

**PRESCRIPTION DRUG ABUSE, ADDICTION AND DIVERSION:
OVERVIEW OF STATE LEGISLATIVE AND POLICY INITIATIVES**

A THREE PART SERIES

**PART 2:
STATE REGULATION OF PAIN CLINICS
&
LEGISLATIVE TRENDS RELATIVE TO REGULATING PAIN CLINICS**

**PREPARED BY
THE NATIONAL ALLIANCE FOR MODEL STATE DRUG LAWS**



**AND
THE NATIONAL SAFETY COUNCIL**

Research current through April, 2014.

For comprehensive information about the series, please see Part 1: State Prescription Drug Monitoring Programs (PMPs) and Part 3: Prescribing of Controlled Substances for Non-Cancer Pain.

NATIONAL ALLIANCE FOR MODEL STATE DRUG LAWS

HEADQUARTERS:

215 LINCOLN AVENUE, SUITE 201

SANTA FE, NEW MEXICO 87501

703-836-6100 (Phone)

505-820-1750 (Fax)

www.namsdl.org

NATIONAL SAFETY COUNCIL

HEADQUARTERS:

1121 SPRING LAKE DRIVE

ITASCA, IL 60143

800-285-1121 (Phone)

630-285-1121 (Phone)

630-285-1315 (Fax)

www.nsc.org

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PURPOSE OF OVERVIEW

The National Alliance for Model State Drug Laws (NAMSDL) and the National Safety Council (NSC) present a three-part overview to assist federal, state and local policymakers, criminal justice and health care professionals, drug and alcohol specialists, and other stakeholders with the development of legislative and policy options to address prescription drug abuse, addiction, and diversion. The overview outlines the status of state laws, regulations and, where possible, policies on three key initiatives undertaken by state officials to tackle the spectrum of prescription drug issues. These initiatives are (1) implementation and improvement of state prescription drug monitoring programs (PMPs), (2) regulation of pain clinics, and (3) establishment and enhancement of policies and guidelines for the prescribing of controlled substances for non-cancer pain. Additionally, the overview summarizes practices for these initiatives that various organizations and institutions recommend and identifies which states are following those practices.

The three-part overview uses the phrase “recommended practices” rather than the phrase “best practices.” Many of the practices discussed find support in the anecdotal evidence drawn from the knowledge, experiences, and wisdom of people responsible for the practical application and enforcement of efforts on PMPs, pain clinics, and the prescribing of controlled substances. However, numerous suggested practices have not yet been subjected to the scientific rigor and outcome evaluation traditionally associated with a “best practice.” In the absence of complementary scientific information, what is deemed “best” may depend in part on the approach and perspective of those making the determinations. Staff of each organization and institution promoting certain practices necessarily use their acquired information, combined experiences, and beliefs to shape their proposals. Consequently, the overview focuses on “recommended practices” that are common among the organizations and institutions referenced herein.

The status information reflects only that information publicly available through laws, regulations, or official policy. Such formalization of a practice or principle often comes after months of preparation involving multiple stages of drafting, review and input, modification, and trial and error experimentation. A state not listed in the overview as following a particular practice may indeed be in the midst of preparatory work designed to help write language that will ultimately pass in the form of a statute, rule, or written policy or guideline.

Finally, the ultimate choice to adopt a “recommended practice” and the timing of the adoption lies with state and local decision-makers. State and local policymakers must carefully weigh the benefits of a specific practice against the costs of implementation, current state priorities, and other factors. The balancing process may result in a variance among states regarding the emphasis on certain practices over others. Some state officials may proceed with a more gradual implementation than neighboring states because of differences in available funds. Others may find it necessary to delay initiation of a particular practice. Despite their differences, all state and local leaders strive to improve their states’ ability to address prescription drug abuse, addiction, and diversion with increasingly scarce public funds. The three-part overview is intended to add value to the decision-making process of those leaders so they can make the most effective judgments possible for their respective jurisdictions.

PRESCRIPTION DRUG ABUSE, ADDICTION AND DIVERSION: A NATIONAL PROBLEM

Prescription drug abuse is the fastest growing drug problem in the Nation proclaimed federal officials in the 2011 strategy entitled *Epidemic: Responding to America's Prescription Drug Abuse Crisis*. Statistic after statistic confirmed reports that the problem had reached significant proportions.

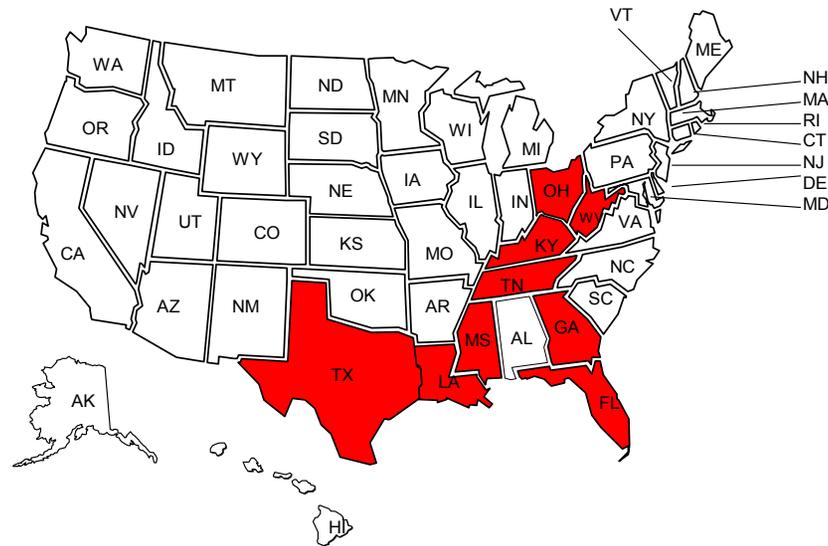
- In 2010, about 12 million Americans (age 12 or older) reported nonmedical use of prescription pain relievers in the past year. (Centers for Disease Control, Vital Signs, November 2011)
- Among new abusers of pain relievers, 68 percent of new users (those who began misuse of pain relievers in the past year) obtained their abused pills from a friend or relative for free or took them without asking, 17 percent received prescriptions from one or more doctors, and 9 percent purchased pills from a friend, dealer, or the Internet. (Office of National Drug Control Policy Press Release identifying key findings using data from 2009 and 2010 National Survey on Drug Use and Health, April 25, 2012)
- Among occasional abusers of pain relievers (less than once a week on average in the past year), 66 percent obtained the pills for free from a friend or relative or took them without asking, 17 percent received prescriptions from one or more doctors, and 13 percent purchased pills from a friend or relative, dealer, or the Internet. (Office of National Drug Control Policy Press Release identifying key findings using data from 2009 and 2010 National Survey on Drug Use and Health, April 25, 2012)
- Among chronic abusers of pain relievers, only 41 percent obtained the pills for free or without asking from a friend or relative, 26 percent received prescriptions from one or more doctors, and 28 percent purchased pills from a friend or relative, dealer, or the Internet. (Office of National Drug Control Policy Press Release identifying key findings using data from 2009 and 2010 National Survey on Drug Use and Health, April 25, 2012)
- Chronic nonmedical use (use 200 days or more in the past year) of opioid pain relievers has increased 75% since 2002-2003. (Letter identifying key findings of CDC research using data from National Survey on Drug Use and Health, July 3, 2012, Grant Baldwin, Director, Division of Unintentional Injury Prevention, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention)
- The largest increase in chronic nonmedical use of opioid pain relievers was seen among people aged 26-34 (81%) and 35-49 (135%). (Letter identifying key findings of CDC research using data from National Survey on Drug Use and Health, July 3, 2012, Grant Baldwin, Director, Division of Unintentional Injury Prevention, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention)
- Treatment admissions for abuse of prescription pain relievers rose 430% from 1999-2009. (Substance Abuse and Mental Health Services Administration News Release, December 8, 2011)

- Estimated number of emergency department visits for misuse or abuse of pharmaceuticals nearly doubled from 2004 to 2009. Nearly 630,000 emergency department visits in 2004 were related to the misuse or abuse of pharmaceuticals, compared to more than 1.2 million in 2009. (Center for Substance Abuse Research, University of Maryland, College Park, CESAR Fax, February 7, 2011, Vol. 20, Issue 5)
- Nearly half a million of the emergency department visits in 2009 were due to people misusing or abusing prescription pain relievers. (Centers for Disease Control, Vital Signs, November 2011)
- Overdose deaths from prescription pain relievers is now greater than those of deaths from heroin and cocaine combined. (Centers for Disease Control, Vital Signs, November 2011)

Recent data from the 2011 National Survey on Drug Use and Health (NSDUH) showed a slight decline from the prior year in first time use for persons aged 12 or older, a decrease of 100,000 people. Regular nonmedical users of prescription-type psychotherapeutic drugs also dropped by about 900,000 people. Despite this welcome news, prescription drug abuse, addiction, and diversion remains a challenge for federal, state, and local leaders. The number of citizens in 2011 using psychotherapeutic drugs for nonmedical purposes is significant, 6.1 million people according to NSDUH. Of these, 4.5 million users abused pain relievers. Confronted by the devastating social and economic consequences of the abuse, policymakers search for solutions to the prescription drug problem. In so doing, they must reflect a balance with their words and actions that they have never before had to create. Twenty years ago, policymakers drafted and implemented laws and policies to address concerns with cocaine, methamphetamine, and heroin. Leaders did not have to consider aspects of legitimate use because these substances generally have no legitimate use among the public. The drug problems that leaders face today flow from a very different environment. Prescription drugs have many legal uses and many legal users. Laws and policies of today must simultaneously prevent abuse, addiction, and diversion while allowing and supporting the legal use of prescription drugs by those who need the medications to maintain quality of life. To create this delicate yet necessary balance, policymakers can draw upon the skills and expertise of criminal justice officials, health care professionals, prevention experts, and drug and alcohol addiction treatment specialists. As policymakers implement effective prescription drug abuse laws and policies, they must also be prepared to address the substantial number of current prescription drug addicts who will be cut off from their drug supply. If left untreated, these addicts may turn to heroin, a transition that will bring about increased hepatitis, HIV, and crime.

PART A: STATE REGULATION OF PAIN CLINICS

States that Regulate Pain Clinics by Statute and Rules



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“PILL MILLS” VS. PAIN CLINICS

One of the most visible signs of the prescription drug problem in some states is the “pill mill.” To create a veil of legitimacy, “pill mill” operators often label their activities as “pain management” and their facilities as “pain clinics.” In the eyes of the public, the phrases “pill mill” and “pain clinic” may seem synonymous.

On September 25, 2012, the National Alliance for Model State Drug Laws (NAMSDL) convened nineteen people to identify legislative and policy options for addressing “pill mills” and safeguarding the legitimate practice of pain management (Working Group). The participants included doctors, pain management experts, law enforcement representatives, a district attorney, a pharmacist, regulatory officials, and prevention and addiction treatment specialists. This initial meeting was the beginning of a multi-step, multi-disciplinary approach to provide policymakers with practical solutions to preventing prescription drug abuse, addiction, and diversion while safeguarding legitimate access to prescription drugs. In early 2013 the Working Group’s proposals were distributed to a wide variety of stakeholders for comment and after reviewing the comments received NAMSDL compiled them into a final report.

The meeting process was designed to facilitate an exchange of ideas and to gather the information necessary for drafting model language for statutes, regulations, policies, and guidelines. The participants were divided into three subgroups based on professional background. During the morning, each subgroup, with the help of a facilitator, brainstormed the relevant issues and identified options for effectively responding to the designated interests, needs, and concerns. In the afternoon, each subgroup shared its ideas and related comments. All Working Group members then had the opportunity to discuss the recommendations.

A consistent, prominent theme of NAMSDL’s Working Group recommendations is that a “pill mill” is not indicative of a particular medical facility or location. It is indicative of a set of behaviors that have never represented the legitimate practice of medicine. Many “pill mill” operators have criminal intent. They are driven by financial, not medical, interests and they have no regard for therapeutic benefit or medical necessity. Doling out pills becomes the focus of their business because it is the primary method of feeding their monetary desires regardless of the consequences.

Working Group members noted that indicators of a “pill mill” include, but are not limited to, the following behaviors:

- No previous medical records
- No adequate history
- No physical exam or an inadequate exam
- No exhaustion of conservative care
- No use or misuse or inappropriate use of diagnostics

- Non-individualization of care, e.g., no variance in visit schedules, no referrals to other specialists, combinations of medications do not vary from patient to patient
- Physicians/prescribers are frequently at the end of their careers
- Physicians/prescribers have their own abuse or addiction problems
- Primary mode of therapy often is controlled substances
- Non-therapeutic prescribing occurs
- High volume practice
- No appointments; only walk-ins
- Only cash payments accepted
- Failure to screen for substance use disorders
- Patients travel very long distances to the facility without any legitimate reason
- Physical appearance of significant number of patients suggests possible active abuse or addiction.

Working Group members listed the following indicators of legitimate pain management practices:

- Interdisciplinary with multiple resources and therapies; resources not always under one roof
- Principal focus is the treatment of pain with goals of pain relief and improvement in function
- No primary reliance on pills or any single modality
- Controlled substances prescribing based on sound clinical judgment, not patient demand
- No automatic prescribing of controlled substances to begin treatment
- Individualized assessment of patient
- Reassessment for some type of primary benefit
- Patient centered
- Patient held accountable
- Appropriate monitoring
- Appropriate utilization of urine drug testing
- Appropriate documentation and recordkeeping.

Central elements of any state legislation designed to regulate pain clinics are definitions of “pain clinic” and “pain management” that facilitate legitimate practices. Other suggested statutory components that would be based on and shaped by the definitions include, but are not limited to:

- Narrowly crafted exemptions from regulation
- Mandated certification or licensing of the clinic
- Required ownership by a physician or other prescriber who is held accountable by a licensing board
- Adherence by clinic professionals to standards of practice, including educational requirements, established by licensing authorities
- Treatment agreements or comparable alternatives that outline patient and provider responsibilities and establish a basis for alteration or termination of treatment
- Rules on dispensing of controlled substances, including a ban on pharmacies in clinics and safeguards for filling out-of-state prescriptions
- A ban on operating a detox center as part of the clinic’s services
- Designation of a regulatory agency to develop and enforce the licensing or certification process and operational requirements.

To assist state officials with specific language to capture the components, Working Group members suggested development of a model pain clinic law.

STATES WITH PAIN CLINIC REGULATION ACTS

As of August 2013, policymakers in nine states have adopted pain clinic regulation acts to try and target “pill mill” activities.

FLORIDA

FLA. STAT. ANN. §§ 456.037, 456.057, 458.3265, 458.327, 458.331, 459.013, 459.0137, 459.015 and 893.138 (West 2014)

FLA. ADMIN. CODE. ANN. R. 64B-4.005, 64B-4.006, 64B-7.001, 64B-7.002, 64B8-8.001, 64B8-9.0131, 64B8-9.0132, 64B15-14.0051, 64B15-14.0052 and 64B15-19.002 (2014)

GEORGIA

GA. CODE ANN. §§ 43-34-280 through 290 (West 2014)

KENTUCKY

KY. REV. STAT. ANN. § 218A.175 (West 2013)

201 KY. ADMIN. REGS. § 9:250 (2014)

902 KY. ADMIN. REGS. § 20:420 (2014)

LOUISIANA

LA. REV. STAT. ANN. §§ 40:971.2, 40:2006 and 40:2198.11 through 40:2198.13 (2013)

LA. ADMIN. CODE TIT. 46, pt. XLV § 7603 (2013)

LA. ADMIN. CODE TIT. 48, pt. I §§ 7801 through 7861 (2013)

MISSISSIPPI

MISS. CODE R. §§ 30-17-2640:1.2, 1.15, 1.16 and Appendix E (2014)

OHIO

OHIO REV. CODE ANN. §§ 4729.01, 4729.51, 4729.54, 4929.541, 4729.55, 4729.552, 4729.571, 4731.054, 4731.22 and 4776.04 (West 2014)

OHIO ADMIN. CODE 4729-5-30, 4729-9-26 and 4731-29-01 (2014)

TENNESSEE

TENN. CODE ANN. §§ 63-1-301 through 63-1-313 (West 2014)

TENN. COMP. R. & REGS. §§ 1200-34-01.01 to .10 (2014)

TEXAS

TEX. OCC. CODE ANN. §§ 168.001, 168.002, 168.051, 168.052, 167.053, 168.101, 168.102, 168.151, 168.152, 168.201 and 168.202 (Vernon 2013)

22 TEX. ADMIN CODE §§ 177.16, 195.1 through 195.4 and 291.29 (2014)

28 TEX. ADMIN CODE §§ 133.10 (2014)

WEST VIRGINIA

W. VA. CODE ANN. §§ 16-5H-1 through 16-5H-10 (West 2014)

COMMON LEGISLATIVE COMPONENTS

There are 14 common legislative components among these state laws and accompanying regulations.

1. DEFINITIONS: State statutes or regulations provide definitions of key terms such as “pain clinic,” “pain management clinic,” and “chronic pain.”
2. REGISTRATION, CERTIFICATION OR LICENSING: State statutes or regulations require certification or registration of pain clinics and enumerate certification or registration procedures.
3. EXEMPTIONS: State statutes or regulations exempt certain facilities from provisions governing pain clinics.
4. OWNERSHIP QUALIFICATIONS: State statutes or regulations require clinic owners to hold certain licenses and/or board certifications.
5. MEDICAL DIRECTOR OR CLINIC MANAGER: State statutes or regulations require clinics to designate an individual to bear certain responsibilities relative to clinic operation and compliance.
6. HOURLY REQUIREMENTS: State statutes or regulations stipulate that certain individuals must be on-site at a pain clinic for a certain percentage of the clinic’s operating hours.
7. PRESCRIBING/DISPENSING RESTRICTIONS: State statutes or regulations place restrictions on the prescribing/dispensing of controlled substances in a pain clinic setting.
8. PMP (PRESCRIPTION DRUG MONITORING PROGRAM): State statutes or regulations reference certain requirements with respect to the state’s PMP program.
9. TRAINING REQUIREMENTS: State statutes or regulations require persons practicing in pain clinics to meet certain qualifications or receive specific training.
10. CLINIC ENVIRONMENT: State statutes or regulations include requirements related to the physical appearance of the clinic such as lighting, restroom availability, and signage.

11. INSPECTIONS: State statutes or regulations include clinic inspection requirements and/or procedures.
12. RECORDS: State statutes or regulations require that pain clinics maintain certain records and/or collect certain data.
13. VIOLATIONS AND PENALTIES: State statutes or regulations enumerate administrative and/or criminal penalties for violating pain clinic provisions.
14. FEES: State statutes or regulations permit the collection of fees (licensing fees, inspection fees, etc.).

The second part of this overview summarizes or gives examples of the applicable statutory and regulatory provisions for each component. For easy reference, the summaries are followed by maps and a table of the fourteen components that identify the states that have relevant language. The information contained herein applies only to a state's pain clinic statute and regulations. Other sections of a state's statutory or regulatory code may contain relevant language. For example, a state may have restrictions on prescribing beyond those that apply in a pain management clinic setting. For purposes of Part 2, the overview focuses its discussions on the statutes and regulations cited above.

DEFINITIONS

A key definition in all state pain clinic acts is the phrase "pain management clinic." The official description of such a clinic establishes who must comply with the acts' other provisions that establish numerous requirements and responsibilities.

- **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....*
- **Georgia** law defines a pain management clinic as *...a medical practice advertising treatment of pain or utilizing pain in the name of the clinic or a medical practice or clinic with greater than 50 percent of its annual patient population being treated for chronic pain for nonterminal conditions by the use of Schedule II or III substances...*
- **Kentucky** law defines a pain management facility as *...a facility where the majority of patients of practitioners at the facility are provided treatment for pain that includes the use of controlled substances and: 1. The facility's primary practice component is the treatment of pain; or 2. The facility advertises in any medium for any type of pain management services....*

- **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....* “Primarily engaged” means 51 percent or more of the patients seen on any day a clinic is in operation, are issued a narcotic prescription for the treatment of chronic non-malignant pain..., with noted exceptions.
- **Mississippi** regulations define a pain management medical practice as a *...public or privately owned medical practice that provides pain management services to patients, a majority (more than 50%) of which are issued a prescription for, or are dispensed opioids, barbiturates, benzodiazepines, carisoprodol, butalbital compounds, or tramadol for more than one hundred eighty days (180) in a twelve month period.*
- **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 and (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 by the board....*
- **Tennessee** law defines a pain management clinic as *...a privately-owned facility in which a majority of the facility’s patients, seen by any or all of its medical doctors, osteopathic physicians, advanced practice nurses with certificates of fitness to prescribe, or physician assistants, are provided pain management services by being prescribed opioids, benzodiazepines, barbiturates, or carisoprodol, but not suboxone, for more than ninety (90) days in a twelve (12) 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....*
- **West Virginia** law defines a pain management clinic as all privately owned facilities or offices where *...in any month more than fifty percent of patients of the prescribers or dispensers are prescribed or dispensed opioids or other controlled substances ... for chronic pain resulting from non-malignant conditions and the facility meets any other identifying criteria established by the Secretary of the Department of Health and Human Resources.*

REGISTRATION, CERTIFICATION OR LICENSING

All nine states specify general procedures for registering, certifying, or licensing a pain management clinic. The types of requirements often found as part of the registration or other comparable procedure are discussed below.

- 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.
- 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

EXEMPTIONS

Some states exempt facilities from registration, certification, or licensing under certain circumstances. Examples of such circumstances include (1) if the clinic was in existence prior to the state's adoption of relevant laws and regulations, or (2) if the clinic is owned and operated by individuals who meet a particular set of enumerated criteria. Entities that states typically exempt from pain management clinic statutes and regulations include, but are not limited to:

- 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

- Long-term care facilities
- State-operated facilities

OWNERSHIP QUALIFICATIONS

Statutes and regulations often require pain management clinic owners to possess certain professional licenses and certifications. Additionally, owners must not have specified criminal convictions, or have had a license denied or restricted, or be subject to disciplinary actions by their licensing bodies.

Georgia law states that:

- All pain management clinics must be owned by physicians licensed in the State of Georgia.
- The Georgia Pain Management Clinic Act defines a physician as *...a person who possesses a current license to practice medicine in the State of Georgia...who, during the course of his or her practice, has not been denied the privilege of prescribing, dispensing, administering, supplying, or selling any controlled substance; and who has not during the course of his or her practice, had board action taken against his or her medical license as a result of dependency on drug or alcohol...*
- The physician ownership requirement does not apply to clinics in existence on June 30, 2013, which are jointly owned by one or more physician assistants or advanced practice registered nurses and one or more physicians.
- The physician ownership requirement does not apply to clinics in existence on June 30, 2013, which are not majority owned by physicians licensed in the state.
- Persons who have been convicted of felonies are not permitted to own or have an ownership interest in a pain management clinic.
- The Georgia Composite Medical Board may establish minimum standards of continuing medical education for all physicians owning a pain management clinic.

Florida laws and regulations stipulate that:

- The direct or indirect owner of a pain management clinic must never have been subject to Drug Enforcement Administration (DEA) 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.

Kentucky law states that:

- Only a physician having a full and active license to practice medicine shall have an ownership or investment interest in a pain management facility (not enforced against facilities existing on April 24, 2012 unless there are certain administrative sanctions or criminal convictions imposed on the facility or person employed by the facility, or any person working at the facility as an independent contractor).
- At least one of a clinic's owners or an owner's designee (who is a physician employed by and under the supervision of that owner) must:
 - ◆ hold a current subspecialty certification in pain management or hospice and palliative care by a member board of the American Board of Medical Specialties, or hold a current certificate of added qualification in pain management or hospice and palliative medicine by the American Osteopathic Association Bureau of Osteopathic Specialists; or
 - ◆ hold a current board certification by the American Board of Pain Medicine or the American Board of Interventional Pain Physicians; or
 - ◆ have completed a fellowship in pain medicine or an accredited residency program that included a rotation of at least five months in pain management; or
 - ◆ meet certain qualifications if he was an owner or practiced in that specific pain management facility prior to and continuing through July 20, 2012; or

- ◆ if the facility is operating under a registration filed with the Board of Medical Licensure, have completed or hold, or be making reasonable progress toward completing or holding a certification or training substantially equivalent to the specified certifications or training.

Louisiana laws and regulations mandate that:

- A pain management clinic shall not be owned by a physician who has been denied the privilege of prescribing, dispensing, administering, supplying, or selling a controlled dangerous substance or had board action taken as a result of dependency on drugs or alcohol.
- Pain management clinics may not be owned by a person who has been convicted of, pled guilty or nolo contendere to a felony offense or, for clinics operating on or before June 15, 2005, of a misdemeanor offense related to the distribution or illegal prescription of any narcotic.
- Pain management clinics operating on or before June 15, 2005 must be owned by a medical director who is a physician.
- 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.

Mississippi regulations provide that:

- A pain management practice must be owned and operated by a hospital or medical director who is a physician who (i) practices full time in Mississippi, with full time defined as at least 20 hours per week of direct patient care; (ii) holds an unrestricted medical license; and, (iii) holds a certificate of registration for that pain management practice.
- Owners or operators of a pain management practice, certain clinic employees, and persons with whom the clinic contracts for services may not (i) have been denied a DEA license by any jurisdiction; (ii) have held a restricted DEA license; or (iii) have been subject to a disciplinary action involving controlled substances.

- No physician or physician assistant may practice in a pain management medical practice if such practitioner has been convicted of, pled nolo contendere to, or received deferred adjudication for an offense that constitutes a felony or an offense that constitutes a misdemeanor, the facts of which relate to the illegal distribution or sale of drugs or controlled substances.

Ohio laws and regulations state that:

- Each pain management clinic must be owned and operated by one or more physicians.
- Every physician owner must meet one of the following qualifications:
 - ◆ hold a subspecialty certification in pain management or hospice and palliative medicine by the American Board of Medical Specialties or an added qualification in pain management or hospice and palliative medicine by the American Osteopathic Association Bureau of Osteopathic Specialists; or
 - ◆ hold a board certification by the American Board of Pain medicine or the American Board of Interventional Pain Physicians; or
 - ◆ hold a board certification or primary certification in designated specialties by the American Board of Medical Specialties and demonstrated conformance with the minimal standards of care.
- No physician owner shall have been 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, administering, supplying or selling a controlled substance or other dangerous drug....*
- No physician owner shall have been denied or held a restricted license to prescribe, dispense, administer, supply, or sell a controlled substance by DEA or a state licensing entity *...based in whole or in part, on the prescriber's inappropriate prescribing, dispensing, administering, supplying or selling a controlled substance or other dangerous drug....*

Tennessee laws and regulations provide that:

- The Department of Health may deny a certificate to a pain management clinic if an owner (1) has been denied or held a restricted license to prescribe, dispense, administer, supply, or sell a controlled substance; or (2) has been the subject of a disciplinary action by any licensing entity that was ... *the result of inappropriate prescribing, dispensing, administering, supplying or selling a controlled substance....*
- A pain management clinic may not be owned by a person who has been convicted of, pled nolo contendere to, or received deferred adjudication for a felony offense or a misdemeanor, *the facts of which relate to the distribution of illegal prescription drugs or a controlled substance or controlled substance analog.*

Texas laws and regulations stipulate that:

- A pain management clinic must be owned and operated by a medical director who is a physician who practices in Texas under an unrestricted license. A clinic may have multiple owners, all of whom must be physicians.
- A pain management clinic cannot be wholly or partly owned by a person who's been convicted of, pled nolo contendere to, or received deferred adjudication for a (1) felony offense, or (2) a misdemeanor offense related to the distribution of illegal prescription drugs or controlled substances.
- An owner of a pain management clinic may not have previously been denied or had a restricted license to prescribe, dispense, administer, supply, or sell a controlled substance.
- An owner of a pain management clinic may not have been subject to disciplinary action by any licensing entity for conduct that was a result of inappropriately prescribing, dispensing, administering, supplying, or selling a controlled substance.

West Virginia law and regulations mandate that:

- At least one owner of each clinic must be a physician actively licensed to practice medicine, surgery, or osteopathic medicine or surgery in West Virginia.

- A clinic may not be owned, nor may it employ any prescriber or physician (1) whose DEA number has been revoked; (2) whose application for a license to prescribe or administer controlled substances has been denied; or (3) who has been convicted of a felony offense related to the receipt of illicit and diverted drugs.

MEDICAL DIRECTOR OR CLINIC MANAGER

Nearly all of the states require clinics to designate an individual to bear certain responsibilities relative to clinic operation and compliance.

Georgia statute provides that:

- Whenever an applicable rule requires or prohibits action by a pain management clinic, responsibility shall be that of the owner and the physicians practicing at the clinic.

Kentucky law and regulations mandate that:

- The facility shall have a medical director who is board certified and has an unencumbered license to practice in the Commonwealth.
- The medical director shall be responsible for complying with all requirements related to the licensure and operation of the facility.

Louisiana statutes and regulations stipulate that:

- Each clinic shall be under the direction of a medical director who shall be a physician with an unrestricted license to practice medicine in Louisiana.
- The medical director, during the course of his practice, cannot have been denied the privilege of prescribing, dispensing, administering, supplying, or selling any controlled substance, or had board action taken as a result of dependency on drugs or alcohol.

Ohio statutes and regulations state that:

- Each owner shall supervise, control, and direct the activities of each individual who provides treatment of pain or chronic pain at the clinic or is associated with the provision of that treatment.

Tennessee laws and regulations provide that:

- A pain management clinic must have a medical director who has an unrestricted, unencumbered license to practice in Tennessee.
- The medical director shall oversee all pain management services at the clinic.

West Virginia laws and regulations require that:

- Each pain management clinic must designate a physician owner who bears responsibility for the clinic's operation and compliance with all applicable licensing and operating requirements.
- The designated responsible physician must:
 - ◆ have a full and unencumbered license to practice medicine, surgery, or osteopathic medicine or surgery in West Virginia;
 - ◆ practice at the licensed location for which the physician has assumed responsibility; and,
 - ◆ supervise, control, and direct the activities of each individual working or operating at the facility.

HOURLY REQUIREMENTS

Some states mandate that an owner, medical director, or clinic manager be on-site for a certain percentage of the clinic's operating hours.

Georgia statute provides that:

- Pain management clinics cannot provide medical treatment or services unless a practitioner who is authorized to prescribe controlled substances is on-site (practitioner can include a physician, a physician assistant or an advanced practice registered nurse acting pursuant to a physician protocol).

Kentucky law requires that:

- Beginning July 20, 2012, at least one clinic owner or an owner's designee be physically present practicing medicine in the clinic at least 50% of the time that patients are in the facility.

Louisiana statutes and regulations state that:

- The medical director must be on-site 50% of the time during the clinic's operating hours. When not on-site, the medical director must be available by means of telecommunication and must be able to be at the clinic within 30 minutes.

Tennessee regulations require that:

- The medical director of a clinic be onsite for at least 20% of the clinic's total number of operating hours.

Texas law provides that:

- The owner or operator of the clinic must be on-site for at least 33% of the clinic's operating hours.

PRESCRIBING/DISPENSING RESTRICTIONS

State legislation often places restrictions on the prescribing or dispensing of controlled substances in a pain clinic setting.

Florida law stipulates that:

- A physician, a physician assistant, or a registered nurse must perform a physical exam of a patient on the same day a physician prescribes controlled substances for that patient.
- A physician who prescribes more than a 72 hour dose of controlled substances for the treatment of chronic pain must document the reason for prescribing that quantity in the patient's record.

Kentucky statutes and regulations require that:

- Each prescriber employed or contracted by a pain management facility shall be board certified and have a full, active license to practice in Kentucky.

Louisiana regulations provide that:

- Clinics shall verify the identity of each patient treated for chronic pain who is prescribed a controlled substance.
- On each clinic visit that results in the prescribing of a controlled substance, the patient receiving the prescription must be personally examined by a pain specialist.
- Written prescriptions may not exceed a 30 day supply and shall not be refillable.

Ohio legislation states that:

- Licensees with a pain management clinic classification must meet requirements for holding a Category III terminal distributor classification, which permits the distribution of controlled substances in Schedules I-V.

Tennessee statutes and regulations require that:

- No pain management clinic or authorized prescriber working at a pain management clinic is permitted to dispense controlled substances, with the exception of providing a maximum 72-hour sample supply of a Schedule IV or V controlled substance.

West Virginia provisions stipulate that:

- Pain management clinics may not dispense more than a 72 hour supply of a controlled substance.
- A physician, physician assistant, certified registered nurse anesthetist, or advanced nurse practitioner must perform a physical exam of a patient on the same day that the physician initially prescribes, dispenses, or administers a controlled substance to a patient.

PMPs

State statutes and regulations sometimes impose requirements on medical directors, physicians, or other treating professionals at a pain clinic to access and use the state's PMP. Also, some government officials may receive PMP data to more effectively monitor a clinic's compliance with applicable legal requirements.

Kentucky law stipulates that:

- The Board of Medical Licensure has authority to obtain KASPER (Kentucky's PMP) reports and analyses for each practitioner at a pain management facility.
- At least once per year, the Board of Medical Licensure must obtain a KASPER review and analysis for each physician who owns, is employed by or practices in a pain management facility.

Louisiana regulations require that:

- A clinic's medical director apply to access and query the Louisiana Prescription Monitoring Program. The medical director and pain specialist shall use the PMP information to help ensure adherence to a patient's treatment agreement.

Mississippi regulations state that:

- Physicians and physician assistants practicing in a registered pain practice must be registered with the Mississippi Prescription Monitoring Program; a report must be obtained on the initial visit and at intervals deemed appropriate for good patient care.

Tennessee regulations mandate that:

- A pain clinic's medical director must establish quality assurance policies and procedures related to health care provider access to the state's controlled substance monitoring database as clinically indicated, but at a minimum, for each new patient admission and once every six months thereafter.

West Virginia law states that:

- A treating physician in a pain management clinic, prior to dispensing or prescribing controlled substances, shall access the state's Controlled Substance Monitoring Program to ensure that a patient is not obtaining controlled substances from multiple physicians. For ongoing treatment involving controlled substances, the physician shall check the database at each patient exam or at least every 90 days.

TRAINING REQUIREMENTS

Health care practitioners in pain clinics often must undergo specified training or satisfy certain professional qualifications.

Georgia law provides that:

- Licensed health care professionals practicing in a pain management clinic may be subject to minimum standards of continuing education as established by the respective licensing board for that healthcare professional.

Florida laws and regulations stipulate that:

- A physician who prescribes or dispenses 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 20 hours per week) in pain management.

Kentucky statutes and regulations provide that:

- The medical director shall:
 - ◆ hold a current subspecialty certification in pain management or hospice and palliative care by a member board of the American Board of Medical Specialties, or hold a current certificate of added qualification in pain management or hospice and palliative medicine by the American Osteopathic Association Bureau of Osteopathic Specialists; or
 - ◆ hold a current board certification by the American Board of Pain Medicine or the American Board of Interventional Pain Physicians; or
 - ◆ have completed a fellowship in pain management or an accredited residency program that included a rotation of at least five months in pain management; or
 - ◆ meet certain qualifications if he was an owner or practiced in the specific pain management facility applying for licensure as a pain management facility; or
 - ◆ if the facility is operating under a registration filed with the Board of Medical Licensure, have completed or hold, or be making reasonable progress toward completing or holding a certification or training substantially equivalent to the certifications or training specified in this subsection, as authorized by the Kentucky Board of Medical Licensure by administrative regulation; or
 - ◆ be an owner of or practice in the specific facility applying for licensure as a pain management facility and who (i) has completed an accredited residency which included a component in the practice of pain management, (ii) is eligible for and has provided the Kentucky Board of Medical Licensure and the Office of the Inspector General with written verification that the facility's medical director has registered to complete the certification examination offered by the American Board of Pain Medicine or the American Board of Interventional Pain Physicians in April 2013 and (iii) becomes certified by the American Board of Pain Medicine or by the American Board of Interventional Pain Physicians by September 1, 2013.

Louisiana legislation states that:

- The medical director of a clinic operating after June 15, 2005 shall have a subspecialty certification in pain management by a member board of the American Boards of Medical Specialties.

Mississippi regulations require the following:

- All physicians prescribing or dispensing controlled substance medications in pain management practices must meet one of five listed qualifications including (1) board certification by a specialty board recognized by the American Board of Medical Specialties or American Board of Addiction Medicine, (2) board certification by a specialty board recognized by the American Osteopathic Association Bureau of Osteopathic Specialists in pain management, (3) board certification in pain medicine by the American Board of Pain Medicine, (4) successful completion of a residency program in physician medicine and rehabilitation, anesthesiology, neurology, or neurosurgery or (5) successful completion of 100 hours in-person, live participatory AMA or AOA Category I CME courses in pain management.
- Physicians must additionally document completion of 15 hours of live lecture format Category I CME in pain management every year that a physician practices pain management.
- Physician assistants practicing in pain management practices are also required to meet stated qualifications.

Ohio provisions mandate that:

- Every physician who is an owner or who provides care must complete at least 20 hours of category I continuing medical education (CME) courses in pain management every two years, including one or more courses addressing the potential for addiction.

Tennessee laws and regulations require that:

- The medical director meet at least one of the following requirements:

- ◆ successful completion of a residency program or Board certification in physical medicine and rehabilitation, anesthesiology, addiction medicine, or other designated specialty approved by the Accreditation Council for Graduate Medical Education (ACGME) or American Osteopathic Association Bureau of Osteopathic Specialists (AOABOS);
 - ◆ a subspecialty certification in pain management, hospice and palliative medicine, or other designated subspecialty recognized by the ABMS or AOABOS with a certificate of added qualification from the Bureau of Osteopathic Specialists;
 - ◆ Board certification by the American Board of Pain Medicine or American Board of Interventional Pain Physicians; or
 - ◆ completion of forty (40) hours of in-person, live-participatory AMA Category I or AOABOS Category I CME coursework in pain management completed within three (3) years prior to implementation of the rule or prior to serving as medical director for the clinic, whichever event is most recent.
- Each health care provider providing pain management services at a clinic shall complete ten hours in continuing education courses during each health care provider's licensure renewal cycle which shall be a part of the continuing education requirements established by each of the health care provider's respective boards. The ten continuing education hours shall address at least one or more of the designated topics related to pain management.

Texas statutes and regulations provide that:

- The medical director must annually ensure that all personnel are properly licensed and trained, including ten hours of CME on pain management.

West Virginia legislation mandates that:

- The physician owner responsible for the clinic's operation must either complete an accredited pain medicine fellowship or hold a current board certification from the American Board of Pain Medicine, the American Board of Anesthesiology, or another approved board.

CLINIC ENVIRONMENT

Physical location specifications outlined in pain clinic statutes and regulations include, but are not limited to:

- A clean environment
- Clearly posted required signage and notifications
- A reception area, waiting room and restrooms
- Private examination rooms
- Adequate file storage
- Secure storage for controlled substances

INSPECTIONS

State laws and regulations sometimes authorize various officials to conduct inspections of pain management clinics.

Louisiana regulations require:

- An annual fire marshal inspection,
- An annual inspection by the Office of Public Health,
- A quarterly fire alarm system test by facility staff, and
- Regular inspections of the clinic elevators.

Tennessee law provides that:

- ... *[E]ach 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 state 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....*

RECORDS

Pain clinics often have to comply with detailed requirements regarding the collection of patient data and the maintenance and storage of patient records. The information that has to be retained in patient records includes, but is not limited to:

- Patient identifiers
- Medical history
- Prescription monitoring report (if applicable)
- The chief complaint and diagnosis
- Lab orders and results
- Pathology and radiology reports
- Substances prescribed or dispensed
- A patient-signed treatment agreement.

Ohio law mandates that:

- A log of patients must be maintained for each day the clinic is in operation and must contain the month/day/year, the legible first and last name of each patient, and the patient's signature at each visit. The logs must be maintained for seven years.

Texas legislation provides that:

- A clinic owner or operator shall review at least 33% of the total number of patient files.

VIOLATIONS AND PENALTIES

Violations relative to operation of a pain management clinic can include, but are not limited to:

- 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
- 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
- Committing medical malpractice in relation to operation of a pain management clinic.

Georgia statute provides that:

- Anyone who operates a pain management clinic in the State of Georgia without a license in violation of the Georgia Pain Management Clinic Act is guilty of a felony.

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....*

Kentucky statutes and regulations provide that:

- Violating the state's pain management facility provision constitutes a Class A misdemeanor.

Louisiana provisions stipulate that:

- ... *[W]hoever 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....*

Mississippi regulations state that:

- The prescribing, administering or dispensing of any legend drug or other medication in violation of the pain management medical practice provision constitutes unprofessional conduct, dishonorable or unethical conduct likely to deceive, defraud or harm the public.

Ohio statutes and regulations indicate 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 no less than one thousand dollars (\$1,000) per day and which shall not exceed five thousand dollars (\$5,000) per day....*

Texas law provides that:

- *...A violation of this chapter or a rule adopted under this chapter is grounds for disciplinary action... against a pain management clinic....*

West Virginia law stipulates that:

- A violator of the Chronic Pain Clinic Licensing Act will be assessed a civil penalty, with each violation considered and penalized separately.

FEES

Pain clinic regulation acts frequently permit the collection of fees to help pay the enforcement costs associated with the acts.

Florida regulations stipulate that

- ... *[A]n inspection fee of \$1,500 shall be paid annually for each location required to be inspected....*

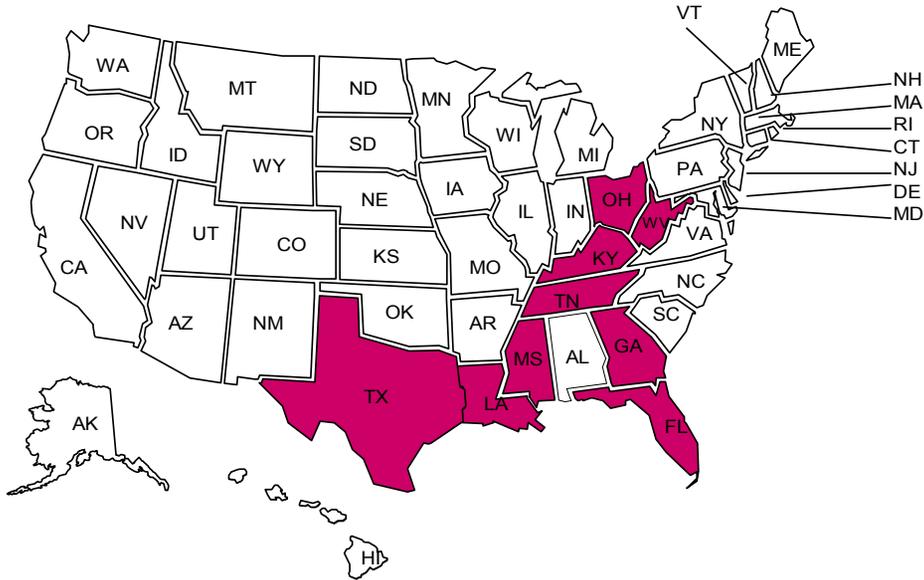
Louisiana statutes and regulations state that:

- ... *[T]here 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....*

Tennessee regulations provide for:

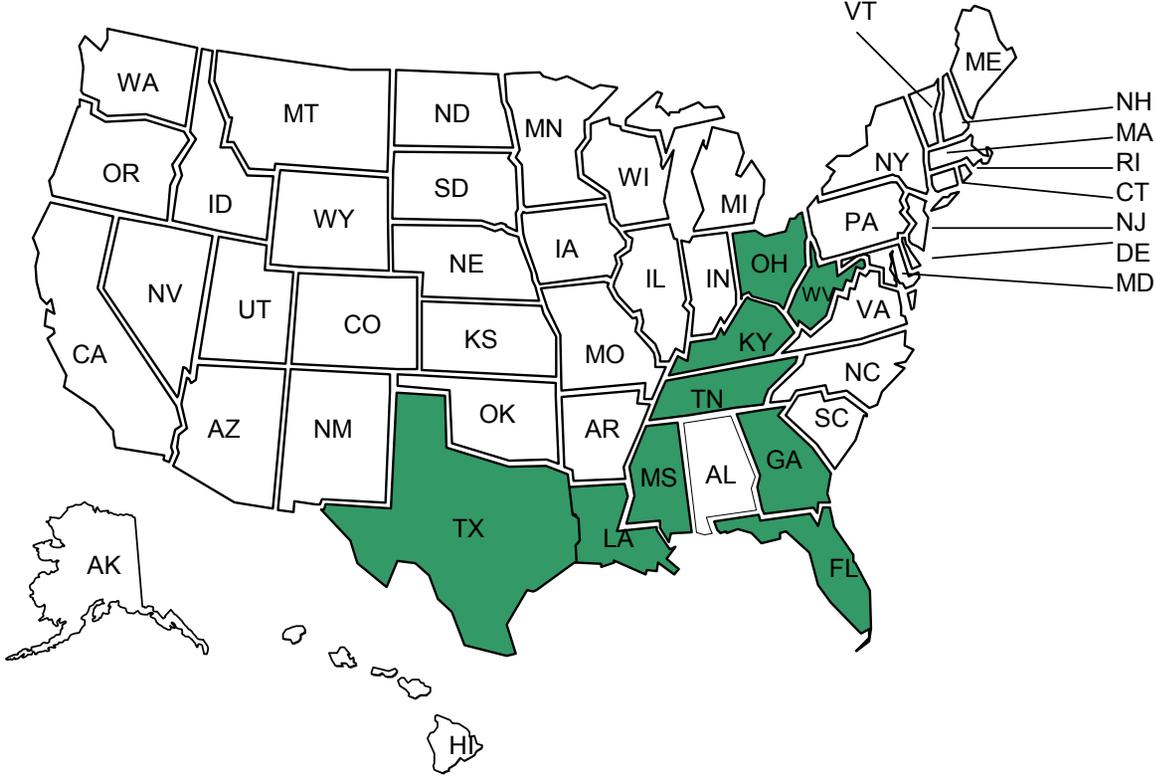
- A fee schedule for pain management clinics including a \$405.00 Initial Certificate Fee, a Renewal Fee of \$405.00, a Regulatory Fee of \$10.00, and a late renewal penalty fee of \$100.00 per month for each month or fraction of a month that renewal is late.

States in Which Pain Clinic Statutes and/or Regulations Include a Section that Defines Key Terms



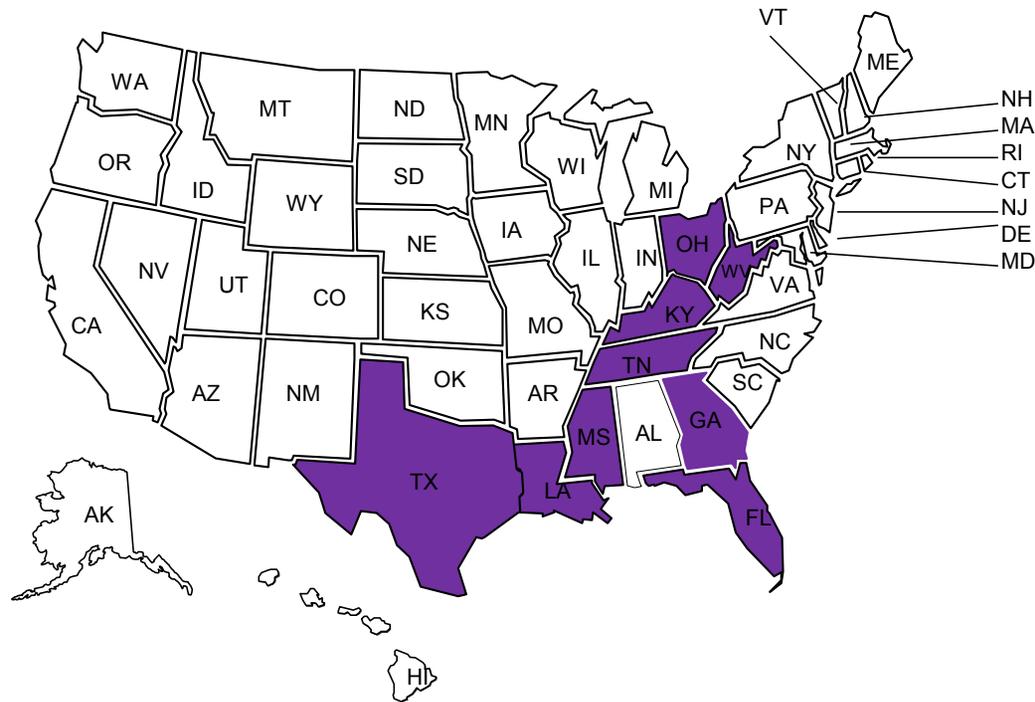
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States in Which Pain Clinic Statutes and/or Regulations Require Certification or Registration of Pain Clinics



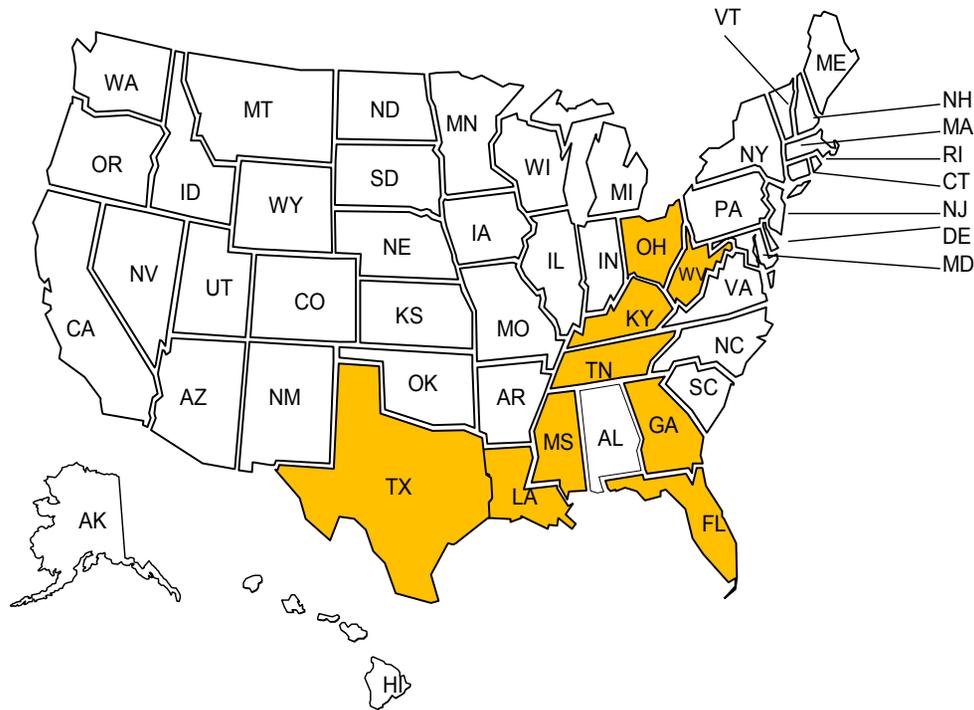
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States in Which Pain Clinic Statutes and/or Regulations Stipulate Which Facilities are Exempt from Regulation as a Pain Clinic



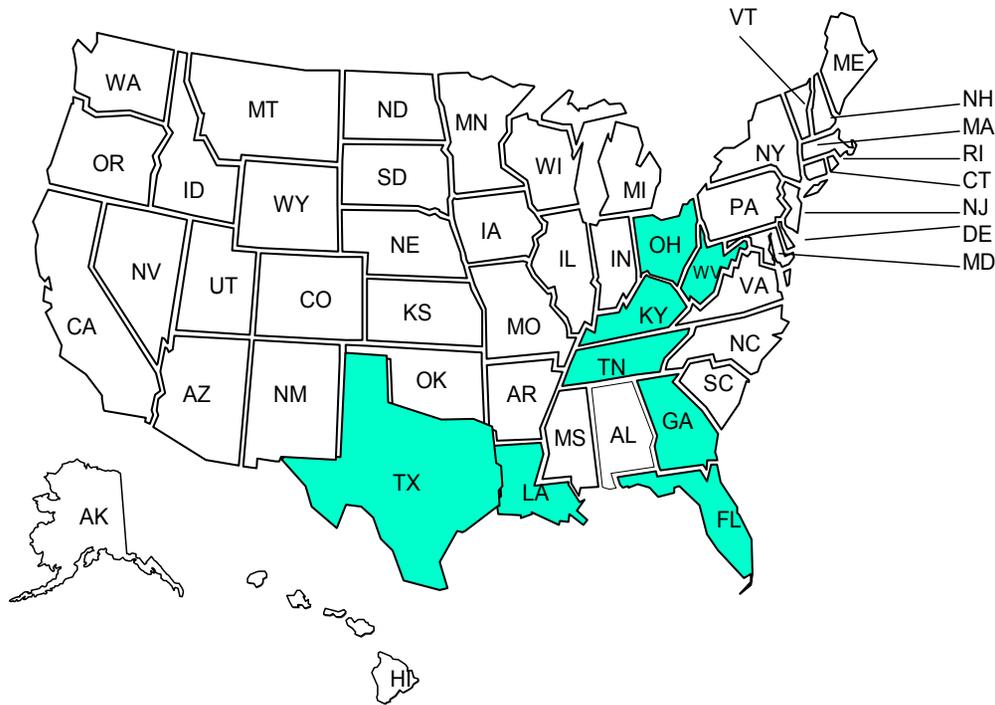
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States in Which Pain Clinic Statutes and/or Regulations Require Clinic Owners to Hold Certain Licenses and/or Board Certifications



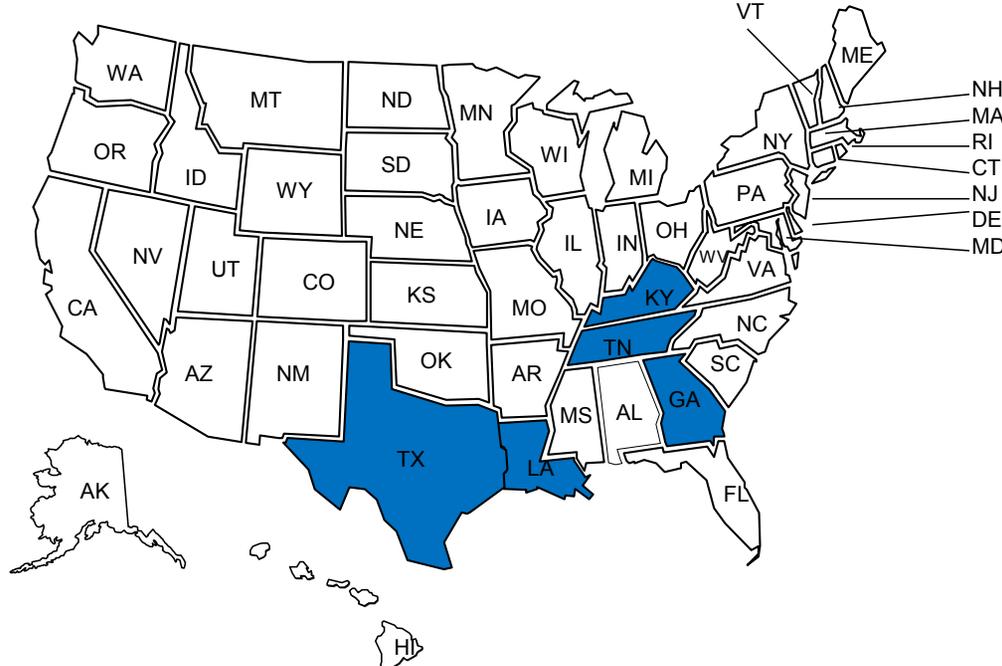
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States in Which Pain Clinic Statutes and/or Regulations Require Clinics to Designate an Individual to Take Responsibility for Clinic Operation and Compliance with Relevant Laws.



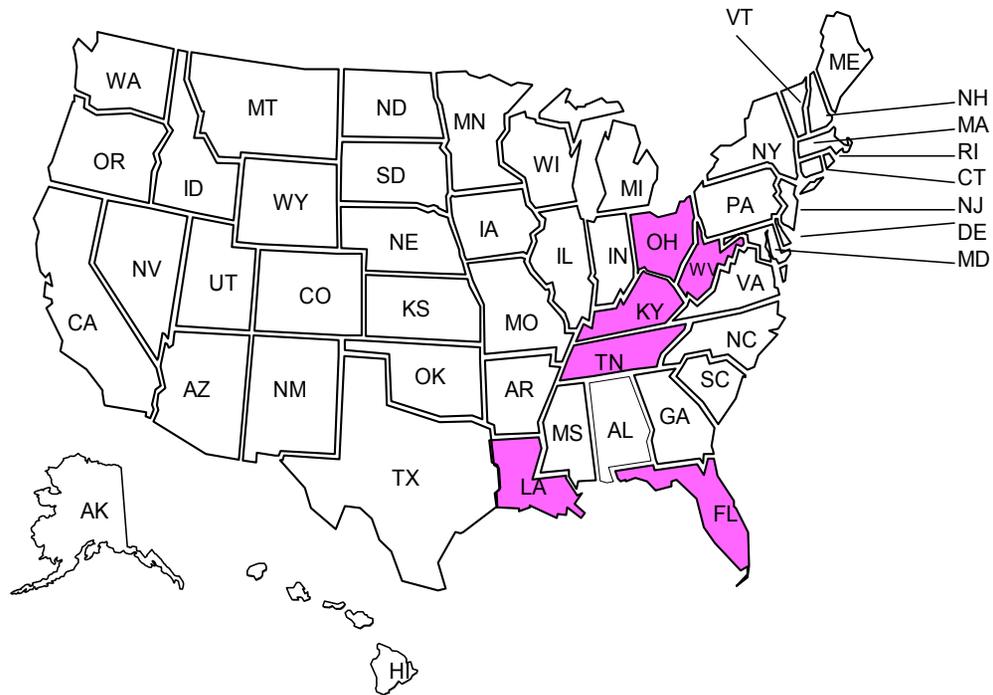
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States in Which Pain Clinic Statutes and/or Regulations Stipulate that Certain Individuals Must be On-Site at a Pain Clinic for a Certain Percentage of the Facility's Operating Hours



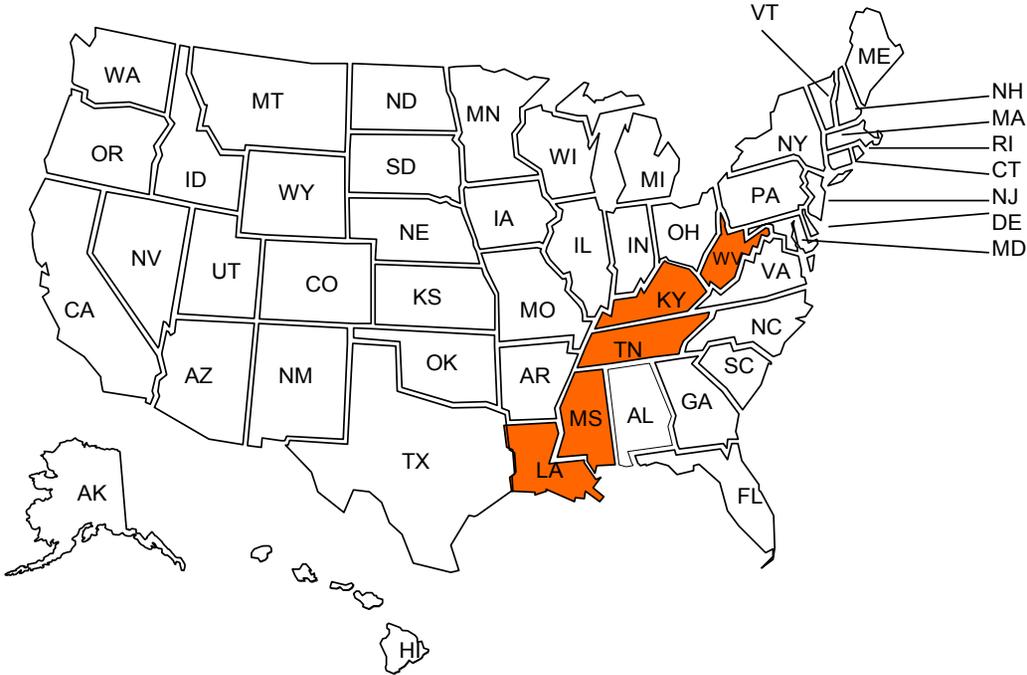
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States in Which Pain Clinic Statutes and/or Regulations Place Restrictions on the Prescribing/Dispensing of Controlled Substances in a Pain Clinic Setting



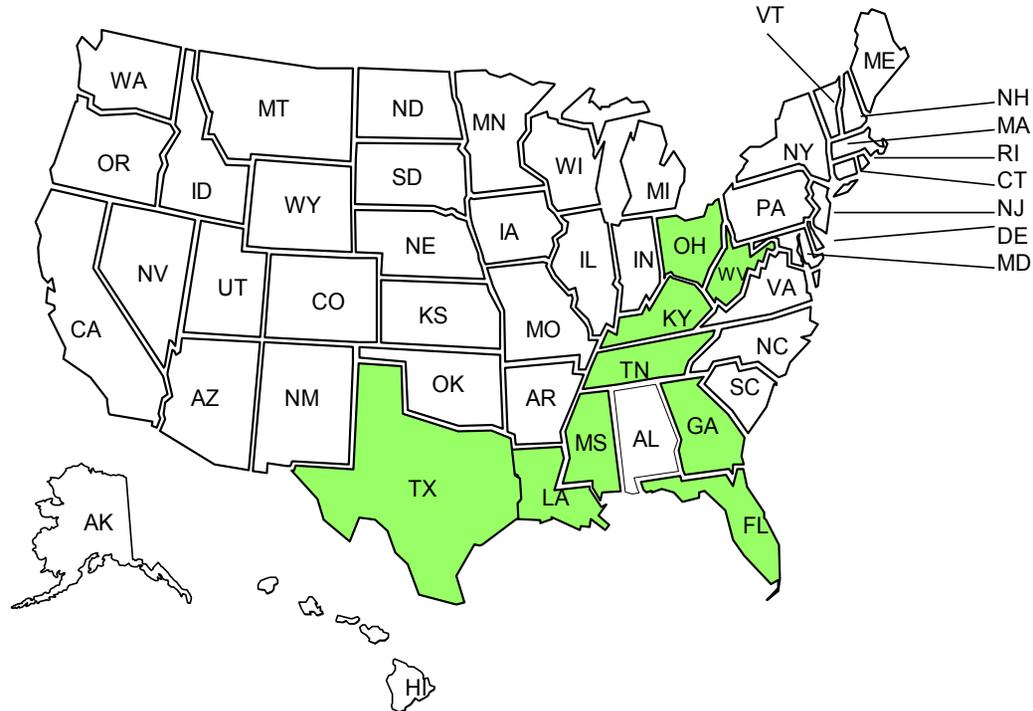
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States in Which Pain Clinic Statutes and/or Regulations Reference Certain Requirements with Respect to the State's Prescription Drug Monitoring Program



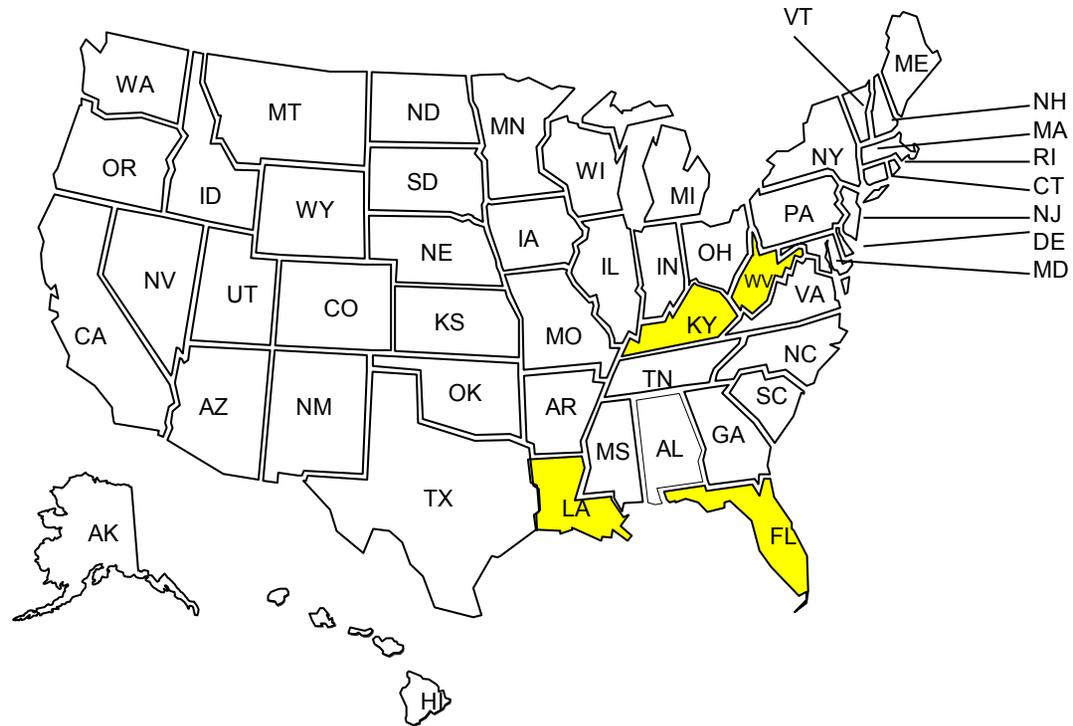
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States in Which Pain Clinic Statutes and/or Regulations Require Persons Practicing in Pain Clinics to Meet Certain Qualifications or Receive Specific Training



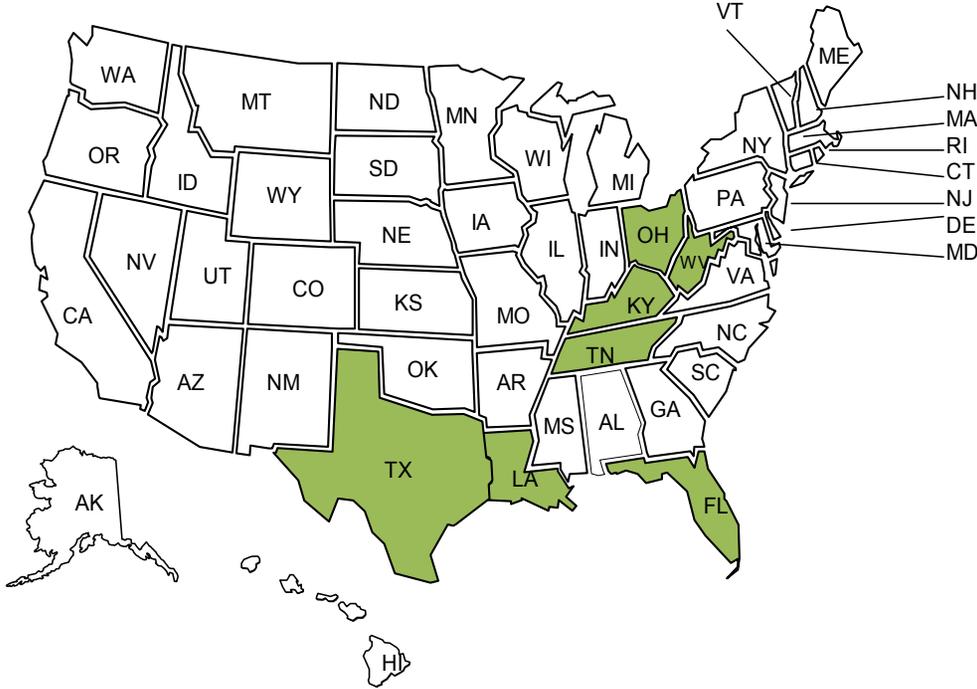
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States in Which Pain Clinic Statutes and/or Regulations Include Requirements Related to the Physical Appearance of the Clinic Such as Lighting, Restroom Availability and Signage.



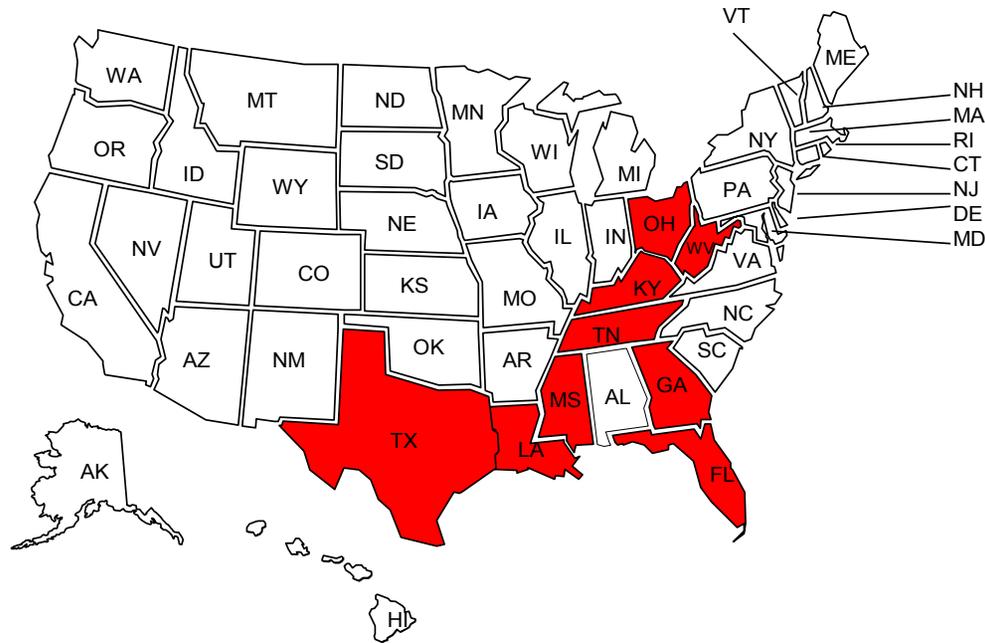
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States in Which Pain Clinic Statutes and/or Regulations Require that Clinics Maintain Certain Records and/or Collect Certain Data



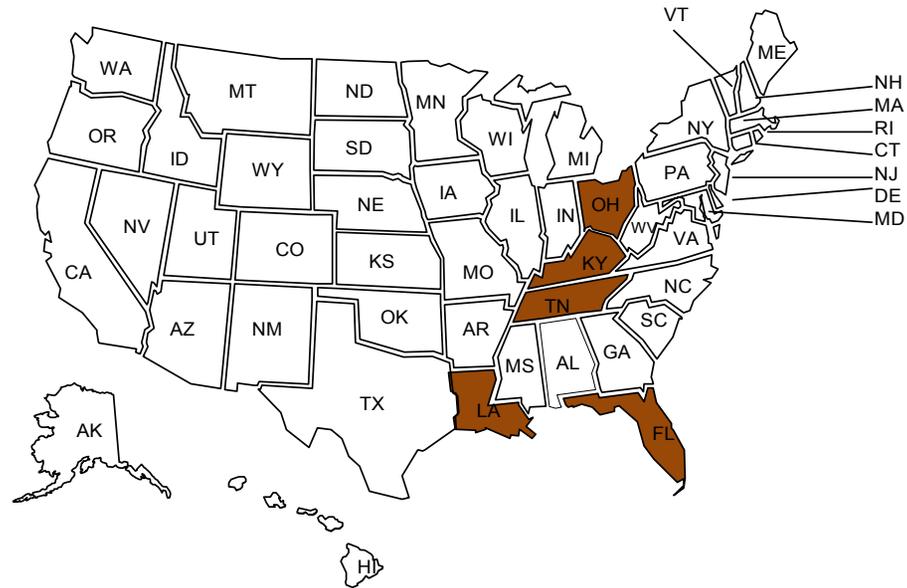
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States in Which Pain Clinic Statutes and/or Regulations Enumerate Administrative and/or Criminal Penalties for Violating Pain Clinic Provisions.



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States in Which Pain Clinic Statutes and/or Regulations Permit the Collection of Fees (Licensing Fees, Inspection Fees, etc.)



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TABLE: COMPONENTS OF STATE PAIN MANAGEMENT CLINIC STATUTES AND REGULATIONS

DEFINITIONS: State statutes or regulations provide definitions of key terms such as “pain clinic,” “pain management clinic,” and “chronic pain.”

REGISTRATION, CERTIFICATION OR LICENSING: State statutes or regulations require certification or registration of pain clinics and enumerate certification or registration procedures.

EXEMPTIONS: State statutes or regulations exempt certain facilities from provisions governing pain clinics.

OWNERSHIP QUALIFICATIONS: State statutes or regulations require clinic owners to hold certain licenses and/or board certifications.

MEDICAL DIRECTOR OR CLINIC MANAGER: State statutes or regulations require clinics to designate an individual to bear certain responsibilities relative to clinic operation and compliance.

HOURLY REQUIREMENTS: State statutes or regulations stipulate that certain individuals must be on-site at a pain clinic for a certain percentage of the clinic’s operating hours.

PRESCRIBING/DISPENSING RESTRICTIONS: State statutes or regulations place restrictions on the prescribing/dispensing of controlled substances in a pain clinic setting.

PDMP (PRESCRIPTION DRUG MONITORING PROGRAM): State statutes or regulations reference certain requirements with respect to the state’s PDMP program.

TRAINING REQUIREMENTS: State statutes or regulations require persons practicing in pain clinics to meet certain qualifications or receive specific training.

CLINIC ENVIRONMENT: State statutes or regulations include requirements related to the physical appearance of the clinic such as lighting, restroom availability, and signage.

INSPECTIONS: State statutes or regulations include clinic inspection requirements and/or procedures.

RECORDS: State statutes or regulations require that pain clinics maintain certain records and/or collect certain data.

VIOLATIONS AND PENALTIES: State statutes or regulations enumerate administrative and/or criminal penalties for violating pain clinic provisions.

FEES: State statutes or regulations permit the collection of fees (licensing fees, inspection fees, etc.)

COMPONENTS OF STATE PAIN MANAGEMENT CLINIC STATUTES AND REGULATIONS

	FLORIDA	GEORGIA	KENTUCKY	LOUISIANA	MISSISSIPPI	OHIO	TENNESSEE	TEXAS	WEST VIRGINIA
DEFINITIONS	X	X	X	X	X	X	X	X	X
REGISTRATION, CERTIFICATION OR LICENSING	X	X	X	X	X	X ⁱ	X	X	X
EXEMPTIONS	X ⁱⁱ	X	X	X	X	X	X	X	X
OWNERSHIP QUALIFICATIONS	X ⁱⁱⁱ	X	X ^{iv}	X ^v	X ^{vi}	X ^{vii}	X	X ^{viii}	X ^{ix}
MEDICAL DIRECTOR OR CLINIC MANAGER	X	X ^x	X ^{xi}	X ^{xii}		X ^{xiii}	X ^{xiv}	X	X ^{xv}
HOURLY REQUIREMENTS		X ^{xvi}	X ^{xvii}	X ^{xviii}			X ^{xix}	X ^{xx}	
PRESCRIBING or DISPENSING RESTRICTIONS	X ^{xxi}		X ^{xxii}	X ^{xxiii}		X ^{xxiv}	X ^{xxv}		X ^{xxvi}
PMP			X ^{xxvii}	X ^{xxviii}	X ^{xxix}		X ^{xxx}		X ^{xxxi}
TRAINING REQUIREMENTS	X ^{xxxii}	X ^{xxxiii}	X ^{xxxiv}	X ^{xxxv}	X ^{xxxvi}	X ^{xxxvii}	X ^{xxxviii}	X ^{xxxix}	X ^{xl}
CLINIC ENVIRONMENT	X		X	X					X ^{xli}
INSPECTIONS	X		X	X	X	X	X	X	X
RECORDS	X		X	X		X	X	X	X
VIOLATIONS AND PENALTIES	X	X	X	X	X	X	X	X	X
FEES	X		X	X		X	X		

ⁱ Pain management clinics must hold a license as a terminal distributor of dangerous drugs and must comply with licensing procedures related to obtaining such a license.

ⁱⁱ State law exempts clinics that are wholly owned and operated by board-eligible or board certified anesthesiologists, physiatrists, rheumatologists, or neurologists from registration.

ⁱⁱⁱ The Department Health is required to deny registration for any pain management clinic that is not fully owned by a licensed physician, group of physicians (each of whom is licensed), or a licensed health care clinic.

^{iv} State law limits ownership and investment interests in pain management facilities to licensed physicians; beginning July 20, 2012 at least one owner or owner's designee must meet specific criteria such as holding a board certification from one of a list enumerated in statute or completing an accredited residency or fellowship in pain management.

^v All pain management clinics must be one hundred 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.

^{vi} Pain management clinics must be owned and operated by a hospital or medical director whose practice includes at least twenty hours per week of direct patient care.

^{vii} Pain management clinics must be owned and operated by one or more physicians; physician owners must meet one of the qualifications related to board certification enumerated in Ohio's administrative regulations.

^{viii} A pain management clinic may not operate in Texas unless it is owned by a medical director who is a physician.

^{ix} At least one owner of each pain management clinic must be a physician who is actively licensed to practice medicine, surgery, or osteopathic medicine or surgery in West Virginia.

^x Whenever an applicable rule requires or prohibits action by a pain management clinic, responsibility shall be that of the owner and the physicians practicing at the clinic.

^{xi} A facility's medical director must be physically present practicing medicine at least fifty percent of the time patients are present at the facility.

^{xii} Pain management clinics must be operated by a medical director who must be a physician.

-
- ^{xiii} The physician owner provides supervision, direction, and control of individuals at a pain management clinic.
- ^{xiv} A pain management clinic must have a medical director who is a physician.
- ^{xv} Each pain management clinic must designate a physician owner, who practices at the clinic, who will bear responsibility for operating the clinic.
- ^{xvi} Pain management clinics cannot provide medical treatment or services unless certain practitioners with authority to prescribe controlled substances are on-site at the clinic.
- ^{xvii} Beginning July 20, 2012 at least one clinic owner or an owner's designee physician must be physically present practicing medicine at least fifty percent of the time patients are present at the facility.
- ^{xviii} The medical director must be on-site fifty percent of the time during clinic operating hours; when not on-site, the medical director must be available by means of telecommunication and must be able to be at the clinic within thirty minutes.
- ^{xix} A medical director must be on-site at least twenty percent of the clinic's weekly total number of operating hours.
- ^{xx} The owner or operator of a pain management clinic must be on-site at least thirty-three percent of the clinic's total number of operating hours and must review at least thirty-three percent of the total number of patient files.
- ^{xxi} State law requires a physician, a physician assistant or a registered nurse to perform a physical exam of a patient on the same day a physician prescribes a controlled substance for that patient.
- ^{xxii} Each physician who prescribes or dispenses controlled substances to patients, as part of employment at a pain management facility, must be board certified at the time of prescribing or dispensation.
- ^{xxiii} On each clinic visit that results in the prescribing of a controlled substance, the patient receiving the prescription must be personally examined by a pain specialist; written prescriptions may not exceed a thirty day supply and refills are permitted only after a patient is personally examined by a pain specialist.
- ^{xxiv} Licensees with a pain management clinic classification must meet requirements for holding a Category III terminal distributor classification, which permits the distribution of controlled substances in Schedules I, II, III, IV, and V.
- ^{xxv} No pain management clinic or authorized prescriber working at a pain management clinic is permitted to dispense controlled substances, with the exception of providing a maximum 72-hour sample supply of a Schedule IV or V controlled substance.

^{xxvi} Pain management clinics may not dispense more than a seventy-two hour supply of a controlled substance; a physician, physician assistant, certified registered nurse anesthetist, or advanced nurse practitioner must perform a physical examination of a patient on the same day that the physician initially prescribes, dispenses or administers a controlled substance to a patient.

^{xxvii} The Board of Medical Licensure has authority to obtain KASPER (Kentucky's PMP) reports and analyses for each practitioner at a pain management facility; at least once per year the Board of Medical Licensure must obtain a KASPER review and analysis for each physician who owns, is employed by or practices in a pain management facility.

^{xxviii} The medical director is responsible for applying for access to the state's PDMP, which is to be used as part of the clinic's quality assurance program.

^{xxix} Physicians and physician assistants practicing in a registered pain practice must be registered with the Mississippi PMP; a patient report must be obtained on the initial visit and at intervals deemed appropriate for patients receiving controlled substances.

^{xxx} A pain clinic's medical director must establish quality assurance policies and procedures related to health care provider access to the state's PMP as clinically indicated, but at a minimum, for each new patient admission and once every six months thereafter.

^{xxxi} Prior to dispensing controlled substances at a pain management clinic, a treating physician must access the Controlled Substances Monitoring Program to ensure the patient is not seeking controlled substances from multiple sources.

^{xxxii} Effective July 1, 2012 physicians practicing in pain clinics must either complete a pain medicine fellowship, pain medicine residency or hold one of a list of board certifications enumerated in state regulations.

^{xxxiii} Licensed healthcare professionals practicing in pain management clinics may be subject to minimum standards of continuing education established by the respective licensing board for that practitioner.

^{xxxiv} The clinic's medical director must meet specific criteria such as holding a board certification from one of a list enumerated in statute or completion of an accredited fellowship in pain management.

^{xxxv} The medical director must be certified in the subspecialty of pain management (medical directors working at clinics that were in existence on or before June 15, 2005 are exempt from this provision).

^{xxxvi} All physicians prescribing or dispensing controlled substance medications in pain management practices must meet one of five listed qualifications including (1) board certification by a specialty board recognized by the American Board of Medical Specialties or American Board of Addiction Medicine, (2) board certification by a specialty board recognized by the American Osteopathic Association Bureau of Osteopathic Specialists in pain management, (3) board certification in pain medicine by the American Board of Pain Medicine, (4) successful completion of a residency program in physician medicine and rehabilitation, anesthesiology, neurology, or neurosurgery or (5) successful completion of 100 hours in-person, live participatory AMA or AOA Category I CME courses in pain management; physicians must also document completion of 15 hours of live lecture Category I CME in pain management for every year the physician practices pain management.

^{xxxvii} Each physician owner of a pain management clinic must complete at least twenty hours of Category I continuing medical education in pain medicine every two years; the twenty hours must include at least one course that addresses addiction potential.

^{xxxviii} Each physician who serves as the medical director of a pain management clinic must meet one of six criteria related to board certification or in-person, live-participatory coursework/education; every health care provider who provides pain management services at a clinic must complete ten hours in continuing education courses that must address pain management.

^{xxxix} The medical director must complete at least ten hours of continuing medical education in the area of pain management and must also ensure that clinic personnel receive appropriate training, including ten hours of continuing medical education in the area of pain management.

^{xl} The physician owner responsible for the clinic's operation must either complete an accredited pain medicine fellowship or hold a current board certification from the American Board of Pain Medicine, the American Board of Anesthesiology or another approved board.

^{xli} State statute stipulates that rules must be promulgated, including rules relative to facility operation, physical operation and health/safety requirements.

PART B:

LEGISLATIVE TRENDS RELATIVE TO REGULATING PAIN CLINICS

As of 2011 there has been a spike in legislative activity at the state level related to regulating pain management clinics as part of the effort to eliminate pill mill activities. States introduced bills establishing pain clinic acts closely mirroring statutes that already existed in Florida, Louisiana and Texas. However, the 2013 legislative session marked the beginning of a shift in how states are proposing to tackle pill mills, a shift marked by an emphasis on regulating a prescriber and his or her prescribing practices rather than a specific physical location where prescribing occurs. Two states that followed this approach are Alabama and Indiana, both enacting new legislation that regulates prescribers and specific prescribing activity, which may allow for a greater variety of options with regards to enforcement. The specific measures are cited and summarized below.

Please note that all states have laws and administrative regulations related to prescribers and the prescribing of controlled substances. Relative to prescribing for pain, NAMSDL identified seven recommended prescribing practices – these practices are discussed and presented along with a comparative 50-state legislative analysis in Part 3 of this report titled “Prescribing of Controlled Substances for Non-Cancer Pain.”

Highlights of the Act and implementing regulations are as follows:

- Pain Management Services are defined as ...Those medical services that involve the prescription of controlled substances in order to treat chronic nonmalignant pain by a physician who treats pain...
- All physicians providing pain management services must register with the medical board by submitting a completed application form, proof of a current DEA registration, proof of an Alabama controlled substances certificate, proof of a current registration with the Alabama Prescription Drug Monitoring Program, a list of all registrants who own, operate or provide pain management services at the practice location, disclosure of any controlled substances certificate or registration denial, restriction or discipline imposed on the registrant, payment of the initial registration fee and a certification listing the name of the physician who will serve as the medical director.
- The Act provides exemptions such as hospice programs and facilities operated by the federal government.
- Initial registration fees, to be set by the Board of Medical Examiners, must not exceed \$300.
- Registrants may only provide pain management services at facilities owned and operated by (1) one or more licensed physicians (2) a business entity registered with the Secretary of State or (3) a governmental entity or body or political subdivisions, including state schools and universities.
- All registrants providing pain management services must obtain access to the Alabama Prescription Drug Monitoring Program maintained by the Department of Health.
- Physicians serving as medical directors at a practice location must meet one of the following requirements: (1) successful completion of a residency program in physical medicine, neurology, neurosurgery, family practice, preventive medicine, internal medicine, surgery, orthopedics or psychiatry (2) board certification in physical medicine and rehabilitation, anesthesiology, addiction medicine, neurology, neurosurgery, family practice, preventive medicine, internal medicine, surgery, orthopedics, or psychiatry (3) specialty certification in pain management, pain medicine, hospice and palliative medicine, geriatric medicine, rheumatology, hematology, medical oncology, gynecologic oncology, infectious disease, pediatric hematology-oncology or pediatric rheumatology (4) Board certification by the American Board of Pain Medicine (5) Board certification by the American Board of Interventional Pain Physicians or (6) completion of specified CME prior to serving as medical director.
- The Act authorizes inspections of physician notes/files/records and authorizes the suspending of a physician's pain management services registration.
- The Board of Medical Examiners is permitted to impose fines of up to \$10,000 per violation, or registration revocation, or both.

INDIANA - IND. CODE ANN. §§ 25-22.5-2-7, 25-22.5-13-1, 35-31.5-2-224 and 35-48-3-1 through 9 (West 2014)

On May 7th, 2013 the Governor of Indiana signed into law Senate Bill 246, which both amended existing state statutes related to the registration and control of controlled substances and added new statutory language governing ownership of offices, facilities, clinics or locations where controlled substances are dispensed. Highlights of the affected statutory sections, of newly added language and emergency regulations are as follows:

- An “owner” is defined as *...a person that employs or contracts with at least one (1) individual to dispense a controlled substance in an office, facility, clinic, or location owned or controlled by the person...*
- Certain persons and entities are exempted from the definition of “owner” and the requirement associated therewith including but not limited to dentists, podiatrists, optometrists, community health centers, rural health clinics and hospice facilities.
- Effective January 1, 2014 all owners must have a registration issued by the Board of Pharmacy and must adopt reasonable procedures to ensure that employees and contracted individuals who dispense in the office/facility/clinic/location dispense controlled substances in a manner that complies with existing laws, rules and regulations.
- Beginning January 1, 2014 the attorney general may file a petition to obtain an injunction against an owner who violates the Registration and Control Chapter of the state’s controlled substances act; the courts are permitted to issue an injunction, order the owner to pay a civil penalty not to exceed \$5,000 and order the owner to pay the state the reasonable costs of the attorney general’s investigation and prosecution.
- The State Medical Licensing Board was tasked with adopting emergency rules establishing standards and protocols for prescribing controlled substances; before November 1, 2014 the Board must adopt permanent rules.
- The emergency rules, effective as of December 15, 2013 establish requirements concerning the use of opioids for chronic pain management in patients prescribed more than (1) 60 opioid-containing pills in a month or (2) a morphine equivalent dose of more than 15 milligrams a day for more than 3 consecutive months.
- Physicians (1) must discuss potential risks and benefits of opioid treatment with patients, (2) must schedule periodic visits for patients who are prescribed opioids and (3) must at the outset of treatment, and at least annually thereafter, run a PMP report on the patient.