

POSITION PAPER ON UTILIZING PRESCRIPTION MEDICATIONS FOR THE TREATMENT OF INTRACTABLE PAIN (January 2004)

I. PURPOSE

The purpose of this document is to briefly review the current literature and regulatory requirements pertaining to the use of prescription medications for the treatment of intractable pain, provide the State Medical Board of Ohio rules regarding this treatment, and explain the Ohio Bureau of Workers' Compensation position regarding this type of treatment as it applies to treatment and claim management issues in Ohio Workers' Compensation claims.

II. BACKGROUND

Since the early 1990's there have been several articles in the medical literature addressing the use and lack of use of prescription medications, particularly opioids, by physicians in the treatment of chronic intractable (non-malignant, benign) pain. Several large medical societies have also addressed this issue with position papers, statements, and other documents. Primary reasons generally given for the lack of use of these medications include physician lack of knowledge regarding use and safety of the medications, fear of developing drug addiction/dependence in the patient, and concern regarding regulatory authorities.

Several of these concerns were addressed in a joint statement from health organizations and the Drug Enforcement Administration.¹ The concerns included:

- “Undertreatment of pain is a serious problem in the United States, including pain among patients with chronic conditions and those who are critically ill or near death. Effective pain management is an integral and important aspect of quality medical care, and pain should be treated aggressively.
- For many patients, opioid analgesics when used as recommended by established pain management guidelines are the most effective way to treat their pain, and often the only treatment option that provides significant relief.
- Because opioids are one of several types of controlled substances that have potential for abuse, they are carefully regulated by the Drug Enforcement Administration and other state agencies. For example, a physician must be licensed by State medical authorities and registered with the DEA before prescribing a controlled substance.
- In spite of regulatory controls, drug abusers obtain these and other prescription medications by diverting them from legitimate channels in several ways, including fraud, theft, forged prescriptions, and via unscrupulous health professionals.
- Drug abuse is a serious problem. Those who legally manufacture, distribute, prescribe and dispense controlled substances must be mindful of and have respect for their inherent abuse potential. Focusing only on the abuse potential of a drug,

however, could erroneously lead to the conclusion that these medications should be avoided when medically indicated, generating a sense of fear rather than respect for their legitimate properties.

- Helping doctors, nurses, pharmacists, other healthcare professionals, law enforcement personnel and the general public become more aware of both the use and abuse of pain medications will enable all of us to make proper and wise decisions regarding the treatment of pain.”

In 1998 the Federation of State Medical Boards of the United States, Inc. provided its policy document “Model Guidelines for the Use of Controlled Substances for the Treatment of Pain”. This document could be used by states to create their own guidelines for the use of controlled substances for the treatment of pain. Section I of the document is the “Preamble” and discusses the use of controlled substances, addresses some of the concerns for physicians, and describes the position of a state medical board regarding the use of controlled substances. Section II is “Guidelines” and provides the guidelines and expectations for physicians prescribing controlled substances. These include conducting and documenting a complete medical history and physical examination; the documentation of a treatment plan including objectives; informed consent and agreement for treatment including limiting the patient to receiving prescriptions from one physician and one pharmacy where possible; periodic review of treatment and any new information about the etiology of pain; consultation and physician willingness to refer the patient as necessary; maintenance of medical records and the type of records that should be maintained; and compliance with controlled substances laws and regulations. Section III is “Definitions” and provides a list of definitions for terms used in the guidelines.²

In October 1997 the Ohio General Assembly passed Sub.H.B. 187 which required the State Medical Board of Ohio to establish standards and procedures for physicians regarding the diagnosis and treatment of intractable pain. The State Medical Board of Ohio’s pain management rules became effective in November 11, 1998. These rules are contained in Chapter 4731-21 of the Ohio Administrative Code.³ These rules are to be followed by physicians licensed to practice in the State of Ohio.

III. STATE MEDICAL BOARD OF OHIO ADMINISTRATIVE RULE 4731-21-02

The State Medical Board of Ohio Administrative Rule 4731-21-02 pertains to “utilizing prescription drugs for the treatment of intractable pain”. Appendix A contains this rule.

IV. KEY REGULATORY OR STATUTORY FACTORS REGARDING THE USE OF CONTROLLED SUBSTANCE IN THE TREATMENT OF CHRONIC INTRACTABLE PAIN

Regarding BWC payment of services, the Ohio Administrative Code (OAC) 4123-6-25 (A) states “medical supplies and services will be considered for payment when they are

medically necessary for the diagnosis and treatment of conditions allowed in the claim, are causally related to the conditions allowed in the claim, and are rendered by a health care provider.” In addition, Ohio Administrative Code (OAC) 4123-7-02 states “medical or other services to be approved for payment must be rendered as a direct result of an injury sustained or occupational disease contracted by a claimant in the course of and arising out of employment for which the claim was allowed by an order of the bureau of workers’ compensation or of the industrial commission, or for which the claim was recognized by a self-insuring employer.”

The Ohio Supreme Court ruled in *State ex rel. Miller v. Indus. Comm.* 71 Ohio St. 3d 229, 643 N.E.2d 113 (1994) that a three pronged test must be applied in decisions pertaining to the authorization of medical services. The three prongs or criteria are (1) are the medical services “reasonably related to the industrial injury, that is the allowed conditions”? (2) are the services “reasonably necessary for treatment of the industrial injury”? and (3) is “the cost of such service medically reasonable”?

The State Medical Board of Ohio guidelines RULES for utilizing prescription drugs for the treatment of intractable pain must be followed by physicians in Ohio for prescribing controlled substances. Since these guidelines RULES provide the legal authorization and criteria for use of the prescription drugs for treatment of intractable pain, they must also be followed by physicians providing opinions for authorization of payment of such medications in claims in either file reviews or independent medical evaluations for BWC.

According to 4731-21-01 “Definitions” of The State Medical Board of Ohio Administrative Rules:

“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 experience 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.”

To comply with this definition, reasonable medical efforts should have been made to relieve the pain or cure its cause and that the pain has a cause for which no treatment or cure is possible or at least none has been found. Therefore, intractable pain would be considered only after reasonable medical efforts have been made to diagnose the cause of the pain and adequate and appropriate medical treatment has been provided to treat the cause. Many medical conditions seen in workers’ compensation patients could be considered “intractable pain” such as, but not limited to, complex regional pain syndrome I or the chronic pain frequently associated with lumbar procedures such as postlaminectomy syndrome. Due to wide variance of symptoms and treatment over the clinical course of a condition, not all patients with these allowed conditions in the claim meet the definition of “intractable pain”.

4731-21-02 provides the guidelines or expectations of physicians managing intractable pain with prescription drugs. Paragraph (A) requires an initial evaluation that includes complete medical, pain, alcohol and substance abuse histories; assessment of the impact of pain on physical and psychological functions; review of previous diagnostic studies

and previously utilized therapies; an assessment of coexisting illnesses, diseases or conditions; and an appropriate physical examination. The medical diagnosis must be documented that indicates the intractable pain along with the signs, symptoms, and causes of the pain. An individual treatment plan is required to be documented specifying the medical justification of the treatment of intractable pain with prescription drugs on a protracted basis, the intended role of prescription drug therapy within the overall plan, and other medically reasonable treatment for relief of the intractable pain that have been offered or attempted without adequate or reasonable success. The response to the treatment must be documented along with modifications to the treatment plan. Section (4)(a) of Paragraph (A) states that the diagnosis of intractable pain can be made only 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 pain.” The prescribing physician is to maintain a copy of the report of the evaluation. The evaluation is not required if the patient has been evaluated and treated within a “reasonable period of time” by one or more other practitioners who specialize in the anatomic area, system, or organ perceived to be the source of pain and the treating practitioner is satisfied that he or she can rely on the evaluation to meet the requirements of the Rule. The practitioner is required to obtain and maintain a copy of the records or report on which he/she relied to meet the requirements of an evaluation by a specialist. Last, Paragraph (A) requires an informed consent be present **RETAINED IN THE MEDICAL RECORD** informing the patient of the risk and benefits of receiving prescription drug therapy and of available treatment alternatives.

Paragraph (B) requires that the practitioner see the patients at “appropriate periodic intervals to assess the efficacy of treatment, assure that prescription drug therapy remains indicated, evaluate patient’s progress, and note any adverse drug effects”. The paragraph also requires assessment of functional status, the pain intensity, and its interference with activities of daily living, quality of life, and social activities. If there is evidence or behavioral indications of drug abuse, the practitioner may obtain a drug screen. According to Paragraph (B) (3), “It is within the practitioner’s discretion to decide the nature of the screen and which type of drug(s) to be screened.” Results of the screening should be documented in the patient’s medical record.

Paragraph (C) requires immediate consultation with an addiction medicine or substance abuse specialists if the practitioner believes or has reason to believe the patient is suffering from addiction or drug abuse.

V. BWC POSITION ON UTILIZATION OF PRESCRIPTION MEDICATION FOR THE TREATMENT OF CHRONIC INTRACTABLE PAIN

Based on the above statutory and regulatory documents described, the use of prescription medication for the treatment of chronic intractable pain is acceptable in Ohio **ON A PROTRACTED BASIS OR IN AMOUNTS OR COMBINATIONS THAT MAY NOT BE APPROPRIATE WHEN TREATING OTHER MEDICAL CONDITIONS** so long as the treating physician complies with The State Medical Board of Ohio Administrative Rules. Based on Ohio Supreme Court decision, it is also required that the authorization of payment for services be reasonably related, reasonably necessary for treatment of the allowed injury, and that the costs are medically reasonable. To support the reasonably

necessary requirement, practitioners can be expected to provide medical documentation to support intractable pain and the need to use prescription medication for the treatment of intractable pain when present. Medical records should also reflect or explain how the intractable pain and its treatment are reasonably related to the allowed injury in the claim.

Key elements expected to be present in the medical file include but are not limited to:

- Reasonable medical efforts (diagnostic study, consultation, and treatment) have been performed to relieve the pain, identify the source, and cure its cause.
- No other treatment or cure is possible or none has been found.
- The initial evaluation by the treating practitioner meets the requirement REQUIREMENTS of Administrative Rule 4731-21-02. (Note: This is not intended to be point-by-point specific, but that the medical records do document sufficient history, pain description, relatedness of the pain to the allowed condition in the claim, alcohol and substance abuse history, assessment of physical and psychological function, diagnostic studies and treatment performed, and an appropriate physical examination.)
- Appropriate consultation has been performed either by consultation or previous treating specialist as defined by Administrative Rule 4731-21 within A REASONABLE PERIOD OF TIME, NOT TO EXCEED six months of FROM the beginning of such treatment.
- Medical records provide appropriate documentation to support continued use of the medication and consistent with Administrative Rule 4731-21. This includes adequate monitoring of the patient on a periodic basis to determine the continued need for prescription medication.

BWC can expect as part of the treatment guidelines practitioners will be permitted to perform or receive authorization for the following services:

- Periodic office visitation to monitor treatment compliance, results, physiologic and psychological functioning.
- In certain claims, it may be necessary to obtain periodic urine drug testing to determine drug abuse based on evidence or behavioral indications of addiction as described in 4731-21-02 Paragraph (B)(3). This most likely would be no more frequent than quarterly.
- Referral to addiction medicine specialist or substance abuse specialist for consultation and evaluation (most likely each case would need to be evaluated for treatment) if the practitioner believes or has reason to believe the patient is suffering from addiction or drug abuse as described in 4731-21-02 Paragraph (C).

There is no specific allowance of “chronic intractable pain”, BWC personnel involved with claim management determinations and physicians performing file reviews or Independent Medical Evaluations for BWC should consider the following criteria in regard to the use of prescription medication to treat chronic intractable pain:

1. that the medical records meet the definition of “intractable pain” as defined by the State Medical Board of Ohio particularly in relation to reasonable medical efforts to determine the source and treat the cause of the pain have been documented;
2. that a second opinion from an appropriate specialist has been performed;

3. that the medical records provide a reasonable relationship of the symptoms to the allowed conditions in the claim; and
4. that the use of such medication is reasonably necessary to help manage the symptoms experienced by the injured worker.

Should the above criteria be met, even though there is no allowance for chronic intractable pain on the claim, then the BWC may authorize reimbursement for prescription medication used in the treatment of chronic intractable pain.

In claim management, many, if not most, cases would be a continuation of or “flow-through” of treatment of a condition that is presumed to be the cause of pain and for which the injured worker has received appropriate diagnostic testing, treatment, and evaluations. Many individuals considered to have “chronic intractable pain” will have obvious limitation of activity and difficulty controlling pain following treatment of the allowed condition. Other claims will be more difficult to assess. There may be issues of (1) need for additional diagnostic testing; (2) need for specialist consultation, (3) uncertainty of diagnosis or relationship to the allowed conditions in the claim, or (4) medical records do not support the apparent need for continued treatment. It can be anticipated that some employers may also request an independent medical evaluation of injured workers for the purpose of justification of ongoing treatment in many of these cases.

In questionable cases or those requested by the employer, independent medical evaluation performed by a specialist appropriate for the body part or system considered to be the source of “chronic intractable pain” would be appropriate to determine issues such as:

- Recommendations for any additional testing to identify source of pain
- Other treatment that should be considered
- Specialty consultation that may be beneficial
- Provide description of the pain and impact on daily living, functioning, etc.
- Clarify relationship of symptoms (pain) to the allowed conditions or work injury
- Determine the apparent need for continued treatment
- Other issues as deemed necessary.

In most workers’ compensation cases, the presumed source of pain will be limited to the musculoskeletal system. Appropriate independent medical evaluating specialists would, in general, be limited to orthopedists, hand surgeons for the upper extremity, neurosurgeons, physical medicine and rehabilitation specialists, and possibly occupational medicine and pain specialists depending on the nature of the issue.

Treating physicians who consistently fail to provide appropriate medical records or follow The State Medical Board of Ohio Guidelines RULES should be referred to DEP Central or Provider Relations along with the specific claim numbers of injured workers being treated.

APPENDIX A

The State Medical Board of Ohio

Administrative Rules

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

(F) "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.

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

(I) "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.

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

(K) "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) "Podiatrist" means an individual holding a certificate under Chapter 4731. of the Revised Code to practice podiatry and practicing within his or her scope of practice as defined by section 4731.51 of the Revised Code.

(M) "Protracted basis" means for a period in excess of twelve (12) continuous weeks.

(N) "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 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, 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.

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

(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 pain.

(A) When utilizing any prescription drug for the treatment of intractable 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 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, 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 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 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 pain or the condition underlying the intractable 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 pain or the condition underlying the intractable 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, 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 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 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 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 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.

(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 or other substance abuse specialist. For purposes of this rule, "addiction medicine or substance abuse 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. Prescription drug therapy may be continued consistent with the recommendations of the consultation, including, if the consulting addiction medicine or other substance abuse specialist recommends that it is necessary, prompt referral to an addiction medicine or other substance abuse specialist for physical examination and evaluation of the patient and a review of the referring practitioner's medical records of the patient. The practitioner shall document the recommendations of the consultation in the patient's record. The practitioner shall continue to actively monitor the patient for signs and symptoms of addiction, drug abuse or diversion. The practitioner shall maintain a copy of any written report made by any practitioner to whom referral for evaluation was made under this paragraph.

4731-21-03 Continuing medical education.

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

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.

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.

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 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.

Eff. 11/11/98

¹ “Promoting Pain Relief and Preventing Abuse of Pain Medications: A Critical balancing Act – A Joint Statement From 21 Health Organizations and the Drug Enforcement Administration”:
<http://www.ampainsoc.org/advocacy/promoting.htm>

² “Model Guidelines for the Use of Controlled Substances for the Treatment of Pain”, Federation of State Medical Boards of the United States, Inc., May 1998.

³ “Chapter 4731-21 Intractable Pain”, Administrative Rules, The State Medical Board of Ohio:
<http://www.state.oh.us/med/rules/4731-21.htm>