# Office-based Opioid Treatment

*A guide for physicians and physician assistants*

Ohio Administrative Code 4731-33

State Medical Board of Ohio

## General Requirements:

- 8 hours of Category 1 CME relating to substance abuse and addiction every two years
- Follow the law (such as the DATA 2000 waiver requirements)
- Comply with SAMHSA's treatment improvement protocol https://store.samhsa.gov.
- Comply with the "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/.
- Offer the patient a prescription for a naloxone kit
    - Must include instructions on how to use the kit
    - Upon expiration or use of the old kit, the physician must offer a prescription for a new kit
    - Note the patient's refusal of prescription

**Note: PA's can also provide office-based opioid treatment**

## Assessment Must Include:

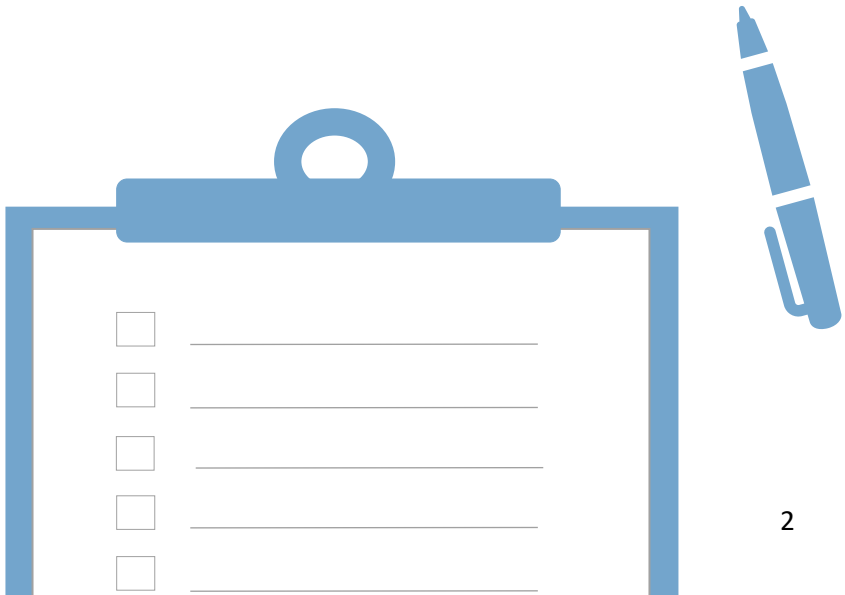
- A medical and psychiatric history
- A brief mental status exam
- Substance abuse history
- Family history and psychosocial supports
- Physical exam
- Urine drug screen
- Pregnancy test for women of childbearing age and ability
- OARRS check
- HIV testing
- Hepatitis B testing
- Hepatitis C testing
- Consideration of screening for TB and STD's in patients with known risk factors

A physician may rely on prior treatment records for most of the assessment requirements except the tox screen, medical histories, and pregnancy test. If any part of the assessment cannot be conducted, the provider shall document the reasons in the medical records.



## Treatment Plan:

- Rationale for the selection of the specific drug to be used in treatment. Must provide the patient information about all drugs approved by the FDA for OBOT both orally and in writing, and the communication must be documented in the patient chart.
- Patient education
- Written informed consent from the patient
- Treatment contract signed by the patient
- Random drug screens at least twice per quarter for the first year of treatment; at least once per quarter, thereafter
- A plan for psychosocial treatment (see Behavioral Health Care Requirements on page 3)
- Provider shall determine appropriate frequency of office visits and pill counts
- OARRS checks every 90 days
- Verification of counseling
- Lowest effective dose



## Behavioral Health Care Requirements:

- If the provider providing OBOT is a board certified addictionologist, psychiatrist, or board-certified psychiatrist, they may personally provide behavioral health services for addiction and must include, at a minimum:
    - Psychosocial needs assessment
    - Supportive Counseling
    - Links to existing family supports
    - Referral to community services
- Otherwise, referrals must be documented in the patient record and shall include, at a minimum
- Cognitive behavioral treatment
    - Community reinforcement approach
    - Contingency management/motivational incentives
    - Motivational interviewing
    - Behavioral couples counseling

**OR**

- Participation in a self-help or 12-step program, three per week for the first year. After the first year, frequency can be determined by provider.

## Buprenorphine Requirements:

- Must comply with the FDA's "Risk Evaluation and Mitigation Strategy" for buprenorphine products https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm.
- Only buprenorphine/naloxone combination products (Suboxone) are to be used except:
    - When a patient is pregnant or breast-feeding
    - When converting a patient from buprenorphine-only product to buprenorphine/naloxone combination product;
    - In formulations other than tablet or film form for indications approved by the FDA
    - For withdrawal management, only when a buprenorphine/naloxone combination product is contraindicated. The contraindication must be documented in the patient record.
    - When the patient has an allergy to, or intolerance of, a buprenorphine/ naloxone combination product. Only after explaining to the patient the difference between an allergic reaction and symptoms of opioid withdrawal precipitated by buprenorphine or naloxone, and subsequently documenting discussion in the patient record.
- Provider must document the rationale for prescribed doses exceeding 16mg/day. The physician shall not prescribe a dosage exceeding 24mg/day.

## Buprenorphine Induction Phase:

- Cannot exceed FDA dosage recommendations "except for medically indicated circumstances as documented in the patient chart"
- Physician must see the patient at least once a week

## Buprenorphine Stabilization Phase – Oral formulation:

- During the first ninety days of treatment, the physician shall prescribe no more than a two-week supply of the buprenorphine product containing naloxone.
- Starting with the ninety-first day of treatment and until the completion of twelve months of treatment, the physician must prescribe no more than a thirty-day supply of the buprenorphine product containing naloxone.
- Dosage must be increased in safe and effective increments to achieve the lowest dose that avoids intoxication, withdrawal, or significant drug craving

## Buprenorphine Stabilization Phase - Extended-release, injectable, or implanted products:

- Must be administered by an Ohio licensed health care professional acting in accordance with the scope of the professional license (no unlicensed practice).
- Provider shall comply with any required risk evaluation and mitigation strategy program for the drug
- Provider shall comply with FDA labeling
- Provider shall document rationale for use

**Buprenorphine in Conjunction with Other Controlled Substances:**

- If other opioids, benzodiazepines, sedative hypnotics, carisoprodol, or tramadol are being prescribed:
- The provider must 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. Coordination must be documented in the patient record.
- If there is co-prescribing of buprenorphine by the same provider, the provider must taper the other drug to discontinuation, if it is safe to do so. The physician must educate the patient about the serious risks of the combined use. The tapering plan must be documented in the patient record.

**Naltrexone:**

- The provider must inform the patient about the risk of opioid overdose if the patient ceases naltrexone and then uses opioids.
- The provider must take measures to ensure that the patient is adequately detoxified from opioids and is no longer physically dependent prior to treatment with naltrexone.
- The provider must use oral naltrexone only for treatment of patients who can be closely supervised and who are highly motivated.
- Provider must encourage the patient to have a support person (family member, close friend, employer) administer and supervise the medication
- Drug screening must be conducted at least every three months for the first year of treatment; at east every six months, thereafter
- Non-compliant patients may be treated with extended-release naltrexone for opioid dependence or for co-occurring opioid and alcohol use disorders



## Additional Resources

**Takechargeohio.org**
**Med.ohio.gov/Resources**
**RecoveryOhio.org**

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