1 STATE OF OKLAHOMA 2 1st Session of the 58th Legislature (2021) 3 COMMITTEE SUBSTITUTE SENATE BILL NO. 888 4 By: Standridge of the Senate 5 and Echols of the House 6 7 8 9 COMMITTEE SUBSTITUTE An Act relating to controlled dangerous substances; 10 defining terms; requiring pain management clinics to register with State Board of Medical Licensure and 11 Supervision; providing exemptions; stipulating registration procedures; requiring clinics to 12 designate physician; stipulating procedures for revocation and suspension of registration; limiting 13 period of suspension; requiring new registration application if clinic changes ownership; specifying 14 physician responsibilities; providing facility and physical operations requirements; stipulating certain 15 infection control requirements; providing health and safety requirements; providing certain quality 16 assurance requirements; stipulating certain data collection and reporting requirements; providing that 17 designated physician is responsible for ensuring compliance with all requirements; providing 18 penalties; directing promulgation of rules; amending 59 O.S. 2011, Section 355.1, as amended by Section 19

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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 an effective date.

providing exception; providing for codification; and

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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 2-1101 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.

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- 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-

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 shall 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 shall notify the State 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 State 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 State 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:
- 12 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 State Board of Medical Licensure and Supervision finds that a pain management clinic does not meet the requirement of

subsection D of this section or is owned, directly or indirectly, by a person meeting any criteria listed in subsection E of this section, the State Board of Medical Licensure and Supervision shall revoke the certificate of registration previously issued by the State Board of Medical Licensure and Supervision. As determined by rule, the State 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. 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.
- H. 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.
- I. 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.
 - J. The period of suspension for the registration of a pain management clinic shall be prescribed by the State Board of Medical Licensure and Supervision but shall not exceed one (1) year.

- K. 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 2-1103 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 State 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 State 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 prescribed 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

prescribe a controlled dangerous substance on the premises of a registered pain management clinic. No person shall dispense any controlled dangerous substance on the premises of a 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 shall 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 State 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 State 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,

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

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- 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 State Board of Medical Licensure and Supervision; and
- 2. The designated physician shall also report to the State 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 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 2-1104 of Title 63, unless there is created a duplication in numbering, reads as follows:

- A. The State 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 State Board of Medical Licensure and Supervision. In determining whether a penalty is to be imposed, and in fixing the amount of the fine, the State 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 State Board of Medical Licensure and Supervision constitutes an additional, separate and distinct violation.
- C. The State 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 5. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 2-1105 of Title 63, unless there is created a duplication in numbering, reads as follows:
- All affected agencies and boards shall promulgate such rules as are necessary to implement the provisions of this act.

SECTION 6. AMENDATORY 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), is amended to read as follows:

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

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

- C. A prescriber who dispenses professional samples to patients shall be exempt from the requirement of subsection B of this section if:
- 1. The prescriber furnishes the professional samples to the patient in the package provided by the manufacturer;
 - 2. No charge is made to the patient; and

- 3. An appropriate record is entered in the patient's chart.
- D. This section shall not apply to the services provided through the State Department of Health, city/county health departments τ or the Department of Mental Health and Substance Abuse Services.
- E. This section shall not apply to organizations and services incorporated as state or federal tax-exempt charitable nonprofit entities and/or organizations and services receiving all or part of their operating funds from a local, state or federal governmental entity; provided, such organizations and services shall comply with the labeling and recordkeeping requirements set out in subsection A of this section.
- F. A prescriber who issues a prescription for a controlled dangerous substance shall not dispense the controlled dangerous substance pursuant to such prescription. A prescriber shall not dispense a controlled dangerous substance pursuant to a prescription issued by another prescriber if the dispensing prescriber has a financial interest in the practice of the prescribing prescriber.

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The restrictions on dispensing of controlled dangerous substances
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    provided by this subsection shall not apply to substance abuse
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    treatment programs or services.
        SECTION 7. This act shall become effective November 1, 2021.
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