



Public Health Law

Office for State, Tribal, Local and Territorial Support
Centers for Disease Control and Prevention

Menu of Pain Management Clinic Regulation

The United States is in the midst of an unprecedented epidemic of prescription drug overdose deaths.¹ More than 38,000 people died of drug overdoses in 2010, and most of these deaths (22,134) were caused by overdoses involving prescription drugs.² Three-quarters of prescription drug overdose deaths in 2010 (16,651) involved a prescription opioid pain reliever (OPR), which is a drug derived from the opium poppy or synthetic versions of it such as oxycodone, hydrocodone, or methadone.³ The prescription drug overdose epidemic has not affected all states equally, and overdose death rates vary widely between states.

States have the primary responsibility to regulate and enforce prescription drug practice. Although state laws are commonly used to prevent injuries and their benefits have been demonstrated for a variety of injury types,⁴ there is little information on the effectiveness of state statutes and regulations designed to prevent prescription drug abuse and diversion. This menu is a first step in assessing pain management clinic laws by creating an inventory of state legal strategies in this domain.

Introduction

One type of law aimed at preventing inappropriate prescribing is regulation of pain management clinics, often called “pill mills” when they are sources of large quantities of prescriptions. Pill mills have become an increasing problem in the prescription drug epidemic, and laws have been enacted to prevent these facilities from prescribing controlled substances inappropriately. A law was included in this resource as a pain management clinic regulation if it requires state oversight and contains other requirements concerning ownership and operation of pain management clinics, facilities, or practice locations. For example, a law may specify operational and personnel requirements, inspection and complaint investigations, license procedures, health

¹ For the purpose of this document, “overdose death” refers to death resulting from either intentional overdose or accidental overdose, which could be caused by a patient being given the wrong drug, taking the wrong drug in error, or taking too much of a drug inadvertently. CDC’s National Center for Injury Prevention and Control also refers to overdose as a drug poisoning, which may or may not result in death.

² Centers for Disease Control and Prevention, Wide-ranging Online Data for Epidemiologic Research (WONDER) Database (2012) <http://wonder.cdc.gov> [hereinafter *WONDER Database 2012*].

³ *Id.*

⁴ Schieber RA, Gilchrist J, and Sleet DA. *Legislative and Regulatory Strategies to Reduce Childhood Injuries*, 10 *FUTURE CHILD*. 1, 111–36 (2000).

and safety requirements, standards of care, or patient billing procedures. As of August 31, 2010, three states⁵ had such pain management clinic laws; as of September 28, 2012, eight states did.⁶

Definitions of Pain Management Clinics

All eight states define pain management clinics within their laws.⁷ These definitions typically provide a description of facility activities that constitute pain management services. For example, **Louisiana's** pain management statute broadly reads, "'Pain management clinic' means a publicly or privately owned facility which primarily engages in the treatment of pain by prescribing narcotic medications."⁸ Some pain management laws specify the types of drugs used in treatment that fall under pain management. In **Texas**, for example, "pain management clinic" means 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."⁹ States such as Kentucky and Florida also include advertisement of pain management services in their definitions.¹⁰ **Kentucky's** statute provides that, "'pain management facility' means a facility where the majority of patients of the 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."¹¹

All eight states describe the level of pain management activities that will establish a facility as a pain management clinic. States use language that describes pain management activity as either the primary practice component of such facilities,¹² the provision of pain treatment to a "majority" (or more than 50 percent) of facility patients,¹³ or both in order to qualify as pain management clinics.¹⁴

State Oversight of Pain Management Clinics

All eight states require pain management clinics to register with the state or obtain a license or certificate from the state. For example, a **Florida** law provides that "[e]ach pain-management clinic must register with the

⁵ Florida, Louisiana, and Texas.

⁶ Florida, Kentucky, Louisiana, Mississippi, Ohio, Tennessee, Texas, and West Virginia. As of July 2013, some of these states have passed additional laws and the number of states with pain management clinic laws has also increased to 11, with the addition of Alabama, Georgia and Indiana. Discussion of these laws will be included in the next update of pain management clinic laws.

⁷ In this menu, the first effective dates of the specific provisions referenced are cited as "[legal citation] (eff. [year])." Where dates were either not provided within the laws or were unclear due to multiple revisions, this fact is cited as "[legal citation] (eff. date unclear, [estimated year])."

⁸ LA. REV. STAT. ANN. § 40:2198.11(3) (eff. 2005).

⁹ 22 TEX. ADMIN. CODE § 195.1(2) (eff. 2010); TEX. OCC. CODE ANN. § 168.001 (eff. 2009).

¹⁰ See FLA. STAT. ANN. § 458.3265(1)(a)(1)(c)(I) (eff. 2010); FLA. STAT. ANN. § 459.0137(1)(a)(1)(c)(I) (eff. 2010); KY. REV. STAT. ANN. § 218A.175(1)(a)(2) (eff. 2012).

¹¹ KY. REV. STAT. ANN. § 218A.175(1)(a).

¹² Louisiana. See LA. REV. STAT. ANN. § 40:2198.11(3) (eff. 2005).

¹³ Florida, Mississippi, Tennessee, Texas, and West Virginia. See FLA. STAT. ANN. § 458.3265(1)(a)(1)(c)(II); FLA. STAT. ANN. § 459.0137(1)(a)(1)(c)(II); 30-17 MISS. CODE R. § 2640:1.2(G) (eff. 2012); TENN. CODE ANN. § 63-1-301(5) (eff. 2011); 22 TEX. ADMIN. CODE § 195.1(2); TEX. OCC. CODE ANN. § 168.001; W. VA. CODE ANN. § 16-5H-2(d) (eff. 2012).

¹⁴ Kentucky and Ohio. See KY. REV. STAT. ANN. § 218A.175(1)(a) (eff. 2012); OHIO REV. CODE ANN. § 4731.054(A)(5)(a)(i), (ii) (eff. 2011).

department,” with some exceptions.¹⁵ **Mississippi** law reads, “[a] pain management clinic may not operate in the state of Mississippi without obtaining a certificate from the Mississippi State Board of Medical Licensure.”¹⁶ **Tennessee** law provides that “every pain management clinic shall submit an application to the department [of health] . . . for a certificate to operate the clinic.”¹⁷

State oversight in pain management clinic laws can include legal provisions establishing state inspection authority.¹⁸ In some states, inspections of pain management clinics are mandated at regular intervals to determine compliance with license/administrative regulations.¹⁹ In **West Virginia**, for example, “[t]he Office of Health Facility Licensure and Certification shall inspect each pain management clinic annually, including a review of the patient records, to ensure that it complies with this article and the applicable rules.”²⁰ **Louisiana** regulation states, “[a]fter the initial licensing survey, the department shall conduct a licensing survey at regular intervals as it deems necessary to determine compliance with licensing regulations. These surveys shall be unannounced to the clinic.”²¹ In other states, inspections are permissive wherein states have inspection authority and may inspect pain management clinics to ensure enforcement/compliance of rules.²² **Tennessee** law provides, “[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 with this part and all other applicable laws and rules.”²³ Texas has laws that include both permissive inspections and mandated inspections in certain situations. **Texas** law states,

The board may conduct inspections to enforce these rules, including inspections of a pain management clinic and of documents of a physician's 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.²⁴

Some states also mandate the investigation of complaints in their pain management laws.²⁵ A **Kentucky** regulation provides that “[a]n unannounced inspection shall be conducted: (a) In response to a credible, relevant complaint or allegation; and (b) According to procedures established in this section.”²⁶ A **Texas** statute provides that “[t]he board shall investigate a complaint alleging a violation of this chapter or a rule adopted under this chapter by a pain management clinic certified under this chapter or a physician who owns or operates

¹⁵ FLA. STAT. ANN. § 458.3265(1)(a)(2); FLA. STAT. ANN. § 459.0137(1)(a)(2).

¹⁶ 30-17 MISS. CODE R. § 2640:1.15 (B) (eff. 2012).

¹⁷ TENN. CODE ANN. § 63-1-306(c) (eff. 2011).

¹⁸ Analysis conducted is specifically for provisions within the pain clinic management laws and state agencies such as boards of pharmacy may have general inspection authority over such facilities that dispense prescription drugs.

¹⁹ Four states, Florida, Kentucky, Louisiana, and West Virginia. *See, e.g.*, FLA. STAT. ANN. § 458.3265(3) (eff. 2010); FLA. STAT. ANN. § 459.0137(3) (eff. 2010); FLA. ADMIN. CODE ANN. r. 64B8-9.0132(2) (eff. 2010); FLA. ADMIN. CODE ANN. r. 64B15-14.0052(2) (eff. 2010); 902 KY. ADMIN. REGS. 20:420E (Sec. 10) (eff. 2012); LA. ADMIN. CODE tit. 48, pt. I, § 7815(B) (eff. 2008); and W. VA. CODE ANN., § 16-5H-6(a) (eff. 2012).

²⁰ W. VA. CODE ANN. § 16-5H-6(a).

²¹ LA. ADMIN. CODE tit. 48, pt. I, § 7815(B).

²² Three states: Kentucky, Tennessee, and Texas. *See* 902 KY. ADMIN. REGS. 20:420E (Sec. 5) (eff. 2012); TENN. CODE ANN. § 63-1-304 (eff. 2011) TEX OCC. CODE ANN. § 168.052 (eff. 2009); 22 TEX. ADMIN. CODE § 195.3 (eff. 2010).

²³ TENN. CODE ANN. § 63-1-304.

²⁴ 22 TEX. ADMIN. CODE § 195.3.

²⁵ Two states: Kentucky and Texas. *See* 902 KY. ADMIN. REGS. 20:420E (Sec. 10)(4); TEX. OCC. CODE ANN. § 168.053.

²⁶ 902 KY. ADMIN. REGS. 20:420E (Sec. 10)(4).

a clinic in the same manner as other complaints under this subtitle.”²⁷ In other states, investigations of complaints are permissive wherein states have the authority to investigate complaints.²⁸ In **Louisiana**, for example, “[t]he department may conduct a complaint investigation for any complaint received against a clinic. A complaint survey shall be unannounced to the clinic.”²⁹

Ownership and Operation Requirements for Pain Management Clinics

State pain management clinic laws often provide specific requirements pertaining to the ownership and operation of pain management clinics. Many of the states with pain management laws require pain management clinic owners or medical directors or designated physicians to meet training requirements in pain medicine.³⁰ These requirements include the completion of an accredited pain medicine fellowship or being certified in pain medicine or other approved certification. For example, a **Louisiana** statute requires that “all pain management clinics shall be owned and operated by a physician certified in the subspecialty of pain management by a member board of the American Boards of Medical Specialties.”³¹ A **West Virginia** statute provides that,

The designated physician shall: B) Meet one of the following training requirements: (i) Complete a pain medicine fellowship that is accredited by the Accreditation Council for Graduate Medical Education or such other similar program as may be approved by the secretary; or (ii) Hold current board certification by the American Board of Pain Medicine or current board certification by the American Board of Anesthesiology or such other board certification as may be approved by the secretary.³²

Some states mandate that a pain management clinic owner(s) shall be a physician.³³ For example, **Ohio** law provides that, “[i]n the operation of a pain management clinic, the following requirements shall be met: 1) The pain management clinic shall be owned and operated by one or more physicians.”³⁴ Similarly, **West Virginia** law states that, “[a]t least one owner shall be a physician actively licensed to practice medicine, surgery, or osteopathic medicine or surgery in this state.”³⁵ Some states permit pain management clinic owners to be physicians or non-physicians (for example, hospitals or public corporations).³⁶ Other states require that the medical director must be a physician.³⁷ For example, a **Tennessee** regulation requires that, “[a] pain

²⁷ TEX. OCC. CODE ANN. § 168.053.

²⁸ Two states: Louisiana and Tennessee. See LA. ADMIN. CODE tit. 48, pt. I, § 7815(C); TENN. CODE ANN. § 63-1-305 (eff. 2011).

²⁹ LA. ADMIN. CODE tit. 48, pt. I, § 7815(C).

³⁰ Six states: Florida, Kentucky, Louisiana, Ohio, Tennessee, and West Virginia. See FLA. ADMIN. CODE ANN. r. 64B8-9.0131 (eff. 2010); KY. REV. STAT. ANN. § 218A.175(3) (eff. 2012); LA. REV. STAT. ANN. § 40:2198.12(A) (eff. 2005); OHIO ADMIN. CODE 4731-29-01(B)(2) (eff. 2011); TENN. COMP. R. & REGS. 1200-34-01-.09 (eff. 2012); W. VA. CODE ANN. § 16-5H-4(3)(B) (eff. 2012).

³¹ LA. REV. STAT. ANN. § 40:2198.12 (A).

³² W. VA. CODE ANN. § 16-5H-4.

³³ Four states: Kentucky (with an exception), Louisiana (with an exception), Ohio, and Texas. See KY. REV. STAT. ANN. § 218A.175(2); 201 KY. ADMIN. REGS. 9:250E (Sec. 2)(1)(a) (eff. 2012); LA. REV. STAT. ANN. § 40:2198.12(A); LA. ADMIN. CODE tit. 48, pt. I, § 7803(A) (eff. 2008); OHIO REV. CODE ANN. § 4729.552(B)(1) (eff. 2011); OHIO ADMIN. CODE 4731-29-01(B)(1); TEX. OCC. CODE ANN. § 168.102(a) (eff. 2009).

³⁴ OHIO ADMIN. CODE 4731-29-01(B)(1).

³⁵ W. VA. CODE ANN. § 16-5H-4(a)(2).

³⁶ Three states: Florida, Mississippi, and Tennessee. See FLA. STAT. ANN. § 458.3265(2) (eff. 2010); FLA. STAT. ANN. § 459.0137(2) (eff. 2010); 30-17 MISS. CODE R. § 2640:1.15(C) (eff. 2012); TENN. COMP. R. & REGS. 1200-34-01-.02 (eff. 2012).

³⁷ Four states: Louisiana, Mississippi, Tennessee, and Texas. See LA. REV. STAT. ANN. § 40:2198.12(D)(2); 30-17 MISS. CODE R. § 2640:1.15(C); TENN. CODE ANN. § 63-1-306(a) (eff. 2011); TEX. OCC. CODE ANN. § 168.102(a) (eff. 2009).

management clinic . . . must have a medical director who is a physician that practices in this state under an unrestricted and unencumbered license.”³⁸

All eight states have some form of provision prohibiting non-law-abiding or restricted licensees from becoming owners or employees of pain management clinics. Seven states have pain management clinic laws that stipulate that pain management clinic owners and employees must not have been *denied the privilege* of prescribing, dispensing or administering any controlled substance *during the course of their practice*.³⁹ Four states provide that pain management clinic owners and employees must not have held a *restricted license* to prescribe, dispense, or administer controlled substances.⁴⁰ Four states also provide that pain management clinic owners and employees must not have been disciplined for improper or inappropriate controlled substance prescribing or dispensing.⁴¹ An **Ohio** law encompasses all of the above characteristics and states,

No physician owner of a pain management clinic, employee of the clinic, or person with whom the clinic contracts for services shall:

(1) Have ever been denied a license to prescribe, dispense, administer, supply, or sell a controlled substance by the drug enforcement administration or appropriate issuing body of any state or jurisdiction, based, in whole or in part, on the prescriber's inappropriate prescribing, dispensing, administering, supplying or selling a controlled substance or other dangerous drug.

(2) Have held a license issued by the drug enforcement administration or a state licensing agency in any jurisdiction, under which the person may prescribe, dispense, administer, supply or sell a controlled substance, that has ever been restricted, based, in whole or in part, on the prescriber's inappropriate prescribing, dispensing, administering, supplying, or selling a controlled substance or other dangerous drug.

(3) Have been subject to disciplinary action by any licensing entity that was based, in whole or in part, on the prescribers inappropriate prescribing, dispensing, diverting, administering, supplying or selling a controlled substance or other dangerous drug.⁴²

Five states require that pain management clinics may not be owned by any person who has been convicted of a felony.⁴³ For example, a **Texas** statute states that, “[a] pain management clinic may not be owned wholly or partly by a person who has been convicted of, pled *nolo contendere* to, or received deferred adjudication for an

³⁸ TENN. CODE ANN. § 63-1-306(a).

³⁹ Seven states: Florida, Kentucky, Louisiana, Mississippi, Ohio, Texas, and West Virginia. See e.g., FLA. STAT. ANN. § 458.3265(1)(e)(2) (eff. 2010); FLA. STAT. ANN. § 459.0137(1)(e)(2) (eff. 2010); 201 KY. ADMIN. REGS. 9:250E (eff. 2012); LA. REV. STAT. ANN. § 40:2198.12(D)(1) (eff. 2005); 30-17 MISS. CODE R. § 2640:1.15(D)(1) (eff. 2012); OHIO ADMIN. CODE 4731-29-01(D)(1) (eff. 2011); TEX. OCC. CODE ANN. § 168.201(a)(1); W. VA. CODE ANN. § 16-5H-4(a)(6)(B) (eff. 2012).

⁴⁰ See 201 KY. ADMIN. REGS. 9:250E(Sec.5)(3); MISS. CODE R. § 2640:1.15(D)(2); OHIO ADMIN. CODE 4731-29-01(D)(2); TEX. OCC. CODE ANN. § 168.201(a)(2).

⁴¹ Four states: Kentucky, Mississippi, Ohio, and Texas. See 902 KY. ADMIN. REGS.20:420E(Sec.4)(2); MISS. CODE R. § 2640:1.15(D)(3); OHIO ADMIN. CODE 4731-29-01(D)(3); TEX. OCC. CODE ANN. § 168.201(a)(3).

⁴² OHIO ADMIN. CODE 4731-29-01(D) (eff. 2011).

⁴³ Louisiana, Mississippi, Tennessee, Texas, and West Virginia. LA. REV. STAT. ANN. § 40:2198.12; 30-17 MISS. CODE R. § 2640:1.15(E)(1) (eff. 2012); TENN. CODE ANN. § 63-1-309(2)(b)(1) (eff. 2011); TEX. OCC. CODE ANN. § 168.201(b)(1) (eff. 2009); W. VA. CODE ANN. § 16-5H-4(a)(5) (eff. 2012).

offense that constitutes a felony . . . ”⁴⁴ Some states specify that owners and employees must not have been convicted of felony for receipt of illicit and diverted drugs, including controlled substances.⁴⁵ For example, **Florida’s** statute states,

The department shall deny registration to any pain-management clinic owned by or with any contractual or employment relationship with a physician . . . [w]ho has been convicted of or pleaded guilty or nolo contendere to, regardless of adjudication, an offense that constitutes a felony for receipt of illicit and diverted drugs, including a controlled substance listed in Schedule I, Schedule II, Schedule III, Schedule IV, or Schedule V . . . in this state, any other state, or the United States.⁴⁶

Most states expressly state that the physician owner or medical director or designated physician of pain management clinics shall have active and unrestricted license to practice in state.⁴⁷ For example, a **Louisiana** statute provides that, “[e]ach clinic shall be under the direction of a medical director who shall be a physician who: 1) possesses a current, unrestricted license from the board to practice medicine in Louisiana . . . ”⁴⁸

Four states require that a physician owner or medical director or designated physician shall be on site at the clinic for a specified percentage of operation time.⁴⁹ For example, **Kentucky** statute provides that, “beginning on July 20, 2012, at least one (1) of the owners or an owner’s designee who is a physician employed by and under the supervision of the owner shall be physically present practicing medicine in the facility for at least fifty percent (50%) of the time that patients are present in the facility . . . ”⁵⁰ Some states limit pain management clinic dispensing quantities or specify additional requirements such as documentation or licensure for pain management clinic practitioners to dispense on premises.⁵¹ For example, a **West Virginia** statute reads,

A person may not dispense any medication, including a controlled substance . . . on the premises of a licensed pain management clinic unless he or she is a physician or pharmacist licensed in this state. Prior to dispensing or prescribing controlled substances . . . at a pain management clinic, the treating physician must access the Controlled Substances Monitoring Program database maintained by the Board of Pharmacy to ensure the patient is not seeking controlled substances from multiple sources . . . A pain management clinic shall not dispense to any patient more than a seventy-two-hour supply of a controlled substance.⁵²

⁴⁴ TEX. OCC. CODE ANN. § 168.201(b)(1).

⁴⁵ Three states: Florida, Kentucky, and West Virginia. FLA. STAT. ANN. § 458.3265(1)(e)(3) (eff. 2010); FLA. STAT. ANN. § 459.0137(1)(e)(3) (eff. 2010); 902 KY. ADMIN. REGS. 20:420 E (Sec. 4)(2)(c)(7)(d) (eff. 2012); W. VA. CODE ANN. § 16-5H-4(a)(6)(C) (eff. 2012).

⁴⁶ FLA. STAT. ANN. § 458.3265(1)(e)(3) (eff. 2010).

⁴⁷ Seven states: Florida, Kentucky, Louisiana, Mississippi, Tennessee, Texas, and West Virginia. *See e.g.*, FLA. ADMIN. CODE ANN. r. 64B-7.001(2) (eff. 2011); KY. REV. STAT. ANN. § 218A.175 (2); LA. ADMIN. CODE tit. 48, pt. I, § 7831 (eff. 2008); 30-17 MISS. CODE R. § 2640:1.15 (C)(2) (eff. 2012); TENN. CODE ANN. § 63-1-306(a) (eff. 2011); 22 TEX. ADMIN. CODE § 195.4 (c) (eff. 2010); W. VA. CODE ANN. § 16-5H-4(a)(3)(A).

⁴⁸ LA. ADMIN. CODE tit. 48, pt. I, § 7831.

⁴⁹ Kentucky, Louisiana, Tennessee, and Texas. KY. REV. STAT. ANN. § 218A.175(3) (eff. 2012); LA. ADMIN. CODE tit. 48, pt. I, § 7831(C); TENN. CODE ANN. § 63-1-309(2)(d) (eff. 2011); 22 TEX. ADMIN. CODE § 195.4(f)(1).

⁵⁰ KY. REV. STAT. ANN. § 218A.175(3).

⁵¹ Three states: Florida, Tennessee, and West Virginia. *See e.g.*, FLA. STAT. ANN. § 458.3265(2)(b), (2)(c) (eff. 2010); FLA. STAT. ANN. § 459.0137(2)(b), (2)(c) (eff. 2010); TENN. CODE ANN. § 63-1-309(2)(c); W. VA. CODE ANN. § 16-5H-4.

⁵² W. VA. CODE ANN. § 16-5H-4.

Conclusion

This inventory provides a collection of pain management clinic regulation laws. Additional legal strategies related to prescription drug overdose fall outside the scope of this section. This inventory does not contain a full assessment of all relevant prescription drug laws, which often include provisions setting forth professional licensing penalties or criminal sanctions. Practitioners should consult with legal counsel to become fully informed of the legal landscape concerning prescription drugs and how the laws are implemented and enforced in their state.

This document was written by researchers in the Public Health Law Program in the Office for State, Tribal, Local and Territorial Support,⁵³ with assistance from the Division of Unintentional Injury Prevention in the National Center for Injury Prevention and Control.⁵⁴ For further technical assistance with this inventory or prescription drug laws, please contact the Public Health Law Program.⁵⁵ For technical assistance on all other prescription drug topics, please contact the Division of Unintentional Injury Prevention.⁵⁶

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This menu includes laws enacted through September 28, 2012.

⁵³ Akshara Menon, J.D., M.P.H., Carla Chen, J.D., Rina Lieberman, J.D., M.P.H., and Matthew Penn, J.D., M.L.I.S. We thank Catherine Clodfelter for her research and editorial assistance.

⁵⁴ Noah Aleshire, J.D. and Leonard Paulozzi, M.D., M.P.H.

⁵⁵ Public Health Law Program, Centers for Disease Control and Prevention.

Telephone: (404) 498-0470. Fax: (404) 498-6882. Email: mpenn@cdc.gov. Web: <http://www.cdc.gov/phlp>.

⁵⁶ Division of Unintentional Injury Prevention, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention. Email: lpaulozzi@cdc.gov. Web: <http://www.cdc.gov/HomeandRecreationalSafety/Poisoning/laws/index.html>.