



**RE: Pain Management Clinics and the New Law:  
What Every Owner Should Know**

**DATE: January 7, 2011**

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The Florida Legislature passed a new law, which came into effect on October 1, 2010, aimed to discourage so-called “pill mills” that have flourished across the state in recent years. While the law imposes tighter restrictions and requirements on pain management clinics (PMCs) in an effort to discourage rampant dispensing and prescribing of controlled substances to addicts and drug dealers, legitimate PMCs with no previous problems need to strictly comply with the new state requirements or risk having their clinics shut down. The following article summarizes key aspects of the new law. For a more detailed analysis, and how it may apply to your PMC, please refer to one of our attorneys.

### **Registration with the Department of Health**

The most significant change in the new law (codified in part under Section 458.3265, Florida Statutes) is the requirement that all privately-owned PMCs which advertise, or employ a physician who is primarily engaged in the treatment of pain by prescribing or dispensing controlled substance medications, be registered with the Department of Health (DOH) prior to operation. Further, any PMC that is not fully owned by a licensed physician, or group of physicians, may have its registration denied under the new law. However, as with almost any law, there are some exceptions to this registration requirement.

### **Exceptions to Registration**

A PMC is not required to register with the DOH under the new law if any of the following exceptions apply:

1. The PMC is already licensed as a facility under Chapter 395 (Hospital Licensing and Regulation).
2. The majority of the physicians who provide services in the clinic are engaged primarily in providing surgical services.

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3. The PMC 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 exceed \$50 million at the end of the corporation's most recent fiscal quarter.
4. The PMC is affiliated with an accredited medical school at which training is provided for medical students, residents, or fellows.
5. The PMC does not prescribe or dispense controlled substances for the treatment of pain.
6. The clinic is owned by a corporate entity exempt from federal taxation under 26 U.S.C. s. 501(C)(3).

Any analysis of these exceptions should take statutory definitions, and other statutory references, into account before a privately-owned PMC relies on an exception under this section.

### **Registration Requirements**

One requirement for registration under the new law is the designation of a responsible doctor to oversee the operation of the PMC and ensure compliance with the new requirements. This designated physician must have a full, active and unencumbered license and must practice at the clinic location for which he/she has assumed responsibility. Furthermore, the DOH will deny registration to any PMC owned by, or with any contractual or employment relationship with, any doctor:

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; or
3. who has been convicted of or plead 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, II, III, IV, or V of section 893.03, in this state, any other state or the United States

It is important to note that each clinic location must be separately registered, regardless of whether the clinic is operated under the same business name or management as another clinic and these requirements apply to each clinic individually.

The DOH has taken the position (as posted on its website) that any PMC that submits an application for registration with the DOH after January 4, 2010, may not operate until the registration has been issued and the clinic has been assigned a registration number. If you are required to register with the Agency for Health Care Administration (AHCA), you will not receive your PMC registration from the DOH until the AHCA registration has been approved.

### **Physician Responsibilities**

A doctor who provides professional services in a PMC must be licensed under chapter 458 or 459, and practicing in a registered PMC. The physician must perform a physical examination of the patient on the same day that he or she dispenses or prescribes a controlled substance at the PMC. If the doctor prescribes or dispenses more than a 72-hour dose of controlled substances for the treatment of chronic nonmalignant pain, the doctor must document in the patient's record the reason for prescribing or dispensing that quantity.

In another section of the new law, the dispensing restriction goes even further: for any patient who pays for medication by cash, check, or credit card in a clinic registered under chapters 458 or 459, a doctor may not *dispense* more than a 72-hour supply of a controlled substance listed in Schedule II, III, IV or V of section 893.03. Practitioners in violation of this dispensing restriction commit a felony of the third degree. Of course, there are some exceptions, including doctors dispensing medication to a workers' compensation patient or an insured patient who pays by cash, check or credit card to cover a co-payment or deductible.

The doctor authorized to prescribe controlled substances who practices at a PMC 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 physician shall comply with the requirements for counterfeit-resistant prescription blanks as set forth in section 893.065, Florida Statutes. Any theft or loss of a prescription blank or breach of any other method for prescribing pain medication must be reported in writing to the DOH within 24 hours by the prescribing physician.

The designated physician of a PMC must notify the applicable board at the DOH, in writing, of any employment termination within 10 days after terminating his or her employment with a PMC that is required to be registered under the new law.

### **Inspection of PMCs**

Florida PMCs are subject to an annual inspection by the DOH to ensure compliance under the new law. Each inspection includes a review of the clinic's patient records. (Note: PMCs accredited by a nationally-recognized accrediting agency approved by the Board of Medicine are exempt from the inspection requirements.)

During any onsite inspection, DOH personnel is obligated to make a "reasonable attempt to discuss" any alleged violation with the owner or designated physician of the PMC before issuing a formal written notification. Any action to correct a violation must be submitted to the DOH in writing by the owner or designated physician of the PMC, and verified by the DOH by follow-up visits to the clinic.

### **Once DOH Revokes Registration of PMC**

While parties affected by Agency action may request a formal administrative hearing on the merits of a revocation, the new PMC law requires certain affirmative acts to take place once DOH registration revocation has occurred. As of the effective date of any revocation or suspension of a PMC's registration:

1. The PMC must cease all operations as a pain management clinic.
2. All signs and symbols identifying the business as a PMC must be removed.
3. The designated physician must advise the DOH of the disposition of all medicinal drugs located on the premises.

Additionally, any person named in the registration documents of the PMC may not (either individually or as part of a group) apply to operate a PMC for 5 years after date of revocation.

### **Penalties and Enforcement**

PMCs in violation of the new requirements may be fined up to \$5,000 per violation. In determining the amount to be imposed, the department must consider certain enumerated factors, such as the gravity of the violation, the potential harm to a patient, any corrective action taken by the designated physician, previous violations and any financial benefits derived from the violation.

In the case of any alleged knowing or intentional misrepresentation of corrective actions taken by the designated physician of an owner-operated PMC, the DOH may impose a fine as well as revoke the clinic's registration.

Any change of ownership of a registered PMC requires submission of a new registration application. A new owner that operates the clinic without re-registering the PMC with the DOH is subject to a \$5,000 fine.

### **Rules for the Administration and Inspection Procedures, Forms and Fees**

The new law requires that the DOH adopt rules necessary to administer the registration and inspection of PMCs and set forth specific requirements, procedures, forms and fees. It also requires the Board of Medicine to adopt rules establishing the maximum number of prescriptions for certain controlled substances within a 24-hour period and standards of practice for physicians primarily engaged in the prescribing and dispensing of such medications at privately-owned PMCs. No such rules have been adopted to date.

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Because of another rulemaking law which was originally vetoed by Governor Crist, then overridden by the Legislature during the 2010 Special Session, any proposed agency rule must be submitted to the Legislature with a Statement of Estimated Regulatory Costs (SERC) if the proposed rule is expected to reach a certain level of adverse economic impact (i.e., cost \$200,000 or more to administer per year, or \$1 million to businesses over a 5-year period). The Board of Osteopathic Medicine standards of practice for DO physicians practicing in PMCs, Rules 64B15-14.0051 and 64B15-14.0052, Florida Administrative Code, are in effect now and are not impacted by the new legislation. However, proposed Rules 64B 8-9.0131 and 9.0132, Florida Administrative Code, the Board of Medicine's proposed rules on standards of practice for MD physicians practicing in PMCs, are affected by the new rulemaking legislation and have not yet been reviewed or ratified by the Legislature.

**Rights of Privately-Owned PMCs Affected by New Law**

Under Chapter 120, Florida Statutes, any person or entity affected by an agency's action has the right to seek a formal administrative hearing to challenge the agency's action to resolve disputed issues of fact. There are other statutory rights that can be pursued on behalf of affected parties, including the right to participate in rule development proceedings, challenge agency decisions which are not based on statute or rule, challenge the validity of rules or proposed rules, and the right to seek a waiver or variance of a rule once rules are adopted.

For questions regarding the new PMC law and how it may affect your pain PMC, please feel free to contact any of the attorneys at Smith & Associates.