ENGROSSED SENATE
BILL NO. 1124 By: Yen of the Senate

and

Derby of the House

[pain management clinics - definitions - register with Board of Medical Licensure and Supervision - exemptions - registration procedures - period of suspension - new registration application - physician responsibilities - facility and physical operations - infection control - health and safety requirements - quality assurance - data collection and reporting - compliance with all requirements - inspection procedures - Board of Medical Licensure and Supervision to promulgate certain rules - penalties - codification - effective date]

BE IT ENACTED BY THE PEOPLE OF THE STATE OF OKLAHOMA:

SECTION 1. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 2-1000 of Title 63, unless there is created a duplication in numbering, reads as follows:

As used in this act:

1. "Board eligible" means successful completion of an anesthesia, physical medicine and rehabilitation, rheumatology or neurology residency program approved by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association for a period of six (6) years from successful completion of such residency program;

2. "Chronic nonmalignant pain" means pain unrelated to cancer which persists beyond the usual course of disease or the injury that is the cause of the pain or more than ninety (90) calendar days after surgery; and

3. "Pain-management clinic" or "clinic" means any publicly or privately owned facility:

a. that advertises in any medium for any type of pain-management services, or

b. where in any month a majority of patients are prescribed opioids, benzodiazepines, barbiturates, or carisoprodol for the treatment of chronic nonmalignant pain.

SECTION 2. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 2-1001 of Title 63, unless there is created a duplication in numbering, reads as follows:

A. Each pain-management clinic shall register with the Board of Medical Licensure and Supervision unless:

1. The majority of the physicians who provide services in the clinic primarily provide surgical services;

2. The clinic is owned by a publicly held corporation whose shares are traded on a national exchange or on the over-the-counter market and whose total assets at the end of the corporation's most recent fiscal quarter exceeded Fifty Million Dollars ($50,000,000.00);

3. The clinic is affiliated with an accredited medical school at which training is provided for medical students, residents or fellows;

4. The clinic does not prescribe controlled dangerous substances for the treatment of pain;

5. The clinic is owned by a corporate entity exempt from federal taxation under 26 U.S.C., Section 501(c)(3) (1954);

6. The clinic is wholly owned and operated by one or more board-eligible or board-certified anesthesiologists, physiatrists, rheumatologists or neurologists; or

7. The clinic is wholly owned and operated by a physician multispecialty practice where one or more board-eligible or board-certified medical specialists, who have also completed fellowships in pain medicine approved by the Accreditation Council for Graduate Medical Education or who are also certified in pain medicine by the American Board of Pain Medicine or a board approved by the American Board of Medical Specialties, the American Association of Physician Specialists or the American Osteopathic Association, perform interventional pain procedures of the type routinely billed using surgical codes.

B. Each clinic location shall be registered separately regardless of whether the clinic is operated under the same business name or management as another clinic.

C. As a part of registration, a clinic must designate a physician who is responsible for complying with all requirements related to registration and operation of the clinic in compliance with this act. Within ten (10) calendar days after termination of a designated physician, the clinic must notify the Board of Medical Licensure and Supervision of the identity of another designated physician for that clinic. The designated physician shall have a full, active and unencumbered license pursuant to Section 480 et seq. or Section 620 et seq. of Title 59 of the Oklahoma Statutes and shall practice at the clinic location for which the physician has assumed responsibility. Failing to have a licensed designated physician practicing at the location of the registered clinic may be the basis for a summary suspension of the clinic registration certificate as described in this section.

D. The Board of Medical Licensure and Supervision shall deny registration to any clinic that is not fully owned by a physician licensed pursuant to Section 480 et seq. or Section 620 et seq. of Title 59 of the Oklahoma Statutes or group of physicians, each of whom is licensed pursuant to Section 480 et seq. or Section 620 et seq. of Title 59 of the Oklahoma Statutes.

E. The Board of Medical Licensure and Supervision shall deny registration to any pain-management clinic owned by or with any contractual or employment relationship with a physician:

1. Whose Drug Enforcement Administration number has ever been revoked;

2. Whose application for a license to prescribe, dispense or administer a controlled substance has been denied by any jurisdiction;

3. Who has been convicted of or pleaded guilty or nolo contendere to, regardless of adjudication, an offense that constitutes a felony for receipt of illicit or diverted drugs, including a controlled substance listed in Schedule I, II, III, IV or V of the Uniform Controlled Dangerous Substances Act, in this state, any other state or the United States.

F. If the Board of Medical Licensure and Supervision finds that a pain-management clinic does not meet the requirement of subsection D of this act or is owned, directly or indirectly, by a person meeting any criteria listed in subsection E of this act, the Board of Medical Licensure and Supervision shall revoke the certificate of registration previously issued by the Board of Medical Licensure and Supervision. As determined by rule, the Board of Medical Licensure and Supervision may grant an exemption to denying a registration or revoking a previously issued registration if more than ten (10) years have elapsed since adjudication. As used in this section, the term "convicted" includes an adjudication of guilt following a plea of guilty or nolo contendere or the forfeiture of a bond when charged with a crime.

G. The Board of Medical Licensure and Supervision may revoke the clinic's certificate of registration and prohibit all physicians associated with that pain-management clinic from practicing at that clinic location based upon an annual inspection and evaluation of the factors described in Section 4 of this act.

H. If the registration of a pain-management clinic is revoked or suspended, the designated physician of the pain-management clinic, the owner or lessor of the pain-management clinic property, the manager and the proprietor shall cease to operate the facility as a pain-management clinic as of the effective date of the suspension or revocation.

I. If a pain-management clinic registration is revoked or suspended, the designated physician of the pain-management clinic, the owner or lessor of the clinic property, the manager or the proprietor is responsible for removing all signs and symbols identifying the premises as a pain-management clinic.

J. Upon the effective date of the suspension or revocation, the designated physician of the pain-management clinic shall advise the Board of Medical Licensure and Supervision of the disposition of the medicinal drugs located on the premises. The disposition is subject to the supervision and approval of the Board of Medical Licensure and Supervision. Medicinal drugs that are purchased or held by a pain-management clinic that is not registered may be deemed

adulterated pursuant to Section 1-1401 et seq. of Title 63 of the Oklahoma Statutes.

K. If the clinic's registration is revoked, any person named in the registration documents of the pain-management clinic, including persons owning or operating the pain-management clinic, shall not, as an individual or as a part of a group, apply to operate a pain-management clinic for five (5) years after the date the registration is revoked.

L. The period of suspension for the registration of a pain-management clinic shall be prescribed by the Board of Medical Licensure and Supervision, but shall not exceed one year.

M. A change of ownership of a registered pain-management clinic requires submission of a new registration application.

SECTION 3. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 2-1002 of Title 63, unless there is created a duplication in numbering, reads as follows:

A. A physician shall not practice medicine in a pain-management clinic if the clinic is not registered with the Board of Medical Licensure and Supervision as required by this act. Any physician who qualifies to practice medicine in a pain-management clinic pursuant to rules adopted by the Board of Medical Licensure and Supervision may continue to practice medicine in a pain management clinic as long as the physician continues to meet the qualifications set forth in the rules. A physician who violates this subsection is

subject to disciplinary action by his or her appropriate medical regulatory board.

B. Only a physician licensed pursuant to Section 480 et seq. or Section 620 et seq. of Title 59 of the Oklahoma Statutes may dispense medication or prescribe a controlled dangerous substance on the premises of a registered pain-management clinic.

C. A physician, a physician assistant or an advanced practice registered nurse shall perform a physical examination of a patient on the same day that the physician prescribes a controlled substance to a patient at a pain-management clinic. If the physician prescribes more than a seventy-two-hour dose of controlled dangerous substances for the treatment of chronic nonmalignant pain, the physician must document in the patient's record the reason for prescribing that quantity.

D. A physician authorized to prescribe controlled dangerous substances who practices at a pain-management clinic is responsible for maintaining the control and security of his or her prescription blanks and any other method used for prescribing controlled dangerous substance pain medication. The physician shall notify, in writing, the Board of Medical Licensure and Supervision within twenty-four (24) hours following any theft or loss of a prescription blank or breach of any other method for prescribing pain medication.

E. The designated physician of a pain-management clinic shall notify the applicable board in writing of the date of termination of

employment within ten (10) calendar days after terminating his or her employment with a pain-management clinic that is required to be registered pursuant to this act. Each physician practicing in a pain-management clinic shall advise the Board of Medical Licensure and Supervision, in writing, within ten (10) calendar days after beginning or ending his or her practice at a pain-management clinic.

F. Each physician practicing in a pain-management clinic is responsible for ensuring compliance with the following facility and physical operations requirements:

1. A pain-management clinic shall be located and operated at a publicly accessible fixed location and shall:

a. display a sign that can be viewed by the public that contains the clinic name, hours of operations, and a street address,

b. have a publicly listed telephone number and a dedicated phone number to send and receive facsimiles with a facsimile machine that shall be operational twenty-four (24) hours per day,

c. have emergency lighting and communications,

d. have a reception and waiting area,

e. provide a restroom,

f. have an administrative area, including room for storage of medical records, supplies and equipment,

g. have private patient examination rooms,

h. have treatment rooms, if treatment is being provided to the patients, and

i. display a printed sign located in a conspicuous place in the waiting room viewable by the public with the name and contact information of the clinic's designated physician and the names of all physicians practicing in the clinic; and

2. This section does not excuse a physician from providing any treatment or performing any medical duty without the proper equipment and materials as required by the standard of care. This section does not supersede the level of care, skill or treatment recognized in general law related to health care licensure.

G. Each physician practicing in a pain-management clinic is responsible for ensuring compliance with the following infection control requirements:

1. The clinic shall maintain equipment and supplies to support infection prevention and control activities;

2. The clinic shall identify infection risks based on the following:

a. geographic location, community and population served,

b. the care, treatment and services it provides, and

c. an analysis of its infection surveillance and control data; and

3. The clinic shall maintain written infection prevention policies and procedures that address the following:

a. prioritized risks,

b. limiting unprotected exposure to pathogens,

c. limiting the transmission of infections associated with procedures performed in the clinic, and

d. limiting the transmission of infections associated with the clinic's use of medical equipment, devices and supplies.

H. Each physician practicing in a pain-management clinic is responsible for ensuring compliance with the following health and safety requirements:

1. The clinic, including its grounds, buildings, furniture, appliances and equipment shall be structurally sound, in good repair, clean and free from health and safety hazards;

2. The clinic shall have evacuation procedures in the event of an emergency, which shall include provisions for the evacuation of disabled patients and employees;

3. The clinic shall have a written facility-specific disaster plan setting forth actions that will be taken in the event of clinic closure due to unforeseen disasters and shall include provisions for the protection of medical records and any controlled dangerous substances; and

4. Each clinic shall have at least one employee on the premises during patient care hours who is certified in basic life support and is trained in reacting to accidents and medical emergencies until emergency medical personnel arrive.

I. The designated physician is responsible for ensuring compliance with the following quality assurance requirements:

1. Each pain-management clinic shall have an ongoing quality assurance program that objectively and systematically:

a. monitors and evaluates the quality and appropriateness of patient care,

b. evaluates methods to improve patient care,

c. identifies and corrects deficiencies within the facility,

d. alerts the designated physician to identify and resolve recurring problems, and

e. provides for opportunities to improve the facility's performance and to enhance and improve the quality of care provided to the public; and

2. The designated physician shall establish a quality assurance program that includes the following components:

a. the identification, investigation and analysis of the frequency and causes of adverse incidents to patients,

b. the identification of trends or patterns of incidents,

c. the development of measures to correct, reduce, minimize or eliminate the risk of adverse incidents to patients, and

d. the documentation of these functions and periodic review no less than quarterly of such information by the designated physician.

J. The designated physician is responsible for ensuring compliance with the following data collection and reporting requirements:

1. The designated physician for each pain-management clinic shall report all adverse incidents to the Board of Medical Licensure and Supervision; and

2. The designated physician shall also report to the Board of Medical Licensure and Supervision, in writing, on a quarterly basis the following data:

a. the number of new and repeat patients seen and treated at the clinic who are prescribed controlled dangerous substance medications for the treatment of chronic, nonmalignant pain,

b. the number of patients discharged due to drug abuse,

c. the number of patients discharged due to drug diversion, and

d. the number of patients treated at the pain clinic whose domicile is located somewhere other than in this

state. A patient's domicile is the patient's fixed or permanent home to which he or she intends to return even though he or she may temporarily reside elsewhere.

SECTION 4. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 2-1003 of Title 63, unless there is created a duplication in numbering, reads as follows:

A. An authorized representative of the Board of Medical Licensure and Supervision shall inspect all pain-management clinics annually, including a review of the patient records to ensure they comply with this act and the rules of the Board of Medical Licensure and Supervision adopted pursuant to Section 5 of this act unless the clinic is accredited by a nationally recognized accrediting agency approved by the Board of Medical Licensure and Supervision.

B. During an onsite inspection, the authorized representative of the Board of Medical Licensure and Supervision shall make a reasonable attempt to discuss each violation with the owner or designated physician of the pain management clinic before issuing a formal written notification.

C. Any action taken to correct a violation shall be documented in writing by the owner or designated physician of the pain-management clinic and verified by follow up visits by the authorized representative of the Board of Medical Licensure and Supervision.

SECTION 5. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 2-1004 of Title 63, unless there is created a duplication in numbering, reads as follows:

A. The Board of Medical Licensure and Supervision shall adopt rules necessary to administer the registration and inspection of pain-management clinics which establish the specific requirements, procedures, forms and fees.

B. The Board of Medical Licensure and Supervision shall adopt rules setting forth training requirements for all facility health care practitioners who are not regulated by another board.

SECTION 6. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 2-1005 of Title 63, unless there is created a duplication in numbering, reads as follows:

A. The Board of Medical Licensure and Supervision may impose an administrative fine on a clinic of up to Five Thousand Dollars ($5,000.00) per violation for violating the requirements of this act or the rules of the Board of Medical Licensure and Supervision. In determining whether a penalty is to be imposed, and in fixing the amount of the fine, the Board of Medical Licensure and Supervision shall consider the following factors:

1. The gravity of the violation, including the probability that death or serious physical or emotional harm to a patient has resulted, or could have resulted, from the pain-management clinic's actions or the actions of the physician, the severity of the action

or potential harm and the extent to which the provisions of the applicable laws or rules were violated;

2. What actions, if any, the owner or designated physician took to correct the violations;

3. Whether there were any previous violations at the pain-management clinic; and

4. The financial benefits that the pain-management clinic derived from committing or continuing to commit the violation.

B. Each day a violation continues after the date fixed for termination of the violation as ordered by the Board of Medical Licensure and Supervision constitutes an additional, separate and distinct violation.

C. The Board of Medical Licensure and Supervision may impose a fine and, in the case of an owner-operated pain-management clinic, revoke or deny a pain-management clinic's registration, if the clinic's designated physician knowingly and intentionally misrepresents actions taken to correct a violation.

D. An owner or designated physician of a pain-management clinic who concurrently operates an unregistered pain-management clinic is subject to an administrative fine of Five Thousand Dollars ($5,000.00) per day.

E. If the owner of a pain-management clinic that requires registration fails to apply to register the clinic upon a change of

ownership and operates the clinic under the new ownership, the owner is subject to a fine of Five Thousand Dollars ($5,000.00).

SECTION 7. This act shall become effective November 1, 2018.

Passed the Senate the 8th day of March, 2018.

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Presiding Officer of the Senate

Passed the House of Representatives the ____ day of _____, 2018.

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Presiding Officer of the House of Representatives