



# CSI - Ohio

The Common Sense Initiative

## Business Impact Analysis

Agency Name: State Medical Board of Ohio

Regulation/Package Title: Office based treatment of opioid addiction

Rule Number(s): 4730-4-01, 4730-4-03, 4730-4-04, 4731-11-12, 4731-33-01, 4731-33-03,  
4731-33-04

Date: August 3, 2018

**Rule Type:**

New

5-Year Review

Amended

Rescinded

The Common Sense Initiative was established by Executive Order 2011-01K and placed within the Office of the Lieutenant Governor. Under the CSI Initiative, agencies should balance the critical objectives of all regulations with the costs of compliance by the regulated parties. Agencies should promote transparency, consistency, predictability, and flexibility in regulatory activities. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

### Regulatory Intent

1. Please briefly describe the draft regulation in plain language.

*Please include the key provisions of the regulation as well as any proposed amendments.*

Sections 4730.55 and 4731.056, Ohio Revised Code, require the Medical Board to adopt rules that establish standards and procedures to be followed by physician assistants and physicians in the use of all drugs approved by the FDA for use in medication-assisted treatment, including controlled substances in Schedules III, IV, or V. The required rules must address:

- detoxification,
- relapse prevention,
- patient assessment,
- individual treatment planning,
- counseling and recovery supports,
- diversion control, and
- any other topics selected by the Medical Board after considering best practices in medication assisted treatment.

The Revised Code sections state that the Medical Board may apply the rules to all settings or limit the application of the rules to medication-assisted treatment in the office setting or other practice types and locations.

The rules submitted in this package address the statutorily required components except for detoxification. In the future rule 4730-4-02 and 473-33-02 will be drafted to set standards and procedure for detoxification. For efficiency, the discussion in this rule uses the proposed physician rules (Chapter 4731-33) because the physician assistant rules (Chapter 4730-4) are consistent with the physician rules.

The rules provide treatment parameters for prescribers who wish to treat opiate addiction via office-based treatment with controlled substances in schedule III, IV, or V (“OBOT”) that have been specifically approved by the U.S. Food and Drug Administration (hereinafter “FDA”) or by a non-controlled substance. At this time the only approved controlled substances are buprenorphine products, including the drug with the brand name of Suboxone. The only FDA approved non-controlled substance for treating opioid addiction is Naltrexone, which is sold under the brand name Vivitrol, among others.

The need for regulation is urgent, as there are reports that some prescribers are setting up “pill mills” for specifically approved buprenorphine products, similar to the “pill mills” where prescription opiates such as OxyContin and Vicodin were prescribed for other than legitimate medical purposes (see [http://www.nytimes.com/2013/11/17/health/in-demand-in-clinics-and-on-the-street-buprecan-be-savior-or-menace.html?\\_r=1&](http://www.nytimes.com/2013/11/17/health/in-demand-in-clinics-and-on-the-street-buprecan-be-savior-or-menace.html?_r=1&) ). Recognizing the constellation of factors related to opiate addiction, treatment, and illegal activity, the rules attempt to strike a proper balance between access to opiate addiction treatment and diversion of specifically approved buprenorphine products by setting forth the requirements for treating opiate addiction in a non-institutional setting so that the treatment can be performed in a safe manner for the patient and reduce the risk of unlawful behavior of patients, practitioners, and others.

Current rule 4731-11-12, Ohio Administrative Code, will be repealed.

**2. Please list the Ohio statute authorizing the Agency to adopt this regulation.**

The rules are authorized by Sections 4730.07, 4730.55, 4731.05, and 4731.056 of the Revised Code.

- 3. Does the regulation implement a federal requirement? Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program?**

*If yes, please briefly explain the source and substance of the federal requirement.*

The rules do not implement a federal requirement.

- 4. If the regulation includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.**

Sections 4730.55 and 4731.056 of the Revised Code require the Medical Board to adopt the rules.

- 5. What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?**

The rules implement the policy of the State of Ohio to set minimum standards and procedures for the provision of medication-assisted treatment. The policy reflects concerns that some medication-assisted treatment programs have provided such treatment outside of the minimal standards of care.

- 6. How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?**

The success of the rules will be measured by having rules written in plain language, licensee compliance with the rules, and minimal questions from licensees, medical practices, and medical facilities regarding the provisions of the rule.

### **Development of the Regulation**

- 7. Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.**

*If applicable, please include the date and medium by which the stakeholders were initially contacted.*

The initial draft of the rules was completed with significant input from the Ohio Department of Mental Health and Addiction Services (“ODMHAS”) and the Ohio Board of Nursing (“Nursing Board”). The physician assistant rules (Chapter 4730-4) were then discussed with the members of the Physician Assistant Policy Committee (“PAPC”), which is composed of three physician assistants, an M.D., a D.O., and a physician member of the Medical Board, at a public meeting held on February 12, 2018. The physician rules (Chapter 4731-33) were discussed by the Medical Board’s Policy Committee at a public meeting on February 14, 2018.

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On February 21, 2018, the draft rules were sent to interested parties. The parties included, but not limited to: Ohio State Medical Association, Ohio Osteopathic Association, Ohio Academy of Family Physicians, Ohio Association of Physician Assistants, Academy of Medicine of Cleveland and Northern Ohio, physicians at Medical Board approved treatment facilities, persons who requested notice of proposed rules applicable to prescribing, and organizations and individuals who have a standing request to receive notice of Medical Board rule activity.

**8. What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?**

Input from the stakeholders significantly affected the draft rules. The proposed rules were circulated twice for comments from interested parties.

1. Thirty-three comments were received in response to the first circulation. The spreadsheet summarizing the comments is attached to this memo.
2. The rules were then revised and sent for comment by all persons who had commented initially. Four comments were received. The spreadsheet summarizing the comments is attached to this memo.

**I. Discussion of comments and proposed resulting changes to the draft rules**

**RULE 4731-33-01 DEFINITIONS:**

**Paragraph (A):** As originally drafted, the definition of “OBOT” did not list the exceptions to the definition. Instead, the exceptions were in rule 4731-33-03. As suggested by the Nursing Board, moving the exceptions to the definition of OBOT adds clarity. Also, wording referencing “alcoholism” was deleted as it is misleading. OBOT is only applicable to treatment for opioid addiction.

Also, at the suggestion of the Nursing Board, a youth services facility was added as an exception.

**Paragraphs (C) and (D):** Substance use disorder is substituted for alcoholism or drug addiction because it is the term used by professionals in the field.

**Paragraph (F):** The definition of “qualified behavioral healthcare provider” is amended in paragraph (F)(3) to include marriage and family therapists and in (F)(2) to list out the professionals licensed under Chapter 4758 of the Revised Code, as recommended by the Ohio Council of Behavioral Health & Family Services Providers.

The Ohio Association of Physician Assistants (“OAPA”) commented that a physician assistant should be included in “behavioral health care provider,” and the rules should reflect that a board certified addictionologist, board certified addiction psychiatrist, or psychiatrist who supervises a

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**[CSIOhio@governor.ohio.gov](mailto:CSIOhio@governor.ohio.gov)**

physician assistant may authorize the physician assistant to provide whatever services are within the physician's normal course of practice. However, the professions included as "behavioral health care provider" are those that have formal education focused in behavioral health in order to obtain advanced certification or licensure. The formal education usually requires fulfillment of academic and supervised practice requirements. The original draft of the rules submitted to the PAPC included within the definition a physician assistant who had successfully completed a postgraduate program residency or fellowship program in psychiatry from an accredited program for physician assistants. However, PAPC members stated that those programs no longer exist. The physician assistant's basic medical education is an internal medicine focus. There are not formal education programs through which the physician assistant may complete formal education focused on behavioral health that will result in an advanced degree or certification after examination. Accordingly, the OAPA comment has not resulted in amendment of the language.

**Paragraph (G):** The definition of "mental health service provider" is deleted because we learned that mental health services are included within behavioral healthcare services.

**New paragraph (G):** "Community addiction services provider" is added, as recommended by the Ohio Counsel of Behavioral Health & Family Service Providers.

**Paragraph (H):** "Community mental health services provider" is added, as recommended by the Ohio Counsel of Behavioral Health & Family Service Providers.

**Paragraphs (I) and (J)** added to define terms for clarification.

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

**Old paragraph (A):** Originally paragraph (A) listed the entities where the rule would not be applicable. However, those exceptions to the rule were moved to the definition of "office based treatment for opioid addiction" in rule 4731-33-01.

**New paragraph (A):** This paragraph now states that the physician must comply with all federal and state laws and regulations. A requirement to complete at least eight hours of Category 1 CME related to substance abuse and addiction every two years has been added, as is in current rule 4731-11-12.

**Paragraph (B):** In Subparagraph 12, TB testing is no longer required, but screening must be considered.

Basis: ASAM recommends that TB testing "be considered." TIP 63 is silent as to TB testing. Comments received are that TB is rare and expensive so should be at physician's discretion. A physician member of the Medical Board expressed that TB is now on the rise. Dr. Hurst suggests use of "screening" instead of testing. The rule does not require screening, but defers to the physician's judgement after consideration of screening.

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There were comments that requiring HIV, Hepatitis B, and Hepatitis C testing is expensive and discourages patient entry into treatment. However, ASAM and Tip 63 recommend they be included in the assessment. The language was not changed.

**Paragraph (D):** Subparagraph (2), the web link for the ASAM guideline is changed to the general ASAM website.

**Paragraph (E):** Language is added to clarify that if the physician providing OBOT is a board-certified addictionologist, board certified addiction psychiatrist, or psychiatrist, the physician may personally provide the behavioral health services for addiction. Added at ODMHAS' suggestion.

- Language is also added to include community mental health services providers and community addiction services providers for purposes of referring and collaborating for the psychosocial treatment. Basis: This reflects the comments by the Ohio Council of Behavioral Health & Family Services Providers that these agencies are important providers of such needed services, especially for patients on Medicaid.
- Subparagraph (2): Some comments were that the list of treatments should not be included. However, they are recommended superior psychosocial treatments by ASAM.
- Subparagraph (3): The word “renegotiation” was changed to “revision,” at the suggestion of ODMHAS.
- Subparagraph (5): Two subparagraphs were added. One clarifies when the prescribing physician may provide the behavioral health services. The other requires documentation when the patient is referred to a behavioral health services provider, community addiction services provider, or community mental health services provider.

**Paragraph (F):** The language is amended to require the physician to offer a prescription for a naloxone kit, instead of providing a kit or a prescription for one. Subparagraph (2) states that if the patient refuses the prescription the physician shall give the patient information on where to obtain a kit without a prescription.

**Paragraph (G):** This paragraph applies to OBOT using buprenorphine products.

- Subparagraph (1): Wording is added to require that the provision of buprenorphine products be in compliance with the FDA approved REMS. According to the FDA, “[a] Risk Evaluation and Mitigation Strategy (REMS) is a drug safety program that the U.S. Food and Drug Administration (FDA) can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks. REMS are designed to reinforce medication use behaviors and actions that support the safe use of that medication. While all medications have labeling that informs health care stakeholders about medication risks, only a few medications require a REMS.”  
<https://www.fda.gov/Drugs/DrugSafety/REMS/default.htm>

- Subparagraph (2)(a): Adds “breast-feeding” to the situations in which the buprenorphine mono-product may be prescribed.
- Subparagraph (2)(d): Is added to recognize that the mono-product is used for withdrawal management.
- Subparagraph (2)(e): Is added because numerous comments were received stating that although rare, allergy to naloxone does occur. Commenters indicated that documentation of the allergy should be required.
- Subparagraph (3): Several comments suggested it is not always possible to taper the patient off of other CNS depressants. Language added to reflect information in the 9-20-17 FDA Drug Safety Announcement concerning co-prescribing of buprenorphine and a benzodiazepine, which increases the risks of overdose.
- Subparagraph (4): The language is changed to be less specific as to dosage but instead to require that during the induction phase the physician shall not prescribe a dosage that exceeds the recommendation in the FDA approved labeling, except for medically indicated circumstances documented in the medical record.

Basis: The original language provided a cap of 8mg to start induction, but it was read as not to exceed 8mg during the entire induction period. The changed language reflects TIP 63, which cites the FDA label recommendation of a maximum of 8mg on day 1 and 16 mg on day 2 of induction, and also states that the clinical rationale must be documented when dosing outside of the FDA recommendation.

- Subparagraph (5): The phrase “when using a buprenorphine transmucosal product” is added to clarify that requirements of the paragraph do not prevent the usage of extended-release forms of buprenorphine.
- Subparagraph (5)(b): The phrase “and until the completion of twelve months of treatment” is added to clarify that the patient should only be given a thirty-day prescription for the first twelve months of treatment, as is required by current Rule 4731-11-12.
- Subparagraph (7): Several comments suggested that the cap of twenty-four mgs per day was too low. However, it is not proposed to be changed because TIP 63 says that dosage above 24 mg shows no clinical advantage. ASAM discusses the FDA approval of a dosing limit of 24 mg per day, and does not contradict it or suggest that documentation might cure prescribing of a dosage exceeding 24 mg.
- Subparagraph (9): The language is amended to clarify that the provisions apply to an extended-release, injectable, or implanted buprenorphine product.

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### III. RULE 4731-33-04 Medication assisted treatment using a non-controlled substance

- The rule requires use of a dosage regime that strictly complies with the FDA labeling.
- Several commenters asked why there are requirements to discourage diversion of Naltrexone when it is not a controlled substance and has no street value. Therefore, the language regarding diversion was deleted. However, the requirement for urine drug screens remains in the proposed rule because urine screens are recommended by ASAM when treatment is by Naltrexone.

#### 9. What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?

The rule was developed based upon the two published protocols.

- “TIP 63, Treatment Improvement Protocol, Medications for Opioid Use Disorder for Healthcare and Addiction Professionals, Policymakers, Patients, and Families,” published by the Substance Abuse and Mental Health Services Administration: <https://store.samhsa.gov/product/TIP-63-Medications-for-Opioid-Use-Disorder-Executive-Summary/SMA18-5063EXSUMM>
- “The ASAM National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use,” published by the American Society of Addiction Medicine: <https://www.asam.org/docs/default-source/practice-support/guidelines-and-consensus-docs/asam-national-practice-guideline-supplement.pdf>

The rule also benefited from the input of the medical director and other staff of the Ohio Department of Mental Health and Addition Services. ODMHAS certifies community behavioral health agencies that provide behavioral health services and is the lead Ohio agency for addiction services information.

#### 10. What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn't the Agency consider regulatory alternatives?

See response to question #8, above.

#### 11. Did the Agency specifically consider a performance-based regulation? Please explain. *Performance-based regulations define the required outcome, but don't dictate the process the regulated stakeholders must use to achieve compliance.*

The proposed rules set out the required activities but do not specify the means of performing the required activities.

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**12. What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?**

The Medical Board is the only agency authorized to regulate the prescribing practices of physicians and physician assistants. The Medical Board worked closely with ODMHAS so that the rules do not conflict with that agency's recommendations concerning medication-assisted treatment for opioid addiction.

**13. Please describe the Agency's plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community.**

The rules will be posted on the Medical Board's website, information concerning the rules will be included in informational materials e-mailed to licensees, and notices will be sent to associations, individuals, and groups. Medical Board staff members are available by telephone and e-mail to answer questions. Medical Board staff members also give presentations to groups and associations who seek an update on physician practice regulations.

**Adverse Impact to Business**

**14. Provide a summary of the estimated cost of compliance with the rule. Specifically, please do the following:**

**a. Identify the scope of the impacted business community;**

The impacted business community is composed of physicians and physician assistants who provide medication-assisted treatment for opioid addiction.

**b. Identify the nature of the adverse impact (e.g., license fees, fines, employer time for compliance); and**

The adverse impact is the cost of continuing education related to substance abuse and addiction. While the physician or physician assistant is already required to complete continuing education (See Section 4730.14 and 4731.282 of the Ohio Revised Code), the rule requires eight hours to be completed in coursework related to substance abuse and addiction. The eight hours will be counted as part of the overall continuing education hours.

The physician or physician assistant who chooses to provide medication-assisted treatment for opioid addiction will also incur the cost of the time needed to perform the required assessment, formulation of an appropriate treatment plan for each patient, and documentation of compliance with the activities required by the rule. However, the required activities should not add significantly to the practice costs of a physician or physician assistant who practices within the minimal standards of care.

The U.S. Drug Enforcement Administration (DEA) requires, pursuant to 21 USC § 823(g)(2), that a physician or physician assistant who intends to prescribe certain controlled substance medications for the purposes of maintenance and detoxification of opiate addiction receive a waiver from special registration requirements (waiver). There is no fee associated with applying for the waiver. A physician or physician assistant who intends to prescribe specifically approved buprenorphine products, which are a schedule III, IV, or V controlled substance, must have a current DEA certificate of registration (also known as a DEA number).

Individuals who receive formal disciplinary action for violating these rules will be subject to civil penalties as set forth in Sections 4730.252 and 4731.225, Ohio Revised Code

**c. Quantify the expected adverse impact from the regulation.**

*The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a “representative business.” Please include the source for your information/estimated impact.*

The fee associated with the DEA registration is \$731.00 for the initial application and for every three year renewal cycle. In order to qualify for a waiver, the physician or physician assistant must obtain and maintain a certain enumerated specialty certification required by the DEA or eight hours of training approved by certain associations (See [http://buprenorphine.samhsa.gov/SMA-167\\_Increase\\_Patients.pdf](http://buprenorphine.samhsa.gov/SMA-167_Increase_Patients.pdf) ). Some courses may have a fee, but the courses are offered free of charge by Providers of Clinical Support System: <https://pcssnow.org/>.

Continuing education course options range from a three-day, eight hour course by the American Society of Addiction Medicine for up to \$890 (depending on membership status): <https://www.asam.org/education/live-online-cme/the-asam-state-of-the-art-2018/registration-rates> to “Opioid Use Disorder,” a ten-hour course offered by NetCE for \$40: <https://www.netce.com/courseoverview.php?courseid=1611>.

Individuals who receive formal disciplinary action for violating these rules will be subject to civil penalties as set forth in 4731.225, Ohio Revised Code.

**15. Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community?**

Ohio is experiencing an epidemic of opiate abuse and overdose deaths. Specifically approved buprenorphine products have been used successfully for the maintenance treatment for opioid dependence as part of a treatment plan that includes counseling and psychosocial

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support. However, specifically approved buprenorphine products are themselves opioids that are subject to abuse. Concerns have been brought forward by law enforcement, treatment providers, and governmental agencies that office based maintenance treatment with specifically approved buprenorphine products may be contributing to the opiate problem in Ohio. In compliance with Sections 4730.55 and 4731.056 Ohio Revised Code, protection of the public, in general, and persons with opiate addiction, in particular, necessitates that the Medical Board regulate the office based maintenance treatment of persons with opiate addiction in a safe manner, yet at the same time providing greater access to that treatment in Ohio.

### **Regulatory Flexibility**

**16. Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.**

Treatment of patients with opioids is a complex matter which impacts the health and safety of patients. The public safety requirements relevant to these rules require consistency in their application to all licensees and are not amenable to exemptions or alternative means of compliance for small businesses.

**17. How will the agency apply Ohio Revised Code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation?**

Due process requires the Medical Board to consistently apply its rules regarding controlled substance prescribing such that all prescriber licensees are equally treated.

**18. What resources are available to assist small businesses with compliance of the regulation?**

Medical board staff members are available by telephone and e-mail to answer questions.

4730-4-01 Definitions

(A) "Office-based Opioid Treatment" or "OBOT" means medication-assisted treatment, as that term is defined in section 4729.553 of the Revised 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 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 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 or legal or illegal drugs, as determined by diagnostic criteria in the 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 provider" means the following who is practicing within the scope of practice 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 Administrative Code;

- (3) Professional clinical counselor, or 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.

4730-4-03 Office based treatment for opioid addiction

- A. A physician assistant shall provide OBOT in compliance with the following requirements:
1. Comply with all federal and state laws and regulations governing the prescribing of the medication;
  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 continuing medical education requirement for biennial renewal of the physician assistant's license; and
  3. 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 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 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/list/series?name=TIP-Series-Treatment-Improvement-Protocols-TIPS-&pageNumber=1>.

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 Ohio department of mental health and addiction services at <https://www.asam.org/docs/default-source/practice-support/guidelines-and-consensus-docs/asam-national-practice-guideline-supplement.pdf>.
- 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:
    - 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 health service 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 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 FDA approved “Risk Evaluation and Mitigation Strategy” for buprenorphine products. With the exception of those conditions listed in paragraph (G)(2) of this rule, a physician assistant who treats the opioid use disorder with a buprenorphine product shall only prescribe a combination product of buprenorphine and naloxone 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 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 FDA;
  - 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 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, and tramadol, the physician assistant shall only co-prescribe these substances when there are extenuating circumstances.
  - 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 discussing with the prescriber 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 possible. 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 FDA labeling, except for medically indicated circumstances as documented in the medical record. The physician assistant shall see the patient at least once a week.
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 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 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 or serum medication levels at twice per quarter for the first year of treatment and once per quarter thereafter.
7. The physician assistant shall document in the medical record the rationale for prescribed doses exceeding 16 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 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 program for the drug.
  - b. The physician assistant shall prescribe an extended-release buprenorphine product strictly in accordance with the food and drug administration's approved labeling for the drug's use.
  - c. The physician assistant shall document in the patient record the rational for the use of the extended-release buprenorphine product.

- d. The physician assistant who orders or prescribes extended-release buprenorphine shall require it to be administered by a physician assistant licensed under chapter 4730. of the Revised Code or a nurse licensed under chapter 4723. of the Revised Code, when the physician assistant or nurse is acting in accordance with the scope of practice of their professional license.

4730-4-04 Medication assisted treatment using naltrexone.

- A. In addition to the requirements of 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 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 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 assistant shall incorporate relapse prevention strategies into counseling or assure that they are addressed by a qualified behavioral healthcare or mental health service 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 food and drug administration 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 or mental health service provider, as defined in rule 4730-4-01 of the Administrative Code, who has the education and experience to provide substance abuse counseling.

## 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 Revised 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 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 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 or legal or illegal drugs, as determined by diagnostic criteria in the 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 provider" means the following who is practicing within the scope of practice 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 Administrative Code;

3. Professional clinical counselor, or 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.

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-&pageNumber=1>.
  - 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 Ohio department of mental health and addiction services at <https://www.asam.org/docs/default-source/practice->

[support/guidelines-and-consensus-docs/asam-national-practice-guideline-supplement.pdf](https://www.asam.org/about-us/support/guidelines-and-consensus-docs/asam-national-practice-guideline-supplement.pdf).

- 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 service for addiction.
    - b. If the physician refers the patient to a qualified behavioral health service 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 FDA approved "Risk Evaluation and Mitigation Strategy" for buprenorphine products. 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 FDA;
    - 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 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, and 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 recommendation in the FDA labeling, except for medically indicated circumstances as documented in the medical 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 also require urine drug screens or serum medication levels at twice per quarter for the first year of treatment and once per quarter thereafter.
7. The physician shall document in the medical record the rationale for prescribed doses exceeding 16 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 strictly in accordance with the 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 shall only delegate the administration of extended-release buprenorphine to a physician assistant licensed under chapter 4730. of the Revised Code or a nurse licensed under chapter 4723. of the Revised Code, when the physician assistant or nurse is acting in accordance with the scope of practice of their professional license.

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 qualified behavioral healthcare or mental health service 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-occurring 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 injection dosage shall strictly comply with food and drug administration 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 or mental health service provider, as defined in rule 4731-33-01 of the Administrative Code, who has the education and experience to provide substance abuse counseling.

4731-11-12

**Office based opioid treatment -- TO BE REPEALED.**

(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.