

SENATE BILL 1258

By Yager

AN ACT to amend Tennessee Code Annotated, Title 63,
relative to the regulation of pain management
clinics.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF TENNESSEE:

SECTION 1. Tennessee Code Annotated, Title 63, Chapter 6, is amended by adding a new part as follows:

63-6-1301. For purposes of this part, unless the context otherwise requires:

(1) "Board" shall mean the board of medical examiners;

(2) "Pain management clinic" or "pain clinic" or "clinic" means a privately owned physician's practice or medical offices or an investor-owned clinic in which a physician provides pain management services for which a majority of patients of the pain management clinic are issued a prescription for, or are dispensed, opioids, benzodiazepines, barbiturates, or carisoprodol, but not including suboxone, and treats a patient for more than ninety (90) days in a twelve-month period with these medications; and

(3) "Physician" means any person licensed under this chapter.

63-6-1302. This part does not apply to:

(1) A medical or dental school or an outpatient clinic associated with a medical or dental school;

(2) A hospital as defined in § 68-11-201, including any outpatient facility or clinic of a hospital;

(3) Hospice services as defined in § 68-11-201;

(4) A nursing home as defined in § 68-11-201;

(5) A facility maintained or operated by this state; or

(6) A hospital or clinic maintained or operated by the federal government.

63-6-1303. The board shall adopt rules necessary to implement this part, in accordance with the Uniform Administrative Procedures Act, compiled in title 4, chapter 5, including rules to address, for a pain management clinic:

(1) The operation of the clinic;

(2) Personnel requirements for the clinic, including requirements for a physician who practices at a clinic;

(3) Training requirements for all clinic providers who are not regulated by another board;

(4) Patient records;

(5) Standards to ensure quality of patient care;

(6) Infection control;

(7) Health and safety requirements;

(8) Certificate application and renewal procedures and requirements;

(9) Data collection and reporting requirements;

(10) Inspections and complaint investigations; and

(11) Patient billing procedures.

63-6-1304. The board may inspect a pain management clinic, including the documents of a physician practicing at the clinic, as well as those of any employee or contractor of the clinic, as necessary to ensure compliance with this part. Documents include, but are not limited to, medical records of the clinic. To the extent possible, the clinic should be provided reasonable notice prior to the inspection.

63-6-1305. The board has the authority to investigate a complaint alleging a violation of this part or a rule adopted under this part by a pain management clinic certified under this part

or a physician who owns or operates a clinic. The board shall also have the power to investigate complaints of physician practices or clinics operated by physicians that are not certified as pain management clinics when there is reason to believe that the practice or clinic should be certified as a pain management clinic.

63-6-1306.

(a) Except for an investor-owned clinic, a pain management clinic, as defined in this part, must be majority owned by a physician, or co-owned with other physicians licensed in chapters 6 or 9 of this title. All physician-owned or investor-owned pain clinics must be operated by a medical director who is a physician who practices in this state under an unrestricted license issued pursuant to § 63-6-201. The medical director shall be responsible for all requirements related to certification of the clinic and for applying for a certificate for the clinic under this part.

(b) In the event that the medical director, for whatever reason, no longer meets the requirements of this part, the clinic must notify the board within ten (10) business days of the identity of another physician who meets the requirements of this part and will act as medical director. A change of majority ownership of a certified pain management clinic requires the submission of a new application for a certificate. Failure to notify the board within ten (10) business days may be the basis for a summary suspension of the clinic's certification.

(c) Each clinic location shall be certified separately regardless of whether the clinic is operated under the same business name, ownership, or management as another clinic.

(d) An applicant for a certificate under this part must submit an application to the board on a form prescribed by the board.

(e) The board shall issue a certificate if the board finds that the pain management clinic meets the requirements of this part and the rules adopted by the board under this part and payment of a fee, if required, has been made.

(f) If the board finds that a pain management clinic that has been issued a certificate no longer meets the requirements of this part, the board shall revoke or suspend the certificate previously issued by the board. The pain management clinic shall be entitled to a hearing pursuant to the Uniform Administrative Procedures Act, compiled in title 4, chapter 5, before revocation or suspension occurs. Further, the board has the discretion to lift the suspension of a certificate when the medical director demonstrates compliance to the board.

(g) The clinic shall post the certificate in a conspicuous location so as to be clearly visible to patients.

(h) The board is authorized to promulgate a fee for the issuance of a certificate.

(i) The board shall announce the need for a medical director of a pain clinic to be issued a certificate by adding appropriate language on the board's website and including such language in any routine communication the board sends to all its licensees.

(j) A pain clinic operating on or before the effective date of this act may continue to operate as long as an application for certification is timely filed within thirty (30) days after the board has issued the application and is awaiting consideration for certification.

(k) A pain clinic owned by an advanced practice nurse or physician assistant is not required to apply for a certificate under this section.

63-6-1307.

(a) A certificate issued under this part expires on the second anniversary of the date it is issued.

(b) The board may grant a ninety-day grace period from the expiration date of a certificate to renew the certificate.

(c) No physician who owns, co-owns, operates or provides services in a pain management clinic or an investor-owned pain clinic for which a certificate has expired may continue to operate the clinic or provide services in the clinic until the clinic's certificate is renewed.

63-6-1308.

(a) A medical director may apply to renew a certificate issued to the clinic under this chapter by:

(1) Submitting a renewal application to the board on the form and in a time frame prescribed by the board; and

(2) Complying with any other requirements adopted by board rule.

(b) If a certificate is not renewed before the expiration of the grace period under § 63-6-1307(b), the pain management clinic must reapply for a new certificate to operate the clinic and is not authorized to operate while such new certificate application is pending.

63-6-1309.

(a)

(1) Upon application for a certificate or within ten (10) days of any of the following occurrences, a medical director shall disclose that the physician who owns, co-owns or operates, or otherwise provides services in a pain management clinic, an employee of the clinic, or a person with whom the clinic contracts for services:

(A) Has ever been denied, by any jurisdiction, a license under which the person may prescribe, dispense, administer, supply, or sell a controlled substance;

(B) Has ever held a license issued by any jurisdiction, under which the person may prescribe, dispense, administer, supply, or sell a controlled substance, that has been restricted; or

(C) Has ever been subject to disciplinary action by any licensing entity for conduct that was the result of inappropriately prescribing, dispensing, administering, supplying, or selling a controlled substance.

(2) The board may deny a certificate or renewal of a certificate under any of the circumstances listed in subdivision (a)(1).

(b) 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:

(1) An offense that constitutes a felony; or

(2) An offense that constitutes a misdemeanor, the facts of which relate to the distribution of illegal prescription drugs or a controlled substance as defined in § 39-17-402.

(c) If a physician dispenses or prescribes more than a seventy-two-hour dose of controlled substances for the treatment of chronic nonmalignant pain, the physician must document in the patient's record the reason for prescribing or dispensing that quantity.

(d) A medical director shall be on-site at least thirty-three percent (33%) of the clinic's total number of operating hours.

63-6-1310.

(a) A pain management clinic may accept only a check, credit card or money order for payment for services provided at the clinic except in the circumstances in § 63-6-1310(b).

(b) A payment may be made in cash only for a co-pay, coinsurance or deductible when the charge for the service will be submitted to the patient's insurance plan for reimbursement.

63-6-1311.

(a) A violation of this part or a rule adopted under this part is grounds for disciplinary action against a pain management clinic certified under this part and the medical director or a physician providing services at a pain management clinic certified under this part, or both.

(b) A physician who owns or operates an uncertified pain management clinic after the effective date of this act is subject to an administrative penalty of one thousand dollars (\$1,000) per day.

(c) A violation of this part may be enforced in the same manner as any other violation of this chapter.

SECTION 2. Tennessee Code Annotated, Title 63, Chapter 9, is amended by adding a new part as follows:

63-9-201. For purposes of this part, unless the context otherwise requires:

(1) "Board" means the board of osteopathic examination;

(2) "Pain management clinic" or "pain clinic" or "clinic" means a privately owned physician's practice or medical offices or an investor-owned clinic in which a physician provides pain management services for which a majority of patients of the pain management clinic are issued a prescription for, or are dispensed, opioids, benzodiazepines, barbiturates, or carisoprodol, but not including suboxone, and treats a

patient for more than ninety (90) days in a twelve-month period with these medications;
and

(3) "Physician" means any osteopathic physician licensed under this chapter.

63-9-202. This part does not apply to:

(1) A medical or dental school or an outpatient clinic associated with a medical or dental school;

(2) A hospital as defined in § 68-11-201, including any outpatient facility or clinic of a hospital;

(3) Hospice services as defined in § 68-11-201;

(4) A nursing home as defined in § 68-11-201;

(5) A facility maintained or operated by this state; or

(6) A hospital or clinic maintained or operated by the federal government.

63-9-203. The board shall adopt rules in accordance with the Uniform Administrative Procedures Act, compiled in title 4 chapter 5, necessary to implement this part, including rules to address, for a pain management clinic:

(1) The operation of the clinic;

(2) Personnel requirements for the clinic, including requirements for a physician who practices at a clinic;

(3) Training requirements for all clinic providers who are not regulated by another board;

(4) Patient records;

(5) Standards to ensure quality of patient care;

(6) Infection control;

(7) Health and safety requirements;

(8) Certificate application and renewal procedures and requirements;

- (9) Data collection and reporting requirements;
- (10) Inspections and complaint investigations; and
- (11) Patient billing procedures.

63-9-204. The board may inspect a pain management clinic, including the documents of a physician practicing at the clinic, as well as those of any employee or contractor of the clinic, as necessary to ensure compliance with this part. Documents include, but are not limited to, medical records of the clinic. To the extent possible, the clinic should be provided reasonable notice prior to the inspection.

63-9-205. The board has the authority to investigate a complaint alleging a violation of this part or a rule adopted under this part by a pain management clinic certified under this part or a physician who owns or operates a clinic. The board shall also have the power to investigate complaints of physician practices or clinics operated by physicians that are not certified as pain management clinics when there is reason to believe that the practice or clinic should be certified as a pain management clinic.

63-9-206.

(a) Except for an investor-owned clinic, a pain management clinic, as defined in this part, must be majority owned by a physician, or co-owned with other physicians licensed in chapters 6 or 9 of this title. All physician-owned or investor-owned pain clinics must be operated by a medical director who is a physician who practices in this state under an unrestricted license issued pursuant to § 63-9-106. The medical director shall be responsible for all requirements related to certification of the clinic and for applying for a certificate for the clinic under this part.

(b) In the event that the medical director, for whatever reason, no longer meets the requirements of this part, the clinic must notify the board within ten (10) business days of the identity of another physician who meets the requirements of this part and will

act as medical director. A change of majority ownership of a certified pain management clinic requires the submission of a new application for a certificate. Failure to notify the board within ten (10) business days may be the basis for a summary suspension of the clinic's certification.

(c) Each clinic location shall be certified separately regardless of whether the clinic is operated under the same business name, ownership, or management as another clinic.

(d) An applicant for a certificate under this part must submit an application to the board on a form prescribed by the board.

(e) The board shall issue a certificate if the board finds that the pain management clinic meets the requirements of this part and the rules adopted by the board under this part and payment of a fee, if required, has been made.

(f) If the board finds that a pain management clinic that has been issued a certificate no longer meets the requirements of this part, the board shall revoke or suspend the certificate previously issued by the board. The pain management clinic shall be entitled to a hearing pursuant to the Uniform Administrative Procedures Act, compiled in title 4, chapter 5, before revocation or suspension occurs. Further, the board has the discretion to lift the suspension of a certificate when the medical director demonstrates compliance to the board.

(g) The clinic shall post the certificate in a conspicuous location so as to be clearly visible to patients.

(h) The board is authorized to promulgate a fee for the issuance of a certificate.

(i) The board shall announce the need for a medical director of a pain clinic to be issued a certificate by adding appropriate language on the board's web site and

including such language in any routine communication the board sends to all its licensees.

(j) A pain clinic operating on or before the effective date of the act may continue to operate as long as an application for certification is timely filed within thirty (30) days after the board has issued the application and is awaiting consideration for certification.

(k) A pain clinic owned by an advanced practice nurse or physician assistant is not required to apply for a certificate under this section.

63-9-207.

(a) A certificate issued under this part expires on the second anniversary of the date it is issued.

(b) The board may grant a ninety-day grace period from the expiration date of a certificate to renew the certificate.

(c) No physician who owns, co-owns, operates or provides services in a pain management clinic or an investor-owned pain clinic for which a certificate has expired may continue to operate the clinic or provide services in the clinic until the clinic's certificate is renewed.

63-9-208.

(a) A medical director may apply to renew a certificate issued to the clinic under this chapter by:

(1) Submitting a renewal application to the board on the form and in a time frame prescribed by the board; and

(2) Complying with any other requirements adopted by board rule.

(b) If a certificate is not renewed before the expiration of the grace period under § 63-9-207(b), the pain management clinic must reapply for a new certificate to operate

the clinic and is not authorized to operate while such new certificate application is pending.

63-9-209.

(a)

(1) Upon application for a certificate or within ten (10) days of any of the following occurrences, a medical director shall disclose that the physician who owns, co-owns or operates, or otherwise provides services in, a pain management clinic, an employee of the clinic, or a person with whom the clinic contracts for services:

(A) Has ever been denied, by any jurisdiction, a license under which the person may prescribe, dispense, administer, supply, or sell a controlled substance;

(B) Has ever held a license issued by any jurisdiction, under which the person may prescribe, dispense, administer, supply, or sell a controlled substance, that has been restricted; or

(C) Has ever been subject to disciplinary action by any licensing entity for conduct that was the result of inappropriately prescribing, dispensing, administering, supplying, or selling a controlled substance.

(2) The board may deny a certificate or renewal of a certificate under any of the circumstances listed in subdivision (a)(1).

(b) 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:

(1) An offense that constitutes a felony; or

(2) An offense that constitutes a misdemeanor, the facts of which relate to the distribution of illegal prescription drugs or a controlled substance as defined in § 39-17-402.

(c) If a physician dispenses or prescribes more than a seventy-two-hour dose of controlled substances for the treatment of chronic nonmalignant pain, the physician must document in the patient's record the reason for prescribing or dispensing that quantity.

(d) A medical director shall be on-site at least thirty-three percent (33%) of the clinic's total number of operating hours.

63-9-210.

(a) A pain management clinic as may accept only a check, credit card or money order for payment for services provided at the clinic except in the circumstances in § 63-9-210(b).

(b) A payment may be made in cash only for a co-pay, coinsurance or deductible when the charge for the service will be submitted to the patient's insurance plan for reimbursement.

63-9-211.

(a) A violation of this part or a rule adopted under this part is grounds for disciplinary action against a pain management clinic certified under this part and the medical director or a physician providing services at a pain management clinic certified under this part, or both.

(b) A physician who owns or operates an uncertified pain management clinic after the effective date of this act is subject to an administrative penalty of one thousand dollars (\$1,000) per day.

(c) A violation of this part may be enforced in the same manner as any other violation of this chapter.

SECTION 3. If any provision of this act or the application thereof to any person or circumstance is held invalid, such invalidity shall not affect other provisions or applications of the act which can be given effect without the invalid provision or application, and to that end, the provisions of this act are declared to be severable.

SECTION 4. For purposes of promulgating rules and resolutions, this act shall take effect upon becoming law, the public welfare requiring it. For all other purposes, this act shall take effect January 1, 2012.