

Amendment No. 1 to HB1731

Sexton C
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 health care provider's office is operating as a pain management clinic, the department of health is authorized to conduct an unannounced inspection process, which may include but not be limited to review of business and medical records, when the department has reasonable suspicion that the office is operating as an unlicensed pain management clinic. As part of this inspection process, the health care provider's office shall be required to produce evidence that the majority of its patient population is not receiving chronic nonmalignant pain treatment.

(b) If the health care provider's office is unable during the inspection process to provide satisfactory evidence that the office does not meet the definition of a pain management clinic, there shall be a rebuttable presumption that the provider'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.

(d) Any health care provider's office rebuttably presumed to be operating an unlicensed pain management clinic shall be prohibited from admitting any new patients to the practice immediately upon receipt of written notice to any provider at the clinic and

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all owners and providers at such clinic shall be subject to a hearing upon thirty (30) days' notice before the licensee's licensing board to consider whether the individual's license to practice should be revoked or otherwise disciplined. Pursuant to this part, the commissioner may promulgate rules providing for an informal advisory administrative hearing by a panel appointed by the commissioner to review the department's determination regarding the unlicensed operation of the clinic and to provide nonbinding recommendations to the commissioner concerning those determinations. The informal administrative hearing shall not be subject to the Uniform Administrative Procedures Act, compiled in title 4, chapter 5. Individuals appointed to any panel pursuant to this part shall be considered "state employees" for purposes of title 8, chapter 42, and § 9-8-307.

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 or operate a pain management clinic unless the medical director obtains a license from the department. No license shall be issued 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 of a pain management clinic in this state shall receive from the department a pain management clinic license. 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) 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 until the certificate expires, and the certificate shall be deemed to be a license under this part until it expires. On the expiration of the certificate, the clinic may seek an initial licensure under this section.

(c) The department shall inspect each pain management clinic a minimum of once every two (2) years to ensure compliance with this part. The department shall not refuse license renewal based solely upon 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 medical director shall submit an application on a form to be prepared by the department, showing that the medical director 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 medical director shall also submit any required fees. The application shall contain the following additional information:

(A) The name or names of all owners;

(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;

(D) The names and Tennessee license numbers for any employees of the clinics or other persons with whom the clinic has contracted for services;

(E) Whether any owner, employee, or person with whom the clinic contracts has been convicted of any felony; is under indictment for any offense involving the sale, diversion, or dispensing of controlled substances under state or federal law; or has had any license issued by any jurisdiction, under which the person may prescribe, dispense, administer, supply, or sell a controlled substance, restricted, disciplined, or denied; and

(F) 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; and

(3) If the commissioner finds that the applicant complies with this part and the rules promulgated under this part, then the commissioner may

recommend and approve the issuance of a license, and a license may 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 additional financial requirements, such as bonds or liability insurance, to be required of pain management clinics.

(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 and shall cease operation of the clinic until such time as the clinic is duly licensed. 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 as provided in this part.

(g)

(1) The commissioner may deny, suspend, revoke, or otherwise discipline or restrict 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 license 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;

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

(F) Any owner has been convicted of, pled nolo contendere to, or received deferred adjudication for an offense that constitutes a felony;

(G) Any owner or employee or person who otherwise provides services in the clinic or contracts with the clinic has ever been denied, by any jurisdiction, a license under which the person may prescribe, dispense, administer, supply, or sell a controlled substance;

(H) Any owner or employee or person who otherwise provides services in the clinic or contracts with the clinic 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; and

(I) Any owner or employee or person who otherwise provides services in the clinic or contracts with the clinic 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 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 suspension, revocation, or other discipline of a license or suspension of admissions.

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

(4) 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 (UAPA), compiled in title 4, chapter 5, and shall include the right to appeal and judicial review under the UAPA.

(h) On or after July 1, 2017, no owner of a pain management clinic shall locate or participate in locating a pharmacy, as defined in § 63-10-204, in which any owner has an ownership interest, in a location that is adjacent to the location of the clinic. Locating a pharmacy in which any owner 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, diversion, or dispensing of controlled substances under state or federal law related to the operation of the clinic shall be immediately suspended from employment at the clinic in order to protect the public health and safety.

(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) 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 any 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 of receiving the notice described in subsection (d), 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 may lift the suspension, unless other conditions exist that warrant an additional suspension or continuation of 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 physicians, physician assistants, and advanced practice nurses who are working in the clinic for each month;
 - (2) The number of patients seen by the clinic for each month and the number receiving treatment for chronic nonmalignant pain;
 - (3) Whether the pain management clinic is part of or associated with a hospital; and
 - (4) Any other information requested by the department.
- (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(2), is amended by deleting the subdivision in its entirety.

SECTION 7. 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 8. Tennessee Code Annotated, Section 63-1-303, is amended by deleting the language "Certificate" and substituting the language "License" in subdivision (c)(8).

SECTION 9. 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 10. Tennessee Code Annotated, Section 63-1-306, is amended by deleting the section in its entirety and substituting instead the following:

(a)

(1) Each pain management clinic must have a medical director who is a medical doctor or osteopathic physician who 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.

(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 management specialist.

(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, in writing within ten (10) business days, of the identity of another physician who meets the

requirements of this part and will act as medical director and provide all necessary documentation required by the department to establish that the replacement is qualified as required by this part. Any clinic that fails to provide such timely written notice must cease operations until the notice is provided and the department has confirmed in writing that the replacement medical director is duly qualified. Continuation of operations without the timely written notice required by this subsection (b) constitutes grounds for disciplinary action against the clinic under this part.

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

SECTION 12. Tennessee Code Annotated, Section 63-1-308, is amended by deleting the section in its entirety.

SECTION 13. Tennessee Code Annotated, Section 63-1-309(a), is amended by deleting the subsection in its entirety.

SECTION 14. 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 disciplinary action against the practitioner's license, up to and including revocation, as well as an administrative penalty of no less than one thousand dollars (\$1,000) per day of unlicensed operation and not exceeding five thousand dollars (\$5,000) per day of unlicensed operation, 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) Any owner of an unlicensed pain management clinic is subject to disciplinary action against the practitioner's license, up to and including revocation, as well as an administrative penalty of no less than one thousand dollars (\$1,000) per day of unlicensed operation and not exceeding five thousand dollars (\$5,000) per day of unlicensed operation, imposed by the department of health, in accordance with the Uniform Administrative Procedures Act, compiled in title 4, chapter 5. Any owner may also be charged the costs of any inspection or investigation pursuant to this part, as well as the costs of prosecution and other costs permitted under § 63-1-144 and that formed the basis of disciplinary action provided for in this part. Before such a penalty may be assessed by the department, the department shall give at least thirty (30) days' notice to the owners of the alleged violation of this part.

SECTION 15. Tennessee Code Annotated, Section 63-1-312, is amended by deleting the section in its entirety.

SECTION 16. 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 17. 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.