

Ohio Administrative Code

Rule 4723-9-13 Office-based opioid treatment.

Effective: September 14, 2025

- (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 medications for opioid use disorder treatment during which the patient is started on an FDA approved medication for substance use disorder treatment.
- (6) "Maintenance phase" means the ongoing period of time when the patient's medication dose reaches a therapeutic level, allowing the patient to focus on other recovery activities.
- (7) "Medications for Opioid Use Disorder" or "MOUD" refers to all medications approved by the FDA for the treatment of opioid use disorder.
- (8) "Office-based opioid treatment" or "OBOT" means pharmacotherapy 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 use disorder. OBOT includes treatment with all controlled substance medications approved by the FDA for such treatment. OBOT does not include treatment utilizing non-controlled medications. OBOT does not



include treatment that occurs in the following settings:

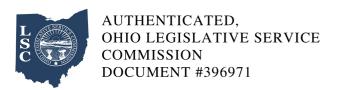
- (a) A state or local correctional facility, as defined in section 5163.45 of the Revised Code;
- (b) A hospital, as defined in section 3722.01 of the Revised Code;
- (c) A provider certified to provide residential and inpatient substance use disorder services, including withdrawal management, by the 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.
- (f) An emergency medical services agency as authorized under chapter 4729 of the Revised Code.
- (9) "OARRS" means the "Ohio Automated RX Reporting System" drug database established and maintained pursuant to section 4729.75 of the Revised Code.
- (10) "Overdose reversal drug" has the same meaning as in Chapter 4729. of the Revised Code.
- (11) "Qualified behavioral healthcare provider" means the following healthcare providers practicing within the scope of professional licensure:
- (a) A medical doctor or doctor of osteopathic medicine and surgery who is a board certified addiction medicine specialist or addiction psychiatrist, 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 this paragraph shall be construed to prohibit an advanced practice registered nurse who collaborates with a physician licensed under Chapter 4731. of the Revised Code and board certified as an addiction psychiatrist, board certified addiction medicine specialist, 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.

- (12) "SAMHSA" means the United States substance abuse and mental health services administration.
- (13) "Stabilization phase" means the period of time following the induction phase, when medication doses are adjusted to target a reduction in substance use disorder symptoms.
- (14) "Substance use disorder" indicates a problematic pattern of substance use leading to clinically significant impairment or distress as determined by application of the diagnostic criteria in the "Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition-Text Revision" or "DSM-5-TR."



- (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 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 use disorder 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 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, an assessment of the patient to gather sufficient information and data to justify the use of this treatment intervention. The assessment shall include a thorough medical history, examination and laboratory testing. If any part of the assessment cannot be completed prior to the initiation of OBOT, the advanced practice registered nurse shall complete it as soon as possible following the initiation of treatment;
- (3) The advanced practice registered nurse shall provide accurate, objective, and complete



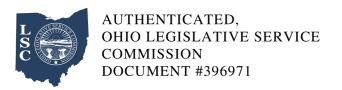
documentation of all patient encounters, including referrals, test results, and significant changes to the treatment plan.

- (4) 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 treatment based upon discussion of all MOUDs and non-medication options with the patient;
- (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) Documentation regarding psychosocial interventions as discussed in paragraph (C)(5) of this rule;
- (g) The treatment plan shall be revised if the patient does not show improvement with the original plan.
- (5) 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) TIP 63 "Medications for Opioid Use Disorder" (2021) available from the SAMHSA website at: https://library.samhsa.gov/product/tip-63-medications-opioid-use-disorder/pep21-02-01-002;
- (b) "ASAM National Practice Guideline for the Treatment of Opioid Use Disorder: 2020 Focused Update," available from the website of the American society of addiction medicine at

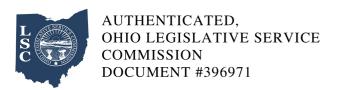


https://www.asam.org/quality-care/clinical-guidelines/national-practice-guideline.

- (6) The advanced practice registered nurse shall do the following with respect to psychosocial treatment for patients receiving OBOT:
- (a) Assess for psychosocial treatment needs in addition to medication;
- (b) Offer psychosocial interventions or referrals for psychosocial interventions to all patients, but OBOT should not be declined or discontinued if the patient is unable or unwilling to engage in psychosocial interventions;
- (c) Ensure that psychosocial interventions are person-centered and tailored to the patient's insight, motivation, and stage of recovery;
- (d) Focus the psychosocial interventions on retaining the patient in treatment, stabilizing the patient and assisting with progress in the patient's treatment and recovery;
- (e) If the psychosocial interventions are not available or if the patient declines to participate, the advanced practice registered nurse shall continue to treat the patient with OBOT provided that the patient adheres to all other treatment requirements;
- (f) Psychosocial treatment or intervention includes the following:
- (i) Cognitive behavioral treatment;
- (ii) Community reinforcement approach;
- (iii) Contingency management and motivational incentives;
- (iv) Motivational interviewing;
- (v) Behavioral couples counseling;



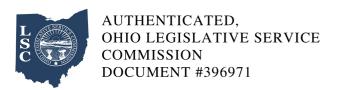
- (vi) Twelve-step facilitation; and
- (vii) Other therapies based on the patient's individual needs;
- (g) When necessary, the advanced practice registered nurse may make referrals for psychosocial treatment to qualified behavioral healthcare providers, community addiction services or community mental health services providers as defined in rule 4723-9-13(A) of the administrative code; and
- (h) The advanced practice registered nurse may also refer patients for treatment with non-licensed paraprofessionals such as case managers and peer support specialists if the advanced practice registered nurse determines such intervention would benefit the patient.
- (7) The advanced practice registered nurse who provides OBOT shall offer the patient a prescription for an overdose reversal drug, directly provide the patient with an overdose reversal drug, or direct the patient to an easily accessible source to obtain an overdose reversal drug, such as, http://www.naloxone.ohio.gov, a local health department, or other agency or facility that provides overdose reversal drugs.
- (a) The advanced practice registered nurse shall ensure that the patient, and if possible, those residing with the patient, receives instruction on the overdose reversal drug's use including, but not limited to, recognizing the signs and symptoms of opioid overdose and calling 911 in an overdose situation.
- (b) The advanced practice registered nurse shall offer the patient a new prescription for an overdose reversal drug upon expiration or use of the old overdose reversal drug.
- (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 an overdose reversal drug without a prescription.
- (8) If the advanced practice registered nurse provides OBOT using buprenorphine products, the following additional requirements must be met:



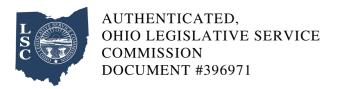
- (a) Treatment with a buprenorphine product must be in compliance with the FDA approved "Risk Evaluation and Mitigation Strategy" for buprenorphine products, which can be found on the FDA website at the following address: https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm. With the exception 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 may 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; or
- (iv) When the patient has a genuine allergy to or intolerance of a buprenorphine/naloxone combination product.
- (c) Due to a higher risk of fatal overdose when buprenorphine is prescribed with other opioids, benzodiazepines, sedative hypnotics, carisoprodol, gabapentin, or 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 acceptable alternative treatments are available and whether it is possible to lower the dose or discontinue the drug. If the advanced practice registered nurse prescribing buprenorphine is the prescriber of the other drug, the advanced practice registered nurse shall also consider these options and consider consultation with another healthcare provider. 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 the rationale for discontinuing, lowering, or continuing the medication given potential risks and benefits .
- (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 maintenance phase, the advanced practice registered nurse shall prescribe a dosage of buprenorphine that avoids intoxication or sedation, prevents withdrawal, and suppresses significant drug craving. For the first twelve months of treatment, the advanced practice registered nurse shall prescribe no more than a one-month supply of the buprenorphine product unless utilizing a formulation with duration of action exceeding one month, such as injections or implants.
- (f) The advanced practice registered nurse shall reduce the risk of buprenorphine diversion by using the lowest effective dose, scheduling appropriate frequency of office visits, conducting random pill counts, checking OARRS, and utilizing drug testing, serum medication levels, and oral fluid testing to assess for patient adherence to prescribed buprenorphine treatment.
- (g) When using any sublingual formulation of buprenorphine, the advanced practice registered nurse shall not prescribe a dosage exceeding twenty-four milligrams of buprenorphine per day, unless the advanced practice registered nurse is licensed as a clinical nurse specialist or certified nurse practitioner who holds a 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 an advanced practice registered nurse who holds additional certification as a certified addictions advanced practice registered nurse issued by the addictions nursing certification board, or a consultation has been obtained from a physician who is a board certified addiction specialist or addiction psychiatrist recommending the higher dose. Dosage shall not exceed thirty-two milligrams of buprenorphine 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, as defined in this rule, who has the education and experience to provide substance use disorder 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.
- (9) 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) Before initiating naltrexone, the advanced practice registered nurse shall take measures to ensure that the patient is opioid abstinent for an adequate period of time after completing opioid withdrawal to avoid precipitated withdrawal. The advanced practice registered nurse shall alert the patient of the risk of potentially lethal opioid overdose if they stop naltrexone and use opioids.;
- (b) The advanced practice registered nurse shall use oral naltrexone only for treatment of patients 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 administer 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 drug 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 eduction and experience to provide substance abuse counseling.
- (e) The advanced practice registered nurse may treat a patient with extended-release naltrexone for opioid or alcohol 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 difficulties with treatment adherence;
- (ii) The 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.