

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) Certification from the American board of preventive medicine; or
 - ~~(4)~~(5) Board certification with additional qualification in addiction medicine from the American osteopathic association.
- (K) "Office based opioid treatment", or "OBOT", means treatment of opioid addiction utilizing a schedule III, IV or V controlled substance narcotic.
- (L) "Acute pain" means pain that normally fades with healing, is related to tissue damage, significantly alters a patient's typical function and is expected to be time limited.
- (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:

- (1) Has United States food and drug administration approved labeling indicating that it is an extended-release or controlled release formulation;
- (2) Is administered via a transdermal route; or
- (3) Contains methadone.
- (P) “Opioid analgesic” has the same meaning as in section 3719.01 of the Revised Code and means a controlled substance that has analgesic pharmacologic activity at the opioid receptors of the central nervous system, including but not limited to the following drugs and their varying salt forms or chemical congeners: buprenorphine, butorphanol, codeine (including acetaminophen and other combination products), dihydrocodeine, fentanyl, hydrocodone (including acetaminophen combination products), hydromorphone, meperidine, methadone, morphine sulfate, oxycodone (including acetaminophen, aspirin, and other combination products), oxymorphone, tapentadol, and tramadol.
- (Q) “Hospice care program” has the same meaning as in section 3712.01 of the Revised Code.
- (R) “Palliative care” has the same meaning as in section 3712.01 of the Revised Code.
- (S) “Terminal condition” has the same meaning as in section 2133.01 of the Revised Code.

Effective:

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Certification

Date

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Statutory Authority: 3719.062, 4731.05
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4731-11-02

General provisions.

- (A) A physician shall not utilize a controlled substance other than in accordance with all of 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.

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4731-11-13

Prescribing of opiate 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 and that limiting the duration of opioid use to the necessary period will decrease the likelihood of subsequent chronic use or dependence;

(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. The number of days of the prescription shall not exceed the amount required to treat the expected duration of the pain as noted in paragraph (A) (2) of this rule; 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, except when all of the following apply:

(i) The patient suffers from medical conditions, surgical outcomes or injuries of such severity that pain cannot be managed within the 30 MED average limit as determined by the treating physician based upon prevailing standards of medical care, such as:

(a) Traumatic crushing of tissue;

(b) Amputation;

(c) Major orthopedic surgery;

(d) Severe burns

(ii) The physician determines that exceeding the 30 MED average limit is necessary based on the physician's clinical judgment and the patient's needs.

(iii) The physician shall document in the patient's medical record the reason for exceeding the 30 MED average and the reason it is the lowest dose consistent with the patient's medical condition.

(iv) Only the prescribing physician for the conditions in paragraph (A)(3)(c)(i) of this rule may exceed the 30 MED average. The prescribing physician shall be held singularly accountable for prescriptions that exceed the 30 MED average.

(v) In circumstances when the 30 MED average is exceeded, the dose shall not exceed the dose required to treat the severity of the pain as noted in paragraph (A) (2) of this rule.

(d) Prescriptions that exceed the five or seven day supply or 30 MED average daily dose are subject to additional review by the state medical board. The dosage, days supplied, and condition for which the opioid analgesic is prescribed will be considered as part of this additional review.

(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 Chapter 4729. of the Administrative Code.

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