

1 STATE OF OKLAHOMA

2 2nd Session of the 56th Legislature (2018)

3 SENATE BILL 1124

By: Yen

6 AS INTRODUCED

7 An Act relating to pain management clinics; providing
8 definitions; requiring clinics to register with Board
9 of Medical Licensure and Supervision; providing
10 exemptions; setting forth registration procedures;
11 requiring clinics to designate physician; setting
12 forth procedures for revocation and suspension of
13 registration; limiting period of suspension;
14 requiring new registration application if clinic
15 changes ownership; setting forth physician
16 responsibilities; setting forth facility and physical
17 operations requirements; setting forth certain
18 infection control requirements; setting forth health
19 and safety requirements; setting forth certain
20 quality assurance requirements; setting forth certain
21 data collection and reporting requirements; providing
22 that designated physician is responsible for ensuring
23 compliance with all requirements; setting forth
24 inspection procedures; directing Board of Medical
Licensure and Supervision to promulgate certain
rules; providing penalties; providing for
codification; and providing an effective date.

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

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

24 As used in this act:

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

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

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

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

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

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

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

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

3 2. The clinic is owned by a publicly held corporation whose
4 shares are traded on a national exchange or on the over-the-counter
5 market and whose total assets at the end of the corporation's most
6 recent fiscal quarter exceeded Fifty Million Dollars
7 (\$50,000,000.00);

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

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

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

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

18 7. The clinic is wholly owned and operated by a physician
19 multispecialty practice where one or more board-eligible or board-
20 certified medical specialists, who have also completed fellowships
21 in pain medicine approved by the Accreditation Council for Graduate
22 Medical Education or who are also certified in pain medicine by the
23 American Board of Pain Medicine or a board approved by the American
24 Board of Medical Specialties, the American Association of Physician

1 Specialists or the American Osteopathic Association, perform
2 interventional pain procedures of the type routinely billed using
3 surgical codes.

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

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

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

1 whom is licensed pursuant to Section 480 et seq. or Section 620 et
2 seq. of Title 59 of the Oklahoma Statutes.

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

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

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

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

17 F. If the Board of Medical Licensure and Supervision finds that
18 a pain-management clinic does not meet the requirement of subsection
19 D of this act or is owned, directly or indirectly, by a person
20 meeting any criteria listed in subsection E of this act, the Board
21 of Medical Licensure and Supervision shall revoke the certificate of
22 registration previously issued by the Board of Medical Licensure and
23 Supervision. As determined by rule, the Board of Medical Licensure
24 and Supervision may grant an exemption to denying a registration or

1 revoking a previously issued registration if more than ten (10)
2 years have elapsed since adjudication. As used in this section, the
3 term "convicted" includes an adjudication of guilt following a plea
4 of guilty or nolo contendere or the forfeiture of a bond when
5 charged with a crime.

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

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

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

22 J. Upon the effective date of the suspension or revocation, the
23 designated physician of the pain-management clinic shall advise the
24 Board of Medical Licensure and Supervision of the disposition of the

1 medicinal drugs located on the premises. The disposition is subject
2 to the supervision and approval of the Board of Medical Licensure
3 and Supervision. Medicinal drugs that are purchased or held by a
4 pain-management clinic that is not registered may be deemed
5 adulterated pursuant to Section 1-1401 et seq. of Title 63 of the
6 Oklahoma Statutes.

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

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

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

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

21 A. A physician shall not practice medicine in a pain-management
22 clinic if the clinic is not registered with the Board of Medical
23 Licensure and Supervision as required by this act. Any physician
24 who qualifies to practice medicine in a pain-management clinic

1 pursuant to rules adopted by the Board of Medical Licensure and
2 Supervision may continue to practice medicine in a pain management
3 clinic as long as the physician continues to meet the qualifications
4 set forth in the rules. A physician who violates this subsection is
5 subject to disciplinary action by his or her appropriate medical
6 regulatory board.

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

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

19 D. A physician authorized to prescribe controlled dangerous
20 substances who practices at a pain-management clinic is responsible
21 for maintaining the control and security of his or her prescription
22 blanks and any other method used for prescribing controlled
23 dangerous substance pain medication. The physician shall notify, in
24 writing, the Board of Medical Licensure and Supervision within

1 twenty-four (24) hours following any theft or loss of a prescription
2 blank or breach of any other method for prescribing pain medication.

3 E. The designated physician of a pain-management clinic shall
4 notify the applicable board in writing of the date of termination of
5 employment within ten (10) calendar days after terminating his or
6 her employment with a pain-management clinic that is required to be
7 registered pursuant to this act. Each physician practicing in a
8 pain-management clinic shall advise the Board of Medical Licensure
9 and Supervision, in writing, within ten (10) calendar days after
10 beginning or ending his or her practice at a pain-management clinic.

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

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

- 16 a. display a sign that can be viewed by the public that
17 contains the clinic name, hours of operations, and a
18 street address,
- 19 b. have a publicly listed telephone number and a
20 dedicated phone number to send and receive facsimiles
21 with a facsimile machine that shall be operational
22 twenty-four (24) hours per day,
- 23 c. have emergency lighting and communications,
- 24 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

1 the protection of medical records and any controlled dangerous
2 substances; and

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

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

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

- 11 a. monitors and evaluates the quality and appropriateness
12 of patient care,
- 13 b. evaluates methods to improve patient care,
- 14 c. identifies and corrects deficiencies within the
15 facility,
- 16 d. alerts the designated physician to identify and
17 resolve recurring problems, and
- 18 e. provides for opportunities to improve the facility's
19 performance and to enhance and improve the quality of
20 care provided to the public; and

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

- 23 a. the identification, investigation and analysis of the
24 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

1 d. the number of patients treated at the pain clinic
2 whose domicile is located somewhere other than in this
3 state. A patient's domicile is the patient's fixed or
4 permanent home to which he or she intends to return
5 even though he or she may temporarily reside
6 elsewhere.

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

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

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

22 C. Any action taken to correct a violation shall be documented
23 in writing by the owner or designated physician of the pain-

1 management clinic and verified by follow up visits by the authorized
2 representative of the Board of Medical Licensure and Supervision.

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

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

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

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

16 A. The Board of Medical Licensure and Supervision may impose an
17 administrative fine on a clinic of up to Five Thousand Dollars
18 (\$5,000.00) per violation for violating the requirements of this act
19 or the rules of the Board of Medical Licensure and Supervision. In
20 determining whether a penalty is to be imposed, and in fixing the
21 amount of the fine, the Board of Medical Licensure and Supervision
22 shall consider the following factors:

23 1. The gravity of the violation, including the probability that
24 death or serious physical or emotional harm to a patient has

1 resulted, or could have resulted, from the pain-management clinic's
2 actions or the actions of the physician, the severity of the action
3 or potential harm and the extent to which the provisions of the
4 applicable laws or rules were violated;

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

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

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

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

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

20 D. An owner or designated physician of a pain-management clinic
21 who concurrently operates an unregistered pain-management clinic is
22 subject to an administrative fine of Five Thousand Dollars
23 (\$5,000.00) per day.
24

1 E. If the owner of a pain-management clinic that requires
2 registration fails to apply to register the clinic upon a change of
3 ownership and operates the clinic under the new ownership, the owner
4 is subject to a fine of Five Thousand Dollars (\$5,000.00).

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

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