

CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: State Medical Board of Ohio

Regulation/Package Title: Operation of a pain management clinic

Rule Number(s): 4731-29-01

Date: July 11, 2016

Rule Type:

New

Amended

5-Year Review

Rescinded

The Common Sense Initiative was established by Executive Order 2011-01K and placed within the Office of the Lieutenant Governor. Under the CSI Initiative, agencies should balance the critical objectives of all regulations with the costs of compliance by the regulated parties. Agencies should promote transparency, consistency, predictability, and flexibility in regulatory activities. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Regulatory Intent

1. Please briefly describe the draft regulation in plain language.

Please include the key provisions of the regulation as well as any proposed amendments.

Rule 4731-29-01 sets out the standards and procedures for the operation of a pain management medical clinic. The proposed amendments to the rule reflect amendments to

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Section 4731.054, Ohio Revised Code, the statute that requires the Medical Board to adopt the rule. The proposed amendments are as follows:

Paragraph (A)(6): Deletes the definition of “pain” as it is no longer used in the pain management clinic definition. Remaining paragraphs are renumbered.

Paragraph (A)(7): Changes definition of pain management clinic to match the statutory definition;

Paragraph (A)(7)(c)(ii): Deletes tramadol and carisprodol as they are now controlled substances and do not need to be separately listed;

Paragraph (A)(8): Adds nursing home and clinical research facility to the exemption from the pain management definition. This is consistent with changes to Section 4731.054.

Paragraph (B)(2): Changes the word “management” to “medicine” to correct the name of the specialty board certification to pain medicine instead of pain management.

Paragraph (B)(3): Deletes subparagraphs (a) and (b) and adds language so that the Board may determine whether the physician demonstrates conformance with minimal standards of care through an inspection of the facility under 4731.054(E), Ohio Revised Code.

2. Please list the Ohio statute authorizing the Agency to adopt this regulation.

Sections 4731.05 and 4731.054, Ohio Revised Code.

3. Does the regulation implement a federal requirement? Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program? If yes, please briefly explain the source and substance of the federal requirement.

No, the rule does not implement a federal requirement.

4. If the regulation includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.

Not applicable.

5. What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?

The rule designated as 4731-29-01 is required by Section 4731.054, Ohio Revised Code. It informs physicians, other health care providers, and the public about the requirements for the ownership and operation of a medical practice that meets the definition of a pain management clinic. The rule facilitates the state of Ohio policy to counter rogue prescribing

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of prescription drugs under the guise of treating pain and the over-prescribing of prescription drugs for treating legitimate pain.

6. How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?

The rule is just one of several tools employed by the State of Ohio to combat prescription drug addiction and abuse. Medical Board enforcement of the rule, the prescription monitoring system (“OARRS”) operated by the State Board of Pharmacy, plus the several prescribing guidelines issued in cooperation with the Governor’s Cabinet Opioid Action Team (“GCOAT”) have increased physician awareness of the problem. The Medical Board measures the success of the rule by the statistics available from the Pharmacy Board showing that the total number of opioid prescriptions written in Ohio have fallen since the implementation of the Medical Board’s Rule 4731-29-01, OARRS, and the GCOACT guidelines. See Pharmacy Board press release at: <http://pharmacy.ohio.gov/Documents/Pubs/NewsReleases/2016/Opioid%20Doses,%20Prescriptions%20for%20Ohio%20Patients%20Continue%20To%20Decrease.pdf>.

Development of the Regulation

7. Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.

If applicable, please include the date and medium by which the stakeholders were initially contacted.

The rule was originally developed in 2011 as an emergency rule under H.B. 93 of the 129th General Assembly. The permanent version of the rule reflected concerns raised by some commentators at the public hearing in June 2011.

The proposed amendments to Rule 4731-29-01 were sent via e-mail on February 2, 2016, to entities including, but not limited to, the Ohio Association of Physician Assistants, Ohio State Medical Association, Ohio Academy of Family Physicians, Academy of Medicine of Cleveland and Northern Ohio, Ohio Coroner’s Association, Ohio Podiatric Association, Ohio Osteopathic Association, governmental affairs representatives for numerous organizations, state agencies such as the Nursing Board, Pharmacy Board, and the Ohio Department of Health, and all other persons and organizations who have requested notice of Medical Board rule activity.

8. What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?

No comments were received on the proposed rule.

9. What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?

In 2011 the rule was developed based upon the provisions necessary for a resulting decrease in the number of prescriptions for prescription pain medications whether by rogue prescribers or by prescribers prescribing for legitimate pain.

10. What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn't the Agency consider regulatory alternatives?

No alternative regulations were considered. The basic framework of the rule has been successful in the effort to combat rogue prescribing of pain medications and the over-prescribing of pain medications for legitimate pain.

11. Did the Agency specifically consider a performance-based regulation? Please explain. *Performance-based regulations define the required outcome, but don't dictate the process the regulated stakeholders must use to achieve compliance.*

The rule is performance based in that it does not specify how required actions are to be performed. For example, paragraph (B)(6) requires there to be proper equipment, materials, and personnel on the premises to provide appropriate medical treatment but does not specify the exact equipment and materials or numbers and types of personnel.

12. What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?

The Medical Board is the only agency authorized to promulgate rules under Section 4731.054, Ohio Revised Code. Moreover, the rule has been shared with the Pharmacy Board, which licenses the pain management clinics.

13. Please describe the Agency's plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community.

Notice of the rule and an explanation of the amendments will be emailed to all Ohio licensed physicians, medical-related organizations, and attorneys who regularly represent persons in matters before the Medical Board and will be posted on the Medical Board website.

Adverse Impact to Business

14. Provide a summary of the estimated cost of compliance with the rule. Specifically, please do the following:

- a. Identify the scope of the impacted business community;**

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The impacted business community is composed of physicians who want to own a medical practice that either specializes in pain management or has a high percentage of patients whose medical conditions result in chronic pain for which controlled substances may be prescribed. The definition of a pain management clinic in Section 4731.054, Ohio Revised Code, incorporates within the definition medical practices that may be actually specialize in care that is not specifically pain management. For example, a family medicine, internal medicine, orthopedics, or occupational medicine practice meets the definition of a pain management clinic if more than fifty percent of the patients of all of the prescribers at a specific facility are prescribed a controlled substance for chronic pain. For a medical practice having more than one office, each office is considered a facility for purposes of the pain management clinic licensure law in Section 4731.054, Ohio Revised Code.

b. Identify the nature of the adverse impact (e.g., license fees, fines, employer time for compliance); and

The nature of the adverse impact is that only Ohio licensed physicians who hold specified credentials may own a medical practice that falls within the definition of a pain management clinic as defined in Section 4731.054, Ohio Revised Code. The rule requires all physicians who own or practice at a pain management clinic to complete specified continuing medical education coursework. The rule requires that in the operation of a pain management clinic certain activities be completed. Examples are maintenance of a log of all patients seen each day, an on-going quality assurance system, completion of background check for all clinical staff, and maintenance of patient records for seven years from the last date of treatment of the patient.

c. Quantify the expected adverse impact from the regulation.

The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a “representative business.” Please include the source for your information/estimated impact.

As an example, in compliance with paragraph (B) of the rule, a physician who holds professional board certification in physical medicine and rehabilitation from the American Board of Physical Medicine and Rehabilitation may own a pain management clinic and apply for the required terminal distributor’s license from the Pharmacy Board in one of two ways: (1) having obtained subspecialty certification in pain management from the American Board of Physical Medicine and Rehabilitation (See paragraph (B)(2)(a)), or (2) by demonstrating conformance with

the minimal standards of care via a Medical Board inspection of the facility and review of patient records (See paragraph (B)(2)(e)).

To qualify for ownership of a pain management clinic under paragraph (B)(2)(e), the physician will have had to have completed medical school and graduate medical education requirements, obtained an Ohio license, obtained an initial level of professional board certification after having completed examination and other requirements, and completed continuing education and other activities required to maintain the state license and the initial form of professional board certification, See “Certification: Booklet of Information 2016 Examinations,” available from the American Board of Physical Medicine and Rehabilitation at the following link: www.abpmr.org. The fee for Part I of the certification examination is currently \$1,395. The fee for Part II of the certification examination is currently \$1,910. (See https://www.abpmr.org/candidates/exam_calendar.html) The administrative fee to participate in the required maintenance of certification activities is \$200 per year, not counting the costs of continuing medical education coursework. (See <https://www.abpmr.org/DiplomateNews/Archive/Spring2014/moc-fees.html>) The application fee for the initial Ohio medical license is \$325. (See Sections 4731.09 and 4731.14, Ohio Revised Code) The biennial Ohio licensure renewal for a physician is \$305. (See Section 4731.281, Ohio Revised Code)

However, to meet the requirements under paragraph (B)(2)(a) of the rule, the physician would have to incur all of the costs in the paragraph above of this document, plus complete additional graduate medical education and examination. See “Certification: Booklet of Information 2016 Examinations,” available from the American Board of Physical Medicine and Rehabilitation at the following link: www.abpmr.org. The current fee for the subspecialty pain medicine examination is: \$1800. (See https://www.abpmr.org/candidates/exam_calendar.html)

Obtaining the required terminal distributor’s license from the Pharmacy Board entails payment of a \$150 application fee and completing an application.

There is no way to survey all continuing medical education coursework that can be taken to satisfy the requirement of paragraph (C) of the rule in order to give a detailed answer to the cost that will be incurred. However, there are currently free courses that meet the requirement listed on the American Medical Association website: <http://www.ama-assn.org/ama/pub/advocacy/topics/preventing-opioid-abuse/opioid-abuse-resource-guide.page>. Other courses, such as the Vanderbilt University School of Medicine’s course “Prescribing Controlled Drugs,” are more expensive. The

Vanderbilt course referenced is a three-day course with a fee of \$2,500. (See <http://www.mc.vanderbilt.edu/root/vumc.php?site=cph&doc=36613>)

The requirements to maintain logs of all patients seen each day, have an on-going quality assurance system, and maintain patient records for seven years from the last date of treatment of the patient depends upon the mechanism chosen by the practice administration. The cost of criminal background checks depends upon the vendor chosen. (See <http://www.ohioattorneygeneral.gov/Business/Services-for-Business/WebCheck/Webcheck-Community-Listing>)

15. Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community?

The rules are required by Section 4731.054, Ohio Revised Code. It is the policy of the State of Ohio that the Medical Board promulgate a rule setting the standards for the operation of a pain management clinic as one of the tools to counter the abuse of prescription pain medications resulting from rogue prescribing and the over-prescribing of pain medications for legitimate pain.

Regulatory Flexibility

16. Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.

No, there are no exemptions or alternative means for compliance for small businesses. The definition of a pain management clinic in Section 4731.054, Ohio Revised Code, applies to medical practices of any size that meet the definition. It captures a practice with just one prescriber who prescribes controlled substances to treat chronic pain to more than fifty percent of the patients as well as larger practices with many prescribers.

17. How will the agency apply Ohio Revised Code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation?

The policy of the State of Ohio is to combat prescription pain drug abuse. The requirements to maintain paperwork for production to the Medical Board should it be asked for, is essential to achieving the goal.

18. What resources are available to assist small businesses with compliance of the regulation?

Medical Board staff members are available to answer questions. Guidance documents are published where needed.

*** DRAFT - NOT YET FILED ***

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) "Hospital" means a hospital registered with the department of health under section 3701.07 of the Revised Code.
- (4) "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 after all of the following subjects are discussed:
 - (a) The patient's diagnosis;
 - (b) The nature and purpose of the proposed treatment or procedure;
 - (c) The risks and benefits of a proposed treatment or procedure;
 - (d) Alternatives regardless of their costs or the extent to which the treatment options are covered by health insurance;
 - (e) The risks and benefits of the alternative treatment or procedure; and
 - (f) The risks and benefits of not receiving or undergoing a treatment or procedure.
- (5) "Owner" means each person included on the list maintained under division (B)(5) of section 4729.552 of the Revised Code.
- ~~(6) "Pain" means an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage.~~

~~(7)~~(6) "Pain management clinic" means a facility ~~to~~ in which ~~all of the following apply~~ the majority of patients of the prescribers at the facility are provided treatment for chronic pain that includes the use of controlled substances. In determining whether the facility meets the requirements of this paragraph:

(a) Calculation of the majority of patients will be based upon the number of patients treated in a calendar month;

(b) Patients receiving controlled substances 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.

~~(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)(7)(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.~~

~~(8)~~(7) "Pain management clinic" does not include the following:

(a) A hospital;

(b) A facility operated by a hospital for the treatment of pain or chronic pain;

(c) A physician practice owned or controlled, in whole or in part, by a hospital or by an entity that owns or controls, in whole or in part, one or more hospitals;

(d) 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;

- (e) A hospice program licensed under Chapter 3712. of the Revised Code;
- (f) An ambulatory surgical facility licensed under section 3702.30 of the Revised Code;
- (g) An interdisciplinary pain rehabilitation program with three-year accreditation from the commission on accreditation of rehabilitation facilities;-
- (h) A nursing home licensed under section 3721.02 of the Revised Code or by a political subdivision certified under section 3721.09 of the Revised Code; or
- (i) A facility conducting only clinical research that may use controlled substances in studies approved by a hospital-based institutional review board or an institutional review board accredited by the association for the accreditation of human research protection programs.

~~(9)~~(8) "Physician" means an individual authorized under chapter 4731. of the Revised Code to practice medicine and surgery or osteopathic medicine and surgery.

~~(10)~~(9) "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, to include one or more courses addressing the potential for addiction. 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) Each physician owner of a pain management clinic must meet one of the following requirements:

- (a) Hold current subspecialty certification in pain ~~management~~ [medicine](#) by the American board of medical specialties, or hold a current certificate of added qualification in pain ~~management~~ [medicine](#) 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; or
 - (e) Meet both of the following:
 - (i) Hold current board certification in anesthesiology, psychiatry, neurology, physical medicine and rehabilitation, occupational medicine, or rheumatology by the American board of medical specialties or hold current primary certification in anesthesiology, psychiatry, neurology, physical medicine and rehabilitation, occupational medicine, or rheumatology by the American osteopathic association bureau of osteopathic specialists.
 - (ii) Demonstrate conformance with the minimal standards of care.
- (3) To demonstrate conformance with the minimal standards of care pursuant to paragraph (B)(2)(e)(ii) of this rule, [the board shall conduct an inspection of the facility pursuant to division \(E\) of section 4731.054 of the Revised Code.](#)
- ~~(a) The physician shall provide to the medical board 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.~~
- ~~(b) The copy of the application shall serve as a complaint which shall authorize the medical board to investigate the physician's practice pursuant to division (F) of section 4731.22 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 to 971, [in effect as of May 1, 2016](#), 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) 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, to include one or more courses addressing the potential for addiction. 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.
- (D) 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 or other dangerous drug.
 - (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 prescribing, dispensing, administering, supplying, or selling a controlled substance or other dangerous drug.
 - (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 or other dangerous drug.
- (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 legible 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 methods to improve patient care, identifies and corrects deficiencies within the clinic, and provides the 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.
 - (a) Billing records shall include the amount paid, method of payment, 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 paragraphs (E)(6)(a)(i) to (E)(6)(a)(vi) of this rule.