

CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: State Medical Board of Ohio

Regulation/Package Title: Chapter 4731-21, Drug Treatment of Intractable Pain

Rule Number(s): 4731-21-01, 4731-21-02, 4731-21-03, 4731-21-04, 4731-21-05, 4731-21-06

Date: July 11, 2016

Rule Type:

New

5-Year Review

Amended

Rescinded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.

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The rules in Chapter 4731-21, OAC, regulate prescribing for what was formerly termed “intractable pain.” The proposed amendments include changing the designation to “chronic pain.” The rules apply to physicians and physician assistants.

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

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

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 rules in Chapter 4731-21, OAC, promote the protection of the public by setting standards for the treatment of pain by the utilization of drugs categorized by the Federal Drug Administration as controlled substances because they pose the possibility of dependence or addiction.

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

The success of the rules will be measured by the number of disciplinary actions brought against physicians and physician assistants for violation of the rules.

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 Medical Board first starting reviewing the Chapter 4731-21 rules in 2012. On April 4, 2012 and April 18, 2012, the Medical Board held telephone conferences with a panel of

physicians specializing in pain management, physician specializing in addiction, and representatives of the Ohio Board of Pharmacy, Ohio Board of Nursing, Ohio State Medical Association, Ohio Academy of Family Medicine, Academy of Medicine of Cleveland and Northern Ohio, and other organizations to discuss the current rules. The review ended, however, when the Governor formed the Governor’s Cabinet Opioid Action Team (“GCOAT”), and the Medical Board was invited to participate in addressing the prescription drug abuse problems via guidelines approved by agencies and organization under GCOAT’s leadership.

In 2016, however, review of the current rules in Chapter 4731-21 was undertaken once more. The proposed rules were sent via email to interested parties on February 12, 2016 to organizations such as, 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 and the Ohio Department of Health, and all other persons and organizations who have requested notice of Medical Board rule activity.

The proposed rules were also reviewed by the Physician Assistant Policy Committee (“PAPC”) of the Medical Board, which is comprised of physician assistants, physicians, and a public member. Section 4730.06 of the Revised Code, requires that PAPC review and submit recommendations to the Medical Board on matters involving physician assistant practice and prescribing.

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

The 2012 panel members generally recognized that many of the current requirements in the rules promote appropriate prescribing and patient care. A majority of the panel members recommended that urine drug screens should be utilized to monitor the patient’s use, except for hospice patients.

No comments were received from the February notice to interested parties.

On March 8, 2016, PAPC recommended that the Medical Board proceed with the rules as proposed.

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?

The amendment from “intractable pain” to “chronic pain” is made pursuant to Section 4731.052 of the Revised Code.

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Many opioid addicts were first exposed to opioid drugs through prescriptions for legitimate pain issues. See the GCOAT website at: <http://mha.ohio.gov/Default.aspx?tabid=828>. Accordingly, the current rules were reviewed for ways to balance the need to protect the public from prescribing practices that might lead to addiction or dependency and the practitioner's ability to use medical knowledge in the utilization of prescription drugs to treat chronic pain. The proposed amendments reflect information from GCOAT, the 2012 panel discussions, and the provisions of Sections 4731.052 and 4731.055 of the Revised Code.

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 Medical Board's proposed rules are required by Section 4731.052 of the Revised Code. There was consideration of a requirement for physicians and physician assistants who prescribe prescription drugs for chronic pain to complete continuing medical education related to treating chronic pain. It was decided not to include the requirement because there was no support for it.

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 rules are performance based. Instead of prohibitions, Rule 4731-21-02 requires documentation of the factors relied upon by the practitioner in determining to prescribe prescription drugs for the treatment of chronic pain. While certain activities are required, the rules do not mandate how the activities are to be performed. For example, Rule 4731-21-02(B)(3) requires the use of a drug screen when there is evidence of addiction or drug abuse. However, the rule also clearly states that it is within the practitioner's discretion to decide the nature of the screen and the type of drugs screened for.

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 regulate prescribing by physicians and physician assistants. In addition, the Medical Board actively consulted with the Board of Pharmacy and State Board of Nursing.

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 circulated to all physicians and physician assistants via email. Notice of their adoption will also be sent via email to all organizations and persons who have provided input and/or who receive notice of Medical Board rule activities.

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 business community impacted is made up of Ohio licensed physicians and physician assistants who prescribe prescription drugs for chronic pain. The physicians and physician assistants may specialize in such areas as, but not limited to, pain management, rheumatology, family medicine, or physical medicine and rehabilitation.

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

Rule 4731-21-01 defines practitioner has a physician, podiatric physician, or physician assistant who is licensed in Ohio.

The rules require the practitioner to obtain and review the patient's records of prior treatment for chronic pain, document information, including a treatment plan, in the patient record, and obtain the patient's prescription history, if any, from the prescription monitoring system ("OARRS") maintained by the Board of Pharmacy. These requirements take time, which may result in the practitioner not being able to see an unlimited number of patients in one day. Moreover, Rule 4731-21-02 requires the practitioner to take certain actions if there are indications that the patient may be showing signs of dependency, addiction, or abuse of the prescribed drugs. Some physicians argue that this impinges on their ability to practice medicine without government interference.

A practitioner who violates the rules is subject to administrative discipline on their license and may also have a monetary penalty imposed.

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.

The license fees for a physician include \$35 for the preliminary education certificate, \$300 for the licensure application fee, and \$305 for renewal every two years. The license fees for a physician assistant include \$500 for the licensure application fee and \$200 for renewal each two years.

The cost of the practitioner having to undertake certain actions, such as documenting in the patient record, is not able to be quantified in terms of dollars. It depends upon such factors as the practitioner's fee, whether electronic medical records are employed, whether the office employs unlicensed persons to act as a scribe for the physician and/or to serve as a delegate to obtain OARRS reports. More over, it is arguable that a practitioner practicing within the minimal standards of care would already be completing these activities.

The discipline that may result from a violation of the rules includes action on the license ranging from reprimand to permanent revocation and a civil penalty of up to \$20,000. See the Medical Board's Fining Guidelines on the Medical Board's website at: <http://med.ohio.gov/Portals/0/DNN/PDF-FOLDERS/For-The-Public/FiningGuidelinesIncludingCivilPenalties.pdf>.

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 4731.052 of the Revised Code. Moreover, the rules facilitate the protection of the public by providing standards under which rogue prescribers are subject to review and possible discipline.

Regulatory Flexibility

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

There are no exemptions or alternative means of compliance for small business. Many medical practices qualify as "small businesses." The patient population must be able to trust that all physicians are held to the same standards, whether they physicians practice in a large medical facility or a one-physician medical practice.

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?

There are no requirements to submit paperwork to the Medical Board. However, Rule 4731-21-02(A) does require the physician (or physician assistant) to document in the patient record, among other things, symptoms, findings, the individualized treatment plan, and

consent for treatment. The fines, civil penalties, and other disciplinary action will not be waived because failure to document the required information is a mechanism employed by rogue prescribers and presents a direct danger to the health or safety of the patient.

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

The Medical Board staff is available to answer questions concerning the rule. Guidance documents explaining rules are created where numerous questions are received concerning compliance.

*** DRAFT - NOT YET FILED ***

4731-21-01

Definitions.

As used in Chapter 4731-21 of the Administrative Code:

(A) "Addiction" means a compulsive disorder in which an individual becomes preoccupied with obtaining and using a substance, despite adverse social, psychological and/or physical consequences, the continued use of which results in a decreased quality of life. Physical dependence alone is not evidence of addiction.

(B) "Believes" or "has reason to believe" does not require absolute certainty or complete unquestioning acceptance; but only an opinion based on reasonable information that a patient is suffering from addiction or drug abuse or engaging in diversion of drugs.

(C) "Board" means the state medical board of Ohio.

(D) "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.

~~(D)~~(E) "Diversion" means the conveyance of a prescription drug to a person other than the person for whom the drug was prescribed or dispensed by a practitioner.

~~(E)~~(F) "Drug abuse" means a maladaptive or inappropriate use or overuse of a medication.

~~(F)~~(G) "Emergency" means an unforeseen combination of circumstances or the resulting state that calls for immediate action.

~~(G)~~(H) "Intractable pain" means a state of pain that is determined, after reasonable medical efforts have been made to relieve the pain or cure its cause, to have a cause for which no treatment or cure is possible or for which none has been found. "Intractable pain" does not include pain experienced by a patient with a terminal condition. "Intractable pain" does not include the treatment of pain associated with a progressive disease that, in the normal course of progression, may reasonably be expected to result in a terminal condition.

~~(H)~~(I) "Pain" means an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage.

~~(I)~~(J) "Physical dependence" means a physiologic state of adaptation to a specific drug or

medication characterized by the development of a withdrawal syndrome following abrupt cessation of a drug or on administration of an antagonist.

~~(H)~~(K) "Practitioner" means any of the following:

- (1) An individual holding a certificate to practice medicine and surgery or osteopathic medicine and surgery under Chapter 4731. of the Revised Code;
- (2) An individual holding a certificate to practice podiatric medicine and surgery under Chapter 4731. of the Revised Code and practicing within his or her scope of practice as defined in section 4731.51 of the Revised Code; or
- (3) An individual holding both of the following:
 - (a) A certificate to practice as a physician assistant under Chapter 4730. of the Revised Code and practicing within his or her scope of practice in compliance with that chapter; and
 - (b) A certificate to prescribe under Chapter 4730. of the Revised Code and exercising physician delegated prescriptive authority in compliance with that chapter.

~~(K)~~(L) "Prescription drug" means a drug which under state or federal law may be administered or dispensed only by or upon the order of a practitioner and includes the term "dangerous drug" as defined by section 4729.02 of the Revised Code.

~~(H)~~(M) "Protracted basis" means for a period in excess of twelve continuous weeks.

~~(M)~~(N) "Terminal condition" means an irreversible, incurable, and untreatable condition caused by disease, illness, or injury, which will likely result in death. A terminal condition is one in which there can be no recovery, although there may be periods of remission.

A terminal condition shall be determined to a reasonable degree of medical certainty in accordance with reasonable medical standards by a patient's attending medical doctor or doctor of osteopathic medicine and one other individual holding a certificate under Chapter 4731. of the Revised Code to practice medicine and surgery or osteopathic medicine and surgery who has examined the patient.

~~(N)~~(O) "Tolerance" means decreasing response to the same dosage of a prescription drug over time as a result of physiologic adaptation to that drug.

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4731-21-01

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~~(O)~~(P) "Utilizing prescription drugs" means prescribing, administering, dispensing, supplying, selling or giving a prescription drug.

4731-21-02

Utilizing prescription drugs for the treatment of **intractable chronic** pain.

(A) When utilizing any prescription drug for the treatment of **intractable chronic** pain ~~on a protracted basis or when managing intractable pain with prescription drugs in amounts or combinations that may not be appropriate when treating other medical conditions~~, a practitioner shall comply with accepted and prevailing standards of care which shall include, but not be limited to, the following:

- (1) An initial evaluation of the patient shall be conducted and documented in the patient's record that includes a relevant history, including complete medical, pain, alcohol and substance abuse histories; an assessment of the impact of pain on the patient's physical and psychological functions; a review of previous diagnostic studies and previously utilized therapies; an assessment of coexisting illnesses, diseases or conditions; and an appropriate physical examination;
- (2) A medical diagnosis shall be established and documented in the patient's medical record that indicates not only the presence of **intractable chronic** pain but also the signs, symptoms, and causes and, if determinable, the nature of the underlying disease and pain mechanism;
- (3) An individualized treatment plan shall be formulated and documented in the patient's medical record. The treatment plan shall specify the ~~medical justification of the treatment of intractable pain by utilizing prescription drugs on a protracted basis or in amounts or combinations that may not be appropriate when treating other medical conditions~~; treatment proposed, the patient's response to treatment, and any modification to the treatment plan. The treatment plan shall include the medical justification and the intended role of prescription drug therapy within the overall plan, ~~and, when applicable, and~~ documentation that other medically reasonable treatments for relief of the patient's **intractable chronic** pain have been offered or attempted without adequate or reasonable success. The prescription drug therapy shall be tailored to the individual medical needs of each patient. ~~The practitioner shall document the patient's response to treatment and, as necessary, modify the treatment plan;~~
- (4)
 - (a) The practitioner's diagnosis of **intractable chronic** pain shall be made after having the patient evaluated by one or more other practitioners who specialize in the treatment of the anatomic area, system, or organ of the body perceived as the source of the pain. For purposes of this rule, a practitioner "specializes" if the practitioner limits the whole or part of his or her practice, and is qualified by advanced training or experience

to so limit his or her practice, to the particular anatomic area, system, or organ of the body perceived as the source of the pain. The evaluation shall include review of all available medical records of prior treatment of the ~~intractable~~chronic pain or the condition underlying the ~~intractable~~chronic pain; a thorough history and physical examination; and testing as required by accepted and prevailing standards of care. The practitioner shall maintain a copy of any report made by any practitioner to whom referral for evaluation was made under this paragraph. A practitioner shall not provide an evaluation under this paragraph if that practitioner would be prohibited by sections 4731.65 to 4731.69 of the Revised Code or any other rule adopted by the board from providing a designated health service upon referral by the treating practitioner; and

(b) The practitioner shall not be required to obtain such an evaluation, if the practitioner obtains a copy of medical records or a detailed written summary thereof showing that the patient has been evaluated and treated within a reasonable period of time by one or more other practitioners who specialize in the treatment of the anatomic area, system, or organ of the body perceived as the source of the pain and the treating practitioner is satisfied that he or she can rely on that evaluation for purposes of meeting the further requirements of this chapter of the Administrative Code. The practitioner shall obtain and review all available medical records or detailed written summaries ~~thereof~~ of prior treatment of the ~~intractable~~chronic pain or the condition underlying the ~~intractable~~chronic pain. The practitioner shall maintain a copy of any record or report of any practitioner on which the practitioner relied for purposes of meeting the requirements under this paragraph; and

(5) The practitioner shall ensure and document in the patient's record that the patient or other individual who has the authority to provide consent to treatment on behalf of that patient gives consent to treatment after being informed of the benefits and risks of receiving prescription drug therapy ~~on a protracted basis or in amounts or combinations that may not be appropriate when treating other medical conditions;~~ for chronic pain and after being informed of available treatment alternatives.

(B) Upon completion and satisfaction of the conditions prescribed in paragraph (A) of this rule, and upon a practitioner's judgment that the continued utilization of prescription drugs is medically warranted for the treatment of ~~intractable~~chronic pain, a practitioner may utilize prescription drugs ~~on a protracted basis or in amounts or combinations that may not be appropriate when treating other medical conditions;~~ provided that the practitioner continues to adhere to accepted and prevailing standards of care which shall include, but not be limited to, the

following:

- (1) Patients shall be seen by the practitioner at appropriate periodic intervals to assess the efficacy of treatment, assure that prescription drug therapy remains indicated, evaluate the patient's progress toward treatment objectives and note any adverse drug effects. During each visit, attention shall be given to changes in the patient's ability to function or to the patient's quality of life as a result of prescription drug usage, as well as indications of possible addiction, drug abuse or diversion. Compliance with this paragraph of the rule shall be documented in the patient's medical record;
- (2) Some patients with **intractable**[chronic](#) pain may be at risk of developing increasing prescription drug consumption without improvement in functional status. Subjective reports by the patient should be supported by objective data. Objective measures in the patient's condition are determined by an ongoing assessment of the patient's functional status, including the ability to engage in work or other gainful activities, the pain intensity and its interference with activities of daily living, quality of family life and social activities, and physical activity of the patient. Compliance with this paragraph of the rule shall be documented in the patient's medical record;
- (3) Based on evidence or behavioral indications of addiction or drug abuse, the practitioner **may** [shall](#) obtain a drug screen on the patient. It is within the practitioner's discretion to decide the nature of the screen and which type of drug(s) to be screened. If the practitioner obtains a drug screen for the reasons described in this paragraph, the practitioner shall document the results of the drug screen in the patient's medical record. If the patient refuses to consent to a drug screen ordered by the practitioner, the practitioner shall make a referral as provided in paragraph (C) of this rule;
- (4) The practitioner shall document in the patient's medical record the medical necessity for utilizing more than one controlled substance in the management of a patient's **intractable**[chronic](#) pain; and
- (5) The practitioner shall document in the patient's medical record the name and address of the patient to or for whom the prescription drugs were prescribed, dispensed, or administered, the dates on which prescription drugs were prescribed, dispensed, or administered, and the amounts and dosage forms of the prescription drugs prescribed, dispensed, or administered, including refills.
- (6) [The practitioner shall, in accordance with the requirements set forth in section 4731.055 of the Revised Code and rule 4731-11-11 of the Administrative Code, request a report from "OARRS," or the successor drug database](#)

[maintained by the board of pharmacy.](#)

(C) If the practitioner believes or has reason to believe that the patient is suffering from addiction or drug abuse, the practitioner shall immediately consult with an addiction medicine specialist or other substance abuse professional to obtain formal assessment of addiction or drug abuse. .

(1) For purposes of this rule:

(a) Addiction medicine specialist means a physician who is qualified by advanced formal training in addiction medicine or other substance abuse specialty, and includes a medical doctor or doctor of osteopathic medicine who is certified by a specialty examining board to so limit the whole or part of his or her practice.

(b) Substance abuse professional includes a psychologist licensed pursuant to Chapter 4732. of the Revised Code and certified as a clinical health psychologist, an independent chemical dependency counselor, or a chemical dependency counselor III.

(2) The practitioner shall do all of the following:

(a) Document the recommendations of the consultation in the patient's record;

(b) Continue to actively monitor the patient for signs and symptoms of addiction, drug abuse or diversion; and

(c) Maintain a copy of any written report made by the addiction medicine specialist or substance abuse professional to whom referral for evaluation was made under this paragraph.

(3) Prescription drug therapy may be continued consistent with the recommendations of the consultation. If the consulting addiction medicine specialist or other substance abuse professional believes the patient to be suffering from addiction or drug abuse, prompt referral shall be made to one of the following:

(a) An addiction medicine specialist or substance abuse professional; or

(b) An addiction medicine or substance abuse treatment facility.

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4731-21-03

Continuing Medical Education.

The board encourages those practitioners who encounter patients with intractablechronic pain in the usual course of their practices to complete continuing medical education related to the treatment of intractablechronic pain, including coursework related to pharmacology, alternative methods of pain management and treatment, and addiction medicine.

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4731-21-04

Tolerance, physical dependence and addiction.

- (A) Physical dependence and tolerance by themselves do not indicate addiction.
- (B) Physical dependence and tolerance are normal physiological consequences of extended opioid therapy, and do not, in the absence of other indicators of drug abuse or addiction, require reduction or cessation of opioid therapy. [A physician shall refer to rule 4731-11-11 of the Administrative Code for a listing of red flags that indicate possible drug abuse or addiction.](#)

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4731-21-05

Violations.

A violation of any provision of any rule in this chapter of the Administrative Code, as determined by the board, shall constitute "failure to use reasonable care discrimination in the administration of drugs," as that clause is used in division (B)(2) of section 4731.22 of the Revised Code; "selling, prescribing, giving away, or administering drugs for other than legal and legitimate therapeutic purposes," as that clause is used in division (B)(3) of section 4731.22 of the Revised Code, if done knowingly or recklessly, as those words are defined in section 2901.22 of the Revised Code; and "a departure from, or the failure to conform to, minimal standards of care of similar practitioners under the same or similar circumstances, whether or not actual injury to a patient is established," as that clause is used in division (B)(6) of section 4731.22 of the Revised Code.

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4731-21-06

Exceptions.

- (A) A practitioner who treats pain by utilizing prescription drugs is not subject to disciplinary action pursuant to this chapter of the Administrative Code under the following circumstances:
- (1) The treatment of pain for a patient with a terminal condition;
 - (2) The treatment of pain associated with a progressive disease that, in the normal course of progression, may reasonably be expected to result in a terminal condition;
 - (3) Treatment utilizing only drugs that do not exert their effects at the central nervous system level; and
 - (4) Treatment utilizing only drugs that are not controlled substances and are classified as antidepressants.
- (B) A practitioner who treats **intractable**[chronic](#) pain by utilizing prescription drugs is not subject to disciplinary action by the board under section 4731.22 of the Revised Code solely because the practitioner treated the **intractable**[chronic](#) pain with prescription drugs. The practitioner is subject to disciplinary action only if the prescription drugs are not utilized in accordance with section 4731.052 of the Revised Code and the rules adopted under this chapter of the Administrative Code.
- (C) A medical doctor or doctor of osteopathic medicine who provides comfort care as described in division (E)(1) of section 2133.12 of the Revised Code to a patient with a terminal condition is not subject to disciplinary action by the board under section 4731.22 of the Revised Code if the treatment of pain for a patient with a terminal condition is provided pursuant to the requirements of section 2133.11 of the Revised Code.