

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 ~~intoxification~~ intoxication and withdrawal management to the attainment of a medically stable, fully supported substance-free state, which may include the use of medications.
- (K) "Withdrawal management" or "detoxification" is a set of medical interventions aimed at managing the acute physical symptoms of intoxication and withdrawal. Detoxification denotes a clearing of toxins from the body of the patient who is acutely intoxicated and/or dependent on a substance of abuse. Withdrawal management seeks to minimize the physical harm caused by the intoxication and withdrawal of a substance of abuse. Withdrawal management occurs when the patient has a substance use disorder and either evidence of the characteristic withdrawal syndrome produced by withdrawal from that substance, or evidence that supports the expectation that such a syndrome would develop without the provision of detoxification services. Withdrawal management alone does not constitute substance abuse treatment or rehabilitation.
- (L) "Ambulatory detoxification" means withdrawal management delivered in a medical office, public sector clinic, or urgent care facility by trained practitioners authorized to prescribe outpatient supplies of drugs approved by the United States food and drug administration for the treatment of addiction, prevention of relapse of drug addiction, or both. Ambulatory detoxification is the provision of medically supervised evaluation, withdrawal management, and referral services without extended onsite monitoring. For purpose of rule 4730-4-02 of the Administrative Code, ambulatory detoxification does not include withdrawal management that occurs in the following settings:
- (1) A state or local correctional facility, as defined in section 5163.45 of the Revised Code;
  - (2) In-patient treatment in 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 addition 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.

Effective: 10/31/2020

Five Year Review (FYR) Dates: 4/30/2024

CERTIFIED ELECTRONICALLY

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Certification

10/19/2020

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Date

Promulgated Under: 119.03  
Statutory Authority: 4730.07, 4730.55  
Rule Amplifies: 4730.55 , 4730.56  
Prior Effective Dates: 04/30/2019

4730-4-02**Standards and procedures for withdrawal management for drug or alcohol addiction.**

(A) In order to provide ambulatory detoxification, as that term is defined in rule 4730-4-01 of the Administrative Code, a physician assistant shall comply with all of the following requirements:

- (1) The physician assistant shall hold a valid prescriber number.
- (2) The physician assistant shall provide withdrawal management under the supervision of a physician who provides withdrawal management as part of the physician's normal course of practice and with whom the physician assistant has a supervision agreement.
- (3) The physician assistant shall comply with all state and federal laws and rules applicable to prescribing, including holding a DATA 2000 waiver to prescribe buprenorphine if buprenorphine is to be prescribed for withdrawal management in a medical office, public sector clinic, or urgent care facility.
- (4) The physician assistant who practices in a healthcare facility shall comply with all policies of the healthcare facility concerning the provision of withdrawal management.

(B) Prior to providing ambulatory detoxification, as that term is defined in rule 4730-4-01 of the Administrative Code, for any substance use disorder the physician assistant shall inform the patient that ambulatory detoxification alone is not substance abuse treatment. If the patient prefers substance abuse treatment, the physician assistant shall comply with the requirements of section 3719.064 of the Revised Code, by completing all of the following actions:

- (1) Both orally and in writing, give the patient information about all drugs approved by the U.S. food and drug administration for use in medication-assisted treatment, including withdrawal management. That information was given shall be documented in the patient's medical record.
- (2) If the patient agrees to enter opioid treatment and the physician assistant determines that such treatment is clinically appropriate, the physician assistant shall refer the patient to an opioid treatment program licensed or certified by the Ohio department of mental health and addiction services to provide such treatment or to a physician, physician assistant, or advanced practice registered nurse who provides treatment using Naltrexone or who holds the DATA 2000 waiver to provide office-based treatment for opioid use disorder. The name of the program, physician, physician assistant, or advanced practice registered

nurse to whom the patient was referred, and the date of the referral shall be documented in the patient record.

(C) When providing withdrawal management for opioid use disorder a physician assistant may be authorized to use a medical device that is approved by the United States food and drug administration as an aid in the reduction of opioid withdrawal symptoms.

(D) Ambulatory detoxification for opioid addiction.

(1) The physician assistant shall provide ambulatory detoxification only when all of the following conditions are met:

(a) A positive and helpful support network is available to the patient.

(b) The patient has a high likelihood of treatment adherence and retention in treatment.

(c) There is little risk of medication diversion.

(2) The physician assistant shall provide ambulatory detoxification under a defined set of policies and procedures or medical protocols consistent with American Society of Addiction Medicine's Level I-D or II-D level of care, under which services are designed to treat the patient's level of clinical severity, to achieve safe and comfortable withdrawal from a mood-altering drug, and to effectively facilitate the patient's transition into treatment and recovery. The ASAM Criteria, Third Edition, can be obtained from the website of the American Society of Addiction Medicine at <https://www.asam.org/>. A copy of the ASAM Criteria may be reviewed at the Medical Board office, 30 East Broad Street, Third Floor, Columbus, Ohio, during normal business hours.

(3) Prior to providing ambulatory detoxification, the physician assistant shall perform an assessment of the patient. The assessment shall include a thorough medical history and physical examination. The assessment must focus on signs and symptoms associated with opioid addiction and include assessment with a nationally recognized scale, such as one of the following:

(a) Objective Opioid Withdrawal Scale ("OOWS");

(b) Clinical Opioid Withdrawal Scale ("COWS"); or

(c) Subjective Opioid Withdrawal Scale ("SOWS").

- (4) Prior to providing ambulatory detoxification, the physician assistant shall conduct a biomedical and psychosocial evaluation of the patient, to include 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
  - (l) Consideration of screening for tuberculosis and sexually transmitted diseases in patients with known risk factors.
  - (m) For other than toxicology tests for drugs and alcohol, appropriate history, substance abuse history, and 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. If any part of the assessment cannot be completed prior to the initiation of treatment, the physician assistant shall document the reason in the medical record.
- (5) The physician assistant shall request and document review of an OARRS report on the patient.
- (6) The physician assistant shall inform the patient about the following before the patient is undergoing withdrawal from opioids:
- (a) The detoxification process and potential subsequent treatment for substance use disorder, including information about all drugs approved by the

United States food and drug administration for use in medication-assisted treatment:

- (b) The risk of relapse following detoxification without entry into medication-assisted treatment;
- (c) The high risk of overdose and death when there is a relapse following detoxification;
- (d) The safe storage and disposal of the medications.
- (7) The physician assistant shall not establish standardized routines or schedules of increases or decreases of medications but shall formulate a treatment plan based on the needs of the specific patient.
- (8) For persons projected to be involved in withdrawal management for six months or less, the physician assistant shall offer the patient counseling as described in paragraphs (F) and (G) of rule 4730-4-03 of the Administrative Code.
- (9) The physician assistant shall require the patient to undergo urine and/or other toxicological screenings during withdrawal management in order to demonstrate the absence of use of alternative licit and/or illicit drugs. The physician assistant shall consider referring a patient who has a positive urine/and or toxicological screening to a higher level of care, with such consideration documented in the patient's medical record, and shall confer with the supervising physician prior to prescribing the buprenorphine/naloxone combination product to the patient.
- (10) The physician assistant shall comply with the following requirements for the use of medication:

  - (a) The physician assistant may treat the patient's withdrawal symptoms by use of any of the following drugs as determined to be most appropriate for the patient.

    - (i) A drug, excluding methadone, that is specifically FDA approved for the alleviation of withdrawal symptoms
    - (ii) An alpha-2 adrenergic agent along with other non-narcotic medications as recommended in the American Society of Addiction Medicine's National Practice Guideline (<https://www.asam.org/>), which is available from the Medical Board's website at <https://med.ohio.gov>;

- (iii) A combination of buprenorphine and low dose naloxone (buprenorphine/naloxone combination product). However, buprenorphine without naloxone (buprenorphine mono-product) may be used if a buprenorphine/naloxone combination product is contraindicated, with the contraindication documented in the patient record
- (b) The physician assistant shall not use any of the following drugs to treat the patient's withdrawal symptoms:

  - (i) Methadone;
  - (ii) Anesthetic agents
- (c) The physician assistant shall comply with the following:

  - (i) The physician assistant shall not initiate treatment with buprenorphine to manage withdrawal symptoms until between twelve and eighteen hours after the last dose of short-acting agonist such as heroin or oxycodone, and twenty-four to forty-eight hours after the last dose of long-acting agonist such as methadone. 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>.
  - (ii) The physician assistant shall determine on an individualized basis the appropriate dosage of medication to ensure stabilization during withdrawal management.

    - (a) The dosage level shall be that which is well tolerated by the patient.
    - (b) The dosage level shall be consistent with the minimal standards of care.
  - (iii) In withdrawal management programs of thirty days or less duration, the physician assistant shall not allow more than one week of unsupervised or take-home medications for the patient.
- (11) The physician assistant shall offer the patient a prescription for a naloxone kit.

- (a) 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.
  - (b) The physician assistant shall offer the patient a new prescription for naloxone upon expiration or use of the old kit.
  - (c) 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.
- (12) The physician assistant shall take steps to reduce the chances of medication diversion by using the appropriate frequency of office visits, pill counts, and weekly checks of OARRS.
- (E) The physician assistant who provides ambulatory detoxification with medication management for withdrawal from benzodiazepines or other sedatives shall comply with paragraphs (A), (B), and (C) of this rule and "TIP 45, A Treatment Improvement Protocol for Detoxification and Substance Abuse Treatment" by the Substance Abuse and Mental Health Services Administration available from the Substance Abuse and Mental Health Services Administration website at the following link: <https://store.samhsa.gov/>. (Search for "TIP 45") and available on the Medical Board's website at: <https://med.ohio.gov/>.
- (1) The physician assistant shall provide ambulatory detoxification with medication management only when a positive and helpful support network is available to the patient whose use of benzodiazepines was mainly in therapeutic ranges and who does not have polysubstance dependence. The patient should exhibit no more than mild to moderate withdrawal symptoms, have no comorbid medical condition or severe psychiatric disorder, and no past history of withdrawal seizures or withdrawal delirium.
  - (2) Prior to providing ambulatory detoxification, the physician assistant shall perform and document an assessment of the patient that focuses on signs and symptoms associated with benzodiazepine or other sedative use disorder and include assessment with a nationally recognized scale, such as the "Clinical Institute Withdrawal Assessment for Benzodiazepines" ("CIWA-B").
  - (3) Prior to providing ambulatory detoxification, the physician assistant shall conduct and document a biomedical and psychosocial evaluation of the patient meeting the requirements of paragraph (B)(4) of this rule.

- (4) The physician assistant shall instruct the patient not to drive or operate dangerous machinery during treatment.
- (5) During the ambulatory detoxification, the physician assistant shall regularly assess the patient during the course of treatment so that dosage can be adjusted if needed.
- (a) The physician assistant shall require the patient to undergo urine and/or other toxicological screenings during withdrawal management in order to demonstrate the absence of use of alternative licit and/or illicit drugs.
- (b) The physician assistant shall document consideration of referring the patient who has a positive urine and/or toxicology screening to a higher level of care.
- (c) The physician assistant shall take steps to reduce the chances of diversion by using the appropriate frequency of office visits, pill counts, and weekly checks of OARRS.
- (F) The physician assistant who provides ambulatory detoxification with medication management of withdrawal from alcohol addiction shall comply with paragraphs (A), (B), and (C) of this rule and "TIP 45, A Treatment Improvement Protocol for Detoxification and Substance Abuse Treatment" by the Substance Abuse and Mental Health Services Administration available from the Substance Abuse and Mental Health Services Administration website at the following link: <https://store.samhsa.gov/> (Search for "TIP 45") and available from the Medical Board's website at: <https://med.ohio.gov>.
- (1) The physician assistant shall provide ambulatory detoxification from alcohol with medication management only when a positive and helpful support network is available to the patient who does not have a polysubstance dependence. The patient should exhibit no more than mild to moderate withdrawal symptoms, have no comorbid medical conditions or severe psychiatric disorders, and no past history of withdrawal seizures or withdrawal delirium.
- (2) Prior to providing ambulatory detoxification, the physician assistant shall perform and document an assessment of the patient. The assessment must focus on signs and symptoms associated with alcohol use disorder and include assessment with a nationally recognized scale, such as the "Clinical Institute Withdrawal Assessment for Alcohol-revised" ("CIWA-AR").

- (3) Prior to providing ambulatory detoxification, the physician assistant shall perform and document a biomedical and psychosocial evaluation meeting the requirements of paragraph (D)(4) of this rule.
- (4) During the course of ambulatory detoxification, the physician assistant shall assess the patient regularly:
- (a) The physician assistant shall adjust the dosage as medically appropriate;
  - (b) The physician assistant shall require the patient to undergo urine and/or other toxicological screenings in order to demonstrate the absence of illicit drugs;
  - (c) The physician assistant shall document the consideration of referring a patient who has a positive urine and/or toxicological screening to a higher level of care;
- (5) If the patient agrees to enter alcohol treatment and the physician assistant determines that such treatment is clinically appropriate, the physician assistant shall refer the patient to an alcohol treatment program licensed or certified by the Ohio department of mental health and addiction services to provide such treatment or to a physician, physician assistant, or advanced practice registered nurse who provides treatment using any FDA approved forms of medication assisted treatment for alcohol use disorder. The name of the program, physician, physician assistant, or advanced practice registered nurse to whom the patient was referred, and the date of the referral shall be documented in the patient record.
- (6) The physician assistant shall instruct the patient not to drive or operate dangerous machinery during treatment.

Effective: 10/31/2020

Five Year Review (FYR) Dates: 10/31/2025

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