

*** DRAFT - NOT YET FILED ***

4723-9-10

Formulary; standards of prescribing for advanced practice registered nurses designated as clinical nurse specialists, certified nurse-midwives, or certified nurse practitioners.

(A) Definitions; for purposes of this rule and interpretation of the formulary, located at <http://www.nursing.ohio.gov/Practice-Prescribing.htm> (effective 2017):

- (1) "Acute pain" means pain that normally fades with healing, is related to tissue damage and significantly alters a patient's typical function, and is expected to be time-limited.
- (2) "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.
- (3) "Family member" means a spouse, parent, child, sibling or other individual with respect to whom a nurse's personal or emotional involvement may render the nurse unable to exercise detached professional judgment in reaching diagnostic or therapeutic decisions.
- (4) "Hospice care program" has the same meaning as in section 3712.01 of the Revised Code.
- (5) "ICD-10-CM code" means the disease code in the most current international classification of diseases, clinical modifications published by the United States department of health and human services.
- (6) "Opioid analgesic" has the same meaning as in section 3719.01 of the Revised Code, and means a controlled substance that has analgesic pharmacological 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.
- (7) "Minor" has the same meaning as in section 3719.061 of the Revised Code.
- (8) "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 Board of Pharmacy at: <http://www.pharmacy.ohio.gov/MED> (effective 2017).

(9) "Palliative care" has the same meaning as in section 3712.01 of the Revised Code.

(10) "Physician consultation" means a clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner may initiate the medication after direct communication with the collaborating physician regarding a particular patient and documenting the consultation in the patient record. Once the medication is initially authorized by the collaborating physician, the nurse may continue, modify, or discontinue the medication without further consultation.

(11) "Physician initiation" means the collaborating physician is required to have personally examined and evaluated the patient before therapy is initiated in accordance with rule 4731-11-09 of the Administrative Code. Following discussion with the collaborating physician, the initial order or prescription may be written by a clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner. Once therapy has been initiated, the nurse may continue, modify, or discontinue the medication without further consultation.

(12) "Terminal condition" has the same meaning as in section 2133.01 of the Revised Code.

(B) The committee on prescriptive governance shall establish a recommended exclusionary _____ formulary, _____ located _____ at <http://www.nursing.ohio.gov/Practice-Prescribing.htm> (effective 2017), that specifies therapeutic devices, or subtypes or individual drugs, within the following types of drugs, that a clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner cannot prescribe or furnish:

(1) Nutrients and nutritional agents;

(2) Hematological agents;

(3) Endocrine and metabolic agents;

(4) Cardiovascular agents;

(5) Renal and genitourinary agents;

(6) Respiratory agents;

(7) Central nervous system agents;

(8) Gastrointestinal agents;

(9) Anti-infective and systemic agents;

(10) Biologic/immunologic agents;

(11) Dermatologic agents;

(12) Ophthalmic and otic agents;

(13) Antineoplastic agents; and

(14) Diagnostic aids.

(C) The recommended exclusionary formulary shall not permit the prescribing or furnishing of any drug or device prohibited by federal or state law, or rules adopted by the board, including this rule.

(D) The formulary established by the committee on prescriptive governance shall be available on the Ohio board of nursing web site, located at <http://www.nursing.ohio.gov/Practice-Prescribing.htm> (effective 2017).

(E) The committee on prescriptive governance shall review the formulary, located at <http://www.nursing.ohio.gov/Practice-Prescribing.htm> (effective 2017), for additions or deletions at least twice a year.

(F) A clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner may prescribe any drug or therapeutic device in any form or route of administration if:

(1) The ability to prescribe the drug or therapeutic device is within the scope of practice in the nurse's specialty area;

(2) The prescription is consistent with the terms of a standard care arrangement entered into with a collaborating physician;

(3) The prescription would not exceed the prescriptive authority of the collaborating physician, including restrictions imposed on the physician's practice by action of the United States drug enforcement administration or the state medical board, or by the state medical board rules, including but not limited to rule 4731-11-09 of the Administrative Code;

(4) The individual drug or subtype or therapeutic device is not one excluded by the formulary, located at <http://www.nursing.ohio.gov/Practice-Prescribing.htm> (effective 2017);

(5) The prescription meets the requirements of state and federal law, including but

not limited to this rule, rule 4729-5-30 of the Administrative Code and rule 4729-5-13 of the Administrative Code;

(6) A valid prescriber-patient relationship exists. This relationship may include, but is not limited to:

(a) Obtaining a thorough history of the patient;

(b) Conducting a physical or mental examination of the patient;

(c) Rendering a diagnosis;

(d) Prescribing medication, ruling out the existence of any recognized contraindications;

(e) Consulting with the collaborating physician when necessary; and

(f) Properly documenting these steps in the patient's medical records;

(7) Notwithstanding paragraph (F)(6) of this rule, the nurse may prescribe or personally furnish a drug according to section 4723.4810 of the Revised Code to not more than a total of two individuals who are sexual partners of the nurse's patient.

(8) If the patient is a family member, acceptable and prevailing standards of safe nursing care require that a nurse maintain detached professional judgment. The nurse shall not prescribe to a family member unless:

(a) The nurse is able to exercise detached professional judgment in reaching diagnostic or therapeutic decisions;

(b) The prescription is documented in the patient's record.

(9) For drugs that are a controlled substance:

(a) The nurse has obtained a United States drug enforcement administration registration, except if not required to do so as provided in rule 4729-17-13 of the Administrative Code, and indicates the number on the prescription;

(b) The prescription indicates the ICD-10-CM code of the primary disease or condition that the controlled substance is being used to treat;

(c) The prescription indicates the intended days' supply of the controlled substance prescription. The intended days' supply is calculated by dividing the total quantity prescribed by the maximum intended number of tablets or doses per day;

(d) The patient is not a family member; and

(e) The nurse shall not self-prescribe a controlled substance.

(G) Except as provided in paragraph (H) of this rule, a clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner may prescribe a schedule II controlled substance only in situations where all of the following apply:

(1) A patient has a terminal condition;

(2) A physician initially prescribed the substance for the patient; and

(3) The prescription is for a quantity that does not exceed the amount necessary for the patient's use in a single, seventy-two hour period.

(H) Subject to the requirements set forth in paragraphs (I) and (J) of this rule, a clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner may prescribe a schedule II controlled substance, if not excluded by the formulary, located at <http://www.nursing.ohio.gov/Practice-Prescribing.htm> (effective 2017), if the nurse issues the prescription to the patient from any of the following locations:

(1) A hospital registered under section 3701.07 of the Revised Code;

(2) An entity owned or controlled, in whole or in part, by a hospital or by an entity that owns or controls, in whole or in part, one or more hospitals;

(3) A health care facility operated by the department of mental health or the department of developmental disabilities;

(4) A nursing home licensed under section 3721.02 of the Revised Code or by a political subdivision certified under section 3721.09 of the Revised Code;

(5) A county home or district home operated under Chapter 5155, of the Revised Code that is certified under the medicare or medicaid program;

(6) A hospice care program;

(7) A community mental health agency, as defined in section 5122.01 of the Revised Code;

(8) An ambulatory surgical facility, as defined in section 3702.30 of the Revised Code;

(9) A freestanding birthing center, as defined in section 3702.141 of the Revised Code;

- (10) A federally qualified health center, as defined in section 3701.047 of the Revised Code;
- (11) A federally qualified health center look-alike, as defined in section 3701.047 of the Revised Code;
- (12) A health care office or facility operated by the board of health of a city or general health district or the authority having the duties of a board of health under section 3709.05 of the Revised Code;
- (13) A site where a medical practice is operated, but only if the practice is comprised of one or more physicians who also are owners of the practice; the practice is organized to provide direct patient care; and the clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner providing services at the site has a standard care arrangement and collaborates with at least one of the physician owners who practices primarily at that site; or
- (14) A residential care facility, as defined in section 3721.01 of the Revised Code.
- (I) A clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner shall not issue to a patient a prescription for a schedule II controlled substance from a convenience care clinic even if the clinic is owned or operated by an entity specified in paragraph (H) of this rule.
- (J) For the treatment of acute pain, a clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner shall comply with the following:

 - (1) Extended-release or long-acting opioid analgesics shall not be prescribed for the treatment of acute pain;
 - (2) Before prescribing an opioid analgesic, the nurse shall first consider non-opioid treatment options. If opioid analgesic medications are required as determined by history and physical examination, the prescription should be 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 (J)(3)(a)(iii) 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. As set forth in section 4723.481 of the Revised Code, a nurse 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 analgesic medication was not appropriate to treat the patient's condition shall be documented in the patient's medical record; and

(iv) If a patient is intolerant of or allergic to an opioid medication initially prescribed, a prescription for a different opioid medication may be issued at any time during the initial seven-day or five-day dosing period, and the new prescription shall be subject to the requirements of this rule. The patient's intolerance or allergy shall be documented in the patient's medical record, and the patient advised to safely dispose 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.

(K) The requirements of paragraph (J) 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 who is receiving palliative care;

(3) To an individual who has been diagnosed with a terminal condition; or

(4) To an individual who has cancer or a condition associated with the individual's cancer or history of cancer.

(L) The requirements of paragraph (J) of this rule do not apply to:

(1) Prescriptions for opioid analgesics for the treatment of opioid addiction utilizing a controlled substance that is approved by the FDA for opioid detoxification or maintenance treatment; or

- (2) Inpatient prescriptions as defined in rule 4729-17-01 of the Administrative Code.
- (M) Drugs approved by the FDA but not yet reviewed and approved by the committee on prescriptive governance may be prescribed, unless later disapproved by the committee on prescriptive governance, if:
- (1) The drug type or subtype is not excluded on the formulary, located at <http://www.nursing.ohio.gov/Practice.htm> (effective 2017); and
- (2) The collaborating physician has agreed in the standard care arrangement that the nurse may prescribe drugs approved by the FDA, that meet the criteria set forth in paragraphs (M)(1) and (M)(2) of this rule, that have not yet been reviewed and approved by the committee on prescriptive governance.
- (N) As specified in section 4723.44 of the Revised Code, a clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner shall not prescribe any drug or device to perform or induce an abortion.
- (O) As specified in section 4723.488 of the Revised Code, notwithstanding the requirements of this rule, a clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner may prescribe or personally furnish naloxone.