

TO BE RESCINDED

4731-11-12 **Office based opioid treatment.**

(A) For the purposes of this rule:

- (1) "Office Based Opioid Treatment," or "OBOT," means treatment of opioid addiction utilizing a "Schedule III, IV, or V" controlled substance narcotic.
- (2) "Board certified addictionologist or addiction psychiatrist" means a medical doctor or doctor of osteopathic medicine and surgery who holds one of the following certifications:
 - (a) Subspecialty board certification in addiction psychiatry from the American board of psychiatry and neurology;
 - (b) Board certification in addiction medicine from the American board of addiction medicine;
 - (c) Certification from the American society of addiction medicine; or
 - (d) Board certification with additional qualification in addiction medicine from the American osteopathic association.

(B) A physician shall provide OBOT in compliance with all of the provisions of this rule.

- (1) The physician shall comply with all federal and state laws applicable to OBOT;
- (2) Prior to providing OBOT, the physician shall conduct an assessment meeting the following requirements:
 - (a) The assessment shall include, at a minimum, an appropriate history and physical, mental status exam, substance use history, appropriate lab tests, pregnancy test for women of childbearing years, toxicology tests for drugs and alcohol, and "hepatitis B" and "hepatitis C" screens.
 - (b) For other than the toxicology tests for drugs and alcohol, appropriate history, substance abuse history, hepatitis "B" and "C" screens and the pregnancy test, the physician may satisfy the assessment requirements by reviewing records from a physical examination of the patient that was conducted by a physician within a reasonable period of time prior to the visit. For purposes of this paragraph, "physician" means an individual holding a certificate under Chapter 4731. of the Revised Code to practice medicine and surgery, osteopathic medicine and surgery, or podiatric medicine and surgery and practicing within his or her scope of practice as defined

by section 4731.51 of the Revised Code, or an individual practicing in another state where the individual holds an active and unrestricted license to practice medicine and surgery, osteopathic medicine and surgery, or podiatric medicine and surgery and practicing within his or her scope of practice.

- (3) The physician shall practice in accordance with an acceptable treatment protocol for assessment, induction, stabilization, maintenance and tapering. Acceptable protocols are any of the following:
 - (a) “Clinical Guidelines For the Use of Buprenorphine in the Treatment of Opioid Addiction” protocol approved by the substance abuse and mental health services administration in 2004, (available from the substance abuse and mental health services administration website at <http://samhsa.gov/>);
 - (b) The low dose protocol approved by the Ohio department of alcohol and drug addiction services in or about 2011 (available from the Ohio department of mental health and addiction services website at <http://mha.ohio.gov/>);
or
 - (c) Any protocol for OBOT approved by the Ohio department of mental health and addiction services and available from the Ohio department of mental health and addiction services website at <http://mha.ohio.gov>.
- (4) The physician shall diagnose an opioid disorder utilizing the criteria contained in the diagnostic and statistical manual of mental disorders, 4th or 5th edition.
- (5) The physician shall develop an individualized treatment plan for each patient
- (6) The physician shall require each patient to actively participate in appropriate behavioral counseling or treatment for their addiction and shall document at each visit that the patient is attending sufficient behavioral health treatment.
 - (a) The physician shall maintain meaningful interactions with the qualified chemical dependency professional, addiction treatment provider, or other behavioral health professional who is treating the patient.
 - (b) If the physician is a psychiatrist, board certified addictionologist, or board certified addiction psychiatrist, the physician may personally provide behavioral health treatment for the addiction.
 - (c) If the physician determines that the patient cannot reasonably be required to obtain professional treatment or if the patient has successfully completed

professional treatment, the physician shall require the patient to actively participate in a recovery care program such as alcoholics anonymous, narcotics anonymous, or other appropriate twelve step program, and to document attendance at program meetings.

- (i) For at least the first year the physician shall require the patient to attend the meetings at least three times weekly.
 - (ii) Following the first year, the physician shall determine the frequency with which the patient shall be required to attend the meetings.
 - (iii) The physician shall document in the patient record the reasons that the patient cannot reasonably be required to obtain professional treatment.
- (7) The physician shall provide OBOT utilizing a drug product that has been specifically approved by the United States food and drug administration for use in maintenance and detoxification treatment. A physician shall not provide OBOT utilizing a drug product that has not been specifically approved by the United States food and drug administration for use in maintenance and detoxification treatment
- (8) The physician shall comply with all of the following:
- (a) During the first twelve months of treatment, the physician shall not prescribe, personally furnish, or administer more than a thirty day supply of OBOT medications at one time.
 - (b) The physician shall personally meet with and evaluate the patient at each visit during the first twelve months of OBOT, and shall document an assessment and plan for continuing treatment.
 - (c) After twelve months of OBOT, the physician shall personally meet with and evaluate the patient at least every three months, unless more frequent meetings are indicated.
- (9) The physician shall not provide OBOT to a patient whom the physician knows or should know is receiving other controlled substances for more than twelve consecutive weeks on an outpatient basis from any provider, without having consulted with a board certified addictionologist or addiction psychiatrist, who has recommended the patient receive OBOT. If the physician is a board certified addictionologist or addiction psychiatrist, the consultation is not required.

- (10) The physician shall not prescribe, personally furnish, or administer greater than 16 milligrams of buprenorphine per day to a patient, except in one of the following situations:
- (a) The dosage greater than 16 milligrams was established before the effective date of this rule;
 - (b) The physician is a board certified addictionologist or addiction psychiatrist and has determined that a dosage greater than 16 milligrams is required for the patient, and has documented patientspecific reasons for the need for a dosage greater than 16 milligrams in the patient’s record; or
 - (c) The physician has consulted with a board certified addictionologist or addiction psychiatrist who has recommended a dosage greater than 16 milligrams and that fact is documented in the patient’s medical record.
- (11) The physician shall access OARRS for each patient no less frequently than every ninety days, and shall document receipt and assessment of the information received.
- (12)) The physician shall provide ongoing toxicological testing in compliance with all of the following:
- (a) The physician shall assure that any inoffice kit used is “Clinical Laboratory Improvement Amendments” waived.
 - (b) The physician shall require toxicological testing be performed at least monthly for the first six months, then randomly at least once every three months thereafter.
 - (c) The physician may accept the results of toxicological testing performed by a treatment program or pursuant to a court order to satisfy the requirements of paragraph (B)(12)(b) of this rule.
 - (d) A screen is failed if the result is inconsistent with the treatment plan. A physician shall address failed screens in a clinically appropriate manner.
- (13) Each physician who provides OBOT shall complete at least eight hours of “Category I” continuing medical education relating to substance abuse and addiction every two years. Courses completed in compliance with this rule shall be accepted toward meeting the physician’s “Category I” continuing medical education requirement for biennial renewal of the physician’s certificate.

- (C) Notwithstanding the provisions of this rule, a physician may provide OBOT to a pregnant patient during the term of her pregnancy and for two months thereafter, in compliance with the minimal standards of care.
- (D) A violation of any provision of this rule, as determined by the board, shall constitute any or all of the following violations:
- (1) “Failure to maintain minimal standards applicable to the selection or administration of drugs,” and “failure to employ acceptable scientific methods in the selection of drugs or other modalities for treatment of disease,” as those clauses are used in division (B)(2) of section 4731.22 of the Revised Code, and “ a departure from, or the failure to conform to, minimal standards of care of similar physicians under the same or similar circumstances, whether or not actual injury to a patient is established,” as that clause is used in division (B) (6) of section 4731.22 of the Revised Code.
 - (2) A violation of paragraph (B)(7) of this rule shall further constitute “selling, prescribing, giving away, or administering drugs for other than legal and legitimate therapeutic purposes,” as that clause is used in division (B)(3) of section 4731.22 of the Revised Code.

Effective:

Five Year Review (FYR) Dates: 10/24/2018

Certification

Date

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