



Common Sense Initiative

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Business Impact Analysis

Agency Name: State Medical Board of Ohio

Regulation/Package Title: Subacute and Chronic Pain Rules

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

Date: 3/19/19

Rule Type:

New

Amended

5-Year Review

Rescinded

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 all regulations 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.

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.

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Proposed Rule 4731-11-01(X) and (Y) definitions of board certified hematologists and board certified oncologists.

Proposed Rule 4731-11-14(E)(1) exempts board certified hematologists and board certified oncologists from the prohibition against prescribing dosages in excess of an average of 120 Morphine Equivalent Dose to patients.

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

The rules are authorized by Sections 3719.062, 4730.39, 4730.07, 4731.052 and 4731.05 of the 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 rules do 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.

This question is 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)?

Ohio is experiencing an opioid epidemic that negatively impacts public health resulting in profound consequences to Ohio's economy and way of life. The state's professional licensing boards take action by rule to help affect change and improve health outcomes. The public purpose for the overall rule package is to establish standards and checkpoints between the physician and patient when prescribing opioids for the treatment of subacute or chronic pain.

The rules became effective in December 2018. Shortly after that time, the Board became aware of two issues that were causing unintended consequences and delays for patients. First, the Board became aware, through interested parties, that non-terminal cancer patients often had pain which required pain medication that exceeded the 120 MED average daily dose and these patients were experiencing delays getting in to see board-certified pain management specialists and board-certified hospice and palliative care specialists. Exempting board-certified hematologists and oncologists from the prohibition in prescribing in excess of 120MED allows those physicians to provide prescriptions to their non-terminal cancer patients without delay.

In addition, the Board became aware that the definition of "terminal" was also causing delays for patients. Terminal patients are exempted from the rule and the definition in Section 2133.01, Ohio Revised Code was used. The language in Section 2133.01 requires a second opinion for determining that a patient has a terminal condition. This was resulting in a delay

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for these patients in obtaining appropriate pain relief. The proposed definition of terminal condition removes this requirement for a second opinion.

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

Outcomes reflecting the impact on subacute and chronic opioid prescribing resulting in benefits for public safety will be measured by OARRS data, public health and law enforcement statistics. 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.

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 Board received feedback on the unintended consequences of the rule from various physicians and the Ohio Hospital Association. The Board also consulted with Dr. Mark Hurst of the Department of Mental Health and Addiction Services, Dr. Clint Koenig of the Ohio Department of Health, and Dr. Amol Soin, a pain management physician and member of the Medical Board.

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

The input caused the Board to move forward with amendments to a rule that only became effective in December 2018.

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?

Scientific data and data from OARRS was used in the original development of the rule. The Board did not utilize additional scientific data for these limited amendments.

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?

The proposed amendments directly address the concerns that were raised.

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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 Board did not propose performance-based regulations in this rule package due to the necessity of setting established processes and standards to achieve its public protection mandate.

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

The Medical Board has worked with other healthcare licensing agencies in the original promulgation of the rule and has notified other healthcare licensing agencies of the proposed amendments.

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.

The rules will be posted on the Medical Board's website, information concerning the rules will be included in informational materials e-mailed to licensees, and notices will be sent to associations, individuals, and groups. 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 physician practice regulations

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;

The scope of the impacted business community would be licensees of the Medical Board who are authorized to prescribe controlled substances, including opioids. This includes physicians holding a M.D., D.O., or D.P.M. license and physician assistants who are authorized to prescribe.

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

The amendments will lessen the adverse impact by allowing board-certified hematologists and oncologists to prescribe higher doses to their cancer patients, when necessary to relieve pain. In addition, the amendments will eliminate the requirement for a second opinion to determine that a patient has a terminal condition.

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.

Individuals who receive formal disciplinary action for violating these rules will be subject to civil penalties as set forth in 4731.225, Ohio Revised Code.

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

The State has a compelling interest in promoting safe treatment of pain while avoiding risks of harm to patients. Allowing some additional options for cancer patients and patient with terminal conditions is consistent with this interest.

Regulatory Flexibility

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

Treatment of patients with 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 businesses.

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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?

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

18. 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.
- (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 section 3719.41 of the Revised Code, or which is classified as a stimulant in controlled substances schedule II, III, or IV pursuant to section 3719.43 or 3719.44 of the Revised 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", or "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” ~~has the same meaning as in section 2133.01 of the Revised Code~~ 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 certified hematologist" means a medical doctor or doctor of osteopathic medicine and surgery who holds one of the following certifications:

- (1) Subspecialty board certification in hematology from the American board of internal medicine;
- (2) Subspecialty board certification in pediatric hematology-oncology from the American board of pediatrics;
- (3) Board certification with additional qualification in hematology from the American osteopathic association;

(Y) "Board certified oncologist" means a medical doctor or doctor of osteopathic medicine and surgery who holds one of the following certifications:

- (1) Subspecialty board certification in medical oncology from the American board of internal medicine;
- (2) Subspecialty board certification in gynecologic oncology from the American board of obstetrics and gynecology;
- (3) Subspecialty board certification in pediatric hematology-oncology from the

American board of pediatrics;

(4) Subspecialty board certification in complex general surgical oncology from the American board of surgery;

(5) Board certification with additional qualification in oncology from the American osteopathic association;

(6) Board certification with additional qualification in gynecological oncology from the American osteopathic association.

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 naloxone 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 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 naloxone 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 naloxone 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, 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, ~~or~~ 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 ~~section 2133.01 of the Revised~~ [rule 4731-11-01 of the Administrative Code](#).

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