



## Ohio Administrative Code

### Rule 4723-9-13 Medication-assisted treatment.

Effective: February 1, 2021

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(A) Definitions; for purposes of this rule and interpretation of the formulary set forth in rule 4723-9-10 of the Administrative Code:

(1) "Community addiction services provider" has the same meaning as in section 5119.01 of the Revised Code.

(2) "Community mental health services provider" has the same meaning as in section 5119.01 of the Revised Code.

(3) "Controlled substance," "schedule III," "schedule IV," and "schedule V" have the same meanings as in section 3719.01 of the Revised Code.

(4) "FDA" means the United States food and drug administration.

(5) "Induction phase" means the phase of opioid treatment during which maintenance medication dosage levels are adjusted until a patient attains stabilization.

(6) "Medication-assisted treatment" means alcohol or drug addiction services that are accompanied by medication that has been approved by the United States food and drug administration for the treatment of substance use disorder, prevention of relapse of substance use disorder, or both.

(7) "Office-based opioid treatment" or "OBOT" means medication-assisted treatment of opioid dependence or addiction utilizing controlled substances, in a private office or public sector clinic that is not otherwise regulated, by practitioners who are authorized to prescribe outpatient supplies of medications approved by the FDA for the treatment of opioid addiction or prevention of relapse. OBOT includes treatment with all controlled substance medications approved by the FDA for such treatment. OBOT does not include treatment that occurs in the following settings:



- (a) A state or local correctional facility, as defined in section 5163.45 of the Revised Code;
  - (b) A hospital, as defined in section 3727.01 of the Revised Code;
  - (c) A provider certified to provide residential and inpatient substance use disorder services, including withdrawal management, by the Ohio department of mental health and addiction services;
  - (d) An opioid treatment program certified by SAMHSA and accredited by an independent, SAMHSA-approved accrediting body; or
  - (e) A youth services facility, as defined in section 103.75 of the Revised Code.
- (8) "OARRS" means the "Ohio Automated RX Reporting System" drug database established and maintained pursuant to section 4729.75 of the Revised Code.
- (9) "Qualified behavioral healthcare provider" means the following who is practicing within the scope of professional licensure:
- (a) A medical doctor or doctor of osteopathic medicine and surgery who holds board certification in addiction medicine or addiction psychiatry, or a psychiatrist, licensed under Chapter 4731. of the Revised Code;
  - (b) A licensed independent chemical dependency counselor-clinical supervisor, licensed independent chemical dependency counselor, licensed chemical dependency counselor III, licensed chemical dependency counselor II, or licensed chemical dependency counselor assistant licensed under Chapter 4758. of the Revised Code;
  - (c) A professional clinical counselor, licensed professional counselor, licensed independent social worker, licensed social worker, or marriage and family therapist, licensed under Chapter 4757. of the Revised Code;
  - (d) An advanced practice registered nurse licensed as a clinical nurse specialist or certified nurse practitioner licensed by the board, who holds national certification in psychiatric mental health, or



clinical nurse specialist who was not required to obtain national certification according to section 4723.41 of the Revised Code, and whose specialty is psychiatric mental health; or

(e) A psychologist, as defined in division (A) of section 4732.01 of the Revised Code, licensed under Chapter 4732. of the Revised Code; or

(f) An advanced practice registered nurse licensed by the board who holds additional certification as a certified addictions registered nurse-advanced practice issued by the addictions nursing certification board.

Nothing in paragraph (A)(9) of this rule shall be construed to prohibit an advanced practice registered nurse who collaborates with a physician licensed under Chapter 4731. of the Revised Code and certified as an addiction psychiatrist, addictionologist, or psychiatrist, from providing services within the normal course of practice and expertise of the collaborating physician, including addiction services, other mental health services, and prescriptive services in compliance with Ohio and federal law and rules.

(10) "SAMHSA" means the United States substance abuse and mental health services administration.

(11) "Stabilization phase" means the medical and psychosocial process of assisting the patient through acute intoxication and withdrawal management to the attainment of a medically stable, fully supported substance-free state, which may include the use of medications.

(B) An advanced practice registered nurse with a current valid license issued by the board and designated as a clinical nurse specialist, certified nurse midwife or certified nurse practitioner may provide medication-assisted treatment, including prescribing controlled substances in schedule III, IV or V, if the advanced practice registered nurse:

(1) Complies with section 3719.064 of the Revised Code, and all federal and state laws and regulations governing the prescribing of the medication, including but not limited to incorporating into the advanced practice registered nurse's practice knowledge of Chapter 4729. of the Revised Code, and Chapter 4731. of the Revised Code and rules adopted under that Chapter that govern the practice of the advanced practice registered nurse's collaborating physician;



(2) Completes at least eight hours of continuing nursing education in each renewal period related to substance abuse and addiction. Courses completed in compliance with this requirement shall be accepted toward meeting the continuing education requirements for biennial renewal of the advanced practice registered nurse license; and

(3) Only provides medication-assisted treatment if the treatment is within the collaborating physician's normal course of practice and expertise.

(C) In addition to the requirements for medication-assisted treatment set forth in paragraph (B) of this rule, an advanced practice registered nurse with a current valid license issued by the board and designated as a clinical nurse specialist or certified nurse practitioner may provide OBOT under the following circumstances:

(1) The standard care arrangement statement of services offered includes OBOT;

(2) The advanced practice registered nurse performs, or confirms the completion of, and documents a patient assessment that includes all of the following:

(a) A comprehensive medical and psychiatric history;

(b) A brief mental status history;

(c) Substance abuse history;

(d) Family history and psychosocial supports;

(e) Appropriate physical examination;

(f) Urine drug screen or oral fluid drug testing;

(g) Pregnancy test for women of childbearing age and ability;



- (h) Review of patient's prescription information in OARRS;
  - (i) Testing for human immunodeficiency virus;
  - (j) Testing for hepatitis B;
  - (k) Testing for hepatitis C;
  - (l) Consideration of screening for tuberculosis and sexually-transmitted diseases in patients with known risk factors.
  - (m) For other than the toxicology tests for drugs and alcohol, appropriate history, substance abuse history, and pregnancy test, the advanced practice registered nurse may satisfy the assessment requirements by reviewing records from a physical examination and laboratory testing of the patient that was conducted within a reasonable period of time prior to the visit.
  - (n) If any part of the assessment cannot be completed prior to the initiation of OBOT, the advanced practice registered nurse shall document the reasons in the medical record.
- (3) The advanced practice registered nurse establishes and documents a treatment plan that includes all of the following:
- (a) The advanced practice registered nurse's rationale for selection of the specific drug to be used in the medication-assisted treatment;
  - (b) Patient education;
  - (c) The patient's written, informed consent;
  - (d) Random urine-drug screens or oral fluid drug testing;
  - (e) A signed treatment agreement with the patient that outlines the responsibilities of the patient and the advanced practice registered nurse;



(f) A plan for psychosocial treatment as discussed in paragraph (C)(5) of this rule;

(4) The advanced practice registered nurse shall provide OBOT in accordance with an acceptable treatment protocol for assessment, induction, stabilization, maintenance and tapering. Acceptable protocols are any of the following:

(a) SAMSHA treatment improvement protocol publications for medication-assisted treatment available from the SAMSHA website at: <https://store.samhsa.gov/>;

(b) "National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use," approved by the American society of addiction medicine in 2015, and available from the website of the American society of addiction medicine at <https://www.asam.org/>.

(5) Except if the advanced practice registered nurse is a qualified behavior healthcare provider, the advanced practice registered nurse shall refer and work jointly with a qualified behavioral healthcare provider, community mental health services provider, or community addiction services provider to determine the optimal type and intensity of psychosocial treatment for the patient and document the treatment plan in the patient record.

(a) The treatment shall at minimum include a psychosocial needs assessment, supportive counseling, links to existing family supports, and referral to community services;

(b) The treatment shall include at least one of the following interventions:

(i) Cognitive behavioral treatment;

(ii) Community reinforcement approach;

(iii) Contingency management/motivational incentives; or

(iv) Behavioral couples counseling;



- (c) The treatment plan shall include a structure for renegotiation of the treatment plan if the patient does not adhere to the original plan.
- (6) When clinically appropriate and if the patient refuses treatment from a qualified behavioral healthcare provider, community mental health services provider, or community addiction services provider, the advanced practice registered nurse shall ensure that the OBOT treatment plan requires the patient to participate in a twelve step program or appropriate self-help recovery program. If the patient is required to participate in a twelve step program or self-help recovery program, the advanced practice registered nurse shall require the patient to provide documentation of on-going participation in the program.
- (7) If the advanced practice registered nurse refers the patient to a qualified behavioral health service provider, community addiction services provider, or community mental health services provider, the advanced practice registered nurse shall document the referral and the advanced practice registered nurse's meaningful interactions with the provider in the patient record.
- (8) The advanced practice registered nurse shall offer the patient a prescription for a naloxone kit.
- (a) The advanced practice registered nurse shall ensure that the patient receives instruction on the kit's use including, but not limited to, recognizing the signs and symptoms of overdose and calling 911 in an overdose situation.
- (b) The advanced practice registered nurse shall offer the patient a new prescription for naloxone upon expiration or use of the old kit.
- (c) The advanced practice registered nurse shall be exempt from this requirement if the patient refuses the prescription. If the patient refuses the prescription the advanced practice registered nurse shall provide the patient with information on where to obtain a kit without a prescription.
- (9) If the advanced practice registered nurse provides OBOT using buprenorphine products, the following additional requirements must be met:
- (a) The provision shall comply with the FDA approved "Risk Evaluation and Mitigation Strategy" for



buprenorphine products, which can be found on FDA website at the following address:  
<https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm>. With the exception of those conditions listed in paragraph (C)(9)(b) of this rule, the advanced practice registered nurse who treats an opioid use disorder with a buprenorphine product shall only prescribe buprenorphine/naloxone combination products for use in OBOT.

(b) The advanced practice registered nurse shall prescribe buprenorphine without naloxone (buprenorphine mono-product) only in the following situations, and shall fully document the evidence for the decision to use buprenorphine mono-product in the patient's record:

(i) When the patient is pregnant or breast-feeding;

(ii) When converting the patient from buprenorphine mono-product to a buprenorphine/naloxone combination product;

(iii) In formulations other than tablet or film form for indications approved by the FDA;

(iv) For withdrawal management when a buprenorphine/naloxone combination product is contraindicated, with the contraindication documented in the patient record; or

(v) When the patient has an allergy to or intolerance of a buprenorphine/naloxone combination product, after explaining to the patient the difference between an allergic reaction and symptoms of opioid withdrawal precipitated by buprenorphine or naloxone, and with documentation included in the patient record.

(c) Due to a higher risk of fatal overdose when buprenorphine is prescribed with other opioids, benzodiazepines, sedative hypnotics, carisoprodol, and tramadol, the advanced practice registered nurse shall only co-prescribe these substances when it is medically necessary, and only if:

(i) The advanced practice registered nurse verifies the diagnosis for which the patient is receiving the other drug and coordinates care with the prescriber for the other drug, including whether it is possible to taper the drug to discontinuation. If the advanced practice registered nurse prescribing buprenorphine is the prescriber of the other drug, the advanced practice registered nurse shall taper





the other drug to discontinuation if it is safe to do so. The advanced practice registered nurse shall educate the patient about the serious risks of the combined use; and

(ii) The advanced practice registered nurse documents progress in achieving the tapering plan in the patient record.

(d) During the induction phase, the advanced practice registered nurse shall not prescribe a dosage that exceeds the recommendation in the FDA approved labeling, except for medically indicated circumstances as documented in the patient record. The advanced practice registered nurse shall see the patient at least once per week during this phase.

(e) During the stabilization phase, when using any oral formulation of buprenorphine, the advanced practice registered nurse shall increase the daily dosage of buprenorphine in safe and effective increments to achieve the lowest dose that avoids intoxication, withdrawal, or significant drug craving.

(i) During the first ninety days of treatment, the advanced practice registered nurse shall prescribe no more than a two-week supply of the buprenorphine product containing naloxone.

(ii) Starting with the ninety-first day of treatment and until the completion of twelve months of treatment, the advanced practice registered nurse shall prescribe no more than a thirty-day supply of the buprenorphine product containing naloxone.

(f) The advanced practice registered nurse shall take steps to reduce the chances of buprenorphine diversion by using the lowest effective dose, appropriate frequency of office visits, pill counts, and checks of OARRS. The advanced practice registered nurse shall also require urine drug screens, serum medication levels, or oral fluid testing at least twice per quarter for the first year of treatment and at least once per quarter thereafter.

(g) When using any oral formulation of buprenorphine, the advanced practice registered nurse shall document in the patient record the rationale for prescribed doses exceeding sixteen milligrams of buprenorphine per day. The advanced practice registered nurse shall not prescribe a dose of buprenorphine exceeding twenty-four milligrams per day.



(h) The advanced practice registered nurse shall incorporate relapse prevention strategies into counseling or assure that they are addressed by a qualified behavioral healthcare provider who has the education and experience to provide substance abuse counseling.

(i) The advanced practice registered nurse may treat a patient using the administration of extended-release, injectable, or implanted buprenorphine under the following circumstances:

(i) The advanced practice registered nurse strictly complies with any required risk evaluation and mitigation strategy program for the drug;

(ii) The advanced practice registered nurse shall prescribe an extended-release buprenorphine product strictly in accordance with the FDA's approved labeling for the drug's use;

(iii) The advanced practice registered nurse documents in the patient record the rationale for the use of the extended-release product; and

(iv) The advanced practice registered nurse who orders or prescribes extended-release, injectable, or implanted buprenorphine product shall administer the drug, or require it to be administered by another Ohio licensed health care provider acting in accordance with the scope of their professional license.

(10) If the clinical nurse specialist or certified nurse practitioner is using naltrexone to treat opioid use disorder, the advanced practice registered nurse shall comply with the following additional requirements:

(a) Prior to treating a patient with naltrexone, the advanced practice registered nurse shall inform the patient about the risk of opioid overdose if the patient ceases naltrexone and then uses opioids. The advanced practice registered nurse shall take measures to ensure that the patient is adequately detoxified from opioids and is no longer physically dependent prior to treatment with naltrexone;

(b) The advanced practice registered nurse shall use oral naltrexone only for treatment of patients who can be closely supervised and who are highly motivated;



- (i) The dosage regime shall strictly comply with the FDA approved labeling for naltrexone hydrochloride tablets;
- (ii) The patient shall be encouraged to have a support person assist with the administration of the medication and supervise the medication. Examples of a support person are a family member, close friend, or employer;
- (c) The advanced practice registered nurse shall require urine drug screens, serum medication levels or oral fluid testing at least every three months for the first year of treatment and at least every six months thereafter;
- (d) The advanced practice registered nurse shall incorporate relapse prevention strategies into counseling or assure that they are addressed by a qualified behavioral healthcare or mental health services provider who has education and experience to provide substance abuse counseling.
- (e) The advanced practice registered nurse may treat a patient with extended-release naltrexone for opioid dependence or for co-occurring opioid and alcohol use disorders.
  - (i) The advanced practice registered nurse should consider treatment with extended-release naltrexone for patients who have issues with treatment adherence;
  - (ii) The injection dosage shall strictly comply with FDA labeling for extended-release naltrexone; and
  - (iii) The advanced practice registered nurse shall incorporate relapse prevention strategies into counseling or assure that they are addressed by a qualified behavioral healthcare provider or mental health services provider who has the education and experience to provide substance abuse counseling.