Common Sense Initiative

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Business Impact Analysis

Agency, Board, or Commission Name: State Medical Board of Ohio

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Regulation/Package Title (a general description of the rules' substantive content):

Controlled Substance Prescribing Rules

Rule Number(s): 4731-11-01, 4731-11-13, 4731-11-14, 4731-29-01

Date of Submission for CSI Review: 8/6/2025

Public Comment Period End Date: 8/22/2025

Rule Type/Number of Rules:

New/___ rules
No Change/__1__ rules (FYR? __y__)
Amended/__3__ rules (FYR? __y__)
Rescinded/____ rules (FYR? ___)

The Common Sense Initiative is established in R.C. 107.61 to eliminate excessive and duplicative rules and regulations that stand in the way of job creation. Under the Common Sense Initiative, agencies must balance the critical objectives of regulations that have an adverse impact on business with the costs of compliance by the regulated parties. Agencies should promote transparency, responsiveness, predictability, and flexibility while developing regulations that are fair and easy to follow. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Reason for Submission

1. **R.C. 106.03 and 106.031 require agencies, when reviewing a rule, to determine whether the rule has an adverse impact on businesses as defined by R.C. 107.52. If the agency determines that it does, it must complete a business impact analysis and submit the rule for CSI review.**

   Which adverse impact(s) to businesses has the agency determined the rule(s) create?

   The rule(s):

   a. ☐ **Requires a license, permit, or any other prior authorization to engage in or operate a line of business.**

   b. ☒ **Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.**

   c. ☐ **Requires specific expenditures or the report of information as a condition of compliance.**

   d. ☐ **Is likely to directly reduce the revenue or increase the expenses of the lines of business to which it will apply or applies.**

Regulatory Intent

2. **Please briefly describe the draft regulation in plain language.**
   Please include the key provisions of the regulation as well as any proposed amendments.

4731-11-01 Definitions: The rule provides the definitions for the rules in Chapter 4731-11, related to controlled substance prescribing. The rule is proposed to be amended to correct a typographical error.

4731-11-13 Prescribing of Opiate Analgesics for Acute Pain: The rule provides guidance for prescribers who are prescribing opioids for acute pain, and includes limits on the amounts of opioid to be prescribed for acute pain. No changes are proposed.

4731-11-14 Prescribing for Subacute and Chronic Pain: The rule provides guidance to prescribers who are prescribing opioids for subacute and chronic pain, and includes specific requirements at different Morphine Equivalent Dose ("MED") levels. The rule is proposed to be amended to update references to rules of the Ohio Board of Pharmacy and correct a spelling error.

4731-29-01 Standards and Procedures for the Operation of a Pain Management Clinic: The rule sets forth requirements for physicians to own and operate a pain management clinic licensed by the Board of Pharmacy. The rule is proposed to be amended to update statute and rule references.

3. **Please list the Ohio statute(s) that authorize the agency, board or commission to adopt the rule(s) and the statute(s) that amplify that authority.**

4731-11-01: Authorized by: 4731.052, 4731.05, 4730.39, 3719.062; Amplifies: 3719.062, 4731.74, 4731.052, 4730.39

4731-11-13: Authorized by: 3719.062, 4731.05; Amplifies: 3719.062

4731-11-14: Authorized by: 3719.062, 4731.05, 4731.052, 4730.39, 4730.07; Amplifies: 3719.062, 4731.052, 4730.39

4731-29-01: Authorized by: 4731.05, 4731.054; Amplifies 4731.054

4. **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.

5. **If the regulation implements a federal requirement, but includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.**

Not applicable.

6. **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 public purpose for the rules is to reduce the frequency and amount of opioids prescribed for acute, subacute and chronic pain and to ensure that pain management clinics are owned by physicians with training in pain management. The rules also provide prescribers of controlled substances with guidance and tools to prescribe when clinically appropriate and with proper documentation. The rules also seek to significantly limit the amount of unused opioids that are available for diversion.

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

Outcomes reflecting the impact of the limits on opioid prescribing resulting in benefits for public safety will be measured by data from OARRS, public health and law enforcement. The success of the regulations will also be measured by having rules written in plain language, licensee compliance with the rules and minimal questions from licensees, medical practices and medical facilities regarding the provisions of the rule.

8. **Are any of the proposed rules contained in this rule package being submitted pursuant to R.C. 101.352, 101.353, 106.032, 121.93, or 121.931?**
If yes, please specify the rule number(s), the specific R.C. section requiring this submission, and a detailed explanation.

No.

Development of the Regulation

9. **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.

On April 16, 2025, the rules were circulated to interested parties, including the Ohio State Medical Association, the Ohio Hospital Association, physician assistant policy council, the Ohio Board of Pharmacy and others.

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

One comment was received, which highlighted a spelling error in Rule 4731-11-14, which is corrected.

11. **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?**

Rules 4731-11-13 and 4731-11-14 were initially developed through guidelines developed by several state agencies, including the Department of Mental Health and Addiction Services, Department of Medicaid, Ohio Board of Pharmacy, Ohio Board of Nursing and Ohio Dental Board, based on data regarding opioid prescribing. Scientific data regarding best practices in opioid prescribing was also used in the development of Rule 4731-29-01.

12. **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?**
Alternative regulations may include performance-based regulations, which define the required outcome, but do not dictate the process the regulated stakeholders must use to

comply.

No alternative regulations were considered. The rules have been effective in regulating the prescribing of controlled substances in Ohio and are necessary for patient safety.

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

The regulations were developed in conjunction with the Ohio Board of Pharmacy, Ohio Board of Nursing and Ohio Dental Board to ensure consistency. The rules are largely unchanged in this filing.

14. 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.

The rules will be posted on the Medical Board's website, information concerning the rules will be included in e-mail newsletters sent to licensees and notices will be sent to interested parties. Medical Board staff members are available by telephone and e-mail to answer questions. Medical Board staff members also give presentations to groups and associations who seek an update on prescriber practice regulations.

Adverse Impact to Business

15. Provide a summary of the estimated cost of compliance with the rule(s). Specifically, please do the following:

a. Identify the scope of the impacted business community, and

The impacted business community includes licensees of the Medical Board who are authorized to prescribe controlled substances, including opioids. This includes physicians holding an MD, DO, or DPM license and physician assistants who are authorized to prescribe.

b. Quantify and identify the nature of all adverse impact (e.g., fees, fines, employer time for compliance, etc.).

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.

Prescribers who prescribe opioids for acute, subacute or chronic pain need to be aware of the practice and documentation requirements when prescribing opioids. Physicians working in a pain management clinic must complete at least 20 hours of continuing medical education in pain medicine every two years. Failure of prescribers to follow the requirements of the rules could be subject to discipline including a civil penalty.

16. Are there any proposed changes to the rules that will reduce a regulatory burden imposed on the business community? Please identify. *(Reductions in regulatory burden may include streamlining reporting processes, simplifying rules to improve readability, eliminating requirements, reducing compliance time or fees, or other related factors).*

The rules do not have provisions that will reduce the regulatory burden on the impacted business community. The rules are largely unchanged and have been in effect for several years. The rules ensure safe prescribing of controlled substances and limit excess unused controlled substances that could be diverted.

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

The Board, along with many other state agencies and boards, determined that consistent regulation of controlled substance prescribing, would effectively treat patient's pain while reducing risks of inappropriate controlled substance prescribing, including diversion and patient death.

Regulatory Flexibility

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

Treatment of patients with controlled substances, including opioids, is a complex matter which impacts the health and safety of patients. The public safety requirements relevant to these rules require consistency in their application to all licensees and are not amenable to exemptions or alternative means of compliance for small business.

19. 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?

Due process requires the Medical Board to consistently apply its rules regarding controlled substance prescribing such that all prescriber licensees are equally treated.

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

Medical Board staff members are available by telephone and e-mail to answer questions.

4731-11-01 **Definitions.**

As used in Chapter 4731-11 of the Administrative Code:

(A) "Controlled substance" means a drug, compound, mixture, preparation, or substance included in schedule I, II, III, IV, or V pursuant to the provisions of Chapter 3719. of the Revised Code and Chapter 4729:9-1 of the Administrative Code.

(B) "Controlled substance stimulant" means any drug, compound, mixture, preparation, or substance which is classified as a stimulant in controlled substance schedule II, III, or IV listed in Chapter 4729:9-1 of the Administrative Code, or which is classified as a stimulant in controlled substances schedule II, III, or IV pursuant to Chapter 4729:9-1 of the Administrative Code.

(C) "Cross-coverage" means an agreement between an Ohio-licensed physician and another Ohio licensed physician or healthcare provider acting within the scope of their professional license under which the physician provides medical services for an active patient, as that term is defined in paragraph (D) of rule this rule, of the other physician or healthcare provider who is temporarily unavailable to conduct the evaluation of the patient.

(1) This type of agreement includes on-call coverage for after hours and weekends.

(2) The medical evaluation required by paragraph (C) of rule 4731-11-09 of the Administrative Code may be a limited evaluation conducted through interaction with the patient.

(D) For purposes of paragraph (D) of rule 4731-11-09 of the Administrative Code, "active patient" as that term is used in paragraph (C) of this rule, means that within the previous twenty-four months the physician or other healthcare provider acting within the scope of their professional license conducted at least one in-person medical evaluation of the patient or an evaluation of the patient through the practice of telemedicine as that term is defined in 21 C.F.R. 1300.04, in effect as of the effective date of this rule.

(E) "Utilize a controlled substance or controlled substance stimulant" means to prescribe, administer, dispense, supply, sell or give a controlled substance or controlled substance stimulant.

(F) "Recognized contraindication" means any contraindication to the use of a drug which is listed in the United States food and drug administration (hereinafter, "F.D.A.") approved labeling for the drug, or which the board determines to be accepted as a contraindication.

(G) "The board" means the state medical board of Ohio.

(H) "BMI" means body mass index, calculated as a person's weight in kilograms divided by height in meters squared.

(I) "Physician" means an individual holding a certificate under Chapter 4731. of the Revised Code to practice medicine and surgery, osteopathic medicine and surgery, or podiatric medicine and surgery and practicing within his or her scope of practice as defined by section 4731.51 of the Revised Code.

(J) "Board certified addictionologist or addiction psychiatrist" means a medical doctor or doctor of osteopathic medicine and surgery who holds one of the following certifications:

(1) Subspecialty board certification in addiction psychiatry from the american board of psychiatry and neurology;

(2) Board certification in addiction medicine from the american board of addiction medicine;

(3) Certification from the American society of addiction medicine;

(4) Subspecialty certification in addiction medicine from the American board of preventive medicine; or

(5) Board certification with additional qualification in addiction medicine from the American osteopathic association.

(K) "Office based opioid treatment (OBOT)" "OBOT" means treatment of opioid addiction utilizing a schedule III, IV or V controlled substance narcotic.

(L) "Acute pain" means pain that normally fades with healing, is related to tissue damage, significantly alters a patient’s typical function and is expected to be time limited and not more than six weeks in duration.

(M) "Minor" has the same meaning as in section 3719.061 of the Revised Code.

(N) "Morphine equivalent daily dose (MED)" means a conversion of various opioid analgesics to a morphine equivalent dose by the use of accepted conversion tables provided by the state of Ohio board of pharmacy at: https://www.ohiopmp.gov/

(effective 2017).

(O) "Extended-release or long-acting opioid analgesic" means an opioid analgesic that:

(1) Has United States food and drug administration approved labeling indicating that it is an extended-release or controlled release formulation;

(2) Is administered via a transdermal route; or

(3) Contains methadone.

(P) "Opioid analgesic" has the same meaning as in section 3719.01 of the Revised Code and means a controlled substance that has analgesic pharmacologic activity at the opioid receptors of the central nervous system, including but not limited to the following drugs and their varying salt forms or chemical congeners: buprenorphine, butorphanol, codeine (including acetaminophen and other combination products), dihydrocodeine, fentanyl, hydrocodone (including acetaminophen combination products), hydromorphone, meperidine, methadone, morphine sulfate, oxycodone (including acetaminophen, aspirin, and other combination products), oxymorphone, tapentadol, and tramadol.

(Q) "Hospice care program" has the same meaning as in section 3712.01 of the Revised Code.

(R) "Palliative care" has the same meaning as in section 3712.01 of the Revised Code.

(S) "Terminal condition" means an irreversible, incurable, and untreatable condition caused by disease, illness, or injury from which, to a reasonable degree of medical certainty as determined in accordance with reasonable medical standards by a physician who has examined the patient, both of the following apply:

(1) There can be no recovery.

(2) Death is likely to occur within a relatively short time if life-sustaining treatment is not administered.

(T) "Medication therapy management" has the same meaning as in rule 4729:5-12-01 of the Administrative Code.

(U) "Subacute pain" means pain that has persisted after reasonable medical efforts have

been made to relieve it and continues either episodically or continuously for more than six weeks but less than twelve weeks following initial onset of pain. It may be the result of underlying medical disease or condition, injury, medical or surgical treatment, inflammation, or unknown cause.

(V) "Chronic pain" means pain that has persisted after reasonable medical efforts have been made to relieve it and continues either episodically or continuously for twelve or more weeks following initial onset of pain. It may be the result of an underlying medical disease or condition, injury, medical treatment, inflammation, or unknown cause. "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.

(W) "Board certification in hospice and palliative care" means either of the following:

(1) Subspecialty certification in hospice and palliative medicine granted by a certification board that is a member of the American board of medical specialties.

(2) Certification of added qualification in hospice and palliative medicine by the American osteopathic association bureau of medical specialties.

(X) "Board certification in hematology" means specialty or subspecialty certification in hematology or a related hematology specialty or subspecialty by a certification board that is a member of the American board of medical specialties or by the American osteopathic ~~ostepathic~~ association bureau of medical specialties.

(Y) "Board certification in oncology" means specialty or subspecialty certification in oncology or a related oncology specialty or subspecialty by a certification board that is a member of the American board of medical specialties or American osteopathic association bureau of medical specialties.

(Z) "Board certification in pain medicine" means any of the following:

(1) Current subspecialty certification in pain medicine by a member board of the American board of medical specialties, or current certificate of added qualification in pain medicine by the American osteopathic association bureau of osteopathic specialists;

(2) Current board certification by the American board of pain medicine; or

(3) Current board certification by the American board of interventional pain physicians.

4731-11-13 **Prescribing of opiate analgesics for acute pain.**

(A) For the treatment of acute pain, the physician shall comply with the following:

(1) Extended-release or long-acting opioid analgesics shall not be prescribed for treatment of acute pain;

(2) Before prescribing an opioid analgesic, the physician shall first consider non-opioid treatment options. If opioid analgesic medications are required as determined by a history and physical examination, the physician shall prescribe for the minimum quantity and potency needed to treat the expected duration of pain, with a presumption that a three-day supply or less is frequently sufficient and that limiting the duration of opioid use to the necessary period will decrease the likelihood of subsequent chronic use or dependence;

(3) In all circumstances where opioid analgesics are prescribed for acute pain:

(a) Except as provided in paragraph (B) of this rule, the duration of the first opioid analgesic prescription for the treatment of an episode of acute pain shall be:

(i) For adults, not more than a seven-day supply with no refills;

(ii) For minors, not more than a five-day supply with no refills. A physician shall comply with section 3719.061 of the Revised Code, including but not limited to obtaining from the parent, guardian, or another adult who is authorized to consent to the minor's medical treatment written consent prior to prescribing an opioid analgesic to a minor;

(iii) The seven-day limit for adults and five-day limit for minors may be exceeded for pain that is expected to persist for longer than seven days based on the pathology causing the pain. In this circumstance, the reason that the limits are being exceeded and the reason that a non-opioid medication was not appropriate to treat the patient’s conditions shall be documented in the patient’s medical record. The number of days of the prescription shall not exceed the amount required to treat the expected duration of the pain as noted in paragraph (A) (2) of this rule; and

(iv) If a patient is allergic to or otherwise unable to tolerate the initially prescribed opioid medication, a prescription for a different,

appropriate opioid may be issued at any time during the initial seven or five-day dosing period and shall be subject to all other provisions of this rule. The allergy and/or intolerance shall be documented in the patient's medical record. The patient or the minor patient's parent, guardian or another adult who is authorized to consent to the minor's medical treatment must be provided education of the safe disposal of the unused medication.

(b) The patient, or a minor's parent or guardian, shall be advised of the benefits and risks of the opioid analgesic, including the potential for addiction, and the advice shall be documented in the patient's medical record; and

(c) The total morphine equivalent dose (MED) of a prescription for opioid analgesics for treatment of acute pain shall not exceed an average of thirty MED per day, except when all of the following apply:

(i) The patient suffers from medical conditions, surgical outcomes or injuries of such severity that pain cannot be managed within the thirty MED average limit as determined by the treating physician based upon prevailing standards of medical care, such as:

(a) Traumatic crushing of tissue;

(b) Amputation;

(c) Major orthopedic surgery;

(d) Severe burns

(ii) The physician determines that exceeding the thirty MED average limit is necessary based on the physician's clinical judgment and the patient's needs.

(iii) The physician shall document in the patient's medical record the reason for exceeding the thirty MED average and the reason it is the lowest dose consistent with the patient's medical condition.

(iv) Only the prescribing physician for the conditions in paragraph (A)(3)(c)(i) of this rule may exceed the thirty MED average. The prescribing physician shall be held singularly accountable for

prescriptions that exceed the thirty MED average.

(v) In circumstances when the thirty MED average is exceeded, the dose shall not exceed the dose required to treat the severity of the pain as noted in paragraph (A)(2) of this rule.

(d) Prescriptions that exceed the five or seven day supply or thirty MED average daily dose are subject to additional review by the state medical board. The dosage, days supplied, and condition for which the opioid analgesic is prescribed will be considered as part of this additional review.

(B) The requirements of paragraph (A) of this rule apply to treatment of acute pain and do not apply when an opioid analgesic is prescribed:

(1) To an individual who is a hospice patient or in a hospice care program;

(2) To an individual receiving palliative care;

(3) To an individual who has been diagnosed with a terminal condition; or

(4) To an individual who has cancer or another condition associated with the individual’s cancer or history of cancer.

(C) This rule does not apply to prescriptions for opioid analgesics for the treatment of opioid addiction utilizing a schedule III, IV or V controlled substance narcotic that is approved by the federal drug administration for opioid detoxification or maintenance treatment.

(D) This rule does not apply to inpatient prescriptions as defined in Chapter 4729. of the Revised Code.

4731-11-14 Prescribing for subacute and chronic pain.

(A) Prior to treating, or continuing to treat subacute or chronic pain with an opioid analgesic, the physician shall first consider and document non-medication and non-opioid treatment options.

(1) If opioid analgesic medications are required as determined by a history and physical examination, the physician shall prescribe for the minimum quantity and potency needed to treat the expected duration of pain and improve the patient's ability to function.

(2) The physician shall comply with the requirements of rule 4731-11-02 of the Administrative Code.

(B) Before prescribing an opioid analgesic for subacute or chronic pain, the physician shall complete or update and document in the patient record assessment activities to assure the appropriateness and safety of the medication including:

(1) History and physical examination including review of previous treatment and response to treatment, patient's adherence to medication and non-medication treatment, and screening for substance misuse or substance use disorder;

(2) Laboratory or diagnostic testing or documented review of any available relevant laboratory or diagnostic test results. If evidence of substance misuse or substance use disorder exists, diagnostic testing shall include urine drug screening;

(3) Review the results of an OARRS check in compliance with rule 4731-11-11 of the Administrative Code;

(4) A functional pain assessment which includes the patient's ability to engage in work or other purposeful activities, the pain intensity and its interference with activities of daily living, quality of family life and social activities, and the physical activity of the patient;

(5) A treatment plan based upon the clinical information obtained, to include all of the following components:

(a) Diagnosis;

(b) Objective goals for treatment;

(c) Rationale for the medication choice and dosage; and

(d) Planned duration of treatment and steps for further assessment and follow-up.

(6) Discussion with the patient or guardian regarding:

(a) Benefits and risks of the medication, including potential for addiction and risk of overdose; and

(b) The patient's responsibility to safely store and appropriately dispose of the medication.

(7) The physician shall offer a prescription for an overdose reversal drug to the patient receiving an opioid analgesic prescription under any of the following circumstances:

(a) The patient has a history of prior opioid overdose;

(b) The dosage prescribed exceeds a daily average of eighty MED or at lower doses if the patient is co-prescribed a benzodiazepine, sedative hypnotic drug, carisprodol, tramadol, or gabapentin; or

(c) The patient has a concurrent substance use disorder.

(C) Prior to increasing the opioid dosage to a daily average of fifty MED or greater the physician shall complete and document the following in the patient's medical record:

(1) The physician shall review and update the assessment completed in paragraph (B) of this rule, if needed. The physician may rely on an appropriate assessment completed within a reasonable time if the physician is satisfied that he or she may rely on that information for purposes of meeting the further requirements of this chapter of the Administrative Code;

(2) The physician shall update or formulate a new treatment plan, if needed;

(3) The physician shall obtain from the patient or the patient's guardian written informed consent which includes discussion of all of the following:

(a) Benefits and risks of the medication, including potential for addiction and risk of overdose.

(b) The patient's responsibility to safely store and appropriately dispose of the medication.

(4) Except when the patient was prescribed an average daily dosage that exceeded fifty MED before the effective date of this rule, the physician who is neither a specialist in the area of the body affected by the pain nor a pain management specialist shall document consideration of the following:

(a) Consultation with a specialist in the area of the body affected by the pain;

(b) Consultation with a pain management specialist;

(c) Obtaining a medication therapy management review by a pharmacist; and

(d) Consultation with a specialist in addiction medicine or addiction psychiatry, if aberrant behaviors indicating medication misuse or substance use disorder are noted.

(5) The physician shall consider offering a prescription for an overdose reversal drug to mitigate risk of overdose.

(D) Prior to increasing the opioid dosage to a daily average of eighty MED or greater, the physician shall complete all of the following:

(1) Enter into a written pain treatment agreement with the patient that outlines the physician's and patient's responsibilities during treatment and requires the patient or patient guardian's agreement to all of the following provisions:

(a) Permission for drug screening and release to speak with other practitioners concerning the patient's condition or treatment;

(b) Cooperation with pill counts or other checks designed to assure compliance with the treatment plan and to minimize the risk of misuse or diversion;

(c) The understanding that the patient shall only receive opioid medications from the physician treating the chronic pain unless there is written

agreement among all of the prescribers of opioids outlining the responsibilities and boundaries of prescribing for the patient; and

(d) The understanding that the dosage may be tapered if not effective or if the patient does not abide by the treatment agreement.

(2) Offer a prescription for an overdose reversal drug to the patient as described in paragraph (B) of this rule.

(3) Except when the patient was prescribed an average daily dosage that exceeded eighty MED before the effective date of this rule, the physician who is neither a specialist in the area of the body affected by the pain nor a pain management specialist shall obtain at least one of the following based upon the patient's clinical presentation:

(a) Consultation with a specialist in the area of the body affected by the pain;

(b) Consultation with a pain management specialist;

(c) Obtain a medication therapy management review; or

(d) Consultation with a specialist in addiction medicine or addiction psychiatry if aberrant behavior indicating medication misuse or substance use disorder may be present.

(E) The physician shall not prescribe a dosage that exceeds an average of one hundred twenty MED per day. This prohibition shall not apply in the following circumstances:

(1) The physician holds board certification in pain medicine, board certification in hospice and palliative care, board certification in hematology, or board certification in oncology;

(2) The physician has received a written recommendation for a dosage exceeding an average of one hundred twenty MED per day from a board certified pain medicine physician or board certified hospice and palliative care physician who based the recommendation on a face-to-face visit and examination of the patient. The prescribing physician shall maintain the written recommendation in the patient's record; or

(3) The patient was receiving an average daily dose of one hundred twenty MED or more prior to the effective date of this rule. The physician shall follow the steps in paragraph (E)(2) of this rule prior to escalating the patient's dose.

(F) During the course of treatment with an opioid analgesic at doses below the average of fifty MED per day, the physician shall provide periodic follow-up assessment and documentation of the patient's functional status, the patient's progress toward treatment objectives, indicators of possible addiction, drug abuse or drug diversion and the notation of any adverse drug effects.

(G) During the course of treatment with an opioid analgesic at doses at or above the average of fifty MED per day, the physician shall complete and document in the patient record the following no less than every three months:

(1) Review of the course of treatment and the patient's response and adherence to treatment.

(2) The assessment shall include a review of any complications or exacerbation of the underlying condition causing the pain through appropriate interval history, physical examination, any appropriate diagnostic tests, and specific treatments to address the findings.

(3) The assessment of the patient's adherence to treatment including any prescribed non-pharmacological and non-opioid treatment modalities;

(4) Rationale for continuing opioid treatment and nature of continued benefit, if present.

(5) The results of an OARRS check in compliance with rule 4731-11-11 of the Administrative Code.

(6) Screening for medication misuse or substance use disorder. Urine drug screen should be obtained based on clinical assessment of the physician with frequency based upon presence or absence of aberrant behaviors or other indications of addiction or drug abuse.

(7) Evaluation of other forms of treatment and the tapering of opioid medication if continued benefit cannot be established.

(H) This rule does not apply to the physician who prescribes an opioid in any of the following situations:

(1) The medication is for a patient in hospice care.

(2) The patient has terminal cancer or another terminal condition, as that term is defined in rule 4731-11-01 of the Administrative Code.

(I) This rule does not apply to inpatient prescriptions or medication orders as defined in paragraph (J) of rule 4729:5-9-01~~4729-17-01~~ of the Administrative Code.

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 an institution or facility that provides inpatient medical or surgical services for a continuous period longer than twenty-four hours as defined in section 3722.01 ~~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 management clinic" means a facility in which 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.

(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.

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

(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 medicine by the American board of medical specialties, or hold a current certificate of added qualification in pain 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.

(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, and all applicable provisions of federal law governing the possession, distribution or use of controlled substances.

(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~~ 4731-11-14 of the Administrative Code in lieu of the requirements of paragraphs (E)(6)(a)(i) to (E)(6)(a)(vi) of this rule.