Ohio Administrative Code

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

Effective: April 30, 2019

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

(1) Before initiating OBOT, the physician 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; and

(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 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 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

(l) 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 pregnancy test, the physician 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 shall document the reasons in the medical record.

(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.

(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) 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, 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 and 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 or appropriate self-help recovery program. If the patient is required to participate in a twelve step program or self-help recovery 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 offer the patient a new prescription for naloxone upon expiration or use of the

old kit.

(3) 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) to (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/naloxone combination products 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 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 documented 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 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 it is medically necessary.

(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 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 it is safe to do so. 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 during this phase.

(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, serum medication levels, or oral fluid 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 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.