

1 **SENATE FLOOR VERSION**

2 February 22, 2021

3 COMMITTEE SUBSTITUTE
4 FOR

5 SENATE BILL NO. 888

By: Standridge of the Senate

and

Echols of the House

9 An Act relating to controlled dangerous substances;
10 defining terms; requiring pain management clinics to
11 register with State Board of Medical Licensure and
12 Supervision; providing exemptions; stipulating
13 registration procedures; requiring clinics to
14 designate physician; stipulating procedures for
15 revocation and suspension of registration; limiting
16 period of suspension; requiring new registration
17 application if clinic changes ownership; specifying
18 physician responsibilities; providing facility and
19 physical operations requirements; stipulating certain
20 infection control requirements; providing health and
21 safety requirements; providing certain quality
22 assurance requirements; stipulating certain data
23 collection and reporting requirements; providing that
24 designated physician is responsible for ensuring
compliance with all requirements; providing
penalties; directing promulgation of rules; amending
59 O.S. 2011, Section 355.1, as amended by Section
21, Chapter 230, O.S.L. 2015 (59 O.S. Supp. 2020,
Section 355.1), which relates to dispensation of
dangerous drugs; providing certain limitations on
dispensation of controlled dangerous substances;
providing exception; providing for codification; and
providing an effective date.

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

1 SECTION 1. NEW LAW A new section of law to be codified
2 in the Oklahoma Statutes as Section 2-1101 of Title 63, unless there
3 is created a duplication in numbering, reads as follows:

4 As used in this act:

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

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

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

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

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

SECTION 2. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 2-1102 of Title 63, unless there is created a duplication in numbering, reads as follows:

A. Each pain management clinic shall register with the State 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-

1 certified medical specialists, who have also completed fellowships
2 in pain medicine approved by the Accreditation Council for Graduate
3 Medical Education or who are also certified in pain medicine by the
4 American Board of Pain Medicine or a board approved by the American
5 Board of Medical Specialties, the American Association of Physician
6 Specialists or the American Osteopathic Association, perform
7 interventional pain procedures of the type routinely billed using
8 surgical codes.

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

12 C. As a part of registration, a clinic shall designate a
13 physician who is responsible for complying with all requirements
14 related to registration and operation of the clinic in compliance
15 with this act. Within ten (10) calendar days after termination of a
16 designated physician, the clinic shall notify the State Board of
17 Medical Licensure and Supervision of the identity of another
18 designated physician for that clinic. The designated physician
19 shall have a full, active and unencumbered license pursuant to
20 Section 480 et seq. or Section 620 et seq. of Title 59 of the
21 Oklahoma Statutes and shall practice at the clinic location for
22 which the physician has assumed responsibility. Failing to have a
23 licensed designated physician practicing at the location of the
24

1 registered clinic may be the basis for a summary suspension of the
2 clinic registration certificate as described in this section.

3 D. The State Board of Medical Licensure and Supervision shall
4 deny registration to any clinic that is not fully owned by a
5 physician licensed pursuant to Section 480 et seq. or Section 620 et
6 seq. of Title 59 of the Oklahoma Statutes or group of physicians,
7 each of whom is licensed pursuant to Section 480 et seq. or Section
8 620 et seq. of Title 59 of the Oklahoma Statutes.

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

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

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

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

23 F. If the State Board of Medical Licensure and Supervision
24 finds that a pain management clinic does not meet the requirement of

1 subsection D of this section or is owned, directly or indirectly, by
2 a person meeting any criteria listed in subsection E of this
3 section, the State Board of Medical Licensure and Supervision shall
4 revoke the certificate of registration previously issued by the
5 State Board of Medical Licensure and Supervision. As determined by
6 rule, the State Board of Medical Licensure and Supervision may grant
7 an exemption to denying a registration or revoking a previously
8 issued registration if more than ten (10) years have elapsed since
9 adjudication. As used in this section, the term "convicted"
10 includes an adjudication of guilt following a plea of guilty or nolo
11 contendere or the forfeiture of a bond when charged with a crime.

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

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

23 I. If the clinic's registration is revoked, any person named in
24 the registration documents of the pain management clinic, including

1 persons owning or operating the pain management clinic, shall not,
2 as an individual or as a part of a group, apply to operate a pain
3 management clinic for five (5) years after the date the registration
4 is revoked.

5 J. The period of suspension for the registration of a pain
6 management clinic shall be prescribed by the State Board of Medical
7 Licensure and Supervision but shall not exceed one (1) year.

8 K. A change of ownership of a registered pain management clinic
9 requires submission of a new registration application.

10 SECTION 3. NEW LAW A new section of law to be codified
11 in the Oklahoma Statutes as Section 2-1103 of Title 63, unless there
12 is created a duplication in numbering, reads as follows:

13 A. A physician shall not practice medicine in a pain management
14 clinic if the clinic is not registered with the State Board of
15 Medical Licensure and Supervision as required by this act. Any
16 physician who qualifies to practice medicine in a pain management
17 clinic pursuant to rules adopted by the State Board of Medical
18 Licensure and Supervision may continue to practice medicine in a
19 pain management clinic as long as the physician continues to meet
20 the qualifications prescribed in the rules. A physician who
21 violates this subsection is subject to disciplinary action by his or
22 her appropriate medical regulatory board.

23 B. Only a physician licensed pursuant to Section 480 et seq. or
24 Section 620 et seq. of Title 59 of the Oklahoma Statutes may

1 prescribe a controlled dangerous substance on the premises of a
2 registered pain management clinic. No person shall dispense any
3 controlled dangerous substance on the premises of a pain management
4 clinic.

5 C. A physician, a physician assistant or an Advanced Practice
6 Registered Nurse shall perform a physical examination of a patient
7 on the same day that the physician prescribes a controlled substance
8 to a patient at a pain management clinic. If the physician
9 prescribes more than a seventy-two-hour dose of controlled dangerous
10 substances for the treatment of chronic nonmalignant pain, the
11 physician shall document in the patient's record the reason for
12 prescribing that quantity.

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

21 E. The designated physician of a pain management clinic shall
22 notify the applicable board in writing of the date of termination of
23 employment within ten (10) calendar days after terminating his or
24 her employment with a pain management clinic that is required to be

1 registered pursuant to this act. Each physician practicing in a
2 pain management clinic shall advise the State Board of Medical
3 Licensure and Supervision, in writing, within ten (10) calendar days
4 after beginning or ending his or her practice at a pain management
5 clinic.

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

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

- 11 a. display a sign that can be viewed by the public that
12 contains the clinic name, hours of operations and a
13 street address,
- 14 b. have a publicly listed telephone number and a
15 dedicated phone number to send and receive facsimiles
16 with a facsimile machine that shall be operational
17 twenty-four (24) hours per day,
- 18 c. have emergency lighting and communications,
- 19 d. have a reception and waiting area,
- 20 e. provide a restroom,
- 21 f. have an administrative area, including room for
22 storage of medical records, supplies and equipment,
- 23 g. have private patient examination rooms,

24

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

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

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

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

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

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

- 20 a. geographic location, community and population served,
21 b. the care, treatment and services it provides, and
22 c. an analysis of its infection surveillance and control
23 data; and
24

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

- 3 a. prioritized risks,
- 4 b. limiting unprotected exposure to pathogens,
- 5 c. limiting the transmission of infections associated
6 with procedures performed in the clinic, and
- 7 d. limiting the transmission of infections associated
8 with the clinic's use of medical equipment, devices
9 and supplies.

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

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

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

19 3. The clinic shall have a written facility-specific disaster
20 plan specifying actions that will be taken in the event of clinic
21 closure due to unforeseen disasters and shall include provisions for
22 the protection of medical records; and

23 4. Each clinic shall have at least one employee on the premises
24 during patient care hours who is certified in basic life support and

1 is trained in reacting to accidents and medical emergencies until
2 emergency medical personnel arrive.

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

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

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

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

- 19 a. the identification, investigation and analysis of the
20 frequency and causes of adverse incidents to patients,
- 21 b. the identification of trends or patterns of incidents,
- 22 c. the development of measures to correct, reduce,
23 minimize or eliminate the risk of adverse incidents to
24 patients, and

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

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

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

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

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

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

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

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

3 SECTION 4. NEW LAW A new section of law to be codified
4 in the Oklahoma Statutes as Section 2-1104 of Title 63, unless there
5 is created a duplication in numbering, reads as follows:

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

13 1. The gravity of the violation, including the probability that
14 death or serious physical or emotional harm to a patient has
15 resulted, or could have resulted, from the pain management clinic's
16 actions or the actions of the physician, the severity of the action
17 or potential harm and the extent to which the provisions of the
18 applicable laws or rules were violated;

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

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

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

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

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

10 D. An owner or designated physician of a pain management clinic
11 who concurrently operates an unregistered pain management clinic is
12 subject to an administrative fine of Five Thousand Dollars
13 (\$5,000.00) per day.

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

18 SECTION 5. NEW LAW A new section of law to be codified
19 in the Oklahoma Statutes as Section 2-1105 of Title 63, unless there
20 is created a duplication in numbering, reads as follows:

21 All affected agencies and boards shall promulgate such rules as
22 are necessary to implement the provisions of this act.

1 SECTION 6. AMENDATORY 59 O.S. 2011, Section 355.1, as
2 amended by Section 21, Chapter 230, O.S.L. 2015 (59 O.S. Supp. 2020,
3 Section 355.1), is amended to read as follows:

4 Section 355.1. A. Except as provided for in Section 353.1 et
5 seq. of this title, only a licensed practitioner may dispense
6 dangerous drugs to such practitioner's patients, and only for the
7 expressed purpose of serving the best interests and promoting the
8 welfare of such patients. The dangerous drugs shall be dispensed in
9 an appropriate container to which a label has been affixed. Such
10 label shall include the name and office address of the licensed
11 practitioner, date dispensed, name of patient, directions for
12 administration, prescription number, the trade or generic name and
13 the quantity and strength, not meaning ingredients, of the drug
14 therein contained; provided, this requirement shall not apply to
15 compounded medicines. The licensed practitioner shall keep a
16 suitable book, file or record in which shall be preserved for a
17 period of not less than five (5) years a record of every dangerous
18 drug compounded or dispensed by the licensed practitioner.

19 B. A prescriber desiring to dispense dangerous drugs pursuant
20 to this section shall register annually with the appropriate
21 licensing board as a dispenser, through a regulatory procedure
22 adopted and prescribed by such licensing board.

1 C. A prescriber who dispenses professional samples to patients
2 shall be exempt from the requirement of subsection B of this section
3 if:

4 1. The prescriber furnishes the professional samples to the
5 patient in the package provided by the manufacturer;

6 2. No charge is made to the patient; and

7 3. An appropriate record is entered in the patient's chart.

8 D. This section shall not apply to the services provided
9 through the State Department of Health, city/county health
10 departments, or the Department of Mental Health and Substance Abuse
11 Services.

12 E. This section shall not apply to organizations and services
13 incorporated as state or federal tax-exempt charitable nonprofit
14 entities and/or organizations and services receiving all or part of
15 their operating funds from a local, state or federal governmental
16 entity; provided, such organizations and services shall comply with
17 the labeling and recordkeeping requirements set out in subsection A
18 of this section.

19 F. A prescriber who issues a prescription for a controlled
20 dangerous substance shall not dispense the controlled dangerous
21 substance pursuant to such prescription. A prescriber shall not
22 dispense a controlled dangerous substance pursuant to a prescription
23 issued by another prescriber if the dispensing prescriber has a
24 financial interest in the practice of the prescribing prescriber.

1 The restrictions on dispensing of controlled dangerous substances
2 provided by this subsection shall not apply to substance abuse
3 treatment programs or services.

4 SECTION 7. This act shall become effective November 1, 2021.

5 COMMITTEE REPORT BY: COMMITTEE ON HEALTH AND HUMAN SERVICES
6 February 22, 2021 - DO PASS AS AMENDED
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