

Amendment No. 2 to SB1466

Crowe  
Signature of Sponsor

**AMEND Senate Bill No. 1466\***

**House Bill No. 1731**

by deleting all language after the enacting clause and substituting instead the following:

SECTION 1. Tennessee Code Annotated, Title 63, Chapter 1, Part 3, is amended by adding the following as a new section:

(a) Notwithstanding this title or title 68, for the purposes of determining if a physician's office is operating as a pain management clinic, the department of health is authorized to conduct an unannounced inspection process that may include a record or chart review when the department has obtained reasonable suspicion that the office is operating as an unlicensed pain management clinic. As part of this inspection process, the physician's office shall be required to produce evidence that the majority of its patient population is not receiving chronic non-malignant pain treatment.

(b) If the physician's office was unable during the inspection process to provide evidence that the office did not meet the definition of a pain management clinic, there shall be a rebuttable presumption that the physician's office was operating as a pain management clinic in any administrative proceeding arising from such inspection process.

(c) The requirements for evidence under this section shall be established by rule.

SECTION 2. Tennessee Code Annotated, Title 63, Chapter 1, Part 3, is further amended by adding the following language as a new, appropriately designated section:

(a) On or after July 1, 2017, no person shall own a pain management clinic unless the person obtains a license from the department. No license shall be issued

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unless the pain management clinic has been inspected and found to be in compliance with this part by the department. The department is authorized to charge a reasonable fee for any application for a license.

(b)

(1) Every medical director licensed under this section in this state shall receive from the department a certificate of licensure. Notwithstanding any provision of this title to the contrary, the department shall establish a system of license renewals at intervals that will allow for the distribution of the license workload as uniformly as is practicable throughout the calendar year. Licenses issued under this section are valid for twenty-four (24) months and expire on the last day of the last month of the license period. However, during a transition period, or at any time thereafter when the department determines that the volume of work for any given interval is unduly burdensome or costly, either the licenses or renewals, or both of them, may be issued for terms of not less than six (6) months nor more than eighteen (18) months. The fee imposed for any license under this section for a period of other than twenty-four (24) months shall be proportional to the annual fee and modified in no other manner, except that the proportional fee shall be rounded off to the nearest quarter of a dollar (25¢).

(2) No renewal application will be accepted after the last day of the month following the license expiration date under the method authorized in subdivision (b)(1).

(3) In order to transition regulation of pain management clinics to a system of licensure, the department is authorized to require the licensure of a clinic with a certificate holder under this part on the date of the expiration of the certificate. The pain management clinic may continue to operate under the certificate holder statute until the certificate expires.

(c) The department shall inspect each pain management clinic a minimum of one (1) time every two (2) years to ensure compliance with this part. The department shall hold a licensee harmless for purposes of renewing a license in a timely manner for any failure of the department to inspect a pain management clinic as required by this subsection (c).

(d) Any medical director, in order to lawfully establish, conduct, operate, or maintain a pain management clinic shall obtain a license from the department in the following manner:

(1) The applicant shall submit an application on a form to be prepared by the department, showing that the applicant is of good moral character and able to comply with the minimum standards for a pain management clinic and with rules lawfully promulgated under this part. The applicant shall also submit any required fees. The application shall contain the following additional information:

(A) The name or names of the owner;

(B) The location of the pain management clinic;

(C) The name of the medical director, and the identification of any other license or application related to a pain management clinic with which the medical director is associated; and

(D) Other information as the department may reasonably require;

(2) If the commissioner determines that a license for any pain management clinic will not be granted in accordance with this section, the

commissioner shall notify the applicant. The decision of the commissioner shall be a final decision for purposes of title 4, chapter 5, part 3; and

(3) If the commissioner finds that the applicant complies with this part and the rules promulgated under this part, then the commissioner shall recommend and approve the issuance of a license, and a license shall be issued by the department licensing the applicant to operate the pain management clinic.

(e)

(1) The commissioner shall promulgate by rule additional licensure requirements that define appropriate health and safety standards necessary to protect the health and welfare of residents.

(2) The commissioner shall promulgate by rule specifying additional financial requirements, such as bonds or liability insurance.

(f) Each license to operate a pain management clinic shall expire as provided in subsection (b) and shall become invalid on that date unless renewed. A licensee may renew its license within sixty (60) days following the license expiration date upon payment of the renewal fee in addition to a late penalty established by the commissioner for each month or fraction of a month that payment for renewal is late. A late penalty shall not exceed twice the renewal fee. If a licensee fails to renew its license within sixty (60) days following the license expiration date, the licensee shall reapply for licensure in accordance with the rules established by the commissioner. A license shall not be assignable or transferable, shall be issued only for the location named in the application, shall be posted in a conspicuous place in the pain management clinic, and may be renewed.

(g)

(1) The commissioner may suspend or revoke the license issued under this part on any of the following grounds:

(A) A violation of this part or of the rules promulgated pursuant to this part;

(B) The permitting, aiding, or abetting the commission of any illegal act in the pain management clinic;

(C) A permit issued in error;

(D) Any conduct or practice found by the commissioner to be detrimental to the welfare of the patients in the pain management clinic;

or

(E) A conviction of any employee of the clinic for an offense involving the sale or dispensing of controlled substances under state or federal law related to the operation of the clinic.

(2) The commissioner may, after a hearing, hold the case under advisement and make a recommendation as to requirements to be met by the pain management clinic in order to avoid either suspension or revocation of license or suspension of admissions.

(3) The commissioner shall promulgate rules defining the sanction structure and associated penalties.

(4) The commissioner shall have the authority to place a pain management clinic on probation for any ground for suspension or revocation of a license under subdivision (g)(1).

(5) The hearing to suspend a license, revoke a license, place a pain management clinic on probation, or impose any other sanction, and judicial review of the commissioner's decision, shall be in accordance with the Uniform Administrative Procedures Act, compiled in title 4, chapter 5.

(h) On and after July 1, 2017, an owner or operator of a pain management clinic shall not locate or participate in locating a pharmacy, as defined in § 63-10-204, in which

the owner or operator has an ownership interest in a location that is adjacent to the location of the clinic. Locating a pharmacy in which the owner or operator of a pain management clinic has an ownership interest adjacent to the clinic shall result in the revocation of the license to operate the pain management clinic.

(i)

(1) An employee of a clinic who is under state or federal indictment in this state for an offense involving the sale or dispensing of controlled substances under state or federal law related to the operation of the clinic shall be suspended from employment at the clinic in order to protect the public health and safety. The employee shall be afforded a notice of suspension and an opportunity for a hearing before the commissioner within ten (10) days after the suspension. The suspension shall continue until the indictment is resolved. At a hearing, the commissioner shall determine by a preponderance of the evidence if it reasonably appears that the employee committed an offense involving the sale or dispensing of controlled substances under state or federal law related to the operation of the clinic. If the commissioner makes that determination, then the suspension shall be affirmed. If the commissioner does not make that determination, then the suspension shall be denied.

(2) If convicted of the offense, the employee shall be terminated from employment at the clinic and the commissioner may consider appropriate action under subsection (g).

(j) Any licensee, applicant for license, or employee aggrieved by a decision or action of the department or commissioner pursuant to this part may request a hearing before the commissioner.

(k) The commissioner is authorized to promulgate, in accordance with the Uniform Administrative Procedures Act, compiled in title 4, chapter 5, rules as are

necessary to set fees for licensure, renewal of licensure, late renewal fees, and other fees.

SECTION 3. Tennessee Code Annotated, Title 63, Chapter 1, Part 3, is further amended by adding the following language as a new, appropriately designated section:

(a) An entity or person who operates a pain management clinic without obtaining a license pursuant to this part commits a Class A misdemeanor. Each day of operation without a license constitutes a separate offense.

(b) The commissioner of health may authorize an investigation of any person or entity to the extent necessary to determine if the person or entity is engaged in the unlawful operation of a pain management clinic.

(c) The commissioner may, through the office of the attorney general and reporter, apply for injunctive relief in any court of competent jurisdiction to enjoin any person from committing an act in violation of this part. Injunctive proceedings are in addition to, and not in lieu of, all penalties and other remedies prescribed in this part.

(d) A person who aids or requires another person to violate this part or rules promulgated pursuant to this part, who permits a license issued by the commissioner to be used by any person other than the licensee, or who acts to violate or evade this part or rules promulgated pursuant to this part is subject to a civil penalty of not more than five thousand dollars (\$5,000) for each violation. Each day in violation of this part constitutes a separate violation.

SECTION 4. Tennessee Code Annotated, Title 63, Chapter 1, Part 3, is further amended by adding the following language as a new, appropriately designated section:

(a)

(1) In those cases where the conditions of any pain management clinic are, or are likely to be, detrimental to the health, safety, or welfare of the patient, the commissioner of health has the authority to suspend treatment of any new or

existing patients to the clinic pending a prompt hearing before an administrative judge.

(2) In the event a suspension under this section affects existing patients, the pain management clinic shall provide written notice and other appropriate notice to patients. The pain management clinic shall develop a transition plan to maintain continuity of care for the patients and to minimize the impact of transition to alternative care arrangements. The plan shall be developed in conjunction with the department. The pain management clinic shall assist each patient in locating an alternative placement or treatment resource, which shall be specified in the transition plan. The transition plan shall also include the most recent version of the patient's plan of care. The commissioner may promulgate rules specifying additional components of the transition plan in accordance with this part.

(b) The commissioner is authorized to withdraw the suspension of treatment, at any time prior to a hearing, based on information presented to the commissioner showing that such conditions have been and will continue to remain corrected.

(c) Whenever the commissioner suspends the treatment of any new patients, the commissioner shall detail, in a notice to the clinic, the specific violations causing the suspension. The notice shall be prominently posted at the clinic so as to be readily available to the public.

(d) The notice shall detail what conditions are considered detrimental to the health, safety, or welfare of the patients.

(e) Within ten (10) days or longer of receiving the notice described in subsection (d), or lesser time frame when deemed necessary by the commissioner to ensure the health, safety, and welfare of clinic patients, a pain management clinic shall submit a corrective action plan to the commissioner delineating the measures to be taken to

address violations and associated time frames. If it is deemed by the commissioner to be necessary to ensure the health, safety, and welfare of clinic patients, the commissioner may require the clinic to take all necessary actions to correct violations immediately.

(f) If the clinic complies with the conditions described in subsection (e), the commissioner shall lift the suspension, unless other conditions exist that warrant an additional suspension or continuation of the suspension. If the clinic complies and receives an order of compliance in accordance with subsection (e), the commissioner shall lift the suspension. The commissioner has the authority to:

- (1) Continue or modify the suspension of treatment;
- (2) Withdraw the suspension of treatment;
- (3) Suspend or condition the license of the clinic; and
- (4) Enter other orders as the commissioner deems necessary.

(g) During a suspension of treatment pursuant to this section, the commissioner may appoint one (1) or more special monitors, if the deficiency threatens serious harm to the patients of the clinic. The commissioner may appoint a special monitor or monitors at any other time, if the commissioner has reason to believe that deficiencies exist in a clinic that are detrimental to the direct care of the patients. Whenever the appointment of monitors is utilized pursuant to this section, the commissioner shall appoint a sufficient number of monitors to ensure their presence in the clinic for a minimum of twenty (20) hours per week. The monitors shall observe the operation of the clinic and shall submit written reports periodically to the commissioner on the operation of the clinic. Persons appointed as monitors shall be duly qualified to discharge their responsibilities. While employed as monitors, they shall represent the department with the power to observe and review all of the clinic's operation, with attention to those aspects for which the suspension of admission was imposed. When appointment of a monitor or monitors is

mandated by this section, the clinic shall be liable for the costs of the special monitors, until it has been determined that the deficiencies have been corrected. The commissioner may retain a monitor in a clinic after acceptance of a correction plan and issuance of compliance to evaluate the clinic's continued compliance, but such continued monitoring shall be at the expense of the department. The costs of the monitors for which a clinic is responsible shall be recoverable as follows:

(1) Addition of such costs to the clinic's licensing fee, the renewal of the clinic's license to be contingent upon the prior payment of the costs; or

(2) By suit of the department in the circuit or chancery court of competent jurisdiction to recover the costs.

(h) Judicial review shall be available pursuant to § 4-5-322.

SECTION 5. Tennessee Code Annotated, Title 63, Chapter 1, Part 3, is further amended by adding the following as a new section to be appropriately designated:

(a) The medical director of each pain management clinic shall report annually to the department of health, on a form promulgated by the department, the following:

(1) The number of physician assistants and advanced practice nurses who are working in the clinic for each month;

(2) The number of pain patients seen by the clinic for each month; and

(3) Whether the pain management clinic is part of or associated with a hospital.

(b) The department is authorized to promulgate a reporting form concerning such information as the commissioner may reasonably require, and establish the reporting period and dates for submission.

SECTION 6. Tennessee Code Annotated, Section 63-1-301, is further amended by adding the following as a new subdivision to be appropriately designated:

( ) "Operator" means the person who is in charge of the actual on-site operation of a pain management clinic;

SECTION 7. Tennessee Code Annotated, Section 63-1-301(2), is amended by deleting the subdivision in its entirety.

SECTION 8. Tennessee Code Annotated, Section 63-1-301(8)(A), is amended by inserting the language "or "clinic"" immediately before the language "means a privately-owned".

SECTION 9. Tennessee Code Annotated, Section 63-1-303(c)(8), is amended by deleting the language "Certificate" and substituting the language "License".

SECTION 10. Tennessee Code Annotated, Section 63-1-305, is amended by deleting the language "facility" and "certified" and respectively substituting the language "pain management clinic" and "licensed".

SECTION 11. Tennessee Code Annotated, Section 63-1-306, is amended by deleting the section in its entirety and substituting instead the following:

(a)

(1) A pain management clinic, as defined in this part, must have a medical director who is a physician that practices in this state under an unrestricted and unencumbered license issued pursuant to § 63-6-201 or § 63-9-104.

(2) In addition to the requirements of subdivision (a)(1), each physician serving as a medical director at a pain management clinic shall be a pain management specialist as defined in this part.

(3) All advanced practice nurses licensed under chapter 7 of this title and physician assistants licensed under chapter 19 of this title, who practice in a licensed pain management clinic, shall be supervised by a pain medicine specialist as defined in this part.

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

(c) Any board that assesses any discipline or penalty against a provider that it licenses for a violation of rules promulgated under this part shall inform the department of any penalty or discipline imposed on such a provider for a violation of rules promulgated under this part within thirty (30) days of imposing the discipline or penalty, and the department may consider such discipline or penalty as a basis for disciplinary action against the pain management clinic pursuant to this subsection (c).

(d) The pain management clinic shall post the license in a conspicuous location so as to be clearly visible to patients.

(e) The department shall have the authority to adopt rules, including emergency rules if deemed necessary, to implement this part for which the department has responsibility.

SECTION 12. Tennessee Code Annotated, Section 63-1-307, is amended by deleting the section in its entirety.

SECTION 13. Tennessee Code Annotated, Section 63-1-308, is amended by deleting the section in its entirety.

SECTION 14. Tennessee Code Annotated, Section 63-1-309(a), is amended by deleting the subsection in its entirety.

SECTION 15. Tennessee Code Annotated, Section 63-1-311, is amended by deleting the section and substituting the following:

(a) A violation of this part, or a rule adopted under this part, is grounds for disciplinary action against a practitioner providing services at a pain management clinic licensed under this part by the board that licensed that practitioner.

(b) A practitioner who provides pain management services at an unlicensed pain management clinic is subject to an administrative penalty of no less than one thousand dollars (\$1,000) per day and that shall not exceed five thousand dollars (\$5,000) per day, imposed by the board that licensed that practitioner, in accordance with the Uniform Administrative Procedures Act, compiled in title 4, chapter 5. Before such a penalty may be assessed by the board, the board shall give at least thirty (30) days' notice to the practitioner of the alleged violation of this part.

(c) An owner, co-owner, or operator of an unlicensed 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, imposed by the department of health, in accordance with the Uniform Administrative Procedures Act. Before such a penalty may be assessed by the department, the department shall give at least thirty (30) days' notice to the owner, co-owner, or operator of the alleged violation of this part.

SECTION 16. Tennessee Code Annotated, Section 63-1-312, is amended by deleting the section in its entirety.

SECTION 17. If any provision of this act or its application to any person or circumstance is held invalid, then the invalidity shall not affect other provisions or applications of the act that can be given effect without the invalid provision or application, and to that end the provisions of this act shall be severable.

SECTION 18. For purposes of rulemaking, this act shall take effect on becoming a law, the public welfare requiring it. For all other purposes, this act shall take effect on July 1, 2017, the public welfare requiring it.