



Section 3719.062 of the Revised Code (effective 4-6-17) allows health related licensing boards to adopt rules limiting the amount of an opioid analgesic that may be prescribed pursuant to a single prescription by an individual licensed by the board.

The Medical Board is accepting comments on proposed amendments to two existing rules and a proposed new rule that will limit initial opioid analgesic prescriptions for acute pain to 5 days for minors and 7 days for adults. The rules also include a 30MED average daily dose limit.

(1) Rule 4731-11-01:

- Is amended by adding definitions for acute pain, morphine equivalent dose, minor, extended-release or long-acting opioid analgesic, opioid analgesic, palliative care and terminal condition.

(2) Rule 4731-11-02

- Is amended by adding a requirement that physicians and physician assistants must follow Rules 4729-5-30 and 4729-5-13, Ohio Administrative Code. This will include the requirement that prescriptions for controlled substances will need to include the diagnosis.

(3) New Rule 4731-11-13

- Limits prescriptions for opioid analgesics to treat acute pain to no more than a seven-day supply for adults and a five-day supply for minors. If the physician determines that the pain is expected to persist for longer than seven days, the physician may prescribe for a longer period, but the reason for exceeding the limits and for prescribing an opioid analgesic must be documented in the patient's medical record.
- Requires that the patient and the parent or guardian of a minor patient is advised of the benefits and risks of the opioid analgesic, including the potential for addiction.
- Allows for exceptions for prescriptions for opioid analgesics used to treat patients receiving hospice or palliative care, cancer and terminal illness, and medication assisted treatment for addiction.

The provisions of these proposed rules will be applicable to physician assistants through Rule 4730-2-07, Ohio Administrative Code, Standards for Prescribing. The Board of Nursing and Dental Board are promulgating rules with the same provisions. The Board of Pharmacy is promulgating rules consistent with these limits.

The comment deadline is **April 28, 2017**. Please send comments to:
Sallie.Debolt@med.ohio.gov.

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; or

(4) 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.

(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: <http://www.ohiopmp.gov/> (effective 2017).

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

_____ (a) Has United States Food and Drug Administration approved labeling indicating that it is an extended-release or controlled release formulation;

_____ (b) Is administered via a transdermal route; or

_____ (c) 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.

4731-11-02 General provisions.

(A) A physician shall not utilize a controlled substance other than in accordance with all the provisions of this chapter of the Administrative Code.

(B) A physician shall not utilize a controlled substance without taking into account the drug's potential for abuse, the possibility the drug may lead to dependence, the possibility the patient will obtain the drug for a nontherapeutic use or to distribute to others, and the possibility of an illicit market for the drug.

(C) A physician shall complete and maintain accurate medical records reflecting the physician's examination, evaluation, and treatment of all the physician's patients. Patient medical records shall accurately reflect the utilization of any controlled substances in the treatment of a patient and shall indicate the diagnosis and purpose for which the controlled substance is utilized, and any additional information upon which the diagnosis is based.

(D) A physician shall obey all applicable provisions of sections 3719.06, 3719.07, 3719.08 and 3719.13 of the Revised Code, and the rules promulgated thereunder, rules 4729-5-30 and 4729-5-13 of the Administrative Code, and all applicable provisions of federal law governing the possession, distribution, or use of controlled substances.

(E) Violations of this rule:

(1) A violation of any provision of this rule, as determined by the board, shall constitute any or all of the following: "failure to maintain minimal standards applicable to the selection or administration of drugs," as that clause is used in division (B)(2) of section 4731.22 of the Revised Code; and "a departure from, or the failure to conform to, minimal standards of care of similar physicians 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.

(2) A violation of paragraph (C) of this rule shall further constitute "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.

4731-11-13 Prescribing of Opioid Analgesics for Acute Pain

- (A) For the treatment of acute pain, the physician shall comply with the following:
- (1) Extended-release or long-acting opioid analgesics shall not be prescribed for treatment of acute pain;
 - (2) Before prescribing an opioid analgesic, the physician shall first consider non-opioid treatment options. If opioid analgesic medications are required as determined by a history and physical examination, the physician shall prescribe for the minimum quantity and potency needed to treat the expected duration of pain, with a presumption that a three-day supply or less is frequently sufficient;
 - (3) In all circumstances where opioid analgesics are prescribed for acute pain:
 - (a) Except as provided in paragraph (B) of this rule, the duration of the first opioid analgesic prescription for the treatment of an episode of acute pain shall be:
 - (i) For adults, not more than a seven-day supply with no refills;
 - (ii) For minors, not more than a five-day supply with no refills. A physician shall comply with section 3719.061 of the Revised Code, including but not limited to obtaining the parent or guardian's written consent prior to prescribing an opioid analgesic to a minor;
 - (iii) The seven-day limit for adults and five-day limit for minors may be exceeded for pain that is expected to persist for longer than seven days based on the pathology causing the pain. In this circumstance, the reason that the limits are being exceeded and the reason that a non-opioid medication was not appropriate to treat the patient's conditions shall be documented in the patient's medical record; and
 - (iv) If a patient is allergic to or otherwise unable to tolerate the initially prescribed opioid medication, a prescription for a different, appropriate opioid may be issued at any time during the initial seven or five-day dosing period and shall be subject to all other provisions of this rule. The allergy and/or intolerance shall be documented in the patient's medical record. The patient or the minor patients, parent, guardian or other responsible adult must be provided education of the safe disposal of the unused medication.
 - (b) The patient, or a minor's parent or guardian, shall be advised of the benefits and risks of the opioid analgesic, including the potential for addiction, and the advice shall be documented in the patient's medical record; and
 - (c) The total morphine equivalent dose (MED) of a prescription for opioid analgesics for treatment of acute pain shall not exceed an average of thirty MED per day.
- (B) The requirements of paragraph (A) of this rule apply to treatment of acute pain and do not apply when an opioid analgesic is prescribed:
- (1) To an individual who is a hospice patient or in a hospice care program;
 - (2) To an individual receiving palliative care;

- (3) To an individual who has been diagnosed with a terminal condition; or
- (4) To an individual who has cancer or another condition associated with the individual's cancer or history of cancer.
- (C) This rule does not apply to prescriptions for opioid analgesics for the treatment of opioid addiction utilizing a schedule III, IV or V controlled substance narcotic that is approved by the Federal drug administration for opioid detoxification or maintenance treatment.
- (D) This rule does not apply to inpatient prescriptions as defined in rule 4729-17-01 of the Administrative Code.