



## Ohio Administrative Code Rule 4730-4-03 Office-based opioid treatment.

Effective: October 31, 2024

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(A) A physician assistant who provides office-based opioid treatment ("OBOT") shall comply with the following requirements:

(1) Before initiating OBOT, the physician assistant shall comply with section 3719.064 of the Revised Code.

(2) Comply with all federal and state laws and regulations governing the prescribing of the medication;

(3) Complete at least eight hours of "Category 1" continuing medical education relating to substance use disorder and addiction every two years. Courses completed in compliance with this requirement shall be accepted toward meeting the continuing medical education requirement for biennial renewal of the physician assistant's license;

(4) Only provide OBOT if the provision of OBOT is within the supervising physician's normal course of practice and expertise;

(5) The physician assistant who provides OBOT shall perform 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 physician assistant shall complete as soon as possible following initiation of treatment; and

(6) The physician assistant shall provide accurate, objective, and complete documentation of all patient encounters, including referrals, test results, and significant changes to the treatment plan.

(B) The physician assistant who provides OBOT shall establish a treatment plan that includes the following:



(1) The physician assistant'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;

(2) Patient education;

(3) Random urine-drug screens;

(4) A signed treatment agreement that outlines the responsibilities of the patient and the physician assistant, and documents the patient's consent for treatment;

(5) Documentation regarding psychosocial intervention, pursuant to paragraph (D) of this rule; and

(6) The treatment plan shall be revised if the patient does not show improvement with the original plan.

(C) The physician assistant shall provide OBOT in accordance with an acceptable treatment protocol for assessment, induction, stabilization, maintenance, and tapering. Acceptable protocols are any of the following:

(1) TIP 63 "Medications for Opioid Use Disorder" (2021) available from the <https://store.samhsa.gov/product/TIP-63-Medications-for-Opioid-Use-Disorder-Full-Document/PEP21-02-01-002>.

(2) "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>.

(D) The physician assistant shall do the following with respect to psychosocial treatment for patients receiving OBOT:

(1) Assess for psychosocial treatment needs in addition to medication;



- (2) 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;
- (3) Ensure that psychosocial interventions are person-centered and tailored to the patient's insight, motivation, and stage of recovery;
- (4) Focus the psychosocial interventions on retaining the patient in treatment, stabilizing the patient and assisting with progress in the patient's treatment and recovery;
- (5) If the psychosocial interventions are not available or if the patient declines to participate, the physician assistant shall continue to treat the patient with OBOT provided that the patient adheres to all other treatment requirements;
- (6) Psychosocial treatment or intervention includes the following:
  - (a) Cognitive behavioral treatment;
  - (b) Community reinforcement approach;
  - (c) Contingency management and motivational incentives;
  - (d) Motivational interviewing;
  - (e) Behavioral couples counseling;
  - (f) Twelve-step facilitation; and
  - (g) Other therapies based on the patient's individual needs;
- (7) When necessary, the physician assistant may make referrals for psychosocial treatment to qualified behavioral healthcare providers, community addiction services or community mental health services providers as defined in rule 4730-4-01 of the Administrative Code; and



(8) The physician assistant may also refer patients for treatment with non-licensed paraprofessionals such as case managers and peer support specialists if the physician assistant determines such intervention would benefit the patient.

(E) The physician assistant who provides OBOT shall offer the patient a prescription for an overdose reversal drug, directly provide the patient with the overdose reversal drug, or direct the patient to an easily accessible source to obtain overdose reversal drugs, such as <http://www.naloxone.ohio.gov>, a local health department, or other agency or facility that provides overdose reversal drugs.

(1) The physician assistant shall ensure that the patient and, if possible, those residing with the patient, receive 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.

(2) The physician assistant shall offer the patient a new prescription for an overdose reversal drug upon expiration or use.

(3) The physician assistant shall be exempt from this requirement if the patient refuses the prescription. If the patient refuses the prescription the physician assistant shall provide the patient with information on where to obtain overdose reversal drugs without a prescription.

(F) In addition to paragraphs (A) to (E) of this rule, the physician assistant who provides OBOT using buprenorphine products shall comply with the following requirements:

(1) Treatment with a buprenorphine product must be in compliance with the United States food and drug administration approved "Risk Evaluation and Mitigation Strategy" for buprenorphine products, which can be found on the United States food and drug administration website at the following address: <https://www.accessdata.fda.gov/scripts/cder/remis/index.cfm>. With the exception of those conditions listed in paragraph (G)(2) of this rule, a physician assistant who treats opioid use disorder with a buprenorphine product shall only prescribe buprenorphine/naloxone combination products for use in OBOT.



(2) The physician assistant may prescribe buprenorphine without naloxone (buprenorphine mono-product) only in the following situations:

(a) When a patient is pregnant or breast-feeding;

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

(c) In formulations other than tablet or film form for indications approved by the United States food and drug administration; or

(d) When the patient has a genuine allergy to or intolerance of a buprenorphine/naloxone combination product.

(3) Due to a higher risk of fatal overdose when buprenorphine is prescribed with other opioids, benzodiazepines, sedative hypnotics, carisoprodol, gabapentin, or tramadol, the physician assistant shall only co-prescribe these substances when it is medically necessary.

(a) The physician assistant shall verify the diagnosis for which the patient is receiving the other drug and coordinate 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 physician assistant prescribing buprenorphine is the prescriber of the other drug, the physician assistant shall also consider these options and consider consultation for another healthcare provider. The physician assistant shall educate the patient about the serious risks of the combined use.

(b) The physician assistant shall document the rationale for discontinuing, lowering, or continuing the medication given potential risks and benefits.

(4) During the induction phase the physician assistant shall not prescribe a dosage that exceeds the recommendation in the United States food and drug administration approved labeling, except for medically indicated circumstances as documented in the medical record. The physician assistant shall see the patient at least once a week during this phase.



(5) During the maintenance phase, the physician assistant 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 physician assistant 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.

(6) The physician assistant shall reduce the risk of buprenorphine diversion by using the lowest effective dose, and by using one or more of the following: scheduling appropriate frequency of office visits, conducting random pill counts, and checking OARRS and utilizing drug testing, serum medication levels, and oral fluid testing to assess for patient adherence to prescribed buprenorphine treatment.

(7) When using any sublingual formulation of buprenorphine, the physician assistant shall not prescribe a dosage exceeding twenty-four milligrams of buprenorphine per day, unless the physician assistant obtains a consultation from an addiction specialist physician recommending the higher dose. Dosage shall not exceed thirty-two milligrams of buprenorphine per day.

(8) The physician assistant shall incorporate relapse prevention strategies into the counseling or assure that they are addressed by a qualified behavioral healthcare provider, as defined in rule 4730-4-01 of the Administrative Code, who has the education and experience to provide substance use disorder counseling.

(9) The physician assistant may treat a patient using the administration of an extended-release, injectable, or implanted buprenorphine product.

(a) The physician assistant shall strictly comply with any required risk evaluation and mitigation strategy for the drug.

(b) The physician assistant shall prescribe an extended-release buprenorphine product strictly in accordance with the United States food and drug administration's approved labeling for the drug's use.

(c) The physician assistant shall document in the patient record the rationale for the use of the



extended-release buprenorphine product.

(d) The physician assistant who orders or prescribes an extended release, injectable, or implanted buprenorphine product shall require it to be administered by an Ohio licensed health care provider acting in accordance within the scope of their professional license.