



# State Medical Board of Ohio

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## Emergency Rule 4731-29-01 Effective June 20, 2011

On Thursday, June 9, 2011, the State Medical Board of Ohio [Medical Board] amended the language of proposed emergency Rule 4731-29-01, *Standards and Procedures for the Operation of a Pain Management Clinic*. The emergency rule will be effective on June 20, 2011.

In amending the proposed emergency rule, the Medical Board considered comments received from individuals and organizations concerning the requirements for ownership of a pain management clinic, requirements for practicing at a pain management clinic, and other provisions of the rule. In summary, the changes include the following:

1. **Adds** definitions for “chronic pain” and “pain.”
2. **Deletes** the definition of “local hospital” and the requirement that a physician owning or practicing at a pain management clinic must have staff privileges at a local hospital.
3. **Establishes** the general requirement for physician ownership of a pain management clinic as current subspecialty certification in pain management or hospice and palliative medicine or current board certification by the American Board of Pain Medicine or the American Board of Interventional Pain Physicians.
4. **Provides** a limited grandfather provision for physicians who wish to own a pain management clinic but who do not meet the general requirements for subspecialty certification or current board certification.
  - The physician must have filed an application for a license as a category III terminal distributor of dangerous drugs with a pain management clinic classification with the State Board of Pharmacy **by June 20**.
  - The physician must meet of one of several educational and practice options. One option is that the physician has provided at least three years of full-time clinical services in pain medicine, pain management, hospice and palliative medicine, addiction psychiatry, physical medicine and rehabilitation, occupational medicine, or rheumatology.
  - The Medical Board must determine, following an investigation, that the physician’s practice appears to comply with the minimal standards of care.
5. **Allows** any physician to provide care at a pain management clinic under the direction, supervision, and control of the owner.
6. **Requires** all physicians who own and/or provide care at a pain management clinic to complete at least 20 hours of category I continuing medical education in pain medicine every two years.
7. **Clarifies** record keeping requirements and other provisions of the proposed rule.

**Emergency rule 4731-29-01 is attached.** Information on other rules proposed to implement H.B. 93 and other topics related to safe prescribing may be found at the **Center for Safe Prescribing**:  
[http://med.ohio.gov/Center\\_for\\_Safe\\_Prescribing.html](http://med.ohio.gov/Center_for_Safe_Prescribing.html).

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4731-29-01 Standards and procedures for the operation of a pain management clinic.

(A) For the purposes of this rule:

- (1) "Board" means state medical board of Ohio.
- (2) "Chronic pain" means pain that has persisted after reasonable medical efforts have been made to relieve the pain or cure its cause and that has continued, either continuously or episodically, for longer than three continuous months. "Chronic pain" does not include pain associated with a terminal condition or with a progressive disease that, in the normal course of progression, may reasonably be expected to result in a terminal condition.
- (3) "Informed consent" means a process of communication between a patient and physician that results in the patient's signed authorization or agreement to undergo a specific medical intervention.
- (4) "Pain" means an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage.
- (5) "Pain management clinic" means a facility to which all of the following apply:
  - (a) The primary component of the practice is treatment of pain or chronic pain;
  - (b) The majority of patients of the prescribers at the facility are provided treatment for pain or chronic pain that includes the use of controlled substances, tramadol, carisoprodol, or other drugs specified in rules by the board; and
  - (c) In determining whether the facility meets the requirement of paragraph (A)(5)(b) of this rule:
    - (i) Calculation of the majority of patients will be based upon the number of patients treated in a calendar month;
    - (ii) Patients receiving controlled substances, tramadol, carisoprodol or other drugs specified by the board, for treatment of an injury or illness that lasts or is expected to last thirty days or less shall not be considered in the calculation of the majority.
- (6) "Pain management clinic" does not include the following:
  - (a) A hospital registered with the department of health under section 3701.07 of the Revised Code or a facility owned in whole or in part by a hospital;

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- (b) A school, college, university, or other educational institution or program to the extent that it provides instruction to individuals preparing to practice as physicians, podiatrists, dentists, nurses, physician assistants, optometrists, or veterinarians or any affiliated facility to the extent that it participates in the provision of that instruction;
  - (c) A hospice program licensed under chapter 3712. of the Revised Code;
  - (d) An ambulatory surgical facility licensed under section 3702.30 of the Revised Code.
- (7) "Physician" means an individual authorized under chapter 4731. of the Revised Code to practice medicine and surgery or osteopathic medicine and surgery.
- (8) "Prescriber" has the same meaning as in section 4729.01 of the Revised Code.
- (B) In the operation of a pain management clinic, the following requirements shall be met:
- (1) The pain management clinic shall be owned and operated by one or more physicians. Each physician owner of a pain management clinic shall complete at least twenty hours of category I continuing medical education in pain medicine every two years. The courses completed in compliance with this rule shall be accepted toward meeting the category I requirement for certificate of registration renewal for the physician.
  - (2) Except as provided in paragraph (B)(3) of this rule, the physician owner of a pain management clinic must meet one of the following requirements:
    - (a) Hold current subspecialty certification in pain management by the American board of medical specialties, or hold a current certificate of added qualification in pain management by the American osteopathic association bureau of osteopathic specialists; or
    - (b) Hold current subspecialty certification in hospice and palliative medicine by the American board of medical specialties, or hold a current certificate of added qualification in hospice and palliative medicine by the American osteopathic association bureau of osteopathic specialists; or
    - (c) Hold current board certification by the American board of pain medicine; or
    - (d) Hold current board certification by the American board of interventional pain physicians.

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- (3) A physician who applies for a category III terminal distributor of dangerous drugs with a pain management clinic classification under section 4729.552 of the Revised Code by June 20, 2011 may own a pain management clinic if the medical board determines that all of the following criteria are met:
- (a) Meet one of the following requirements:
- (i) An internship or residency program that would satisfy post-graduate training requirements for board certification in anesthesiology, psychiatry, neurology, physical medicine and rehabilitation, occupational medicine, or rheumatology conducted in the United States and accredited by either the accreditation council for graduate medical education of the American medical association or the American osteopathic association; or
  - (ii) A clinical fellowship program that would satisfy post-graduate training requirements for board certification in anesthesiology, psychiatry, neurology, physical medicine and rehabilitation, occupational medicine, or rheumatology, conducted in the United States at an institution with a residency program accredited by either the accreditation council for graduate medical education of the American medical association or the American osteopathic association that is in a clinical field the same as or related to the clinical field of the fellowship program; or
  - (iii) An internship program that would satisfy post-graduate training requirements for board certification in anesthesiology, psychiatry, neurology, physical medicine and rehabilitation, occupational medicine, or rheumatology, conducted in Canada and accredited by the committee on accreditation of preregistration physician training programs of the federation of provincial medical licensing authorities of Canada; or
  - (iv) A residency program that would satisfy post-graduate training requirements for board certification in anesthesiology, psychiatry, neurology, physical medicine and rehabilitation, occupational medicine, or rheumatology, conducted in Canada and accredited by either the royal college of physicians and surgeons of Canada or the college of family physicians of Canada; or
  - (v) The provision of at least three years of full-time clinical services, within the last three years, in pain medicine, pain management, hospice and palliative medicine, addiction psychiatry, physical medicine and rehabilitation, occupational medicine, or rheumatology; or

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(vi) At least three years of continuous service as a clinical professor or assistant clinical professor, within the last three years, in pain medicine, pain management, hospice and palliative medicine, addiction psychiatry, physical medicine and rehabilitation, occupational medicine, or rheumatology at a medical school accredited by the liaison committee on medical education or the American osteopathic association.

(b) The physician's practice complies with the minimal standards of care.

(i) The physician shall provide a copy of the application for a category III terminal distributor of dangerous drugs with a pain management clinic classification under section 4729.552 of the Revised Code to the medical board.

(ii) The copy of the application shall serve as a complaint which shall authorize the medical board to investigate the physician's practice pursuant to section 4731.22(F) of the Revised Code.

(4) The pain management clinic shall be licensed as a category III terminal distributor of dangerous drugs with a pain management clinic classification under section 4729.552 of the Revised Code.

(5) The pain management clinic shall be operated in compliance with the drug prevention and control act, 21 U.S.C. 801 et. seq., and chapters 3719., 4729., 4730., and 4731. of the Revised Code.

(6) The pain management clinic shall have proper equipment, materials, and personnel on premises to provide appropriate medical treatment, as required by the minimal standards of care.

(C) No physician owner of a pain management clinic, employee of the clinic, or person with whom the clinic contracts for services shall:

(1) Have ever been denied a license to prescribe, dispense, administer, supply, or sell a controlled substance by the drug enforcement administration or appropriate issuing body of any state or jurisdiction, based, in whole or in part, on the prescriber's inappropriate prescribing, dispensing, administering, supplying or selling a controlled substance.

(2) Have held a license issued by the drug enforcement administration or a state licensing agency in any jurisdiction, under which the person may prescribe, dispense, administer, supply, or sell a controlled substance, that has ever been restricted, based, in whole or in part, on the prescriber's inappropriate

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prescribing, dispensing, administering, supplying, or selling a controlled substance.

- (3) Have been subject to disciplinary action by any licensing entity that was based, in whole or in part, on the prescribers inappropriate prescribing, dispensing, diverting, administering, supplying, or selling a controlled substance.
- (D) Each physician who provides care at a pain management clinic shall complete at least twenty hours of category I continuing medical education in pain medicine every two years. The courses completed in compliance with this rule shall be accepted toward meeting the category I requirement for certificate of registration renewal for the physician.
- (E) In providing supervision, direction, and control of individuals at a pain management clinic the physician owner shall establish and ensure compliance with the following:
  - (1) A requirement that a log of patients be maintained for each day the clinic is in operation.
    - (a) Each log sheet shall contain the month, day, and year;
    - (b) Each log entry shall include the first and last name of each patient;
    - (c) Each patient shall be required to sign the log at each visit; and
    - (d) Patient logs shall be maintained for seven years.
  - (2) A requirement that providers obtain informed consent for each patient prior to the commencement of treatment.
  - (3) An on-going quality assurance program that objectively and systematically monitors and evaluates the quality and appropriateness of patient care, evaluates the methods to improve patient care, identifies and corrects deficiencies within the clinic, and provides for opportunities to improve the clinic's performance and quality of care.
  - (4) A requirement that the background, training, certification, and licensure of all clinical staff be documented. Verification of certification and licensure shall be made on an annual basis.
  - (5) A requirement that adequate billing records are maintained for all patients and made available to the board, immediately upon request.

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- (a) Billing records shall include the amount paid, method of payment, ~~and~~ description of services, sufficient information to identify the patient, and the amounts charged to the patient for each date of service.
  - (b) Billing records shall be maintained for seven years from the last date of treatment of the patient.
- (6) A requirement that adequate patient records are maintained for all patients and made available to the board, immediately upon request.
- (a) Patient records shall contain sufficient information to identify the patient, support the diagnosis, justify the treatment and document the course and results of treatment accurately, by including, at a minimum:
    - (i) Patient history and physical examination, including history of drug abuse or dependence;
    - (ii) Diagnostic, therapeutic, and laboratory results, including drug testing results;
    - (iii) Reports of evaluations, consultations, and hospitalizations;
    - (iv) Treatment objectives, including discussion of risks and benefits;
    - (v) Records of drugs prescribed, dispensed or administered, including the date, type, and dosage;
    - (vi) Treatments;
    - (vii) Receipt and assessment of drug database or prescription monitoring program reports;
    - (viii) Copies of records or reports or other documentation obtained from other health care practitioners at the request of the physician and relied upon by the physician in determining the appropriate treatment of the patient. Records provided by the patient shall be designated as such.
  - (b) Patient records shall be maintained for seven years from the last date of treatment of the patient.
  - (c) In the treatment of chronic pain the patient records shall contain the information required in rule 4731-21-02 of the Administrative Code in lieu of the requirements of paragraph (E)(6)(a)(i) through (vi) of this rule.