

**FAQS for RULE 4731-11-12, Ohio Administrative Code:
OFFICE BASED OPIOID TREATMENT (OBOT)**

Updated February 23, 2015

- 1. Does the rule apply to an Ohio licensed physician who provides OBOT in another state, but whose Ohio practice does not include OBOT, or who does not practice in Ohio at all?**

No. The rule is only applicable to an Ohio licensed physician who provides OBOT within the state of Ohio.

- 2. Must I wait for results of lab tests before I can provide a buprenorphine product to a patient for purposes of office based opioid treatment?**

The rule requires the physician to conduct the initial assessment, not complete it. However, the physician must have sufficient information to identify comorbid or complicating medical or emotional conditions and to determine the appropriate treatment setting and level of treatment intensity for the patient.

- 3. If a patient is stabilized on a dosage that is greater than 16mg per day prior to January 31, 2015, the effective date of the rule, must the patient's dosage be lowered to no more than 16mg per day?**

A patient who was stabilized on a dosage that is greater than 16mg per day prior to January 31, 2015 may be continued on the dosage as long as doing so complies with the minimal standards of care.

- 4. What should be included in the individualized treatment plan?**

The rule does not mandate the contents of a treatment plan. A treatment plan is generally understood to be a written plan that describes the patient's condition and services that will be needed, the treatment to be provided and expected outcome, and expected duration of the treatment. For additional information, please review the "Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction," protocol available from the SAMHSA website at: <http://samhsa.gov/>. Search for "TIP 40."

- 5. If my office protocol calls for monthly toxicology screens, do we have to perform random toxicology screens?**

Toxicology screens must be performed at least monthly during the patient's first six months of treatment, then randomly at last once every three months thereafter.

6. May OBOT be provided to a patient who is prescribed a controlled substance such as Lyrica, a stimulant, or Ambien on an on-going basis?

It depends. If the physician providing OBOT is not a board certified addictionologist or an addiction psychiatrist, the physician must consult with a board certified addictionologist or addiction psychiatrist. If the consulting board certified addictionologist or addiction psychiatrist recommends that the patient receive OBOT, the physician may provide the OBOT treatment. For additional information, please review Chapter 2 of the “Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction,” protocol available from the SAMHSA website at: <http://samhsa.gov/>. Search for “TIP 40.”

7. May OBOT be provided to a patient who is taking a benzodiazepine?

See the answer to Question 6, above. For more information concerning the drug interactions between buprenorphine products and benzodiazepines, see Chapter 2 of the “Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction,” protocol available from the SAMHSA website at: <http://samhsa.gov/>. Search for “TIP 40.”

8. How do you find a board certified addictionologist or addiction psychiatrist?

The Medical Board’s website has a database that lists all physicians, including their practice specialty. Also, local medical societies and hospitals may have information concerning board certified addictionologists and addiction psychiatrists in your area. The website for the American Board of Medical Specialties can also be searched at the following link: <https://www.certificationmatters.org/is-your-doctor-board-certified/search-now/zipcode/43202/state/oh/cert/146.aspx>.

For additional information, please review Chapter 6 of the “Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction,” protocol available from the SAMHSA website at: <http://samhsa.gov/>.

9. If an addiction psychiatrist or board certified addictionologist is performing the counseling, at what frequency must the psychiatrist need to meet with the patient?

The board certified addictionologist or addiction psychiatrist determines the frequency with which the patient must be seen.

10. Does a pregnancy test need to be performed on female patients at every visit?

The rule requires that a pregnancy test be conducted as part of the initial assessment for women of childbearing age. After the initial assessment, the physician should consider periodic re-testing for female patients of child bearing age or, at a minimum, asking the patient whether there is a chance she is pregnant.

- See revised FDA product labeling for Suboxone at the following link: http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/020733Orig1s014lbl.pdf
- See revised product labeling for Subutex at the following link: http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/020732Orig1s010lbl.pdf.

11. Must the Hepatitis B and Hepatitis C testing be performed on a patient who reports never having injected drugs?

Yes. Hepatitis B and Hepatitis C screens are recommended as part of the baseline laboratory evaluation by the “Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction,” protocol available from the SAMHSA website at: <http://samhsa.gov/>. Search for “TIP 40.”

These diseases can be passed from one person to another via various means. For more information see information from the CDC at the following links:

- <http://www.cdc.gov/hepatitis/B/>
- <http://www.cdc.gov/hepatitis/C/>

12. What is required for “meaningful interaction” with the qualified chemical dependency professional, addiction treatment provider, or other behavioral health professional who is providing behavioral counseling or treatment for the patient?

“Meaningful interaction” means the physician has communicated with the qualified chemical dependency professional, addiction treatment provider, or other behavioral health professional sufficiently to ascertain the patient’s progress and status.

13. If I determine that the patient cannot reasonably be required to obtain professional treatment or if the patient has successfully completed professional treatment, the rule states the physician must require the patient to actively participate in a recovery care program. Must the recovery care program be a 12-step program?

Yes. The rule requires that the recovery care program be a 12-step program. It should be noted that faith-based recovery programs may be 12-step programs.

14. If the patient is non-compliant with requirements, such as attending counseling or a recovery care program, or fails a toxicology screen because of the presence of a street drug or another controlled substance, must the patient be dismissed from the program?

A patient should not be automatically dismissed from the program for non-compliance. Please review Chapter 4 of the “Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction,” protocol available from the SAMHSA website at: <http://samhsa.gov/> under the heading, “Discontinuation of Medication,” for suggestions on handling situations where the patient is non-compliant. If it is determined that a patient must be dismissed, the physician must comply with Rule 4731-27-02, Ohio Administrative Code, which sets out the requirements for notifying the patient of the dismissal.

15. If the program requires the patient to be seen more frequently than every thirty days, is the physician required to personally meet with the patient at each of the visits?

No. The physician must personally meet with and evaluate the patient at least every thirty days during the first twelve months of treatment and at least every three months thereafter.

16. Are physician assistants and advanced practice registered nurses allowed to do the initial assessment and treatment plan or conduct future follow-up appointments?

Only physicians may prescribe to patients under the DATA 2000 waiver. The rule requires the physician to make the initial assessment, diagnosis of opioid dependence, and establish the treatment plan. However, where the patient is seen more often than once every thirty days physician assistants and advanced practice registered nurses may see the patient for follow-up appointments, as long as the physician personally meets with and evaluates the patient at least every thirty days during the first twelve months of treatment and at least every three months thereafter.

17. Are there forms prescribed by the Medical Board that a physician must complete to document compliance with the rule?

No. Compliance with the rule should be apparent from the documentation in each patient's chart.

18. Is an individual considered to be a new patient for purposes of 4731-11-12(B)(8) if a new physician takes over the care of a patient who has been on office-based opioid treatment for more than 12 months?

The rule is silent as to how to handle stable patients when the physician changes. However, the subsequent treating physician must always follow the minimal standards of care and can certainly provide more frequent evaluations or limit the length of the prescription as care is being established with the particular patient. The subsequent treating physician should obtain the prior treatment records to ensure the requisite time period of personal evaluations with the patient occurred and to verify the reason for cessation of treatment by the prior treating physician.

19. Is a patient considered to be a "new" patient if the patient relapses?

It depends.

- If the patient is still undergoing treatment when the relapse occurs, the patient can be treated as an established patient. The physician can always choose to be more restrictive with evaluation and dosage.
- If the patient has been released from office-based treatment and then relapses, the patient is considered to be a new patient.

If you have questions about the information contained in this FAQ, please contact:

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