and supervising osteopathic physician by name and professional title who is or are responsible for rendering, ordering, supervising, or billing for each diagnostic or treatment procedure and that justify the course of treatment of the patient, including, but not limited to, patient histories; examination results; test results; records of drugs prescribed, dispensed, or administered; and reports of consultations and hospitalizations"].

(g) Compliance with Controlled Substances Laws and Regulations. To prescribe, dispense, or administer controlled substances, the osteopathic physician must be licensed in the state and comply with applicable federal and state regulations. Osteopathic physicians are referred to the Physicians Manual: An Informational Outline of the Controlled Substances Act of 1970, published by the U.S. Drug Enforcement Agency, for specific rules governing controlled substances as well as applicable state regulations.

Fla. Admin. Code Ann. r. 64B15-14.0051 Training Regulations for Physicians Practicing in Pain-Management Clinics

Effective July 1, 2012, physicians who have not met the qualifications set forth in subsections (1) through (6), below, shall have successfully completed a pain medicine fellowship that is accredited by the Accreditation Council for Graduate Medical Education (ACGME) or the American Osteopathic Association (AOA) or a pain medicine residency that is accredited by ACGME or the AOA. Prior to July 1, 2012, physicians prescribing or dispensing controlled substance medications in pain management clinics registered pursuant to Section 459.0137(1), F.S., must meet one of the following qualifications:

(1) Board certification by a specialty board recognized by the American Board of Medical Specialties (ABMS) and holds a sub-specialty certification in pain medicine; or a Certificate of Added Qualification in Pain Management by the American Osteopathic Association;

(2) Board certification in pain medicine by the American Board of Pain Medicine (ABPM);

Fla. Admin. Code Ann. r. 64B15-14.0051 Training Requirements for Physicians Practicing in Pain-Management Clinics

(3) Successful completion of a pain medicine fellowship that is accredited by the Accreditation Council for Graduate Medical Education (ACGME) or the American Osteopathic Association (AOA) or a pain medicine residency that is accredited by the ACGME or the AOA;

(4) (a) Successful completion of a residency program in physical medicine and rehabilitation, anesthesiology, neurology, neurosurgery, or psychiatry approved by the ACGME or the AOA;

(b) Successful completion of a residency program in family practice, internal medicine, or orthopedics approved by the AOA; or

(c) Current Certificate of Added Qualification approved by the AOA in hospice, palliative medicine or geriatric medicine.

(5) Current staff privileges at a Florida-licensed hospital to practice pain medicine or perform pain medicine procedures;

Fla. Admin. Code Ann. r. 64B15-14.0051 Training Requirements for Physicians Practicing in Pain-Management Clinics

(6) Three (3) years of documented full-time practice**,** which is defined as an average of 20 hours per week each year, in pain-management and attendance and successful completion of 40 hours of in-person, live-participatory AMA Category I or AOA Category IA CME courses in pain management that address all the following subject areas:

(a) The goals of treating both short term and ongoing pain treatment;

(b) Controlled substance prescribing rules, including controlled substances agreements;

(c) Drug screening or testing, including usefulness and limitations;

(d) The use of controlled substances in treating short-term and ongoing pain syndromes, including usefulness and limitations;

(e) Evidenced-based non-controlled pharmacological pain treatments;

(f) Evidenced-based non-pharmacological pain treatments;

(g) A complete pain medicine history and a physical examination;

(h) Appropriate progress note keeping;

(i) Comorbidities with pain disorders, including psychiatric and addictive disorders;

(j) Drug abuse and diversion, and prevention of same;

(k) Risk management; and

(l) Medical ethics.

Fla. Admin. Code Ann. r. 64B15-14.0051 Training Requirements for Physicians Practicing in Pain-Management Clinics

In addition to the CME set forth in subsection (6) above, physicians must be able to document hospital privileges at a Florida-licensed hospital; practice under the direct supervision of a physician who is qualified in subsections (1) through (4) above; or have the practice reviewed by a Florida-licensed risk manager and document compliance with all recommendations of the risk management review.

(7) Upon completion of the 40 hours of CME set forth above, physicians qualifying under subsection (6) above, must also document the completion of 15 hours of in-person, live participatory AMA Category I or AOA Category IA CME in pain management for every year the physician is practicing pain management.

Fla. Admin. Code Ann. r. 64B15-14.0052 Requirement for Pain Management Clinic Registration; Inspection or Accreditation

(1) Registration.

(a) Every designated physician of a pain management clinic, as defined in Section 459.0137(1), F.S., shall register the clinic with the Department of Health. It is the Designated Physician's responsibility to ensure that the clinic is registered ….

(b) In order to register a pain management clinic, the Designated Physician must comply with Department Rules 64B-4.005 [Pain Management Clinic Inspection Fee] and 64B-4.006 [Pain Management Clinic Fees], F.A.C….

(c) The Designated Physician must notify the Board within 10 calendar days, in writing, of any changes to the registration information, including the termination of his or her employment with the pain management clinic.

(d) Documentation of registration shall be posted in a conspicuous place in the waiting room viewable by the public.

(2) Inspection.

(a) Unless the Designated Physician has previously provided written notification of current accreditation by a nationally recognized accrediting agency approved by the Board the clinic shall submit to an annual inspection by the Department. All nationally recognized accrediting organizations shall be held to the same Board-determined practice standards for registering Florida pain management clinic sites.

Fla. Admin. Code Ann. r. 64B15-14.0052 Requirement for Pain Management Clinic Registration; Inspection or Accreditation

(b) The Department shall conduct unannounced annual inspections of pain clinics pursuant to this rule.

(c) The Designated Physician shall cooperate with the inspector(s), make medical records available to the inspector, and be responsive to all reasonable requests.

(d) The inspector(s) shall determine compliance with the requirements of Rule 64B15-14.0051 [Training Requirements for Physicians Practicing in Pain Management Clinics], F.A.C. This shall include review of a random selection of patient records for patients who are treated for pain, selected by the inspector(s) for each physician practicing in the clinic or who has practiced in the clinic during the past six months.

(e) If the clinic is determined to be in noncompliance, the Designated Physician shall be notified and shall be given a written statement at the time of inspection. Such written notice shall specify the deficiencies. Unless the deficiencies constitute an immediate and imminent danger to the public, the Designated Physician shall be given 30 days from the date of inspection to correct any documented deficiencies and notify the Department of corrective action plan. Upon written notification from the Designated Physician that all deficiencies have been corrected, the Department is authorized to re-inspect for compliance. If the Designated Physician fails to submit a corrective action plan within 30 days of the inspection, the Department is authorized to re-inspect the office to ensure that the deficiencies have been corrected.

Fla. Admin. Code Ann. r. 64B15-14.0052 Requirement for Pain Management Clinic Registration; Inspection or Accreditation

(f) The written results of the inspection, deficiency notice and any subsequent documentation shall be forwarded to the Department. This shall include:

1. Whether the deficiencies constituted an immediate and serious danger to the public;
2. Whether the Designated Physician provided the Department with documentation of correction of all deficiencies within 30 days from the date of inspection; and
3. The results of any reinspection.

(g) The Department shall review the results of the inspection(s) and determine whether action against the clinic registration is merited.

(h) Nothing herein shall limit the authority of the Department to investigate a complaint without prior notice.

(i) If the clinic is accredited by a nationally recognized accrediting agency approved by the Board, the Designated Physician shall submit written notification of the current accreditation survey of his or her office(s) in lieu of undergoing an inspection by the Department.

(j) The Designated Physician shall submit, within thirty (30) days of accreditation, a copy of the current accreditation survey of the clinic and shall immediately notify the Board of Osteopathic Medicine of any accreditation changes that occur. For purposes of initial registration, the Designated Physician shall submit a copy of the most recent accreditation survey of the clinic in lieu of undergoing an inspection by the Department.

(k) If a provisional or conditional accreditation is received, the Designated Physician shall notify the Board of Osteopathic Medicine in writing and shall include a plan of correction.

Fla. Admin. Code Ann. r. 64B15-19.002 Violations and Penalties

	Minimum	Maximum
(21) Controlled substance violations. (459.015(1)(t), F.S.)		
FIRST OFFENSE:	probation and $5,000 fine	suspension to be followed by probation and $7,500 fine
SECOND OFFENSE:	suspension to be followed by probation and $7,500 fine	revocation and $10,000 fine
(58) Engaging in a pattern of practice when prescribing medicinal drugs or controlled substances which demonstrates a lack of reasonable skill or safety to patients, a violation of any provision of this chapter, a violation of the applicable practice act, or a violation of any rules adopted under this chapter or the applicable practice act of the prescribing practitioner. (456.072(1)(gg) F.S.)		
FIRST OFFENSE:	probation and $5,000 fine	suspension to be followed by probation and $7, 500 fine
SECOND OFFENSE:	suspension to be followed by probation and $7,500 fine	revocation and $10,000 fine

Fla. Admin. Code Ann. r. 64B15-19.002
Violations and Penalties

(75) Promoting or advertising through any communication media the use, sale, or dispensing of any controlled substance appearing on any schedule in Chapter 893, F.S. (459.015(1)(tt), F.S.)		
FIRST OFFENSE:	letter of concern and a $1,000 fine.	1 year suspension, followed by a period of probation, and a $5,000 fine.
SECOND OFFENSE:	reprimand and a $5,000.00 fine.	1 year suspension, followed by a period of probation, and a $10,000 fine.
(76) Failure to comply with the controlled substance prescribing requirements of Section 456.44, F.S. (456.072(1)(mm), F.S.)		
FIRST OFFENSE:	suspension of license for a period of six(6) months followed by a period of probation and an administrative fine in the amount of $10,000.00.	revocation and an administrative fine in the amount of $10,000.00.
SECOND OFFENSE:	suspension of license for a period of one (1) year followed by a period of probation and an administrative fine in the amount of $10,000.00.	revocation and an administrative fine in the amount of $10,000.00.

Fla. Admin. Code Ann. r. 64B15-19.002
Violations and Penalties

(79) Dispensing a controlled substance listed in Schedule II or Schedule III in violation of Section 465.0276, F.S. (459.015)(1) (uu), F.S.)		
FIRST OFFENSE:	probation and an administrative fine of $1,000.00.	revocation and an administrative fine of $10,000.00.
SECOND OFFENSE:	suspension followed by a period of probation and an administrative fine of $5,000.00.	revocation and an administrative fine of $10,000.00.

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