4731-33-01 **Definitions.**

(A) "Office-based opioid treatment" or "OBOT" means medication-assisted treatment, as that term is defined in section 4729.553 of the Revided Code, in a private office or public sector clinic that is not otherwise regulated, by practitioners authorized to prescribe outpatient supplies of drugs approved by the United States food and drug administration for the treatment of alcoholism or opioid addiction, prevention of relapse of alcoholism or drug addiction, or both. OBOT includes treatment with all controlled substance drugs 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 SAMSHA and accredited by an independent SAMSHA-approved accrediting body; or

(5) A youth services facility, as defined in section 103.75 of the Revised Code.

(B) "SAMSHA" 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) "Qualified behavioral healthcare provder" means the following who is practicing within the scope of the professional license:

(1) Board certified addictionologist, board certified addiction psychiatrist, or psychiatrist, licensed under Chapter 4731. of the Revised Code;

(2) Licensed independent chemical dependency counselor-clinical supervisor, licensed independent chemical dependency counselor, licensed chemical dependency counselor III, or licensed chemical dependency counselor II, licensed under Chapter 4758. of the Revised Code;

(3) 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;

(4) 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.

(5) 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;

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

(7) An 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.

(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 with the assistance of medications.

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4731-33-03 **Office-based treatment for opioid addiction.**

(A) A physician who provides OBOT shall comply with both of the following requirements:

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

(2) 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 physician's "Category 1" continuing medical education requirement for biennial renewal of the physician's license.

(B) The physician who provides OBOT shall perform and document an assessment that includes all of the following:

(1) A comprehensive medical and psychiatric history;

(2) A brief mental status exam;

(3) Substance abuse history;

(4) Family history and psychosocial supports;

(5) Appropriate physical examination;

(6) Urine drug screen;

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

(8) Review of the patient's prescription information in OARRS;

(9) Testing for human immunodeficiency virus;

(10) Testing for hepatitis B;

(11) Testing for hepatitis C; and

(12) Consideration of screening for tuberculosis.

(C) The physician who provides OBOT shall establish and document a treatment plan that includes all of the following:

(1) The physician'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; and

(6) A plan for psychosocial treatment, pursuant to paragraph (E) of this rule.

(D) The physician 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/list/series?name=TIP-Series-Treatment-Improvement-Protocols-TIPS.

(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 2013, available from the website of the American society of addiction medicine at https://www.asam.org/.

(E) Except if the physician providing OBOT is a board certified addictionologist, board certified addiction psychiatrist, or psychiatrist, the physician 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 4731-33-01 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:

(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 4731-33-01 of the Administrative Code, the physician 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 shall require the patient to provide documentation of on-going participation in the program.

(5) Additional requirements related to the provider of behavioral health services:

(a) If the physician providing OBOT is a board certified addictionologist, psychiatrist, or board certified psychiatrist, the physician may personally provide behavioral health services for addiction.

(b) If the physician refers the patient to a qualified behavioral healthcare provider, community addiction services provider, or community mental health services provider, the physician shall document the referral and the physician's maintenance of meaningful interactions with the provider in the patient record.

(F) The physician who provides OBOT shall offer the patient a prescription for a naloxone kit.

(1) The physician 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 shall be exempt from this requirement if the patient refuses the prescription. If the patient refuses the prescription the physician 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 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/rems/index.cfm. With the exception of those conditions listed in paragraph (G)(2) of this rule, a physician who treats the opioid use disorder with a buprenorphine product shall only prescribe buprenorphine products containing naloxone for use in OBOT.

(2) The physician 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 methadone or buprenorphine mono-product to buprenorphine containing naloxone for a period not to exceed seven days;

(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 combination product of buprenorphine and naloxone is contraindicated, with the contraindication documented in the patient record; or

(e) When the patient has an allergy to or intolerance of a combination product of buprenorphine and naloxone, after explaining to the patient the difference between an allergic reaction and symptoms of opioid withdrawal precipitated by buprenorphine or naloxone, and with documenation 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 shall only co-prescribe these substances when there are extenuating circumstances.

(a) The physician shall verify the diagnosis for which the patient is receiving the other drug and coordinate care with the prescriber for the other drug, including discussing with the prescriber whether it is possible to taper the drug to discontinuation. If the physician prescribing buprenorphine is the prescriber of the other drug, the physician shall taper the other drug to discontinuation, if possible. The physician shall educate the patient about the serious risks of the combined use.

(b) The physician shall document progress with achieving the tapering plan.

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

(5) During the stabilization phase, when using any oral formulation of buprenorphine, the physician 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 shall prescribe no more than a two-week supply of the buprenorphine product containing naloxone.

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

(6) The physician 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 shall require urine drug screens or serum medication levels at twice per quarter for the first year of treatment and once per quarter thereafter.

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

(8) The physician shall incorporate relapse prevention strategies into counseling or assure that they are addressed by a qualified behavioral healthcare provider, as defined in rule 4731-33-01 of the Administrative Code, who has the education and experience to provide substance abuse counseling.

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

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

(b) The physician 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 shall document in the patient record the rationale for the use of the extended-release buprenorphine product.

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

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4731-33-04 **Medication-assisted treatment using naltrexone.**

(A) In addition to the requirements of paragraphs (A) through (F) of rule 4731-33-03 of the Administrative Code, the physician 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 shall inform the patient about the risk of opioid overdose if the patient ceases naltrexone and then uses opioids. The physician 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 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 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 shall require urine drug screens or serum medication levels at least every three months for the first year of treatment and at least every six months thereafter.

(d) The physician shall incorporate relapse prevention strategies into counseling or assure that they are addressed by a qualifed behavioral healthcare provider, as defined in rule 4731-33-01 of the Administrative Code, who has the education and experience to provide substance abuse counseling.

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

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

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

(3) The physician shall incorporate relapse prevention strategies into counseling or assure that they are addressed by a qualified behavioral healthcare provider, as defined in rule 4731-33-01 of the Administrative Code, who has the education and experience to provide substance abuse counseling.

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