The statutes requiring the registration of pain-management clinics with the Florida Department of Health (Department) are located in chapter 458, Florida Statutes, the practice act for medical doctors and in chapter 459, Florida Statutes, the practice act for osteopathic physicians. In 2009, the Legislature amended sections 458.309 and 459.005, Florida Statutes, to require clinic registration by January 4, 2010. In 2010, the Legislature expanded on the provisions relating to the registration of the clinics and moved them to sections 458.3265 and 459.0137, Florida Statutes, to further define a pain-management clinic and to provide certain additional exemptions from having to register as a pain-management clinic.

Definition of a Pain-Management Clinic

A pain-management clinic is any publicly or privately owned facility that advertises in any medium for any type of pain-management services or where in any month a majority of patients are prescribed opioids, benzodiazepines, barbiturates, or carisoprodol for the treatment of chronic nonmalignant pain. Chronic nonmalignant pain is pain unrelated to cancer or rheumatoid arthritis that persists more than 90 days after surgery or after the usual course of the disease or injury.

Clinics Meeting the Definition and Not Required to Register

The eight types of clinics not required to register with the Department are those:

1. Licensed as hospitals under chapter 395, Florida Statutes

2. Primarily providing surgical services by a majority of their physicians.

3. Owned by a publicly held corporation with traded shares and most recent fiscal quarter assets exceeding $50 million.

4. Affiliated with an accredited medical school and training medical students, residents, or fellows.


6. Owned by a 501(c)(3) corporation exempt from federal taxation.

7. Wholly owned and operated by board-certified anesthesiologists, physiatrists, or neurologists.

8. Wholly owned and operated by board-certified medical specialist with:
a) Fellowships in pain medicine approved by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association; or
b) Board-certification in pain medicine by a board approved by the American Board of Medical Specialist or the American Osteopathic Association and performing interventional pain procedures routinely billed using surgical codes.

A registered clinic with no pending discipline, having determined that by law no registration is required, has the ability to voluntarily relinquish its registration.

Grounds for Registration Denial

The Department carefully evaluates applications for registration as a pain-management clinic. A clinic will not be granted registration unless the clinic is owned by physicians licensed under chapters 458 or 459, Florida Statutes, or the clinic has a license issued by the Agency for Health Care Administration as a health care clinic under part X of chapter 400, Florida Statutes. A clinic will not be granted registration if the doctor who is to serve as the designated physician lacks a full, active, and unencumbered license or has a license with current disciplinary obligations or has any restrictions on his or her ability to practice.

A clinic will be denied registration if it has a relationship to a physician:

1. Whose DEA number has been revoked.
2. Whose application to prescribe, dispense, or administer a controlled substance has been denied by any jurisdiction.
3. Who has been convicted or pled guilty or nolo to a felony for receipt of illicit and diverted drugs including controlled substances.

A clinic will be denied registration under section 456.0635, Florida Statutes, if the applicant or any principal, officer, agent, managing employee, or affiliated person has been:

1) Convicted of or entered a plea to a felony under chapters 409, 817, 893, Florida Statutes, or to 21 U.S.C. ss. 801-970 or 42 U.S.C. ss 1395-1396 unless the sentence and probation ended 15 years prior to the date of the application;
2) Terminated for cause from the Florida Medicaid program unless in good standing for the most recent 5 years; or
3) Terminated for cause from any other state Medicaid program or the Medicare program unless happened at least 20 years ago and in good standing for the most recent 5 years.

If a clinic required by law to be registered operates without a registration or after having been denied a registration, that clinic is subject to a fine of $5,000 per violation and under section 456.065, Florida Statutes, may be subject to prosecution for unlicensed practice.

Clinic Registration Determinations

The Department does not determine whether a clinic is required to register or falls under one of the exemptions from having to register other than for its own regulatory and prosecutorial purposes. Nor will the Department provide legal advice on whether a registered clinic should relinquish its registration. Physicians and clinic owners should have some familiarity with the governing statutes regulating pain-management clinics and are urged to consult with their attorneys on these issues.

Requirements for filing a Petition for Declaratory Statement

The only way to obtain an official written opinion from the Department with regard to specific clinic registration issues is to file a Petition for Declaratory Statement, but filing a petition is not always appropriate. For a petition to be granted, it should substantially meet the criteria set forth in section 120.565, Florida Statutes, and rule chapter 28-105, Florida Administrative Code. The Department has 90 days to grant or deny the petition. If a petition is granted, the Department will issue a final Order that answers the issue raised by the petition. Before a petition is granted:

1. The person filing the petition has to be substantially affected.

2. The petition must be filed for an appropriate purpose. A declaratory statement is not the appropriate means for determining the conduct of another person.

3. The purpose must include seeking the agency’s opinion as to the applicability of a statutory provision over which the agency has authority, or of any rule or order of the agency to a petitioner’s particular set of circumstances. An agency need not write an order repeating the obvious from a plain reading of the words of a statute, rule, or order.

4. A petition must describe the potential impact of statutes, rules, or orders on the petitioner’s interests and is not appropriate for obtaining a policy statement or general applicability. However, if others have the same factual circumstances as
described within a petition, the Final Order issued by the agency may be relied upon by others.

5. The petition should include:
   a. A caption – Petition for Declaratory Statement Before (name of agency).
   b. The name, address, telephone number and any fax number of the petitioner.
   c. The name, address, telephone number and fax number of the attorney, if any.
   d. The statute, rule, or order on which the declaratory statement is sought.
   e. A description of how the statutes, rules, or orders may substantially affect the petitioner in petitioner’s particular set of circumstances.
   f. The signature of petitioner or petitioner’s attorney.
   g. The date.

6. To file a Petition with the Department (or with the Board of Medicine or Board of Osteopathic Medicine if a board is the agency with authority under the statute, rule, or order in question) send the petition to:

   Department Agency Clerk
   4052 Bald Cypress Way, Bin # A-02
   Tallahassee, Florida 32399-1703

All Other Clinic Registration Information

If you have other questions, please contact the Board of Medicine.

Mail: Board of Medicine
      4052 Bald Cypress Way, Bin # C-03
      Tallahassee, Florida 32399-1703

Phone: (850) 245-4131
PAIN-MANAGEMENT CLINIC
REQUEST TO VOLUNTARILY RELINQUISH REGISTRATION

The pain-management clinic registered as PMC# _______ and located at ________________________________________________________________
requests to voluntarily relinquish its registration on the grounds that this registered entity does not meet the requirements for registration or is not required to register because it either does not fall under the definition of a pain-management clinic or qualifies for a specific exemption from having to register as a clinic.
The exemption I am claiming is ________________________________________________________________

To the best of my knowledge, information, and belief, no disciplinary case is currently pending against this entity.

I understand that any registration or inspection fees previously paid are nonrefundable.

I further understand that a clinic required to be registered and found to be operating in violation of sections 458.3265 and 459.0137, Florida Statutes, is subject to a fine of $5,000 per violation and under section 456.065, Florida Statutes, may be subject to prosecution for unlicensed practice.

______________________________________________________________________________
[print name]

______________________________________________________________________________
[signature]

Designated Physician □ Clinic Owner □ (check one)

______________________________________________________________________________
[date]

Mail completed form to:

Board of Medicine
4052 Bald Cypress Way, Bin # C-03
Tallahassee, Florida 32399-1703