

4730-4-01

Definitions.

- (A) "Office-based opioid treatment" or "OBOT" means medication-assisted treatment, as that term is defined in this rule, in a private office or public sector clinic that is not otherwise regulated, by practitioners authorized to prescribe outpatient supplies of medications approved by the United States food and drug administration for the treatment of opioid addiction or dependence, prevention of relapse of opioid addiction or dependence, or both. OBOT includes treatment with all controlled substance medications approved by the United States food and drug administration for such treatment. OBOT does not include treatment that occurs in the following settings:
- (1) A state or local correctional facility, as defined in section 5163.45 of the Revised Code;
 - (2) A hospital, as defined in section 3727.01 of the Revised Code;
 - (3) 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;
 - (4) An opioid treatment program certified by SAMHSA and accredited by an independent SAMHSA-approved accrediting body; or
 - (5) A youth services facility, as defined in section 103.75 of the Revised Code.
- (B) "SAMHSA" means the United States substance abuse and mental health services administration.
- (C) "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.
- (D) "Substance use disorder" includes misuse, dependence, and addiction to alcohol and/or legal or illegal drugs, as determined by diagnostic criteria in the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition" or "DSM-5."
- (E) "OARRS" means the "Ohio Automated Rx Reporting System" drug database established and maintained pursuant to section 4729.75 of the Revised Code.
- (F) For purposes of the rules in Chapter 4730-4 of the Administrative Code:
- (1) "Qualified behavioral healthcare provider" means the following who is practicing within the scope of the professional license:

- (a) Board certified addictionologist, board certified psychiatrist, or psychiatrist, licensed under Chapter 4731. of the Revised Code;
 - (b) Licensed independent chemical dependency counselor-clinical supervisor, licensed independent chemical dependency counselor, licensed chemical dependency counselor III, or licensed chemical dependency counselor II, or licensed chemical dependency counselor assistant licensed under Chapter 4758. of the Revised Code;
 - (c) 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) Advanced practice registered nurse, licensed as a clinical nurse specialist under Chapter 4723. of the Revised Code, who holds certification as a psychiatric mental health clinical nurse specialist issued by the American nurses credentialing center;
 - (e) Advanced practice registered nurse, licensed as a nurse practitioner under Chapter 4723. of the Revised Code, who holds certification as a psychiatric mental health nurse practitioner issued by the American nurses credentialing center;
 - (f) Psychologist, as defined in division (A) of section 4732.01 of the Revised Code, licensed under Chapter 4732. of the Revised Code;
 - (g) Advanced practice registered nurse, licensed under Chapter 4723. of the Revised Code, who holds subspecialty certification as a certified addiction registered nurse-advanced practice issued by the addictions nursing certification board.
- (2) Nothing in this paragraph shall be construed to prohibit a physician assistant licensed under Chapter 4730. of the Revised Code who practices under a supervision agreement with a board certified addiction psychiatrist, board certified addictionologist, or psychiatrist who is licensed as a physician under Chapter 4731. of the Revised Code, from providing services within the normal course of practice and expertise of the supervising physician, including addiction services, other mental health services, and physician delegated prescriptive services in compliance with Ohio and federal laws and rules.
- (G) "Community addiction services provider," has the same meaning as in section 5119.01 of the Revised Code.

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

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

(J) "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.

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4730-4-03

Office-based treatment for opioid addiction.

(A) A physician assistant who provides 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 abuse 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; and

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

(B) The physician assistant who provides OBOT shall perform and document an assessment of the patient.

(1) The assessment shall include all of the following:

(a) A comprehensive medical and psychiatric history;

(b) A brief mental status exam;

(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 the patient's prescription information in OARRS;

(i) Testing for human immunodeficiency virus;

(j) Testing for hepatitis B;

(k) Testing for hepatitis C; and

- (1) Consideration of screening for tuberculosis and sexually-transmitted diseases in patients with known risk factors.
 - (2) For other than the toxicology tests for drugs and alcohol, appropriate history, substance abuse history, and the pregnancy test, the physician assistant 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.
 - (3) If any part of the assessment cannot be completed prior to the initiation of OBOT, the physician assistant shall document the reasons in the medical record.
- (C) The physician assistant who provides OBOT shall establish and document a treatment plan that includes all of the following:
- (1) The physician assistant's rationale for selection of the specific drug to be used in the medication-assisted treatment;
 - (2) Patient education;
 - (3) The patient's written, informed consent;
 - (4) Random urine-drug screens;
 - (5) A signed treatment agreement that outlines the responsibilities of the patient and the physician assistant; and
 - (6) A plan for psychosocial treatment, pursuant to paragraph (E) of this rule.
- (D) 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) SAMHSA treatment improvement protocol publications for medication assisted treatment available from the SAMHSA website at: <https://store.samhsa.gov/>.
 - (2) "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, available from the website of the American society of addiction medicine at: <https://www.asam.org/>.
- (E) The physician assistant shall refer and work jointly with a qualified behavioral healthcare provider, community mental health services provider, or community addiction services provider, as those terms are defined in rule 4730-4-01 of the

Administrative Code, to determine the optimal type and intensity of psychosocial treatment for the patient and document the treatment plan in the patient record.

- (1) The treatment shall, at a minimum, include a psychosocial needs assessment, supportive counseling, links to existing family supports, and referral to community services.
 - (2) The treatment shall include at least one of the following interventions, unless reasons for exception are documented in the patient record:
 - (a) Cognitive behavioral treatment;
 - (b) Community reinforcement approach;
 - (c) Contingency management/motivational incentives;
 - (d) Motivational interviewing; or
 - (e) Behavioral couples counseling.
 - (3) The treatment plan shall include a structure for revision of the treatment plan if the patient does not adhere to the original plan.
 - (4) When clinically appropriate or if the patient refuses treatment from a qualified behavioral healthcare provider, community mental health services provider, or community addiction services provider, as defined in rule 4730-4-01 of the Administrative Code, the physician assistant shall ensure that the OBOT treatment plan requires the patient to participate in a twelve step program. If the patient is required to participate in a twelve step program, the physician assistant shall require the patient to provide documentation of on-going participation in the program.
 - (5) If the physician assistant refers the patient to a qualified behavioral healthcare provider, community addiction services provider, or community mental health services provider, the physician assistant shall document the referral and the physician assistant's maintenance of meaningful interactions with the provider in the patient record.
- (F) The physician assistant who provides OBOT shall offer the patient a prescription for a naloxone kit.
- (1) The physician assistant 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.

- (2) The physician assistant shall offer the patient a new prescription for naloxone upon expiration or use of the old kit.
- (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 a kit without a prescription.
- (G) In addition to paragraphs (A) through (F) of this rule, the physician assistant who provides OBOT using buprenorphine products shall comply with all of the following requirements:
- (1) The provision shall 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 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 medical record:
- (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;
- (d) For withdrawal management when a buprenorphine/naloxone combination product is contraindicated, with the contraindication included in the patient record; or
- (e) 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.

- (3) Due to a higher risk of fatal overdose when buprenorphine is prescribed with other opioids, benzodiazepines, sedative hypnotics, carisoprodol, 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 it is possible to taper the drug to discontinuation. If the physician assistant prescribing buprenorphine is the prescriber of the other drug, the physician assistant shall taper the other drug to discontinuation, if it is safe to do so. The physician assistant shall educate the patient about the serious risks of the combined use.
- (b) The physician assistant shall document progress with achieving the tapering plan.
- (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 stabilization phase, when using any oral formulation of buprenorphine, the physician assistant 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.
- (a) During the first ninety days of treatment, the physician assistant shall prescribe no more than a two-week supply of buprenorphine product containing naloxone.
- (b) Starting with the ninety-first day of treatment and until the completion of twelve months of treatment, the physician assistant shall prescribe no more than a thirty-day supply of the buprenorphine product containing naloxone.
- (6) The physician assistant 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 physician assistant shall also require urine drug screens, serum medication levels, or oral fluid drug testing at least twice per quarter for the first year of treatment and at least once per quarter thereafter.

- (7) When using any oral formulation of buprenorphine, the physician assistant shall document in the medical record the rationale for prescribed doses exceeding sixteen milligrams of buprenorphine per day. The physician assistant shall not prescribe a dosage exceeding twenty-four 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 abuse 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 with the scope of their professional license.

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4730-4-04

Medication-assisted treatment using naltrexone.

(A) In addition to the requirements in paragraphs (A) through (F) of rule 4730-4-03 of the Administrative Code, the physician assistant using naltrexone to treat opioid use disorder shall comply with all of the following requirements:

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

(2) The physician assistant shall use oral naltrexone only for treatment of patients who can be closely supervised and who are highly motivated.

(a) The dosage regime shall strictly comply with the United States food and drug administration approved labeling for naltrexone hydrochloride tablets.

(b) 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 physician assistant 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 physician assistant shall incorporate relapse prevention strategies into 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 abuse counseling.

(B) The physician assistant may treat a patient with extended-release naltrexone for opioid dependence or for co-occurring opioid and alcohol use disorders.

(1) The physician assistant should consider treatment with extended-release naltrexone for patients who have issues with treatment adherence.

(2) The injection dosage shall strictly comply with the United States food and drug administration approved labeling for extended-release naltrexone.

(3) The physician assistant shall incorporate relapse prevention strategies into 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 abuse counseling.

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