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 and not more than six weeks in duration.

(2) "Chronic pain" means pain that has persisted after reasonable medical efforts have been made to relieve it and continues either episodically or continuously for twelve or more weeks following initial onset of pain. It may be the result of an underlying medical disease or condition, injury, medical treatment, inflammation, or unknown cause. "Chronic pain" does not include pain associated with a terminal condition or with a progressive disease that, in the normal course of progression, may reasonably be expected to result in a terminal condition.

~~(2)~~(3) "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)~~(4) "Family member" means a spouse, parent, child, sibling or other individual with respect to whom ~~a~~an advanced practice registered nurse's personal or emotional involvement may render the advanced practice registered nurse unable to exercise detached professional judgment in reaching diagnostic or therapeutic decisions.

~~(4)~~(5) "Hospice care program" has the same meaning as in section 3712.01 of the Revised Code.

~~(5)~~(6) "ICD-10-CM medical diagnosis 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)~~(7) "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.

(8) "Medication therapy management" has the same meaning as in rules adopted by agency 4729.

~~(7)~~(9) "Minor" has the same meaning as in section 3719.061 of the Revised Code.

~~(8)~~(10) "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: https://www.ohiopmp.gov/MED_Calculator.aspx (effective 2017).

~~(9)~~(11) "Palliative care" has the same meaning as in section 3712.01 of the Revised Code.

(12) "Sub-acute pain" means pain that has persisted after reasonable medical efforts have been made to relieve it and continues either episodically or continuously for more than six weeks but less than twelve weeks following initial onset of pain. It may be the result of an underlying medical disease or condition, injury, medical or surgical treatment, inflammation, or unknown cause.

~~(10)~~(13) "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 may specify the exclusion of therapeutic devices, individual drugs or subtypes ~~or~~ of individual drugs.

(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 advanced practice registered 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, and all prescription issuance rules adopted by agency 4729~~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 relevant history of the patient;

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

(c) Rendering a diagnosis;

(d) Prescribing medication;

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

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

(7) Notwithstanding paragraph (F)(6) of this rule, ~~the~~a clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner ~~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 advanced practice registered nurse's patient.

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

(a) The advanced practice registered 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) Controlled substances. For drugs that are a controlled substance:

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

(b) The prescription indicates the ICD-10-CM medical diagnosis code of the primary disease or condition that the controlled substance is being used to treat. The code shall, at minimum, include the first four alphanumeric characters of the ICD-10 CM medical diagnosis code, sometimes referred to as the category and etiology (ex. M165);

(c) The prescription indicates the days' supply of the controlled substance prescription. ~~;~~

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

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

(G) Schedule II controlled substances. 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), and (M) 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 advanced practice registered 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) Acute pain. 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 advanced practice registered 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~~ the advanced practice registered 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, except when:

(i) The circumstances set forth in paragraph (A)(3)(c) of rule 4731-11-13 of the Administrative Code exist; and

(ii) The patient's treating physician has entered a standard care arrangement with the advanced practice registered nurse that states the understanding of the physician as to when the advanced practice registered nurse may exceed the thirty MED average, and when the advanced practice registered nurse must consult with the physician prior to exceeding the thirty MED average. The standard care arrangement in this circumstance must comply with rule 4731-11-13 of the Administrative Code, and the advanced practice registered nurse must document in the patient's record the reason for exceeding the thirty MED average and the reason it is the lowest dose consistent with the patient's medical condition.

(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 rules adopted by agency 4729~~rule 4729-17-01 of the Administrative Code~~.

(M) Sub-acute and chronic pain. As specified in section 4723.481 of the Revised Code, for treatment of sub-acute and chronic pain, a clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner shall prescribe in a manner not exceeding the prescriptive authority of the collaborating physician or podiatrist. Prescribing parameters specifically include, but are not limited to, the following requirements set forth in rule 4731-11-14 of the Administrative Code:

(1) Prior to treating, or continuing to treat sub-acute or chronic pain with an opioid analgesic, the advanced practice registered nurse shall first consider and document non-medication options. If opioid analgesic medications are required as determined by a history and physical examination, the advanced practice registered nurse shall prescribe the minimum quantity and potency needed to treat the expected duration of pain and improve the patient's ability to function;

(2) Before prescribing an opioid analgesic for sub-acute or chronic pain, the advanced practice registered nurse shall complete or update and document in the patient record assessment activities to assure the appropriateness and safety of the medication, as required by rule 4731-11-14 of the Administrative Code, including but not limited to:

(a) Completing an OARRS check in compliance with rule 4723-9-12 of the Administrative Code;

(b) Offering the patient a prescription for naloxone if the following circumstances exist:

(i) The patient has a prior history of opioid overdose;

(ii) The patient is co-prescribed a benzodiazepine, sedative hypnotic drug, carisprodal, tramadol, or gabapentin;

(iii) The patient has a concurrent substance use disorder; or

(iv) The dosage exceeds eighty MED as discussed in paragraph (M)(5) of this rule;

(c) The advanced practice registered nurse shall consider offering the patient a prescription for naloxone if the dosage exceeds fifty MED as discussed in paragraph (M)(4) of this rule.

(3) During the course of treatment with an opioid analgesic at doses below the average of fifty MED per day, the advanced practice registered nurse shall provide periodic follow-up assessment and documentation of the patient's functional status, the patient's progress toward treatment objectives, indicators of possible addiction, drug abuse or diversion, and any adverse drug effects.

(4) Fifty MED. Prior to increasing the opioid dosage to a daily average of fifty MED or greater, the advanced practice registered nurse shall complete and document in the patient record the activities and information set forth in rule 4731-11-14 of the Administrative Code, including but not limited to the following:

(a) Review and update the assessment completed in paragraph (M)(2) of this rule if needed. The advanced practice registered nurse may rely on an appropriate assessment completed within a reasonable time if the advanced practice registered nurse is satisfied that he or she may rely on that information for purposes of meeting the requirements of Chapter 4723-8 and Chapter 4723-9 of the Administrative Code;

(b) Except when the patient was prescribed an average daily dosage that exceeded fifty MED before the effective date of this rule, document consideration of:

(i) Consultation with a specialist in the area of the body affected by the pain;

(ii) Consultation with a pain management specialist;

(iii) Obtaining a medication therapy management review by a pharmacist;

(iv) Consultation with a specialist in addiction medicine or addiction psychiatry, if aberrant behaviors indicating medication misuse or substance use disorder are noted;

(c) The advanced practice registered nurse shall consider offering the patient a prescription for naloxone if the dosage exceeds fifty MED as discussed in paragraph (M)(4) of this rule;

(d) During the course of treatment with an opioid analgesic at doses at or above the average of fifty MED per day, the advanced practice registered nurse shall complete and document in the patient record all of the information and activities required by rule 4731-11-14 of the Administrative Code not less than every three months.

(5) Eighty MED. Prior to increasing the opioid dosage to a daily average of eighty MED or greater, the advanced practice registered nurse shall complete and document in the patient record the activities and information set forth in rule 4731-11-14 of the Administrative Code, including but not limited to the following:

(a) A written pain management agreement shall be entered with the patient that outlines the advanced practice registered nurse's and patient's responsibilities during treatment, which requires the patient or patient guardian's agreement to all of the provisions set forth in rule 4731-11-14 of the Administrative Code;

(b) The advanced practice registered nurse shall offer the patient a prescription for naloxone;

(c) Except when the patient was prescribed an average daily dosage that exceeded eighty MED before the effective date of this rule, the advanced practice registered nurse shall obtain at least one of the following based upon the patient's clinical presentation:

(i) Consultation with a specialist in the area of the body affected by the pain;

(ii) Consultation with a pain management specialist;

(iii) A medication therapy management review by a pharmacist; or

(iv) Consultation with a specialist in addiction medicine or addiction psychiatry, if aberrant behaviors indicating medication misuse or substance use disorder are noted.

(6) One hundred twenty MED. The advanced practice registered nurse shall not prescribe a dosage that exceeds an average of one hundred twenty MED per day. This prohibition shall not apply under the following circumstances:

(a) The advanced practice registered nurse holds national certification in pain management or hospice and palliative care by a national certifying organization approved according to section 4723.46 of the Revised Code;

(b) The advanced practice registered nurse has received a written recommendation for a dosage exceeding an average of one hundred twenty MED per day from a board certified pain medicine physician, or board certified hospice and palliative care physician, who based the recommendation on a face-to-face visit and examination of the patient. The advanced practice registered nurse shall maintain the written recommendation in the patient's record; or

(c) The patient was receiving an average daily dose of one hundred twenty MED or more prior to the effective date of this rule. However, prior to escalating the patient's dose, the advanced practice registered nurse shall receive a written recommendation as set forth in paragraph (M)(6)(b) of this rule.

(7) The requirements of paragraph (M) of this rule do not apply when an opioid analgesic is prescribed:

(a) To an individual who is in a hospice care program;

(b) To an individual who has terminal cancer or another terminal condition; or

(c) As an inpatient prescription as defined in rules adopted by agency 4729.

~~(M)~~(N) 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 advanced practice registered nurse may prescribe drugs approved by the

FDA, that meet the criteria set forth in paragraphs ~~(M)~~(N)(1) and ~~(M)~~(N)(2) of this rule, that have not yet been reviewed and approved by the committee on prescriptive governance.

~~(N)~~(O) 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)~~(P) 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.

~~(P)~~(Q) The requirements of paragraph (F)(9)(c) of this rule apply to prescriptions for products that contain gabapentin.

Effective:

Five Year Review (FYR) Dates: 10/15/2020

_____

Certification

_____

Date

Promulgated Under:	119.03
Statutory Authority:	4723.50, 4723.07, 3719.062
Rule Amplifies:	4723.481, 4723.492, 4723.491, 4723.49, 4723.488, 4723.487, 4723.486
Prior Effective Dates:	02/01/2002, 02/01/2003, 02/01/2006, 04/01/2006, 02/01/2008, 02/01/2011, 02/01/2012, 11/05/2012, 02/01/2014, 02/01/2016, 08/31/2017, 01/01/2018