

NAMSDL



National Alliance for Model State Drug Laws

**State Statutes and Regulations Relative to Chronic Pain and Pain Management
Special Emphasis on Pain Management Clinics
Brief Summary of Federal Provisions**

October 2011

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The first portion of this document outlines the common components of state statutes and regulations relative to privately and publically owned and operated pain clinics. Provisions cited include existing statutes and both existing and pending regulations from Florida, Ohio, Louisiana, Tennessee and Texas. States have a wide variety of additional statutes and regulations governing pain management more generally and that information is summarized in the second portion of this document.

Citations

FLA. STAT. ANN. §§ 456.037, 458.3265, 458.327, 458.331, 459.013, 459.0137 and 459.015 (West 2011)
FLA. ADMIN. CODE ANN. r. 64B-4.005, 64B-4.006, 64B8-9.0131, 64B8-9.0132, 64B15-14.0051 and 64B15-14.0052 (2011)

OHIO REV. CODE ANN. § 4731.054 (West 2011)
OHIO ADMIN. CODE 4731:29-01 (2011)

LA. REV. STAT. ANN. §§ 40:971.2, 40:2006, 40:2198.11, 40:2198.12 and 40:2198.13 (2011)
LA. ADMIN. CODE tit. 48, §§ 7801 through 7861 (2011)

TENN. CODE ANN. §§ 63-1-302 through 63-1-311 (West 2011)
These sections were added by 2011 Tennessee Laws Pub. Ch. 340 (S.B.1258)
The final version of implementing regulations is currently under consideration – the proposed citation is
TENN. COMP. R. & REGS. §§ 1200-34-01.01 to .10 (2011)

TEX. OCC. CODE ANN. §§ 168.001, 168.002, 168.051, 168.052, 167.053, 168.101, 168.102, 168.151, 168.152, 168.201, 168.202 (Vernon 2011)
22 TEX. ADMIN CODE §§ 195.1 through 195.4 (2011)

Common Components of Pain Clinics Provisions

Defining the Term “Pain Management Clinic”

- Florida law defines a pain management clinic as *...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...*
- Louisiana law defines a pain management clinic as *...a publically or privately owned facility which primarily engages in the treatment of pain by prescribing narcotic medications...*

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- Ohio law defines a pain management clinic as *...a facility to which all of the following apply: (i) the primary component of practice is treatment of pain or chronic pain; (ii) the majority of patients of the prescribers at the facility are provided treatment for pain or chronic pain that includes the use of controlled substances, tramadol, carisoprodol, or other drugs specified in rules adopted under this section; (iii) the facility meets any other identifying criteria established in rules under this section...*
- Tennessee law defines a pain management clinic as *...a privately-owned facility in which a medical doctor, an osteopathic physician, an advanced practice nurse, and/or a physician assistant provides pain management services to patients, a majority of whom are issued a prescription for, or are dispensed, opioids, benzodiazepine, barbiturates, or carisoprodol, but not including suboxone, for more that ninety (90) days in a twelve-month period...*
- Texas law defines a pain management clinic as *...a publicly or privately owned facility for which a majority of patients are issued on a monthly basis a prescription for opioids, benzodiazepines, barbiturates, or carisoprodol, but not including suboxone...*

A Listing of Entities Exempt from Pain Management Clinic Statutes and Regulations

- ambulatory surgical facilities
- clinics that do not prescribe controlled substances for the treatment of pain
- clinics that provides surgical services and thus prescribe narcotics for post-operative pain
- hospice providers
- hospitals and clinics maintained or operated by the federal government
- hospitals and outpatient facilities associated therewith
- medical or dental schools and outpatient clinics associated therewith
- nursing homes
- nursing schools and outpatient clinics associated therewith
- osteopathic schools and outpatient clinics associated therewith
- state-operated facilities

Specific Procedures and Requirements for Certifying (a.k.a. Licensing or Registering) a Pain Management Clinic

- A clinic's certificate must be posted in a conspicuous location that is clearly visible to both patients and inspectors
- A change in a clinic's ownership requires the submission of a new certification application
- Depending on the state, certification is generally valid for a period of one or two years after which time the owner will need to renew the clinic's certification
- Each certification is valid only at the physical address for which it was issued – if a clinic has multiple locations, the owner must obtain a certification for each physical location

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- Any changes in a clinic's name, address, ownership, etc. must be reported to the relevant regulatory body within a certain timeframe – the timeframe and types of changes that must be reported vary by state
- A clinic's certification can be denied or revoked for reasons including but not limited to:
 - failure to comply with certification requirements
 - failure to employ qualified personnel
 - failure to provide a proper duty of care to patients
 - conviction of a felony for a clinic's owner or another principal staff member
 - revocation of an owner's Drug Enforcement Administration number
 - making false/misleading statements or providing false/misleading materials to state inspectors, regulatory bodies or the certifying authority
 - committing any misdemeanor or felony related to the prescribing, distribution or provision of controlled substances
 - failure to file any required reports
 - failure to maintain proper patient and prescription records

Regulation of Ownership of a Pain Management Clinic - Designation and Qualifications of an Operational Physician – Education Requirements

- Florida laws and regulations stipulate the following:
 - the direct or indirect owner of a pain management clinic must never have been subject to Drug Enforcement Administration number revocation, must never have has his license to prescribe, dispense, or administer a controlled substance denied by any jurisdiction and must never have been convicted of a felony for receipt of illicit and diverted drugs; and
 - though not specific to owners, Florida regulations stipulate that physicians who prescribe or dispense controlled substances in a pain clinic must meet one of seven enumerated qualifications ranging from board certification in pain medicine by the American Board of Pain Medicine to three years of documented full-time practice (defined as an average of twenty hours per week) in pain management.
- Louisiana laws and regulations stipulate the following:
 - *...The pain management clinic shall not be owned...by a physician who during the course of his practice has been denied the privilege of prescribing, dispensing, administering, supplying, or selling and controlled dangerous substance...*
 - pain management clinics must be owned by a medical director who is a physician;
 - pain management clinics may not be owned by a person who has been convicted of a felony offense or of a misdemeanor offense related to the distribution or illegal prescription of any narcotic; and

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- pain management clinics in existence since June 15, 2005 must be 100 percent owned and operated by a physician certified in the subspecialty of pain management by a member board of the American Boards of Medical Specialties.
- Ohio laws and regulations stipulate the following:
 - each pain management clinic must be owned and operated by one or more physicians;
 - every physician owner must complete at least twenty hours of category I CME courses in pain management every two years, including one or more courses addressing the potential for addiction;
 - every physician owner must meet one of five listed qualifications ranging from board certification by the American Board of Pain medicine to holding a subspecialty certification in hospice and palliative medicine; and
 - no physician owner was the subject of a disciplinary action by any licensing entity that was *...based in whole or in part, on the prescriber's inappropriate prescribing, dispensing, diverting, administering, supplying or selling a controlled substance or other dangerous drug...*
- Tennessee laws and proposed regulations stipulate the following:
 - *... a pain management clinic...must have a medical director who is a physician that practices in this state under an unrestricted and unencumbered license...;*
 - a medical director must meet at least one of eight qualifications enumerated in the proposed regulations – these qualifications range from board certification in pain medicine by the American Board of Pain Medicine to completion of forty hours of in-person, live-participatory American Medical Association Category I CME courses in pain management; and
 - a pain management clinic may not be owned by a person who has been convicted of a felony offense or a misdemeanor, *...the facts of which relate to the distribution of illegal prescription drugs or a controlled substance...*
- Texas laws and regulations stipulate the following:
 - *... a pain management clinic must be owned and operated by a medical director who is a physician who practices in this state under an unrestricted license...;*
 - a pain management clinic cannot be wholly or partly owned by a person who's been convicted of a (1) felony offense or (2) a misdemeanor offense related to the distribution of illegal prescription drugs or controlled substances;
 - owners of pain management clinics may not have previously been denied or had a restricted Drug Enforcement Administration license in any jurisdiction; and
 - *...a pain management clinic may not operate in Texas unless the clinic is owned and operated by a medical director who is a physician who practices in Texas and has an unrestricted license...*

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Operating a Pain Management Clinic - Responsibilities of an Operational Physician

- Restrictions on the amount of any controlled substance that can be prescribed
 - Louisiana regulations limit prescriptions to a non-refillable thirty-day supply
 - Florida law requires physicians who prescribe more than a seventy-two hour dose of controlled substances, for treatment of chronic pain, to document the patient's record with the reason for prescribing that quantity
- Requirement that a clinic owner be physically present at the clinic for a certain number of hours
 - Texas law requires the owner or operator of the clinic to be on-site for at least 33 percent of the clinic's operating hours
 - Proposed Tennessee regulations require the medical director of a clinic to be onsite for at least twenty percent of the clinic's total number of operating hours
- Patient log maintenance requirements
 - Ohio regulations require that a log of patients be maintained for each day the clinic is in operation – the logs must contain the month/day/year, the legible first and last name of each patient and the patient's signature at each visit – logs must be maintained for seven years
- Requiring that a clinic owner review a certain percentage of the clinic's patient files
 - Texas law requires that a clinic owner or operator review at least thirty-three percent of the total number of patient files
- Patient record maintenance to include patient identification information, medical history, a prescription monitoring report (if applicable), chief complaint and diagnosis, lab orders and results, pathology and radiology reports, substances prescribed or dispensed and a patient-signed treatment agreement
- Physical location specifications, such as a clean environment, clearly posted required signage and notifications, a reception area and waiting room, private examination rooms, adequate file storage, secure storage for controlled substances and restrooms
- Requirements specific to patient visits
 - Louisiana regulations require (1) clinics to verify patient identity for each patient who is seen and treated for chronic pain management and who is prescribed a controlled substance and (2) patients who are prescribed controlled dangerous substances on a particular visit to a clinic to be personally examined by a pain specialist
- Requirement to access the state's prescription monitoring program
 - Louisiana regulations require a clinic's medical director to apply for access to and query capability of the Louisiana Prescription Monitoring Program

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Mandating the Adoption of Implementing Regulations that Address the Following:

- Billing procedures
- Inspection procedures
- Complaint procedures
- Certification application procedures
- Grounds for denial or revocation of certification
- Standards and procedures governing daily operation of the clinic
- Standards for patient care
- Clinic personnel requirements
- Training and education requirements
- Record-keeping
- Defining relevant terms (if definitions are not provided in the state's statute)
- Fee schedules

Inspections

- Louisiana regulations require the following on an annual basis:
 - *...annual fire marshal inspection;*
 - *annual inspection by the Office of Public Health;*
 - *quarterly fire alarm system test by facility staff; and*
 - *regular inspections of the clinic elevators, if any...*
- Tennessee law provides that *...each board shall have the authority to inspect a pain management clinic which utilizes the services of a practitioner licensed by that Board. During such inspections, the authorized representatives of the board may inspect all necessary documents and medical records to ensure compliance...*
- Texas regulations provide that the *...board may conduct inspections...including inspections of a pain management clinic and of documents of a physicians' practice...The board shall conduct inspections of pain management clinics if the board suspects that the ownership or physician supervision is not in compliance with board rules...*

Violations and Penalties

- Violations relative to operation of a pain management clinic can include the following:
 - The practice of medicine without a valid medical license issued by the state in which the clinic is located;
 - Knowingly operating, owning or managing an uncertified pain management clinic;
 - Failing to maintain required records;

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- Providing investigators and regulatory agencies with false or misleading information and/or interfering with an inspection;
- Failing to file required reports;
- Any felony or misdemeanor related to the prescription, distribution or provision of controlled substances
- False or misleading advertising of clinic services; and
- Committing medical malpractice in relation to operation of a pain management clinic.
- Florida law states that the *...department may impose an administrative fine on the clinic of up to \$5,000 per violation for violating the requirement of this section...In determining whether a penalty is to be imposed, and in fixing the amount of the fine, the department shall consider the following factors:*
 - *The gravity of the violation...;*
 - *...What actions, if any, the owner or designated physician took to correct the violations;*
 - *Whether there were any previous violations at the pain management clinic;*
 - *The financial benefits that the pain management clinic derived from committing or continuing to commit the violation...*
- Louisiana law states that *...Whoever violates the provisions of this Section shall be imprisoned, with or without hard labor, for not more than five years, and in addition may be sentenced to pay a fine of not more than fifty thousand dollars...*
- Ohio law states that the *...board may impose a fine of not more than twenty thousand dollars on a physician who fails to comply with rules adopted under this section...*
- Tennessee law states that a *...practitioner who provides pain management services at an uncertified pain management clinic is subject to an administrative penalty of one thousand dollars (\$1,000) per day...*
- Texas law states that a *...violation of this chapter or a rule adopted under this chapter is grounds for disciplinary action against a pain management clinic...*

Fees Associated With Operation of a Pain Management Clinic

- Florida regulations stipulate that *...an inspection fee of \$1,500 shall be paid annually for each location required to be inspected...*
- Louisiana law provides that *...there shall be an annual license fee to be set by the department not to exceed one thousand dollars for any license issued in accordance with the provisions of this Part...*
- Proposed regulations from Tennessee include a fee schedule for pain management clinics including a \$50.00 Application Fee, a \$355.00 Initial License Fee, a Renewal Fee of \$405.00, a Regulatory Fee of \$10.00 and a late renewal penalty fee of \$100.00 per month for each month or fraction of a month that renewal is late.

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Other Types of State Statutes and Regulations Relative to Chronic Pain and Pain Management – Please Note that the States Cited Below are only a Representative Sample of Those With Statutes Relative to the Areas Listed

1. Chronic Intractable Pain Treatment Acts – Use of Controlled Substances to Treat Pain
 - a. Many states have enacted an Intractable Pain Treatment Act, which generally includes a state of purpose, the defining of relevant terms, a patient’s bill of rights, permissible and impermissible practices with regard to prescribing and administering controlled substances for treatment of pain, possible disciplinary actions and authority for the state to promulgate rules and regulations.
 - b. Missouri authorizes a physician to prescribe, administer or dispense controlled substances for a therapeutic purpose to a person diagnosed and treated for a condition resulting in intractable pain. MO. REV. STAT. ANN. § 334.106 (West 2011)
 - c. Oklahoma enacted a provision (1) stating that Schedule II, III, IV and V drugs have a legitimate medical purpose (2) encouraging physicians to view effective pain management as part of quality medical practice and (3) authorizing a doctor to administer a high dosage of controlled drugs if that doctor feels that dosage is part of appropriate pain management for that patient.
OKLA. STAT. ANN. tit. § 63 2-551 (West 2011)
 - d. Washington recently adopted new comprehensive rules on pain management covering numerous practice specialties and a range of topics from dosing criteria, patient evaluation requirements, treatment plans and pain management specialist qualifications. (Authorizing statutes are found in Title 18 of the statutory code Business and Occupations and Implementing Rules are found in Chapter 246 of the administrative code Department of Health, both current as of 2011)

2. Medical Marijuana
 - a. The Arizona Medical Marijuana Act permits the use of an allowable amount of marijuana for an enumerated list of debilitating medical conditions, which includes severe and chronic pain. ARIZ. REV. STAT. ANN. §§ 36-2801 to 2819 (2011)
 - b. The California Compassionate Use Act of 1996 affords those suffering from certain conditions, including chronic pain, the right to obtain and use marijuana for medical purposes where that medical use is deemed appropriate and has been recommended by a physician who has determined that the person’s health would benefit from the use of marijuana. CAL. HEALTH & SAFETY § 11362.5 (West 2011)

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3. Insurance Coverage for Pain Treatment Services - Connecticut mandates that every individual and group health insurance policy must provide access to a pain management specialist and coverage for pain treatment ordered by such a specialist.
CONN. GEN. STAT. ANN. §§ 38a-492i, 518i (West 2011)

4. Patients Bills of Rights – Many states address pain management and access to treatment for pain in a Pain Patient’s Bill of Rights, noting that inadequate treatment of acute and chronic pain is a significant health problem and that patients who suffer from pain should have access to proper treatment for that pain

5. Pain Treatment Medical Education
 - a. California requires all physicians and surgeons to complete a mandatory continuing education course in the subjects of pain management and the treatment of terminally ill and dying patients. CAL. BUS. & PROF. §§2190.5, 2191 and 2196.2 (West 2011)
 - b. The Michigan department of consumer and industry services, together with the department of community health, is tasked with developing, publishing and distributing a booklet on pain. MICH. COMP. STAT. ANN. § 333.16204d (West 2011)
 - c. New Jersey designated September of each year as “Pain Awareness Month.”
N.J. STAT. ANN. §§ 36:2-157, 158 (West 2011)
 - d. New Mexico law provides that all health care providers who have prescriptive authority, who also treat patients for pain, are encouraged to seek pain management continuing education. N.M. STAT. ANN. § 24-2D-5.1 (West 2011)
 - e. Ohio requires the state medical board to approve one or more continuing medical education course of study included within the programs certified by the state medical association and the state osteopathic association.
OHIO REV. CODE ANN. § 4731.283 (West 2011)
 - f. The Texas Education Code stipulates that pain treatment medical education course work should include instruction in pain assessment, pain anatomy and physiology, the advantages and disadvantages of various methods of drug administration, the impacts of chronic pain on patients, the indications for outcomes of pain relieving techniques and the outcome of treatment of pain emanating from a damaged nervous system and neuropathic pain. TEX. EDUC. CODE ANN. § 51.309 (Vernon 2011)

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6. Pain Management Commissions, Authorities and Proclamations

- a. Michigan created an advisory committee on pain and symptom management to help develop an integrated approach to understanding and applying pain management symptoms and techniques. MICH. COMP. LAWS ANN. § 333.16204a (West 2011)
- b. New Mexico created a pain management advisory council tasked with reviewing current pain management practices in the state as well as national pain management standards and educational efforts for both consumers and professionals. N.M. STAT. ANN. § 24-2D-5.2 (West 2011)
- c. Oregon established a Pain Management Commission tasked with developing pain management recommendations, developing ways to improve pain management services and representing the pain management concerns of patients in Oregon to the Governor and the Legislative Assembly. OR. REV. STAT. ANN §§ 409.500 to 570 (West 2011)

Federal Provisions

1. On March 14, 2011 H.R. 1065 a.k.a. the Pill Mill Crackdown Act of 2011 was introduced in the House of Representatives – the measure was referred to the subcommittee on Crime, Terrorism and Homeland Security on March 21, 2011 and this was the last action taken on the bill. The Act enumerates penalties for operation of a pill mill, providing for imprisonment for those involved in distributing Schedule II and III controlled substances through a pill mill operation.
2. As part of the White House’s plan for addressing the epidemic of prescription drug abuse, the Food and Drug Administration is in the process of implementing new Opioid Drugs and Risk Evaluation and Mitigation Strategies (REMS). This program will require manufacturers of long-acting and extended-release opioids to provide educational programs to prescribers of those medications. The plan calls for drug makers to work together to develop a single system for implementing the REMS strategies. Continuing Medical Education (CME) is not currently mandatory under the new REMS plan but federal agencies are working towards passing a law that would link CME requirements to obtaining the Drug Enforcement Administration registration number required for doctors to prescribe controlled substances. Provisions are expected to become effective early in 2012 and will apply to various products including hydromorphone, oxycodone, morphine, oxymorphone, methadone, transdermal fentanyl and transdermal buprenorphine.

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