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RE: Chapter 4731-21 Utilizing Prescription Drugs for the Treatment of Chronic Pain

DATE: February 12, 2016

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Chapter 4731-21, Ohio Administrative Code, sets out rules to regulate prescribing for intractable pain. The proposed amendments include changing the designation to “chronic pain.” The rules apply to physicians and physician assistants. After an initial review of the rules, the Medical Board is proposing no changes to some rules and amendments to others. Primarily, the suggested changes correct any inconsistencies between Section 4731.052, Ohio Revised Code, and the current rules.

The comment deadline is **March 10, 2016**

The following is a summary of the proposed changes:

Rule 4731-21-01 Definitions: Adds new Paragraph (D) to define “chronic pain”, removes the definition of “intractable pain” and “protracted basis” and renumbers the paragraphs.

Rule 4731-21-02 Utilizing Prescription Drugs for the Treatment of Chronic Pain:

Replaces the word “intractable” with “chronic” throughout the rule;

Changes paragraph (B)(3) to require the use of drug screens if evidence or behavioral indications of addiction or drug abuse are seen. Leaves the details of the drug screen up to the practitioner.

Adds paragraph (B)(6) to require OARRS checks in accordance with the Medical Board’s statute and rule.

General clean-up of language throughout the rule.

Rule 4731-21-03 Continuing Medical Education

Replaced the word “intractable” with “chronic”.

The current wording encourages, rather than mandates, practitioners who treat chronic pain to complete continuing medical education related to treating chronic pain. *The Medical Board seeks input on whether such continuing education should be mandatory for all practitioners who have DEA registration.*

Rule 4731-21-04 Tolerance, Physical Dependence and Addiction

Paragraph (B) requires the practitioner to review the listing of red flags in Rule 4731-11-11, Ohio Administrative Code, when assessing possible drug abuse or addiction.

Rule 4731-21-05 Violations

No change proposed

Rule 4731-21-06 Exceptions

Replaced the word “intractable” with “chronic”.

Please send comments to [Sallie.Debolt@med.ohio.gov](mailto:Sallie.Debolt@med.ohio.gov) by **March 10, 2016**.

## 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 for with a progressive disease that, in the normal course of progression, may reasonably be expected to result in a terminal condition.

~~(DE)~~ "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.

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

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

~~(G) "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.~~

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

~~(HI)~~ "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.

~~(I)~~ "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.

~~(JK)~~ "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.

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

~~(KM)~~ "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.

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

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

Promulgated Under: [119.03](#)

Statutory Authority: [4730.07](#), [4730.39](#), [4731.05](#), [4731.052](#)

Rule Amplifies: 4730. 39, [4731.22](#), [4731.052](#)

## **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 chronic 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 treatment proposed, the patient's response to treatment and any modification to the treatment plan. medical justification of the treatment of intractable chronic pain by utilizing prescription drugs on a protracted basis or in amounts or combinations that may not be appropriate when treating other medical conditions, The treatment plan shall include medical justification and the intended role ~~the intended role~~ of prescription drug therapy within the overall plan, and, when applicable, 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 for chronic pain ~~on a protracted basis or in amounts or combinations that may not be appropriate when treating other medical conditions~~, 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.

Promulgated Under: [119.03](#)

Statutory Authority: [4731.05](#), [4731.052](#)

Rule Amplifies: [4731.22](#), [4731.052](#)

## **4731-21-03 Continuing Medical Education.**

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

Promulgated Under: [119.03](#)

Statutory Authority: [4731.05](#), [4731.052](#)

Rule Amplifies: [4731.22](#), [4731.052](#)

## **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.

Promulgated Under: [119.03](#)

Statutory Authority: [4731.05](#), [4731.052](#)

Rule Amplifies: [4731.22](#), [4731.052](#)

## **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.

Promulgated Under: [119.03](#)

Statutory Authority: [4731.05](#), [4731.052](#)

Rule Amplifies: [4731.22](#), [4731.052](#)

## **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 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.

Promulgated Under: [119.03](#)

Statutory Authority: [4731.05](#), [4731.052](#)

Rule Amplifies: [4731.22](#), [4731.052](#)