SAMHSA
Substance Abuse and Mental Health Services Administration

# Practical Tools for Prescribing and Promoting Buprenorphine in Primary Care Settings

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## Abstract

In 2019, 1.6 million people aged 12 or older, across the United States, reported an opioid use disorder (OUD) in the past 12 months. This number likely underestimates the true prevalence of OUD. Opioid prescription records reveal that the number of patients without a formal OUD diagnosis who use opioids at high levels is five times the number of patients formally diagnosed with OUD.[1] This suggests that a significant number of individuals within primary care practices may need diagnosis and treatment.

The primary care setting is a critical intervention point to increase diagnosis and treatment for patients with OUD. The American Academy of Family Physicians asserts that primary care providers' delivery of patient-centered and compassionate care to diverse populations uniquely positions them to address the needs of patients with OUD. This resource document provides practical, evidence-based information for primary care providers and practices on prescribing buprenorphine to individuals in need of intervention. It discusses implementation considerations and strategies for primary care providers and primary care organizations to facilitate their understanding, planning activities, and implementation of buprenorphine prescribing.


[1] Caverly, M., Davenport, S., & Weaver, A. (2019). *Costs and Comorbidities of Opioid Use Disorder: The Impact of Opioid Use Disorder for Patients with Chronic Medical Conditions*. Retrieved July 13, 2021, from https://www.milliman.com/en/insight/costs-and-comorbidities-of-opioid-use-disorder

# Content of the Guide

# Key Terms

| Term | Definition |
|---|---|
| **Buprenorphine** | Buprenorphine is a Schedule III partial opioid receptor agonist. It is a medication that diminishes the physical effects of opioid dependence, and lowers the potential for misuse.[1] Some buprenorphine products are also indicated for pain relief. |
| **Initiation Phase** | During the initiation phase of treatment, a provider screens, engages, and assesses the patient.[2] |
| **Induction Phase** | During the induction phase of treatment, the patient discontinues opioid use and begins taking buprenorphine.[2] |
| **Maintenance Phase** | During the maintenance phase of treatment, the patient continues taking the target buprenorphine dose and has regular visits with the provider.[2] |
| **Medications for opioid use disorders (MOUD)** | The most effective therapies for people with opioid use disorder involve the use of Food and Drug Administration (FDA)-approved medications—methadone, buprenorphine, and naltrexone. Collectively known as medications for opioid use disorders (MOUD), they are offered as part of a treatment program that often includes counseling and other services such as case-management.[1] MOUD replaces the term, medication-assisted treatment (MAT), which implies that medication should have a supplemental or temporary role in treatment. Using "MOUD" aligns with the way other psychiatric medications are understood (e.g., antidepressants, antipsychotics), as critical tools that are central to a patient's treatment plan.[3] |
| **Naloxone** | Naloxone is an opioid antagonist, meaning it binds to opioid receptors to block the effects of opioids and can rapidly reverse an opioid overdose. Some formulations of buprenorphine incorporate naloxone to deter intravenous use.[4] |
| **Opioid use disorder (OUD)** | DSM-5 defines OUD as a problematic pattern of opioid use leading to clinically significant impairment or distress. Opioids produce high levels of positive reinforcement, increasing the odds that people will continue using them despite negative consequences. OUD is a chronic lifelong disorder, with serious potential consequences including disability, relapse, and death.[5] |
| **Pharmacy deserts** | Neighborhoods where residents have low access to pharmacies.[6] |
| **Social determinants of health** | The conditions in the places where individuals are born, live, learn, work, play, worship, age, and include a range of health risks and outcomes such as social and community context, economic stability, racism and discrimination, and lack of community resources.[7] |
| **Stabilization Phase** | During the stabilization phase of treatment, the patient reaches a stable buprenorphine dose. The target dose should eliminate opioid cravings and withdrawal, with minimal to no side effects.[2] |
| **X-Waiver** | The X-Waiver is a type of registration that allows providers to treat patients with OUD using buprenorphine.[8] |

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4 National Alliance on Mental Illness. (2021). *Buprenorphine/Naloxone (Suboxone).* Retrieved July 13, 2021, from https://www.nami.org/About-Mental-Illness/Treatments/Mental-Health-Medications/Types-of-Medication/Buprenorphine/Buprenorphine-Naloxone-(Suboxone)

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Chapter 1.

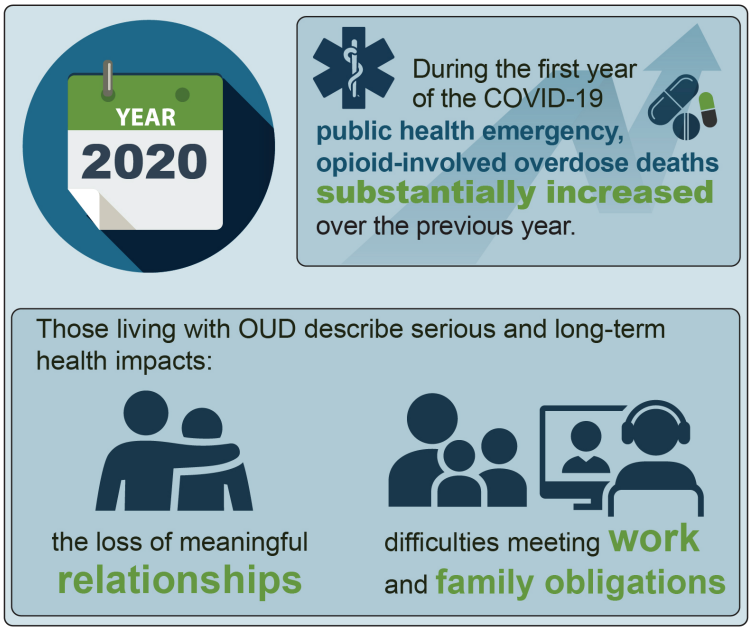
# The Vital Role of Primary Care Providers in Treating Opioid Use Disorders

## 1.1 Opportunity for Primary Care Providers

The opioid epidemic is one of the most pressing public health crises facing the United States. In the United States in 2019, 1.6 million people aged 12 or older reported an opioid use disorder (OUD) in the past 12 months.[1-2] This number likely underestimates the true prevalence of OUD—opioid prescription records reveal that the number of patients who use opioids at levels comparable to the highest use patients, but do not have a formal OUD diagnosis, is five times greater than the number of patients diagnosed with OUD.[3-5]

The high prevalence of OUD has a substantial human toll. According to preliminary data, the number of opioid-related deaths rose to 93,000 in 2020, an annual increase of nearly 30 percent over 2019.[6] Those living with OUD describe serious health impacts, as well a potential loss of meaningful relationships and difficulties meeting work and family obligations.[7] These concerns were exacerbated during the COVID-19 public health emergency.

Reviews of electronic health records (EHRs) reveal that one percent of patients in primary care providers' practices have documented OUD.[8] However, only one in five patients with an OUD received treatment in 2019.[9-11]

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The primary care setting is a critical intervention point to increase diagnosis and treatment rates for patients with OUD. The American Academy of Family Physicians (AAFP) asserts that primary care providers' capacity for delivering patient-centered, continuous, coordinated, and comprehensive care to diverse patients makes them uniquely able to address the needs of individuals with OUD.[12] Primary care providers can have particular impact on increasing access to OUD treatment in rural settings, where individuals often have to travel further to access speciality addiction treatment services.[13-14]

Primary care providers can leverage long-term, trusting relationships with patients to provide meaningful care through diagnosing and treating individuals with OUD and using office-based treatment options that include buprenorphine.[15] This can reduce opioid-related mortality, improve patient outcomes, and respond to community needs.

Buprenorphine is an evidence-based best practice for treating OUD, and it has been shown to be highly effective in promoting long-term recovery.[16] It is often provided in combination with counseling and behavioral therapies.[17] Buprenorphine is a partial agonist that acts on mu opioid receptors, and produces effects such as euphoria or respiratory depression at low to moderate doses. With buprenorphine, however, these effects are weaker than full opioid agonists such as methadone and heroin. The effects of buprenorphine reach a maximum and do not continue to increase linearly with increasing buprenorphine doses. It has unique pharmacological properties that result in: diminished effects of physical dependency to opioids, increased safety in cases of overdose, and lower potential for misuse.[18, 19] A wide range of providers, including physicians, nurse practitioners (NP), physician assistants (PA), clinical nurse specialists (CNS), certified registered nurse anesthetists (CRNA), and certified nurse-midwifes (CNM), across diverse settings (including primary care outpatient clinics and opioid treatment programs [OTP]) are eligible to prescribe buprenorphine.[20] It can be prescribed in-person or through telehealth using the following phases: initiation, induction, stabilization, and maintenance.[1]

## PERCEIVED BARRIER

Many individuals with OUD may not be formally diagnosed. Without a formal diagnosis, patients with OUD may not be connected with appropriate treatment. Primary care providers can improve access to treatment by screening for OUD during patient visits.

**Source**
Kirson, N. Y., Shei, A., Rice, J. B., et al. (2015). The Burden of Undiagnosed Opioid Abuse Among Commercially Insured Individuals. *Pain Medicine, 16*(7), 1325-1332.

## RESOURCES

- FDA-approved medications for MOUD include buprenorphine, methadone, and naltrexone. The Substance Abuse and Mental Health Services Administration (SAMHSA) has published a manual as part of their Treatment Improvement Protocols (TIP) that provides helpful information on the use of these medications and discusses naloxone as well: TIP 63: Medications for Opioid Use Disorder.
- Providers can refer to the SAMHSA website for guidance on up-to-date regulations.

## TIP: Acknowledge the goal of buprenorphine prescribing

The goal of buprenorphine is to reduce or eliminate harmful opioid cravings and use, encourage treatment engagement, restore normal physiologic functions, and improve the patient's quality of life.

1 The Drug Enforcement Administration (DEA) generally requires an in-person medical evaluation prior to prescribing a controlled substance via telehealth (21 USC 829(e)). While this requirement was waived during the COVID-19 public health emergency, refer to current requirements prior to evaluating a patient via telehealth options.

### TIP: Understand the regulatory environment

Regulations around buprenorphine prescribing continue to evolve, primarily with the aim of increasing safe patient access.

*Requirements for providers to start prescribing:* In April 2021, the Department of Health and Human Services revised practice guidelines to allow providers meeting certain conditions to treat up to 30 patients with buprenorphine without required training or certification to counseling activities. Providers are required to submit a Notification of Intent to SAMHSA (see Chapter 3, Section 3.2), which allows providers to treat a small number of patients with buprenorphine. For those wishing to treat a larger number, the education and certification requirements remain.

*Requirements for record keeping:* Before initiating buprenorphine prescribing, providers should understand mandates for buprenorphine record keeping. The Drug Enforcement Administration (DEA) record keeping requirements for buprenorphine treatment go beyond the Schedule III record keeping requirements. Under the Persons Required to Keep Records and File Reports, 21 Code of Federal Regulations (CFR) Part 1304.03, practitioners must keep records and inventories of all controlled substances dispensed, including approved buprenorphine products.

See SAMHSA's Record Keeping Requirements for more information.

**Source**
Federal Register. (2021). *Practice Guidelines for the Administration of Buprenorphine for Treating Opioid Use Disorder.* Retrieved July 13, 2021, from https://www.federalregister.gov/documents/2021/04/28/2021-08961/practice-guidelines-for-the-administration-of-buprenorphine-for-treating-opioid-use-disorder#citation-1-p22440

## 1.2 How to Use This Resource

Primary care providers are well positioned to assist in ameliorating the opioid crisis by improving access to buprenorphine treatment. This resource outlines the steps that primary care providers and practices can take to treat their patients with OUD and to encourage primary care settings to serve the healthcare needs of this population within the context of their busy practices. The tips and practical steps presented in this resource are intended as a guide for planning and implementing buprenorphine treatment. Each chapter presents concise, actionable guidance, resources, and tools to support primary care providers' integration of buprenorphine prescribing within their practice.

- Chapter 2 describes the phases of care for patients and the responsibilities and activities of prescribers and other primary care providers.
- Chapter 3 outlines planning and preparation competencies for primary care providers to consider and establish prior to prescribing buprenorphine.
- Appendices provide helpful resources referenced throughout this document.

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## Chapter 2.

# Supporting Patients Through the Phases of Care

### KEY TAKEAWAYS

1. The sections that follow provide step-by-step guidance, resources, and tools to assist providers in implementing each phase of buprenorphine treatment and care:
    a. **Screening and initiation:** Providers determine if the patient is an appropriate candidate for buprenorphine and engage patients in the screening and initiation phase (pages 8-13). Screening and comprehensively assessing current and past substance use and medical, mental health, and social history will form the basis of the treatment plan. Providers can engage patients and help them overcome ambivalence to change by creating a welcoming, nonjudgmental environment and using motivational approaches.
    b. **Induction:** Induction may occur in the office or in the patient's home (pages 14-18). Providers instruct patients to discontinue opioid use prior to induction. The amount of time required between the last use and scheduled induction varies by substance. Either by telehealth or in person, providers will educate patients on administration, supervise the initial dose(s), monitor the patient's response, and establish a follow-up plan.
    c. **Stabilization:** The goal of stabilization is to determine the patient's target dose. The target dose should eliminate opioid cravings and withdrawal, with minimal or no side effects. The target dose will vary for each patient and generally is between 4 and 24 mg daily (pages 18-19).
    d. **Maintenance:** Once the patient is stable and has achieved the target dose, providers may reduce the frequency of a patient's visits, as clinically indicated (page 20-22).
2. The chapter also contains information on tapering (page 23), providing access to other needed services (pages 24-25), and buprenorphine prescribing in rural practices and emergency departments (pages 26-27).

## PATIENT FLOW THROUGH PHASES OF BUPRENORPHINE TREATMENT

**Initiation**
Patient presents for treatment (self or provider referral)

**Screening**
Assess whether buprenorphine is appropriate for patient

NO → **Refer to other resources**

YES →

**Intake & Assessment**
- Assess substance use
- Review medical and mental health history
- Identify other needs
- Conduct toxicology screening and needed lab texts
- Conduct physical exam
- Review prescription drug use

**Refer to other resources as needed**

**Treatment Agreement**
- Obtain patient consent
- Individualize treatment plan
- Review expectations

**Prescription to pharmacy**

**Engagement/motivational approaches** | **Patient education** | **Patient education**

**Patient discontinues opioid use**

**Induction (Day 1)**
- Patient takes first dose under supervision (either at home or in office)
- Subsequent doses as directed
- Regular monitoring over first 24 hours

**Stabilization (Days 2-7)**
- Adjust dose to eliminate cravings and withdrawal with minimal side effects
- Monitor patient

**Stabilization**
- Weekly visits with patient until target dose achieved
- Write prescriptions for maximum one week at a time

**Engagement/motivational approaches** | **Patient education**

**Maintenance**
- Adjust visits as clinically indicated (weekly, biweekly, monthly)
- Prescription refills coincide with visits
- Conduct toxicology screening and needed lab tests
- Assess medication status, recovery, and medical, psychiatric, and social issues

**Refer to other resources as needed**

**Engagement/motivational approaches**
**Patient education as needed**

Throughout the phases of care, telehealth is an important tool to ensure access to treatment and patient safety for those who cannot physically come into the clinic. Telehealth services may include audio only or audio/video technology, and the content of telehealth visits should mirror those of in-person visits; as discussed in the BMC Clinical Guidelines. This chapter includes where and how providers may use telehealth to meet patients where they are and improve care delivery. SAMHSA's Evidence-based Practices Resource Center Telehealth Guide provides considerations for using telehealth in clinical settings.

## 2.1 Screening and Initiation Phase

During the initiation phase, the provider establishes a therapeutic relationship with the patient or builds on an existing therapeutic relationship to include OUD treatment. Through screening, the provider assesses current and past substance use and medical, mental health, and social history.[1]

**RESOURCE**

- SAMHSA's Buprenorphine Quick Start Guide provides an overview of the treatment process and dosing.

### Screening and Initial Assessment (In Person or Telehealth)

Screening includes assessing the patient's substance use, medical, mental health, and social history as well as current substance use and prescription drug use. The provider and his or her team may also review the patient's demographics, living situation, insurance, safety, and treatment goals. Based on this information, which may be obtained through engaging with the patient and information gathered from the EHR, the provider determines if the patient is an appropriate candidate for buprenorphine treatment in an outpatient setting.[1-2]

**RESOURCES**

- The National Institute on Drug Abuse has compiled evidence-based screening tools that providers can implement during patient visits.
- SAMHSA's Evidence-based Practices Resource Center guide on Treating Concurrent Substance Use Among Adults details screening and assessment tools for substance use.
- SAMHSA's Providers' Clinical Support System (PCSS) has a free online training that provides comprehensive instruction on screening for OUD in primary care settings.
- SAMHSA provides guidance on motivational approaches for treating substance use disorders in TIP 35, Enhancing Motivation for Change in Substance Use Disorder Treatment. A toolkit on motivational interviewing (MI) for substance use and a guide on MI for patients with OUD are also available.
- Several resources are available for patient assessment and screening.
  - Checklist of DSM Diagnostic Criteria for OUD; provided in Appendix A
  - BMC Nursing Intake Form
  - BMC Telephone Screening
  - Social Needs Screening Tool
  - State prescription drug monitoring program (PDMP) profiles and contacts
- Materials to support patient and family education are below.
  - Buprenorphine: What You Need to Know; provided in Appendix B
  - The Facts About Buprenorphine booklet
  - Guide for families on medications for OUD
  - Decision support tool for patients considering medication for OUD

## Engagement

Patients with OUD may be reluctant to discuss their substance use. To engage patients, the prescribing provider should create an environment where patients feel welcome and respected, and treated with empathy and without judgment.[3] A patient's full disclosure of their opioid use may take many appointments.

Motivational approaches can help increase engagement and retention in substance use treatment.[4] Motivation to change is key in treating OUD. Motivation can be intrinsic (e.g., comes from desires, needs, goals) or extrinsic (e.g., comes from social influences, external rewards, or consequences). By helping patients recognize when substance use is incompatible with their goals and through promoting change behaviors, motivational approaches can strengthen intrinsic motivation and increase the likelihood that patients will remain engaged in treatment.[4]

## TIP: Apply principles of motivational interviewing

MI incorporates four interwoven processes: Partnership, Acceptance, Compassion, and Evocation (PACE).

1. **Partnership** is an active collaboration between provider and client. A client is more willing to express concerns when the provider is empathetic and shows genuine curiosity about the client's perspective. In this partnership, the provider gently influences the client, but the client drives the conversation.
2. **Acceptance** is the act of demonstrating respect for and approval of the client. It shows the provider's intent to understand the client's point of view and concerns. Providers can use MI's four components of acceptance—absolute worth, accurate empathy, autonomy support, and affirmation—to help them appreciate the client's situation and decisions.
3. **Compassion** refers to the provider actively promoting the client's welfare and prioritizing the client's needs.
4. **Evocation** is the process of eliciting and exploring a client's existing motivations, values, strengths, and resources.

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Motivational interviewing (MI) is an evidence-based practice in the treatment of individuals with health and behavioral health issues. This counseling approach helps individuals overcome ambivalence to change. During MI, providers offer empathy and support, providing an environment where change can occur.[4] Primary care providers are adept at using MI approaches to effect change or to promote treatment engagement across a variety of chronic conditions, including: diabetes mellitus, smoking cessation, weight management, hypercholesterolemia, and heart conditions. Primary care providers may also use MI to foster buprenorphine treatment engagement.

## TIP: Recognize and support your patients through the stages of change.

| Stage of Change | Description | Provider Strategy |
|---|---|---|
| **Precontemplation** | Patient is not thinking seriously about change and may defend their substance use. | • Establish a strong therapeutic alliance with the patient.<br>• Explore the patient's understanding of the problem.<br>• Raise the patient's doubts and concerns about substance use. |
| **Contemplation** | Patient is considering change but is not sure how to change. | • Reassure the patient that ambivalence to change is normal.<br>• Help the patient decide to change substance use behaviors. |
| **Preparation** | Patient has identified a goal and is forming a plan to change. | • Help the patient identify change goals and develop a plan to change.<br>• Identify barriers to action and help the patient address these. |
| **Action** | Patient is taking steps to change. | • Support the patient's steps to change.<br>• Help the patient determine what is working and what is not working in the change plan. |
| **Maintenance** | Patient has achieved their change goal and the behavior change is stable. | • Help the patient stabilize the behavior change.<br>• Support the patient's lifestyle changes. |

Providers can support patients' progress in reducing their substance use by[4]:

- Identifying and enhancing motivation that already exists.
- Using empathy.
- Recognizing that resistance to change is normal and exploring ambivalence to change in a nonjudgmental and compassionate way.
- Tailoring strategies to the patient's stage of change.

## Comprehensive Assessment (Intake)

A comprehensive assessment is intended to[5]:

- Establish OUD diagnosis and severity.
- Identify contraindicated medications.
- Indicate other medical conditions to address during treatment.
- Identify mental and social issues to address.

### RESOURCES

- Sample inclusion/exclusion criteria are detailed in Chapter 3, Section 3.4.
- Full inclusion/exclusion criteria for integrating buprenorphine treatment in primary care are available in an implementation manual published by the Boston University School of Public Health.
- BMC provides several resources on pain management for buprenorphine patients. The BMC Clinical Guidelines discuss treatment implications for patients with concurrent pain (p. 74-77).

Through the comprehensive assessment process, the provider determines the patient's clinical eligibility for buprenorphine treatment, forms the basis of the treatment plan, and captures baseline measurements to evaluate a patient's response to treatment.[6] Resources for patient assessment are identified in Chapter 3, Section 3.4.

## TIP: Consider special needs of patients with chronic pain

For patients with OUD and chronic pain, referral to a pain management or addiction specialist may be helpful. The provider may also consider non-opioid therapies, such as acupuncture, massage, physical therapy, hydrotherapy, mindful meditation, nonsteroidal anti-inflammatory drugs (NSAIDs), acetaminophen, topical lidocaine, selective serotonin reuptake inhibitors (SSRIs), and tricyclic antidepressants (TCAs). Non-opioid pharmacologic treatment can improve pain and function in the short term, though evidence on longer-term impact is more limited. Nonpharmacological treatments can also have a positive impact on pain and/or function; for example, exercise, psychological therapy, spinal manipulation, massage, mindfulness-based stress reduction, yoga, and/or acupuncture can be effective treatments for chronic pain.

PCSS provides an extensive and up-to-date free chronic pain core training curriculum.

**Sources**


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## RESOURCES

- A sample checklist for the provider to complete prior to induction has been developed by Boston Medical Center. The provider must ensure that the pharmacy processes the prescription and it is available for the patient prior to induction.
- Several resources provide guidance on the buprenorphine induction process:
  - BMC Guidance on Buprenorphine Induction, Stabilization, and Maintenance
  - SAMHSA Buprenorphine Quick Start Guide
  - PCSS Models of Buprenorphine Induction
- Materials supporting patient education on induction are included in Appendix C.
- The Clinical Opiate Withdrawal Scale (COWS) is an 11-item scale for rating common signs and symptoms of opiate withdrawal in inpatient and outpatient settings.
- Guidance on medications to manage withdrawal symptoms can be found in Appendix D.

## 2.2 Induction Phase

Prior to induction, the provider uses collaborative decision making and the informed consent process to review safety issues with the patient. These issues include[7]:

- Discontinuing buprenorphine increases risk of overdose death upon return to opioid use.
- Using alcohol, benzodiazepines, or other central nervous system depressants with buprenorphine increases the risk of overdose and death.
- For women of childbearing age, taking buprenorphine when pregnant may increase the risk of neonatal abstinence syndrome. Patients should tell their provider if they are pregnant or planning to become pregnant.
- Patients need to notify their provider if they are having a procedure that may require pain medication.

Patients should also receive a prescription for naloxone (for emergency use in case of opioid overdose) and receive information on its use for family members or others in the patient's support network.[3, 7] Individuals who use long-term and high dose fentanyl may not be appropriate for buprenorphine. While buprenorphine induction can be attempted with these individuals, they may be better served by an opioid treatment program (OTP) that can prescribe methadone and provide more structure and supervision in an outpatient setting.

Induction generally involves switching from other opioids to buprenorphine.[8] To avoid precipitated withdrawal, the patient discontinues opioid use before buprenorphine induction.[1-2] Buprenorphine has a high affinity for the mu receptor and will displace other opioids on the receptor (e.g., heroin, fentanyl, morphine), causing precipitated withdrawal. If a patient begins buprenorphine before enough time has passed since their last opioid use, precipitated withdrawal can occur. The amount of time required between the last use and scheduled induction varies depending on the substance. If the patient experiences precipitated withdrawal during induction (symptoms are similar to opiate withdrawal), the provider should manage symptoms, instruct the patient to avoid benzodiazepines, and encourage the patient to try induction again soon.[7]

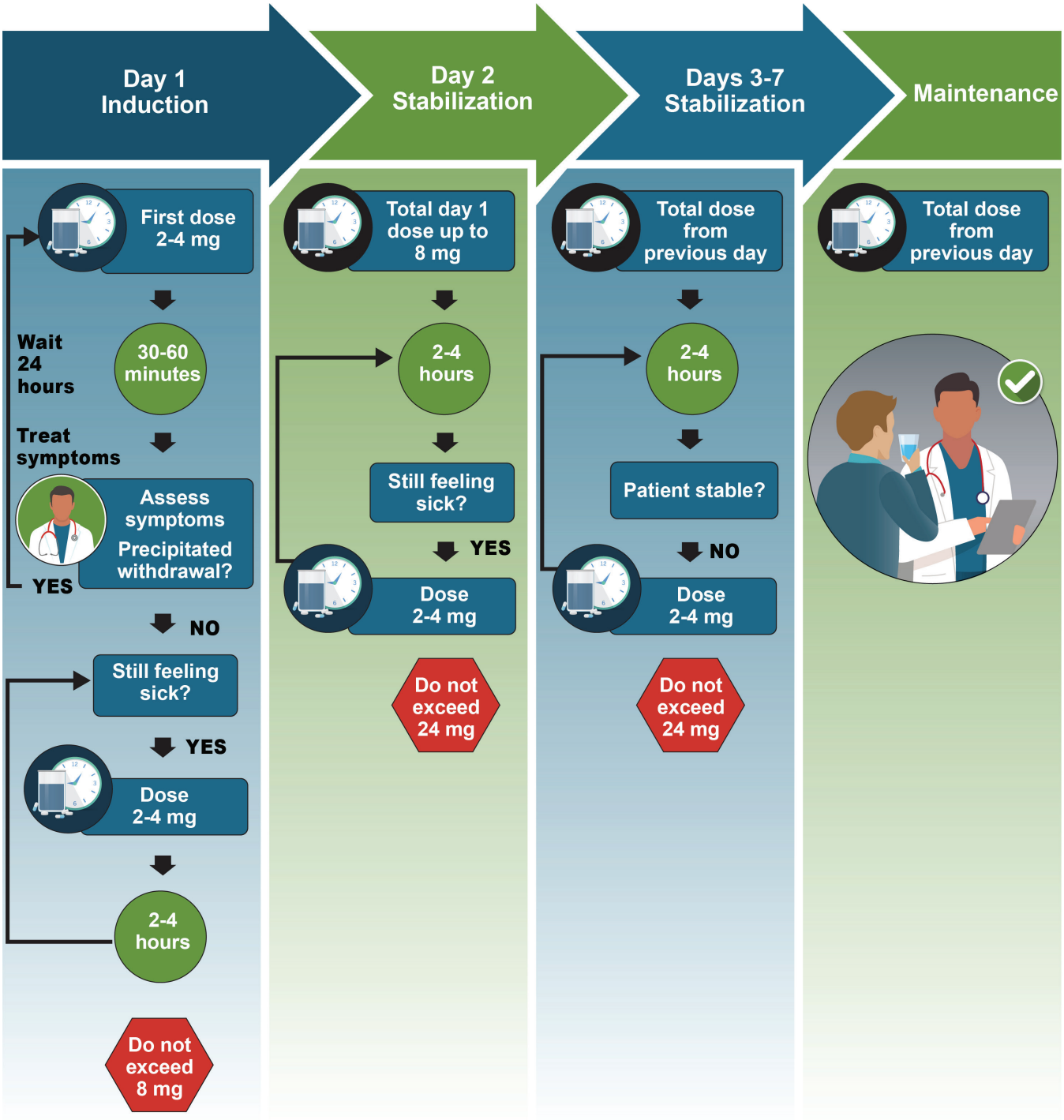
**TIP: Assess substance use to determine induction requirements**

| Substance | # of Hours Required Since Last Use Prior to Scheduled Induction |
|---|---|
| Short-acting opioids (other than fentanyl) | 8-12 |
| Fentanyl | 16-24 |
| Long-acting opioids | 12-24 |
| Methadone | 36-96 |

## Buprenorphine Dosing

Dosing through the phases of care depends on an individual's plan of care. The below graphic provides an overview of the dosing logic throughout the phases of care.[7]

### OVERVIEW OF THE DOSING LOGIC THROUGHOUT THE PHASES OF CARE



## Induction Process

Buprenorphine induction can occur either in the office or at the patient's home; induction in the home occurs with telehealth support from the provider.[1] There are several considerations for whether a home- or office-based induction is most appropriate.

### TIP: Consider patient needs and provider experience when determining induction site

| CONSIDERATIONS | OFFICE | HOME |
|---|---|---|
| Provider is experienced in induction. | ☑ | ☑ |
| Patient has prior buprenorphine experience. | ☑ | ☑ |
| Patient can describe their withdrawal symptoms and understand dosing instructions. | ☑ | ☑ |
| Patient is concerned or anxious about opioid withdrawal symptoms. | ☑ | |
| Patient is transferring from methadone to buprenorphine. | ☑ | |
| Patient has limited ability to take time off work, limited access to transportation, or other limits to attending office-based treatment. | | ☑ |
| Patient is experiencing housing instability. | ☑ | |
| Patient exhibits signs of early withdrawal. | ☑ | ☑ |
| Patient self-administers first and second doses under in-person supervision | ☑ | |
| Patient self-administers first dose with telehealth supervision | | ☑ |
| Provider educates patient on how/when to administer subsequent doses | ☑ | ☑ |
| Provider checks in with patient the first hour, then every two hours for the next four hours, and then as needed | | ☑ |
| Provider checks in with patient by phone later in the day | ☑ | |
| Follow-up visit within 24 hours (in person recommended) | | ☑ |

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Substance Abuse and Mental Health Services Administration (2020). TIP 63: Medications for Opioid Use Disorder. *Treatment Improvement Protocols (TIPs).* Rockville, MD.

## TIP: Day 1—Provider responsibilities for office induction

- ✓ Have induction doses ready (order and store in the office or prescribe medication and instruct patient to bring it with them for induction).
- ✓ Assess patient for withdrawal using the Clinical Opioid Withdrawal Scale (COWS).
  - Patients actively using opioids other than fentanyl should have a COWS score >6-12.
  - Patients actively using fentanyl should have a COWS score >13-15.
- ✓ Provide the following if the patient is not experiencing mild-moderate withdrawal :
  - Educate home initiation of buprenorphine,
  - Keep the patient in the office until target COWS score is achieved,
  - Refer the patient to an inpatient setting for a more supportive transition, or
  - Reschedule the office initiation (this is not recommended due to the risk of continued opioid use or loss to follow-up).

  Note: Educate the patient on the appropriate technique for sublingual/buccal administration if the patient is experiencing withdrawal.
- ✓ Provide an initial 2-4 mg dose under supervision to ensure proper administration.
- ✓ Reassess the patient with COWS after 30-60 minutes. If needed, instruct patient to take their second 2-4 mg dose under supervision.
- ✓ Keep the patient in the office for additional support and supervision or may leave the office.

  Note: Patients should not exceed 8 mg by the end of the first day.
- ✓ Provide patients with contact information for after-hours/emergency care.

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## TIP: Day 1—Provider responsibilities for home induction

### Day 1: Home Induction – Provider Responsibilities

- ✓ Educate patient on:
  - Ideal timing for their first buprenorphine dose based on last use of full-agonist opioid (e.g., heroin, oxycodone, morphine).
  - Clinical signs and symptoms of withdrawal, including how to use COWS.
- ✓ Assess patient (by phone) for withdrawal using COWS.
  - Patients actively using opioids other than fentanyl should have a COWS score >6-12.
  - Patients actively using fentanyl should have a COWS score >13-15.
- ✓ Educate the patient on the appropriate technique for sublingual/buccal administration.

  Note: Patient takes the initial 2-4 mg dose under supervision to ensure proper administration.
- ✓ Educate the patient on how to self-administer subsequent doses, and review dosing information with the patient. Patients should not exceed 8 mg by the end of the first day.
- ✓ Provide patients with contact information for after-hours/emergency care.
- ✓ Establish follow-up plan; a follow-up visit within 24 hours of home initiation is recommended.
- ✓ Check in with the patient during first hour, then every two hours for the next four hours, and then as needed.

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## 2.3 Stabilization Phase

Activities during the stabilization phase stabilize the dose of buprenorphine and continue to engage the patient in treatment.[1] The target dose should eliminate opioid cravings and withdrawal, with minimal to no side effects.[1, 5]

### RESOURCES

- Guidance on buprenorphine stabilization is available for providers.

Target daily dosage ranges from 8-16 mg, and the maximum dosage is 24 mg daily.[2, 5, 8] Better outcomes (treatment retention and reduced opioid use) have been found for doses of 16 mg or greater.[8] The FDA does not recommend doses higher than 24 mg, as there are little data indicating additional benefit at higher doses.[5, 8] Patients may take buprenorphine one to three times per day.[2, 8]

The same stabilization processes exist for office and home inductions.

## TIP: Days 2-7—Provider responsibilities for stabilization

- ✓ Determine the Day 2 dose.
  - If the patient required 8 mg buprenorphine on Day 1, instruct them to take 8 mg upon waking on Day 2.
  - If the patient required less than 8 mg buprenorphine on Day 1, instruct them to take their total Day 1 dose upon waking on Day 2.
- ✓ Encourage patients to check-in on Day 2 (in-person or telehealth visit).

  Note: If the patient experiences opioid withdrawal symptoms or cravings 2-4 hours after their initial Day 2 dose, they may take an additional 2-4 mg; if the patient experiences symptoms or cravings 2-4 hours later, another 2-4 mg may be taken, up to 24 mg daily for Days 2-7.
- ✓ After one week of treatment at the 16-24 mg dose, reassess the patient for a dose change.

  Note: Some patients may require a higher dose on Days 2-7 and should be carefully monitored during this period. For example:
  - Patients with severe uncontrolled OUD,
  - Patients with prior buprenorphine experience of a maintenance dose over 16 mg daily,
  - Patients transitioning from methadone, or
  - Patients with chronic pain.

  Note: Until the patient achieves the target dose and is making progress toward treatment goals, see patient weekly, with prescriptions given for a maximum of one week at a time during this phase.

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## 2.4 Maintenance Phase

Once the patient is stable and has achieved the target dose, providers may reduce visit frequency, as clinically indicated. Frequency can move to biweekly, and eventually to monthly. If a patient requires more support (e.g., they are struggling with continued use, use of multiple substances, or have medical or other needs), then they may continue having weekly or more frequent visits. Prescription refills should coincide with visits,[1] and providers should continue to monitor the state's Prescription Drug Monitoring Program (PDMP) to ensure the patient has not been prescribed benzodiazepines or additional doses of buprenorphine.

**RESOURCES**

- A sample checklist for buprenorphine maintenance visits is available in Appendix E.
- A sample form to use for follow-up buprenorphine visits is available.
- Numerous resources on the appropriate use of drug testing in addiction medicine are available from the American Society of Addiction Medicine (ASAM).

### Injectable Buprenorphine

Patients with moderate to severe OUD who have stabilized on buprenorphine-containing product (i.e., initiated treatment and completed at least 7 days on a stable dose) may switch to extended-release injectable buprenorphine.[2, 5] This monthly subcutaneous injection is available in two doses: 300 mg/1.5 mL and 100 mg/0.5 mL prefilled syringes. It is recommended that patients receive 300 mg monthly for the first two months, then a monthly maintenance dose of 100 mg.

**RESOURCES**

- The FDA provides a Medication Guide for Sublocade.
- Boston Medical Center provides a sample consent form for treatment with injectable buprenorphine as well as recommendations for storage, handling, and administration in the Clinical Guidelines (p. 41-48).

Before beginning injectable buprenorphine, the provider must conduct liver function and pregnancy tests. Injectable buprenorphine is not recommended for

- Patients with moderate to severe hepatic impairment
- Patients with moderate to severe renal impairment
- Patients who are pregnant, unless the potential benefit justifies the potential risk to the fetus

### Monitoring

Once stable, clinic visits should occur every two to four weeks. Visits may be in-person or telehealth, though the patient should visit the clinic in person every 26-28 days for their monthly injection.

Maintenance clinic visits include the following elements, as well as telehealth support as needed[1]:

- Urine drug testing to identify the level of buprenorphine or presence of other substances
- Indicated lab testing (e.g., liver function tests)
- Patient assessment
  - Medication status: dosage, adherence, side effects, cravings, withdrawal symptoms, safe storage
  - Medical, psychiatric, and social issues
  - Other elements of recovery (engagement in counseling, peer support meetings, recovery groups, etc.)

- Treatment plan review
- Confirmation of contact information, including pharmacy
- Review of safety issues (e.g., reduced tolerance to illicit opioids)

During maintenance visits for injectable buprenorphine, the provider should also

- Check injection site for signs of irritation or attempts to remove the depot.
- Assess for potential medication side effects or adverse reactions (e.g., hepatic complications, gastrointestinal distress).

## Addressing Patient Challenges During Maintenance

Revisions to the treatment plan should consider the circumstances around the incident and the patient's overall well-being and engagement.[1-2] Such revisions may include

- More frequent visits
- Prescription adjustment (dose, prescription intervals)
- Referral to counseling or other supports (e.g., local or state agencies providing services for families, children, and/or older adults)
- Referral to higher level of care (intensive outpatient, partial hospitalization, residential)
- Increased family involvement

### TIP: Know the signs of opioid intoxication

- Physical
  - Drowsy but arousable
  - Sleeping intermittently ("nodding off")
  - Constricted pupils
- Mental
  - Slurred speech
  - Impaired memory or concentration
  - Normal to euphoric mood

In the event of substance use during treatment (self-reported or aberrant urine screen; use of opioids or other substances) or buprenorphine nonadherence, the provider should review the treatment plan with the patient.

**Source**

Substance Abuse and Mental Health Services Administration. (2020). *MAT Medications, Counseling, and Related Conditions.* Retrieved July 13, 2021, from https://www.samhsa.gov/medication-assisted-treatment/medications-counseling-related-conditions#medications-used-in-mat

If a patient presents as intoxicated during a visit, the provider should conduct an urgent evaluation, including a safety assessment, and the provider should revise the patient's treatment plan accordingly.[2]

## Diversion

Buprenorphine is sometimes diverted—that is, shared with or sold to people without a prescription.[2, 7-8] Lack of access to prescribed buprenorphine and individuals self-treating their OUD with diverted buprenorphine often drives buprenorphine misuse.[9] Among adults with past-year buprenorphine use in the United States, prevalence of OUD with buprenorphine misuse trended downward during 2015-2019. Misuse is defined as "in any way that a doctor did not direct you to use them, including (1) use without a prescription of your own; (2) use in greater amounts, more often, or longer than you were told to take them; or (3) use in any other way a doctor did not direct you to use them."[10]

**RESOURCES**

- The American Society of Addiction Medicine provides a sample diversion policy for practices to tailor; see Appendix F.
- PCSS offers a training on managing diversion and misuse.

There are several steps providers can take to reduce the risk of diversion, including[7,11,12-13]

1. Assess patient attitudes towards diversion to identify those who require additional oversight, education, or intervention
2. See patients often during early phases of treatment, and reduce visit frequency when the patient is doing well (i.e., the patient has achieved a stable dose and is meeting their treatment goals)
3. Educate patients about safe medication storage, especially if they have young children
4. Limit medication supply and make sure patients are taking their medication
5. Counsel patients to not share or sell medication
6. Ensure patients understand the treatment agreement and program policies related to diversion
7. Ensure patients are being prescribed appropriate and therapeutic doses
8. Monitor patients' use of the medication, and if diversion concerns arise, seek to understand the motivation, and provide support, such as the Community Reinforcement and Family Training (CRAFT) intervention
9. Implement urine drug testing

Signs of diversion include

- Negative urine screening for buprenorphine.
- Request of early refills.
- Reports of lost/stolen/destroyed medication.
- Law enforcement reports of sold or diverted medication.

If diversion is suspected, the provider should document the incident in the patient's EHR, discuss it with the patient, and consider revisions to the treatment plan.[2, 7] Injectable buprenorphine may also be an option to reduce diversion.[7] Providers should ensure policies to prevent diversion are not overly burdensome, particularly for patients who face logistical or financial barriers to attending frequent treatment appointments.[13]

## 2.5 Special Consideration: Tapering

A set treatment duration is not recommended.[2] Patients should take buprenorphine as long as they wish to continue.[5] However, some patients may wish to discontinue buprenorphine. The prescribing provider should consider the following when speaking with the patient about this decision[5]

- Their response to treatment thus far, including OUD remission.
- Their psychosocial supports to maintain recovery.
- Why they want to taper, and what they expect to be different.
- The risks and benefits of discontinuing buprenorphine, including the risk of overdose with a return to illicit opioid use.

If the patient decides to move forward with tapering, the provider should ensure the patient has naloxone available, educate the patient and the family on overdose, and advise the patient they can stop the taper at any time without judgment or viewing it as a failure. Tapering is individualized to the patient and will generally occur over several months. Gradual dose reductions are recommended. The patient may benefit from increased monitoring during this time, and the provider should continue to monitor patients who discontinue buprenorphine use completely.[5] Additional medication may be used to manage withdrawal symptoms.

**RESOURCES**

- BMC provides guidance on tapering.
- A decision tool to assist primary care providers with tapering is available from the Department of Veterans Affairs (VA).

**RESOURCES**

Several resources provide additional guidance on treating patients with buprenorphine:

- SAMHSA's TIP 63: Medications for Opioid Use Disorder reviews three FDA-approved medications for OUD, including buprenorphine.
- Boston Medical Center's Office Based Addiction Treatment Training and Technical Assistance + offers an interactive MOUD quick start guide for providers, available online and as an app through the App Store or Google Play.
- The Agency for Healthcare Research and Quality's (AHRQ) Medication-Assisted Treatment for Opioid Use Disorder Playbook is a practical guide for implementing medication for OUD, including buprenorphine.
- BMC provides guidance on integrating buprenorphine into primary care.

## 2.6 Providing Access to Other Needed Services

Factors related to a patient's geographic location, education level, community, living situation, and access to transportation can affect his or her ability to initiate and adhere to buprenorphine treatment.

**PERCEIVED BARRIER**

Many providers, particularly in small practices or rural communities, may have limited resources and referral networks needed to effectively administer other support services.

**Source**

Hutchinson, E., Catlin, M., Andrilla, C. H., Baldwin, L. M., & Rosenblatt, R. A. (2014) Barriers to primary care physicians prescribing buprenorphine. *Annals of Family Medicine, 12*(2), 128-133.

Those with OUD can often benefit from many different physical health, mental health, and social services. Effectively identifying and connecting the individual to these services makes it more likely that the root causes of their OUD will be addressed, making buprenorphine treatment more effective. Buprenorphine patients benefit from services such as outpatient counseling, peer support groups, and physical health care.[3]

To improve treatment uptake and adherence, providers can assess patients during office visits for social determinants of health (SDOH) that may prevent the patient from engaging in buprenorphine treatment. The table below provides strategies and resources for addressing common SDOH barriers.

Buprenorphine can be administered in combination with counseling and behavioral therapies to ensure the patient receives holistic, patient-centered treatment.[5,14] Many practices have existing local resource directories of behavioral health providers and other community organizations that providers can use for patient referrals. A practice can also leverage hotline call centers (often accessed via "311") to identify local support services.[13]

In areas with limited behavioral health providers and other helpful community resources, providers can provide psychosocial support during the patient visit by implementing shared decision making and MI. Some practices have added prompts to their EHRs that support providers with implementing MI during office visits. Telehealth options, such as virtual cognitive behavioral therapy, can provide a cost-effective option to increase access to behavioral health support.[12]

**RESOURCES**

- The American Academy of Family Physicians Foundation developed a guide for addressing social determinants of health in primary care:

  Addressing Social Determinants of Health in Primary Care: Team-Based Approach for Advancing Health Equity

While buprenorphine treatment is most effective when provided in conjunction with behavioral and psychosocial supports, buprenorphine is also effective as a standalone treatment.[14] Difficulties connecting patients with counseling and behavioral health resources should not prevent providers from prescribing buprenorphine.

A clinic may also decide to bring additional providers with different areas of expertise into their practice:

- A behavioral health provider to coordinate therapy with buprenorphine treatment.
- A social worker to assist with other issues that could exacerbate their OUD such as housing or legal problems.
- A peer recovery specialist to provide support for the patient in their recovery process.

As more treatment team members are added, communication becomes more important to coordinate services.

## TIP: Assess needs and implement strategies to address SDOH barriers

| Area | Barrier | Strategy |
|---|---|---|
| **Transportation** | Many patients may not be able to get to MOUD appointments due to their employment situation, financial barriers, or lack of access to public transportation. | Telehealth can be a cost-effective option for overcoming employment, financial, or transportation-related barriers. |
| **Health Literacy** | More than one-third of the U.S. population is estimated to have limited health literacy, meaning they do not have the skills needed to understand and apply health-related knowledge. Limited health literacy can affect a patient's ability to engage effectively in treatment. | Providers can promote health literacy. They can do this by avoiding jargon, breaking down instructions into concrete steps, limiting a visit to three key ideas, and checking for comprehension. |
| **Social Isolation** | Individuals with OUD face stigma and engage in behaviors that can erode social networks. MOUD is more effective when a patient has strong social supports. | Providers can ask patients about the social challenges in a sensitive way and refer patients out to appropriate community supports such as community-based support groups. |
| **Poverty** | Poverty can decrease the likelihood a patient will access and stay in treatment. Poverty may be associated with lack of health insurance and other determinants of health factors such as lack of social support, housing, stable employment, child care, and transportation. | Many pharmaceutical manufacturers also offer patient assistance programs, which provide products at free or reduced costs to low-income patients. Providers can also screen for social determinants of health factors and connect patients to community resources. |
| **Co-occurring Mental or Other Substance Use Disorders for Patients with OUD** | Individuals with co-occurring disorders access treatment at lower rates due to personal and structural barriers. Personal barriers include vulnerabilities resulting from a mental health disorder and perceptions of stigma. Structural barriers include insurance barriers and racial and ethnic disparities in service access. | Providers can deliver patient-centered care by considering unique patient characteristics including mental and SUD diagnoses. |

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# 2.7 Buprenorphine Prescribing in Different Settings

Buprenorphine prescribing can vary across healthcare settings, community types, and patient populations.

## Rural Practices

**RESOURCE**

The Rural Health Information (RHI) Hub provides rural-specific resources and research.

Primary care practices in rural communities often face provider capacity constraints; have limited specialty providers and other community resources; and encounter unique barriers related to social determinants of health, such as patients' lack of transportation, and access to high-speed broadband internet and phone services.[15] Patients in rural areas also are more likely to be in poor health and have low health literacy, have low income and limited educational attainment, be uninsured, and involved with the criminal justice system.[16]

Rural practices can employ various strategies to overcome these challenges:

- Leverage non-physician providers, such as nurse practitioners, physician assistants, clinical nurse specialists, certified registered nurse anesthetists, certified nurse midwives, and employ group treatment visits for buprenorphine administration to conserve physician capacity.[12]
- Prescribe buprenorphine products that patients can use at home or over extended periods of time to support patients who face barriers related to traveling.[12] Home induction is a feasible and safe method of initiating buprenorphine treatment for many patients. Similarly, extended-release buprenorphine formulations (i.e., injectable buprenorphine) are feasible options for patients with transportation and internet barriers, when a stable dosage of the medication is determined.[2, 17] For more information on home and office induction, see Chapter 2, Section 2.2. For more information on extended-release buprenorphine considerations, see Chapter 2, Section 2.4.
- Engage the local community (e.g., schools, law enforcement, human services) to build treatment resources.[18]
- Collaborate with local health, substance use, and mental health providers to adopt a hub and spoke model, designating regional specialty treatment centers as the "hubs" and community providers as the "spokes."[18] In this model, hubs provide a full range of OUD care and support community providers prescribing buprenorphine by providing consultative support. The "spokes" dispense buprenorphine, monitor adherence to treatment, provide counseling and coordinate access to recovery supports. Through this model, hubs can offer in-office support to spoke providers with limited capacity through embedded clinical staff to support clinical and care coordination.

## Emergency Departments

Emergency departments (EDs) can serve as a critical access point for buprenorphine, particularly for underserved populations that may not visit other healthcare settings regularly. One of the most significant barriers that ED clinicians cite to initiating buprenorphine treatment is inadequate linkages with outpatient follow-up, including through the primary care setting.[19] Strategies include

- Initiating partnerships with ED clinicians. Providers can conduct outreach to EDs in their geographic area to initiate conversations around developing a working relationship. Depending on the hospital's staffing structure, primary care staff may work with care navigators, peer recovery specialists, or directly with ED clinicians to connect patients to treatment. Personal connections between outpatient providers and ED clinicians have improved care coordination when compared to follow-up phone calls.[20]

- Developing clear protocols and pathways. Primary care providers can work with ED providers to understand, streamline, and refine pathways for linking OUD patients with primary care. Well-designed pathways will include timely follow-up to ensure ED clinicians do not have to prescribe over three days of buprenorphine and warm handoffs between ED clinicians and primary care providers.[19, 21] One example could be the Behavioral Health Assessment Officer (BHAO). A BHAO practices within a rural ED. The BHAO is responsible for evaluating and managing care for patients who arrive with behavioral health concerns including substance use disorders (SUD). Incorporating a BHAO in the ED can increase patients' access to care, without the need for an onsite psychiatrist or psychiatric nurse practitioner. The BHAO model has been implemented at two EDs in rural Appalachian New York State.

## RESOURCES

The Boston Medical Center Emergency Department began Project ASSERT (Alcohol & Substance Abuse Services, Education, and Referral to Treatment) to address treatment gaps for patients presenting in the ED with addictions or other complex conditions. Through Project ASSERT, a team of health promotion advocates (HPA) collaborate with ED providers to define tailored treatment plans and connect patients with follow-up services.

**Source**

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## Chapter 3.

# Considerations for Prescribing Buprenorphine

### KEY TAKEAWAYS

1. **Educational efforts and expanding exposure** can increase knowledge and reduce the stigma of substance use disorders within the clinic and the community (pages 31-32).
2. **Training and mentoring activities** enhance providers' understanding of buprenorphine (pages 32-35). Prescribers have the choice to undergo waiver training on buprenorphine prescribing. Once providers have completed the waiver training, or if they intend to seek a training exemption, a provider will need to register with the Substance Abuse and Mental Health Services Administration (SAMHSA), an agency within the Department of Health and Human Services. Providers who opt for the training exemption are currently limited to treating 30 patients.
3. Providers and practices should determine **payment for buprenorphine services**, establish a **relationship with local pharmacies** for dispensing buprenorphine, and develop **patient eligibility and assessment protocols and treatment agreements** (pages 35-39).
4. Providers are encouraged to **provide buprenorphine to any patient in need of this treatment** (page 40). This might be only a small number of patients currently being treated by the provider, and providers may wish to recruit additional patients from their local communities

Preparing for implementation of buprenorphine prescribing in primary care practices can seem like a daunting undertaking at first, but it doesn't have to be. This chapter describes core competencies that providers and organizations should have in place prior to prescribing buprenorphine, as well as additional program enhancements that can be accomplished over time. These core competencies are:

1. Educational efforts for addressing stigma and beliefs
2. Training and mentoring to provide buprenorphine services
3. Payment mechanisms for buprenorphine services
4. Relationships with pharmacies for buprenorphine prescriptions
5. Eligibility assessment protocols and processes
6. Procedures for identifying and recruiting patients

Once these competencies have been considered, providers can confidently begin prescribing buprenorphine services to their patients.

## 3.1 Educational Efforts for Addressing Stigma and Beliefs

OUD-related stigma exists at the provider and patient levels, and can affect a provider's willingness to screen and prescribe, as well as a patient's willingness to access and remain engaged in care. Stigma around SUD has been linked to limited knowledge of these conditions.[1]

Educational efforts to increase knowledge of SUD within the clinic and, when resources permit, within the community, can be powerful mechanisms to alter patient perceptions of stigma and willingness to seek treatment.[2-3]

Increasing a provider's exposure to buprenorphine prescribing can quell fears and reduce stigma associated with OUD and SUD. Having at least one prescribing provider in a practice can motivate other providers to initiate buprenorphine prescribing.[4]

It is important to address stigma among support staff as well, including front desk staff, to ensure that the patient is receiving respectful treatment at all points of care.

Practices can more effectively engage patients in treatment by ensuring they are delivering patient-centered care. Practices that foster patient-centered care ask open-ended questions to understand the patient's perspective; take care to not interrupt the patient; actively listen; and practice shared decision-making.[5]

### PERCEIVED BARRIER

Provider beliefs and patient stigma are among the most commonly cited barriers to increasing access to buprenorphine. Some providers describe patients with OUD negatively and worry that integrating buprenorphine prescribing into their practice will attract new, "difficult" patients. Patients are often hesitant to seek out care due to social stigma, such as discriminatory treatment or concerns about jeopardizing employment. Many patients and providers also do not believe MOUD is effective at treating OUD. Clinicians cite cultural and institutional barriers, such as beliefs favoring abstinence-based treatment, as reducing the likelihood they will prescribe buprenorphine.

**Source**


Louie, D. L., Assefa, M. T., & McGovern, M. P. (2019). Attitudes of primary care physicians toward prescribing buprenorphine: a narrative review. *BMC Family Practice, 20*(1), 157.

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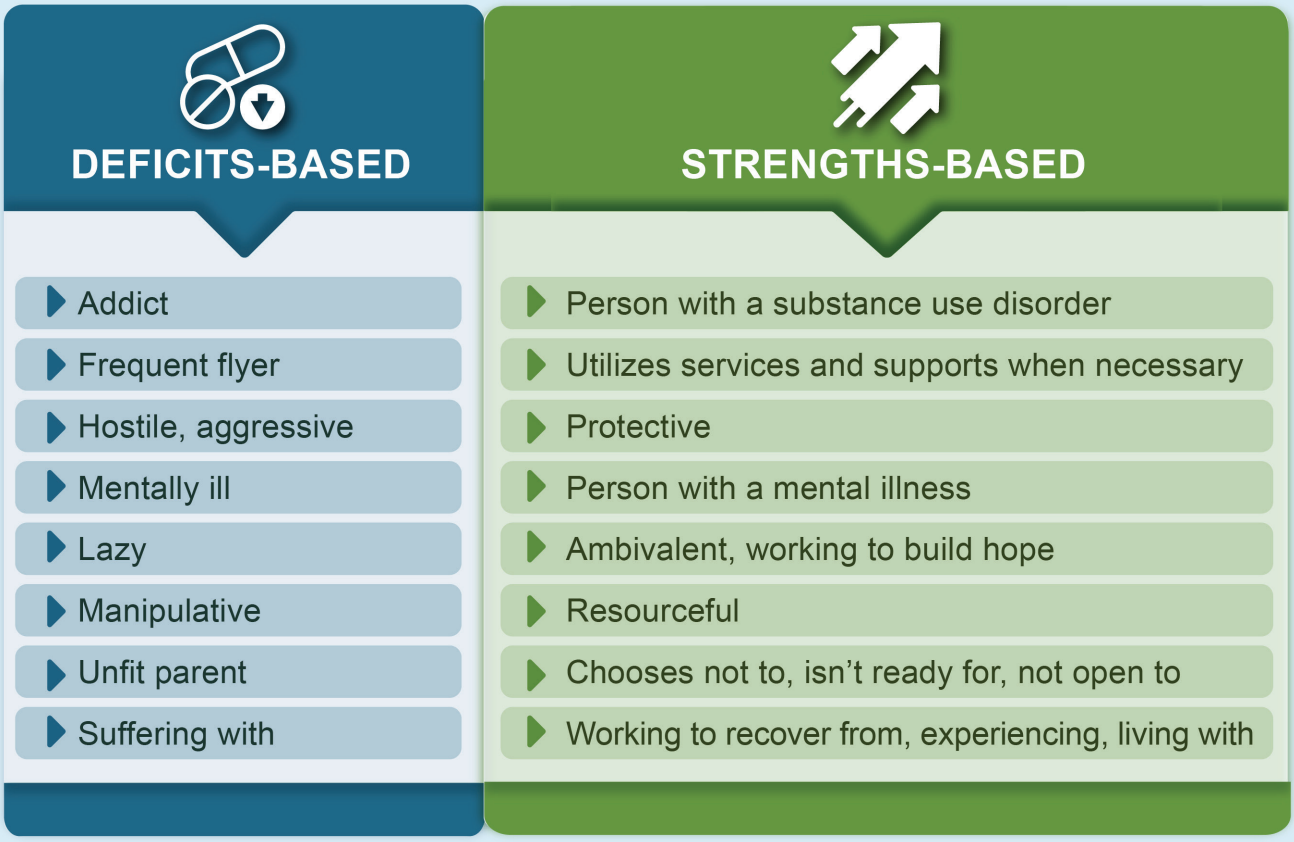
Language also plays a powerful role in shaping patient perceptions of stigma, and those who provide treatment can improve patient experiences by adhering to person-centered, strengths-based (as opposed to deficits-based) language. Person-centered language focuses on the unique characteristics of the patient rather than on their opioid use or the disease.[6]

**TIP: Use strengths-based language**




**Source**

Hyams, K., Prater, N., Rohovit, J., Meyer-Kalos, P. (2018). *Person-Centered Language*. Center for Practice Transformation: University of Minnesota.

## 3.2 Training and Mentoring to Provide Buprenorphine Services

### Initial Training

Training, certification, and mentoring activities are available for providers and clinic coordinators who want to gain knowledge and prescribe buprenorphine.

SAMHSA's Providers Clinical Support System (PCSS), which supports provider education in preventing, identifying, and treating SUD, provides an eight-hour training for physicians who want to prescribe buprenorphine. The training covers topics such as

1. Addiction identification and evidence-based practices.
2. Fundamentals of office-based opioid treatment.
3. The process of buprenorphine induction, stabilization, and maintenance.
4. Medical record documentation.

The training also provides participants with resources to ensure confidence in prescribing buprenorphine, and assistance in applying for the waiver.[7] Registration for the waiver training can be found here.

Nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives are also eligible to prescribe buprenorphine. To do so, these providers need to undergo a 24-hour training. Physician assistants are also eligible, and are required to take a separate 24-hour training.

Recently released practice guidelines for buprenorphine allow for a training exemption.[8] However, providers with this exemption are limited to seeing no more than 30 patients at any one time, and time practicing under this exemption does not qualify the provider for subsequent increases in their patient cap. Alternatively, providers may wish to pursue a waiver with training. This allows providers to treat up to 30 patients at a time in their first year, after which they can submit a notification to SAMHSA which will allow them to treat up to 100 patients in subsequent years.

## PERCEIVED BARRIER

Providers do not feel they are equipped with the knowledge, resources, or referral networks needed to support patients with OUD.

**Source**

Substance Abuse and Mental Health Services Administration. (2020). *MAT Medications, Counseling, and Related Conditions.* Retrieved July 13, 2021, from https://www.samhsa.gov/medication-assisted-treatment/medications-counseling-related-conditions#medications-used-in-mat

## RESOURCES

- Boston Medical Center's Office Based Addiction Treatment Training and Technical Assistance + provides extensive training resources and videos for providers with continuing education credits, including a 2-hour "Waiver-trained: now what? The nuts and bolts of addiction treatment."

Once providers have completed the waiver training, or if they intend to seek a training exemption, they need to submit a Notification of Intent (NOI) form and any applicable certificates of training completion to SAMHSA to obtain a waiver. The NOI must be submitted and approved before the provider can prescribe buprenorphine.

## RESOURCES

The PCSS website provides access to a variety of trainings, which can be filtered by target audience (physicians) and topic (buprenorphine). These include

- Trainings on integration and coordination of buprenorphine services
  - Team-based care to address psychiatric and physical health comorbidities for persons with opioid use disorders
  - Integrating OUD treatment in clinical care
  - Integrating Hepatitis C care into your MAT clinic
  - Telemedicine-delivered buprenorphine in the age of COVID-19
- Trainings on prescribing and maintaining patients on buprenorphine
  - Long-acting buprenorphine treatment for OUD
  - Buprenorphine and benzodiazepines: What's the problem?
  - Transitioning from methadone to buprenorphine
- Trainings on prescribing buprenorphine with specific populations
  - Use of buprenorphine in underserved communities
  - Management of other SUDs: Benzodiazepines, cocaine and other stimulants, and cannabis
  - Mental health and OUD: Working with LGBTQ+ individuals
  - Managing pain in the setting of co-morbid substance use disorder
  - Treating women for OUD during pregnancy

Providers and interested staff can access a large network that provides other forms of support for MOUD.

- SAMHSA has developed an Opioid Response Network that allows providers to connect with a mentor who can provide additional education and training resources.
- New prescribers can connect with those with more experience for answers to a quick question or for more formal one-on-one guidance through the PCSS Mentoring Program or Project ECHO® learning communities.
- The Project ECHO® model is an evidence-based method developed by researchers at the University of New Mexico, connecting interdisciplinary specialists with community-based practitioners through a telementoring hub-and-spoke knowledge-sharing approach. Many states have Project ECHO® learning communities focused on MOUD. These learning communities allow providers to share knowledge and expertise.

### Continued Training and Mentoring Activities

Participating in continuing education around SUD and mentoring can also improve providers' understanding of the benefits of MOUD.

## 3.3 Payment Mechanisms for Buprenorphine Services

Buprenorphine prescribing is financially viable in different types of primary care settings including federally qualified health centers (FQHCs), non-FQHCs in urban high-poverty areas, rural health clinics, and practices outside of high-poverty areas.[2] Different approaches to delivering buprenorphine treatment might yield different revenue levels. Primary care practices could financially sustain buprenorphine treatment if demand and no-show requirements are met.[9]

Providers can typically bill buprenorphine treatment visits as a regular office visit (see codes listed below) and can check with payers to determine whether they offer enhanced billing rates for buprenorphine treatment.[10]

**TIP: Determine payment for services**

Providers can review existing policies designed for payment of other services and follow a similar process for understanding buprenorphine payment.

Providers can use the following CPT (Current Procedural Terminology) codes for billing purposes, as long as the service provided meets the requirements of the payer, or insurance provider:

- SBIRT
  - Structured screening and brief intervention services can be offered and billed for education purposes: 99408
- Pre-Induction Visit
  - New patient: 99205
  - Established patient: 99215
- Induction Visit
  - Established patient E/M (evaluation and management): 99212, 99213, 99214, 99215
- Maintenance Visit
  - Any of the established E/M codes. Counseling codes are commonly used.

Depending on the patient's circumstances and the state in which the services are provided, payment options include Medicaid, Medicare, private insurance, patient assistance programs, or self-payment plans.

A review of Medicaid policies and data revealed that all states reimburse for some form of buprenorphine services.[11] However, depending on the state, they may still impose certain constraints or limitations on obtaining the medication. Likewise, most private insurance companies will cover the cost, but coverage may be tightly controlled.[12] Both Medicaid and private insurers may follow certain regulations, so it is important for the provider and practice to understand their state-specific requirements and those of their patients' private insurers, including[13-15]:

- Need for prior authorizations
- Limits on dosage or duration of treatment
- "Fail first" policies, which require a patient to try non-medication-based treatments first
- Covering buprenorphine, but not the doctor's office visit

Medicare is somewhat different, in that only some Medicare providers will reimburse for buprenorphine, and prior authorization is usually required.[16]

## Other Considerations

Treatment providers should also consider their patient's HIV status, as those living with HIV can get their buprenorphine paid for through the Ryan White HIV/AIDS program.

Staff should be mindful of the payment methods available for buprenorphine visits and prescriptions. Research shows that Ryan White beneficiaries and those with private insurance or who self-pay are the predominant recipients of buprenorphine treatment.[17] Expanding payment options by incorporating Medicaid or offering flexible payment plans will enable more low-income, under-served patients to access buprenorphine.

Patients who are uninsured or who are not covered for buprenorphine through their insurance plan might be able to apply for a patient assistance program (PAP) through the pharmaceutical company that manufactures the buprenorphine.[16] Some states also have assistance programs, called state pharmaceutical assistance programs (SPAPs). These are often available to people who are low-income but not eligible for Medicaid.

# 3.4 Relationships with Pharmacies for Buprenorphine Prescriptions

Relationships and rapport building between a primary care practice and pharmacies can ensure seamless provision of buprenorphine to clients. Utilizing existing relationships with pharmacies and communicating upfront the maximum number of patients the clinic will be seeing may also be beneficial to reassure the pharmacy that overprescribing will not be an issue. In discussions with pharmacies, providers can listen to any concerns the pharmacy has and agree on what the relationship will entail if there are concerns about over-prescribing. Corporate pharmacies and those in urban areas may be the most amenable to dispensing buprenorphine.[18] DEA-registered providers can receive buprenorphine through the mail to improve access for rural patients who do not have pharmacies in their localities, and patients who otherwise live far away from a pharmacy or are unable to go to a pharmacy due to mobility or transportation barriers.[19]

**PERCEIVED BARRIER**

Due to a history of over-prescribing opioids, some pharmacies are reluctant to dispense buprenorphine; this can be especially true when working with a prescriber they are unfamiliar with.

A recent study found that nearly 30 percent of pharmacies reported limitations to filling buprenorphine prescriptions, and one in five would not fill any buprenorphine prescriptions. These limitations were most common among independent pharmacies and those in the southern region of the United States.

**Source**

Hutchinson, E., Catlin, M., Andrilla, C. H., Baldwin, L. M., & Rosenblatt, R. A. (2014) Barriers to primary care physicians prescribing buprenorphine. *Annals of Family Medicine, 12*(2), 128-133.

Different types of buprenorphine products are available. The Food and Drug Administration (FDA) has approved several buprenorphine and buprenorphine/naloxone formulations, including sublingual tablets, sublingual or buccal film, and extended-release injection. Patients must be stabilized on transmucosal formulations before they are eligible for extended-release injections.[20]

It is important to consider individual patient needs when selecting which buprenorphine product to administer. If the patient is pregnant, transmucosal monoproduct is recommended.[21-22] Otherwise, buprenorphine/naloxone combination products are recommended, as the inclusion of naloxone decreases the potential for misuse, especially in people who are opioid-dependent and who might inject buprenorphine.[23-24] However, labeling for buprenorphine/naloxone products cautions those who are dependent on methadone and other long-acting opioids of precipitated withdrawal. Patients who face barriers to treatment retention, including those in justice settings, people experiencing housing instability, and those in rural communities, may benefit from extended-release formulations when a stable dose of the medication is determined.[25]

**TIP: Determine optimal buprenorphine transmucosal products for OUD treatment**

| Product | Active Ingredient | Available Strengths (buprenorphine/naloxone) |
|---|---|---|
| **Generic combination product** | • Buprenorphine hydrochloride<br>• Naloxone hydrochloride | 2 mg/0.5 mg<br>8 mg/2 mg |
| **Generic monoproduct** | • Buprenorphine hydrochloride | 2 mg<br>8 mg |
| **Suboxone** | • Buprenorphine hydrochloride<br>• Naloxone hydrochloride | 2 mg/0.5 mg<br>4 mg/1 mg<br>8 mg/2 mg<br>12 mg/3 mg |
| **Zubsolv** | • Buprenorphine hydrochloride<br>• Naloxone hydrochloride | 0.7 mg/0.18 mg<br>1.4 mg/0.36 mg<br>2.9 mg/0.71 mg<br>5.7 mg/1.4 mg<br>8.6 mg/2.1 mg<br>11.4 mg/2.9 mg |

Buprenorphine or combination buprenorphine formulations are available in different products, ingredients, and strengths.

## 3.5 Eligibility Assessment Protocols and Processes

Clear inclusion and exclusion criteria can streamline patient recruitment and assessment. Sample criteria are presented below. A clinical assessment during the intake process will provide the basis for a treatment plan and can be used as a baseline to measure the patient's response to treatment. A comprehensive assessment protocol is essential. Providers can use an adapted protocol provided in Appendix G.

### TIP: Apply appropriate inclusion and exclusion criteria for buprenorphine treatment

**Sample inclusion criteria**

- ☐ Eligible for care at the treatment site
- ☐ Diagnosed with an opioid use disorder as determined by DSM-5 criteria and desires pharmacotherapy for this disorder
- ☐ Is over age 18 or emancipated minor able to consent for medical and substance use treatment.
- ☐ Able to comply with buprenorphine treatment program policies
- ☐ If female, is using adequate birth control methods
- ☐ Desires buprenorphine treatment

**Sample exclusion criteria, where patients can be referred to appropriate providers**

- ☐ Has severe hepatic dysfunction, i.e., AST and/or ALT ≥ 5x upper limit of normal
- ☐ Meets DSM-5 criteria for benzodiazepine use disorder OR meets DSM-5 criteria for alcohol use disorder
- ☐ Exhibits active suicidal ideation
- ☐ Has psychiatric impairment that impedes ability to provide informed consent regarding own care (dementia, delusional, actively psychotic)
- ☐ Has methadone or opioid analgesic doses that exceed levels allowing for safe transition to buprenorphine (methadone >30-60 mg)
- ☐ Has acute or chronic pain syndrome requiring chronic use of opioid analgesics
- ☐ Has serious/uncontrolled/untreated medical or psychiatric conditions (hypertension, hepatic failure, asthma, diabetes, etc.)
- ☐ Requires a higher level of care than can be offered in the treatment clinic (i.e., methadone maintenance or mental illness chemical addiction [MICA] program)

## Treatment Agreement and Expectations

During intake, a provider or their staff develops and reviews the treatment agreement with the patient and obtains their consent for treatment, encouraging the patient to ask questions. The provider keeps one copy in the patient's record and provides the patient with a copy to keep. The treatment agreement aims to engage patients in the treatment plan and encourage patient involvement with their treatment.[20, 26]

In this process, providers should do the following:

- Develop and review a patient-centered treatment plan, including goals for buprenorphine treatment
- Individualize treatment to meet patient needs, as identified during screening/assessment
- Provide information/referral for counseling or other support services as needed (social support, employment, housing, financial, legal assistance)

- Providers should also have a conversation about what the patient can expect from the provider and what the provider expects from the patient. This should include:
  - Reviewing appointment frequency/ schedule
  - Reviewing program policies and treatment protocols (e.g., clinical appointment policy, counseling policy, urine toxicology screen policy, prescription policies)
  - Providing patient education on medication refills, medication safety, and responsibilities for safe storage, especially if they have young children

**RESOURCES**

- The SAMHSA Buprenorphine Quick Start guide discusses typical lab work that should be requested prior to buprenorphine induction.

Specific considerations arise for patients who are:

- Pregnant – SAMHSA Medications to Treat OUD During Pregnancy: Information for Providers
- Living with Hepatitis C (HCV) – BMC Considerations for Medications for Addiction Treatment in HCV+ Patients
- Living with HIV – BMC Considerations for Medications for Addiction Treatment in HIV+ Patients
- Transitioning from methadone – BMC Transfers from Methadone to Buprenorphine
- Dealing with concurrent pain – BMC Clinical Guidelines

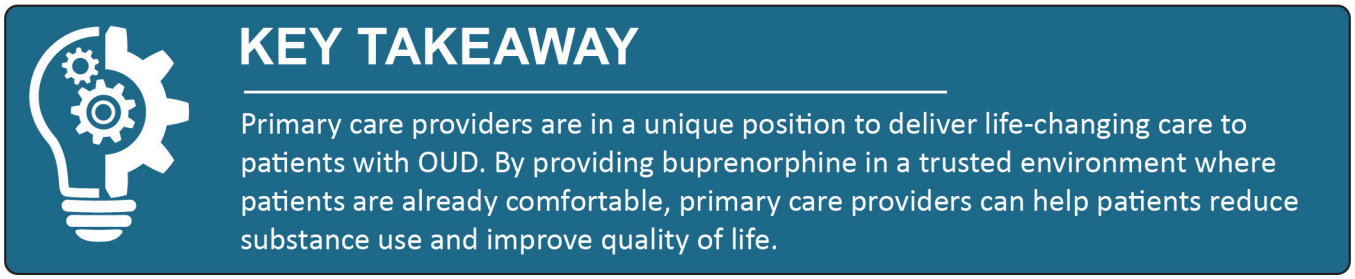
**RESOURCES**

- The Boston Medical Center (BMC) provides several consent forms; copies can be found in Appendices H-I.
  - Consent for Release of Information
  - Appointed Pharmacy Consent
  - Consent for Transmucosal Buprenorphine Pregnancy
  - Consent for Treatment with Transmucosal Buprenorphine
- Sample treatment agreements are available.
  - BMC Treatment Agreement for Buprenorphine, provided in Appendix J
  - American Society of Addiction Medicine (ASAM) Sample Treatment Agreement, provided in Appendix K
- Treatment program policies can be found in the BMC Clinical Guidelines and in the Los Angeles County Department of Public Health patient handbook for MAT.
- BMC provides an intake checklist in BMC Clinical Guidelines, see Appendix L.
- Patient handouts on safety can be found in the BMC Clinical Guidelines.
  - Information on pediatric exposure to buprenorphine/naloxone
  - Overdose education

## 3.6 Procedures for Identifying and Recruiting Patients

To identify and recruit patients, prescribers may first identify current patients who can benefit from buprenorphine treatment.[27] Providers could also post informational posters in the clinic waiting rooms, in restrooms, and in exam rooms so that patients can self-report knowing that they will be supported.

Prescribers may also wish to conduct outreach to individuals who are not patients of the clinic.[27] Current community partners, local social service organizations such as shelters, support groups or food pantries, as well as mental health and substance use treatment programs, are all common referral networks for buprenorphine services. To reach the most vulnerable populations, prescribers could partner with the social service organizations that serve these populations and explain buprenorphine treatment to their service providers, who it is for, and the benefits. With the addition of telehealth services, this can mean partnering with organizations outside of the local area to reach individuals who may not otherwise have access to buprenorphine services.



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# Appendices

This document includes resources to assist primary care practices in all phases of planning, preparation, and implementation of buprenorphine prescribing. Federal agencies, state programs, and organizations have developed these resources to aid providers in a variety of settings, and they can be modified to specific settings, with attribution to and based on the restrictions of the original source.

Appendices include

- Appendix A. BMC Checklist of DSM-5 Diagnostic Criteria for OUD
- Appendix B. California Department of Health Care Services, Buprenorphine – What You Need to Know
- Appendix C. Sample of Patient-facing Materials for Home Induction
- Appendix D. BMC Managing Withdrawal
- Appendix E. BMC Maintenance Visits
- Appendix F. ASAM Diversion Criteria
- Appendix G. Comprehensive Clinical Assessment Adapted from BMC and SAMHSA resources
- Appendix H. BMC Consent for Release of Information
- Appendix I. BMC Appointed Pharmacy Consent
- Appendix J. BMC Treatment Agreement for Buprenorphine
- Appendix K. ASAM Sample Treatment Agreement
- Appendix L. BMC Checklist Prior to Induction

Appendix A.

# BMC Checklist of DSM-5 Diagnostic Criteria for OUD

# DSM-5 CHECKLIST OF DIAGNOSTIC CRITERIA: OPIOID USE DISORDER

**Patient Name:** _____ **Provider Name:** _____

**Date:** _____ **Provider Signature:** _____

*Opioid Use Disorder is defined as a problematic pattern of opioid use leading to clinically significant impairment or distress, as manifested by at least 2 of the following, occurring within a 12-month period:*

| Diagnostic Criteria | Meets Criterion? | Additional/Supporting Information |
|---|---|---|
| 1. Opioids are often taken in larger amounts or over a longer period than was intended. | | |
| 2. There is a persistent desire or unsuccessful efforts to cut down or control opioid use. | | |
| 3. A great deal of time is spent in activities necessary to obtain the opioid, use the opioid, or recover from its effects. | | |
| 4. Craving, or a strong desire or urge to use opioids. | | |
| 5. Recurrent opioid use resulting in a failure to fulfill major role obligations at work, school, or home. | | |
| 6. Continued opioid use, despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of opioids. | | |
| 7. Important social, occupational, or recreational activities are given up or reduced because of opioid use. | | |
| 8. Recurrent opioid use in situations in which it is physically hazardous. | | |
| 9. Continued opioid use, despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the substance. | | |
| 10. Tolerance,* as defined by *either* of the following: | | |
| A. A need for markedly increased amounts of opioids to achieve intoxication or desired effect. | | |
| B. A markedly diminished effect with continued use of the same amount of an opioid. | | |

| Diagnostic Criteria | Meets Criterion? | Additional/Supporting Information |
|---|---|---|
| 11. Withdrawal,* as manifested by *either* of the following: | | |
| A. The characteristic opioid withdrawal syndrome. | | |
| B. Opioids (or a closely related substance) are taken to relieve or avoid withdrawal symptoms. | | |

***Note:** This criterion is not considered to be met for those individuals taking opioids solely under appropriate medical supervision.

*Specify if:*

**In early remission:** After full criteria for opioid use disorder were previously met, none of the criteria for opioid use disorder have been met for at least 3 months but for less than 12 months (with the exception that Criterion 4, "Craving, or a strong desire or urge to use opioids," may be met).

**In sustained remission:** After full criteria for opioid use disorder were previously met, none of the criteria for opioid use disorder have been met at any time during a period of 12 months or longer (with the exception that Criterion 4, "Craving, or a strong desire or urge to use opioids," may be met).

**On maintenance therapy:** This additional specifier is used if the individual is taking a prescribed agonist medication, such as methadone or buprenorphine, and none of the criteria for opioid use disorder have been met for that class of medication (except tolerance to, or withdrawal from, the agonist). This category also applies to those individuals being maintained on a partial agonist, an agonist/antagonist, or a full antagonist such as oral naltrexone or depot naltrexone. In a controlled environment: This additional specifier is used if the individual is in an environment where access to opioids is restricted.

***Current severity:***

☐ *Mild:* Presence of 2–3 symptoms. **Code as: F11.10 (ICD-10)**

☐ *Moderate:* Presence of 4–5 symptoms. **Code as: F11.20 (ICD-10)**

☐ *Severe:* Presence of 6 or more symptoms. **Code as: F11.20 (ICD-10)**

**After completion, scan this form into the patient's record. Make a copy for the patient.**

# Reference List

LaBelle, C. T., Bergeron, L. P., Wason, K. W., and Ventura, A. S. (2016). *Policy and Procedure Manual of the Office Based Addiction Treatment Program for the use of Buprenorphine and Naltrexone Formulations in the Treatment of Substance Use Disorders. Unpublished treatment manual*. Boston Medical Center. Retrieved August 5, 2021, from https://www.bmcobat.org/resources/index.php?filename=34_83_DSM%252BChecklist%252Bof%252BDiagnostic%252BCriteria%252BOpioid%252BUse%252BDisorder.pdf

Appendix B.

# California Department of Health Care Services, Buprenorphine – What You Need to Know

# Buprenorphine

## What You Need to Know

September 2020

## What is buprenorphine?

- Buprenorphine - or bup - is medicine for people who have chronic pain or addiction to opioids (heroin or pain pills). Many people know it by brand names like Suboxone® and Subutex®.
- Buprenorphine helps get rid of cravings and withdrawal, without making you feel high.
- People have less overdoses when they take buprenorphine.
  It is a safe medicine that has been used for 30 years.
- It is not substituting one drug for another—it is a daily medicine that you may need to stay healthy.
- Often buprenorphine and naloxone are taken together in 1 pill. Naloxone is the same as Narcan®, but if you take the medicine under the tongue the naloxone doesn't go in your body and can't make you sick. Naloxone is only there to make sure that people don't crush the pill and inject it—if you do that, the naloxone does go into your body and does make you sick.

## What is it like to take buprenorphine?

- Many people say that their cravings and withdrawal go away, they feel "clear in the head," and their chronic pain gets better.
- Every morning you put a pill or a film strip under your tongue and let it dissolve—don't swallow it.
- People need to take it every day in most cases, and do feel sick if they stop taking it suddenly.
- Usually there are no side effects, but some people have headaches, stomach upset, or trouble sleeping.
- Many people keep taking it for years, or forever. If you want to stop taking it that is ok, but talk to your medical team first.
- The chance of an overdose on buprenorphine is very low, but if mixed with other drugs or alcohol overdose is possible.
- Some people take buprenorphine as a once a month shot under the skin of the belly. This is a great option if taking a medicine every day is hard for you.

## Is buprenorphine right for me?

- If you are currently taking methadone, talk to your medical team before switching.
- Before taking the first dose of buprenorphine, most people need to feel some withdrawal. That is important because if you take it while other opioids are in your system, you can get very sick.
- **Talk to your medical team to see if buprenorphine is a good medicine for you.** There are many good choices for treatment, only you and your team know what is best for you.

## How do I get buprenorphine?

- **You can go to any of the places below to get started.** You may need to visit more than once before getting the first dose. In some clinics (like methadone clinics), you may come in every day to pick up your buprenorphine dose.
- Instead of going to a methadone clinic, you can get the medicine from a **primary care doctor**. At first you may need daily visits, but many people can soon switch to weekly or monthly visits.
- Some **telemedicine groups** offer prescriptions over the internet/phone instead of in a doctor's office, so you need a phone and internet to use those services.

Provider—Please write in other options such as inpatient, medical respite, primary care, etc. as applicable to this patient.

| | | | |
|---|---|---|---|
| Name of Organization | | | |
| Address | | | |
| Phone | | | |
| Hours | | | |

# Reference List

California Department of Health Care Services, Public Health Institute, CA Bridge Program. (2020). *Buprenorphine – What You Need to Know*. Retrieved August 5, 2021, from https://cabridge.org/wp-content/uploads/CA-BRIDGE-PATIENT-MATERIALS-Buprenorphine-What-you-need-to-know-September-2020.pdf

Appendix C.

# Sample of Patient-facing Materials for Home Induction

## DAY ONE

Before taking your first dose of buprenorphine, stop taking all opioids for 12-36 hours. You will feel unwell with mild symptoms of withdrawal. These symptoms are normal. After starting buprenorphine, you will start to feel better again.

Before your first dose of medication, you should feel at least three of the following:

- Very restless
- Anxious or irritable
- Twitching, tremors, or shaking
- Enlarged pupils
- Bad chills or sweating
- Heavy yawning
- Joint and bone aches
- Runny nose, or tears in your eyes
- Goose bumps on your skin
- Cramps, nausea, vomiting or diarrhea

Complete the COWS checklist. You need your COWS score to be at or greater than 12 before taking your first dose of buprenorphine.

### Schedule:

In the morning, take 2 mg of buprenorphine under the tongue (one tablet or one film strip). Do not swallow the medication or chew it. Avoid taking or swallowing while the medicine dissolves. Buprenorphine does not work if swallowed.

### Wait an hour:

- If you feel fine, do not take any more medication today. Record your total for the day dose, and call your provider's office to check in.
- If you continue to have withdrawal symptoms, take a second dose under your tongue (2 mg).
- If you are feeling worse than when you started, you might have precipitated withdrawal. Call and talk with your provider about treatment options.

### Again, wait an hour:

- If you feel fine, do not take any more medication today. Record your total for the day dose, and call your provider's office to check in.
- If you continue to have withdrawal symptoms, take a third dose under your tongue (2 mg).

This can be repeated, but do not take any more than 4 tablets or films (8 mg total dose) in a day without first speaking to your provider.

At the end of the day, call your provider's office to check in.

# COWS:
## Clinical Opiate Withdrawal Scale

Wesson & Ling, J Psychoactive Drugs. 2003 April-June; 35(2): 253-9

**Resting Pulse Rate:_____ beats/minute**
***Measured after patient is sitting or lying for one minute***

| | |
|---|---|
| 0 | Pulse rate 80 or below |
| 1 | Pulse rate 81-100 |
| 2 | Pulse rate 101-120 |
| 4 | Pulse rate greater than 120 |

**Sweating:** ***over past ½ hour not accounted for by room temperature or patient***

| | |
|---|---|
| 0 | No report of chills or flushing |
| 1 | Subjective report of chills or flushing |
| 2 | Flushed or observable moistness on face |
| 3 | Beads of sweat on brow or face |
| 4 | Sweat streaming off face |

**Restlessness** ***Observation during assessment***

| | |
|---|---|
| 0 | Able to sit still |
| 1 | Reports difficulty sifting still, but is able to do so |
| 3 | Frequent shifting or extraneous movements of legs/arms |
| 5 | Unable to sit still for more than a few seconds |

**Pupil size**

| | |
|---|---|
| 0 | Pupils pinned or normal size for room light |
| 1 | Pupils possibly larger than normal for room light |
| 2 | Pupils moderately dilated |
| 5 | Pupils so dilated that only the rim of the iris is visible |

**Bone or Joint aches** ***If patient was having pain previously, only the additional component attributed to opiates withdrawal is scored***

| | |
|---|---|
| 0 | Pulse rate 80 or below |
| 1 | Pulse rate 81-100 |
| 2 | Pulse rate 101-120 |
| 4 | Pulse rate greater than 120 |

**Runny nose or tearing** ***Not accounted for by cold symptoms or allergies***

| | |
|---|---|
| 0 | Not present |
| 1 | Nasal stuffiness or unusually moist eyes |
| 2 | Nose running or tearing |
| 4 | Nose constantly running or tears streaming down cheeks |

**GI Upset:** ***over last ½ hour***

| | |
|---|---|
| 0 | No GI symptoms |
| 1 | Stomach cramps |
| 2 | Nausea or loose stool |
| 3 | Vomiting or diarrhea |
| 5 | Multiple episodes of diarrhea or vomiting |

**Tremor** ***observation of outstretched hands***

| | |
|---|---|
| 0 | No tremor |
| 1 | Tremor can be felt, but not observed |
| 2 | Slight tremor observable |
| 4 | Gross tremor or muscle twitching |

**Yawning** ***Observation during assessment***

| | |
|---|---|
| 0 | No yawning |
| 1 | Yawning once or twice during assessment |
| 2 | Yawning three or more times during assessment |
| 4 | Yawning several times/minute |

**Anxiety or Irritability**

| | |
|---|---|
| 0 | None |
| 1 | Patient reports increasing irritability or anxiousness |
| 2 | Patient obviously irritable anxious |
| 4 | Patient so irritable or anxious that participation in the assessment is difficult |

**Gooseflesh skin**

| | |
|---|---|
| 0 | Skin is smooth |
| 3 | Piloerrection of skin can be felt or hairs standing up on arms |
| 5 | Prominent piloerrections |

**Score:5-12 mild; 13- 24 moderate; 25-36 moderately severe; more than 36 = sever withdrawal**

## DAY TWO

Recall yesterday's total dose.

### If your Day 1 total was 4mg:

- If you feel fine, take 4 mg this morning; however, if you feel some withdrawal symptoms, start with 6 mg this morning (3 tablets or films).
- Later in the day, see how you feel. If you feel okay, do not take more. If you still feel withdrawal, take another 2 mg dose.
- Talk with your provider or office staff.

### If your Day 1 total was 6 mg:

- If you feel fine, take 6 mg this morning; however, if you feel some withdrawal symptoms, start with 8 mg this morning.
- Later in the day, see how you feel. If you feel okay, do not take more. If you still feel withdrawal, try another 2 mg dose.
- Talk with your provider or office staff.

### If your Day 1 total was 8 mg:

- If you feel fine, take 8 mg this morning. If you feel some withdrawal symptoms, start with 10 mg this morning.
- Later in the day, see how you feel. If you feel okay, do not take more. If you still feel withdrawal, try another 2 mg dose.
- Talk with your provider or office staff.

## DAY THREE

If you felt good at the end of the Day 2, repeat the total dose you took on Day 2. If you felt too tired, groggy, or over-sedated on Day 2, take a lower dose on Day 3 (2 mg less).

If you still felt some withdrawal at the end of the Day 2, take the same total dose you took on Day 2 plus another 2 mg dose. Do not take more than 16 mg of buprenorphine in one day.

See how you feel as the day goes on. If withdrawal symptoms persist, take another 2 mg dose.

Different people need different doses of buprenorphine. If symptoms persist, consider seeing your provider or calling their office to discuss additional withdrawal treatments.

Record the dose medication you took on Day 3.

## DAY FOUR +

On Day 4 and beyond, take the total dose you used on Day 3. You can take more medication or less medication depending on how you feel overall, if you still have cravings, or if you are still using.

At this point, you should discuss any dose adjustments with your doctor. If you need to increase your dose, you should not change it by more than 2 mg per day.

## Appendix D.

# BMC Managing Withdrawal

| Prescription Drug | Rationale for Use | Description of Use |
|---|---|---|
| **Clonidine** | Anxiety | Initial, 0.1 to 0.2 mg/dose orally 2 to 4 times daily, increasing to a max of about 1 mg/day. Adjust based on response. Taper and discontinue 7 to 10 days after cessation of opioids. Withhold or reduce for excessive hypotension. |
| **Hydroxyzine** | Anxiety or sleep | 25-50 mg po q 6 hours for anxiety or insomnia. |
| **Loperamide** | Diarrhea | 4 mg orally followed by 2 mg after each loose stool up to a maximum of 16 mg/day. |
| **Promethazine** | Nausea | 25 mg po then doses of 12.5 to 25 mg orally may be repeated every 4 to 6 hours as needed. |
| **Trazadone** | Sleep | 50-100 mg po qhs for sleep. |
| **Tylenol or NSAIDS** | Musculoskeletal pain | As directed. |

# Reference List

LaBelle, C. T., Bergeron, L. P., Wason, K. W., Ventura, A. S., and Beers, D. (2018). *Clinical Guidelines of the Office Based Addiction Treatment Program for the use of Buprenorphine and Naltrexone Formulations in the Treatment of Substance Use Disorders. Unpublished treatment guidelines.* Boston Medical Center. Retrieved August 5, 2021, from https://www.bmcobat.org/resources/index.php?filename=23_Clinical_Guidelines_National.pdf

Appendix E.

# BMC Maintenance Visits

## BUPRENORPHINE/NALOXONE MAINTENANCE CLINIC VISITS

Once stable, schedule clinic visits every 2 to 4 weeks, with refills that coincide with visits.

***Goal:*** Monthly visits for a few months; ultimately, random visits, as needed, if appropriate for patient; random is more effective in assisting patients in their recovery and should be the goal instead of monthly.

- Many patients will remain on more frequent visits than monthly, as patients find these visits important to their recovery process.
- Each decrease in visit frequency requires treatment team review.

**Clinic visits to include (See Appendix 6: Nursing Follow-up Form):**

☐ Collect urine sample/swab for toxicology.

☐ Lab testing: If LFTs were elevated at induction, they must be re-checked within 1–2 months or sooner, depending on degree of elevation, and must continue to be regularly monitored thereafter. Elevations are more common in patients with hepatitis C and HIV infection.

☐ If history of risky alcohol use, conduct a breathalyzer at each visit; if patient is struggling with alcohol use, team must address.

☐ Offer acamprosate (Campral), disulfiram (Antabuse), or topiramate (Topamax) to patients with alcohol dependence, with provider input and agreement.

☐ Patients managed on buprenorphine/naloxone cannot be treated with any naltrexone formulation, as these medications are contraindicated.

☐ Assess patient status: recovery, relapse, medical issues; and address as indicated. Contact other OBAT team members as needed, including OBAT provider and PCP if different and warranted.

☐ Review current buprenorphine/naloxone dose, adherence, and correct administration techniques.

☐ Review treatment plan: counseling, meetings, need for further psychiatric treatment, difficulties with obtaining or using buprenorphine/naloxone, incidence of side effects, presence of cravings or withdrawal, instances of drug use.

☐ Provide medical case management, with brief counseling support.

☐ Review contact information, including pharmacy, at each visit.

☐ Provide refills for up to 6 months, once stable, and fax these to a pharmacy (with pharmacy information kept on file).

☐ Ensure visits with waivered OBAT provider at least every 3–4 months, with review of medical record, lab test results, recovery status, and UTS results.

☐ Perform telephone contact for support, monitor medical issues, check pregnancy status, ask about medication changes, any pending needs for surgery, acute/chronic pain management, and determine need for psychiatric assessment.

# Reference List

LaBelle, C. T., Bergeron, L. P., Wason, K. W., and Ventura, A. S. (2016). *Policy and Procedure Manual of the Office Based Addiction Treatment Program for the use of Buprenorphine and Naltrexone Formulations in the Treatment of Substance Use Disorders. Unpublished treatment manual.* Boston Medical Center. Retrieved August 5, 2021, from https://www.bmcobat.org/resources/index.php?filename=24_99_Buprenorphine-Naloxone%252BMaintenance%252BClinic%252BVisits%252BChecklist.pdf

Appendix F.

# ASAM Diversion Criteria

# XYZ Medical Practice

## Sample Office-Based Opioid Use Disorder Policy and Procedure Manual

**Policy Title:** **Diversion Control for Patients Prescribed Transmucosal (Sublingual) Buprenorphine**

**Effective Date:** **Month, Day, Year**

*This Diversion Control Policy is provided for educational and informational purposes only. It is intended to offer healthcare providers guiding principles and policies regarding best practices in diversion control for patients who are prescribed buprenorphine. This Policy is not intended to establish a legal or medical standard of care. Providers should use their personal and professional judgment in interpreting these guidelines and applying them to the specific circumstances of their individual patients and practice arrangements. The information provided in this Policy is provided "as is" with no guarantee as to its accuracy or completeness. ASAM will strive to update this Policy from time to time but cannot ensure that the information provided herein is always current.*

**Preamble:** As the availability of buprenorphine treatment for opioid use disorder has increased, so have reports of diversion, misuse, and related harms. In addition to potential harms in the community, diversion indicates medication non-adherence and should be proactively addressed by healthcare providers. There are a range of signs that a patient is misusing or diverting buprenorphine including but not limited to: (1) missed appointments; (2) requests for early refills because pills were lost, stolen or other reasons; (3) urine screens negative for buprenorphine, positive for opioids; (4) claims of being allergic to or intolerant of naloxone, and requesting monotherapy; (5) non-healing or fresh track marks; or (5) police reports of selling on the streets. There are a range of reasons for diversion and misuse including diverting to family/friends with untreated opioid addiction to help convince them to also get into treatment or get through time on a waiting list, selling some or all of medication in order to pay off debts/purchase preferred opioid/pay for treatment in places where there are inadequate providers taking private insurance or public Medicaid for multiple reasons [e.g., inadequate reimbursement/no reimbursement/burdensome PA process].

The safety and health of the patient and others in the community could be at risk if misuse and diversion are not addressed proactively and throughout treatment. The reputation of XYZ Medical Practice may also be put at risk.

**Definitions:** *Diversion* is defined as the unauthorized rerouting or misappropriation of prescription medication to someone for whom it was not intended (including sharing or selling a prescribed medication).[1] *Misuse* includes taking medication in a manner, by route or by dose, other than prescribed.[2]

**Purpose:** Misuse and diversion should be defined and discussed with patients at the time of treatment entry, periodically throughout treatment, when the patient has returned to use, and when suspected (e.g., incorrect buprenorphine pill/film count) or confirmed (e.g. police report).

These procedures will establish steps to prevent, monitor, and respond to misuse and diversion of buprenorphine. The providers' response should be therapeutic and matched to the patients' needs as untreated opioid use disorder and treatment drop-out/administrative discharges may lead to increased patient morbidity, mortality, and further use of diverted medications or illicit opioids associated with increased risk for overdose death.

**Procedures for Prevention:**

- **Use buprenorphine/naloxone combination products when cost is not an issue and medically indicated.** Reserve the daily buprenorphine monoproducts for pregnant patients, patients who otherwise could not afford treatment if the combination product (i.e., buprenorphine/naloxone) was required, patients who have a history of stability in treatment and low diversion risk, or patients with arrangements for observed dosing. While the evidence on the safety and efficacy of naloxone in pregnant women remains limited, the combination buprenorphine/naloxone product is frequently used, and the consensus of ASAM's National Practice Guideline for the Treatment of Opioid Use Disorder committee is that the combination product is safe and effective for this population. Naloxone is minimally absorbed when these medications are taken as prescribed. If the patient encounters cost issues (e.g. loses medical insurance), consider utilizing prescription savings and discount programs to find the most affordable option available to the patient.

- **Counsel patients on safe storage of medications.** Patients must agree to safe storage of their medication. This is even more critical if there are children in the home where the patient lives. Counsel patients about acquiring locking devices and avoiding storage in parts of the home where visitors frequent (e.g., recommend against storage in kitchen or common bathrooms). Proactively discuss how medication should be stored/transported when traveling to minimize risk of unintended loss.

- **Counsel patients on taking medication as instructed and not sharing medication. Explicitly explain to patients the definitions of diversion and misuse with examples.** Patients are required to take medication as instructed by the provider, for example, they may not crush or inject the medication.

- **Check PDMP for new patients and check regularly thereafter.** PDMP reports can be a useful resource when there is little patient history available or when there is a concern for the patient based on observation. Check for prescriptions that interact with buprenorphine or if there are other providers currently treating your patient with buprenorphine or other medications.

- **Prescribe a therapeutic dose that is tailored to the patient's needs.** One patient may need a total dose of 24mg while another may only need 16mg. Do not routinely provide an additional supply "just in case." Have a discussion with patients who say they need a significantly higher dose, particularly when they are already at 24 mg/daily of buprenorphine equivalents. Evidence suggests that 16 mg per day or more may be more effective than lower doses. There is limited evidence regarding the relative efficacy of doses higher than 24 mg per day, and the use of higher doses may increase the risk of diversion.

- **Make sure the patient understands the practice's treatment agreement and**

**prescription policies.** The XYZ Medical Practice's treatment agreement and/or other documentation is clear about the practice's policies regarding number of doses in each prescription, refills, and rules regarding "lost" prescriptions. Review the policies in person with the patient. Offer an opportunity for questions. The patient and provider must sign the agreement. Review the policies again with the patient at subsequent appointments. See Sample Treatment Agreement.

**Procedures for Monitoring:**

- **Request random urine tests.** The presence of buprenorphine in the urine indicates that the patient has taken some portion of the prescribed dose. Absence of buprenorphine in the urine may indicate non-adherence. Testing for buprenorphine metabolites (only present if buprenorphine is metabolized) may be included to minimize the possibility that buprenorphine is added directly to the urine sample. Dipstick tests can be subverted or replaced. A range of strategies can be used to minimize falsified urine collections including: (1) observed collection; (2) disallowing carry-in items (purses, backpacks) into the bathroom, (3) turning off running water and coloring toilet water to eliminate possibility of dilution; (4) monitoring the bathroom door so that only one person can go in; and (5) testing the temperature of the urine immediately after voiding.

- **Schedule unannounced pill/film counts.** Periodically ask patients who are at high risk for misuse/diversion to bring in their bottles for a pill/film count.

  With unannounced monitoring (both pill/film counts and urine tests), the patient is contacted and must appear within a specified period (e.g., 24 hours) after contact. If they do not appear, then the provider should consider this as a positive indicator of misuse/diversion.

  In rural areas or where access to treatment is limited, providers may consider partnering with local pharmacies to conduct pill/film counts to reduce potential transportation burdens for patients.

- **Directly observe ingestion.** In this kind of monitoring, the medication is taken in front of a qualified clinician and is observed until the medication dissolves in the mouth (transmucosal, sublingual or buccal absorption). Patients who are having difficulty adhering to their buprenorphine treatment plan can have their medication provided under direct observation in the office for a designated frequency (e.g., three times/week).

- **Limit medication supply.** When directly observed doses in the office are indicated but not practical, short prescription timespans can be used, for example, weekly or three days at a time.

**Procedures to Respond to Misuse or Diversion:**

Misuse or diversion should never mean automatic discharge from the practice. However, it will require a therapeutic response and consideration of one or more of the procedures listed below.

- **Evaluate the misuse and diversion** – for instance, describe the incident of misuse (e.g., patient took prescribed dose on 1, 2, 3 or more occasions by intravenous route immediately after starting treatment stating that they believed the dose would not be adequate by SL route; has just initiated treatment) or diversion (patient gave half of dose to wife who is still

using heroin and was withdrawing) and tailor the response to the behavior (e.g., re-education of patient on buprenorphine pharmacology in first case, assistance with treatment entry for spouse in second case). **Reassess treatment plan and patient progress. Strongly consider smaller supplies of medication and observed dosing for any patient who is misusing or diverting their medication regardless of reason.** Treatment structure may need to be increased, including more frequent appointments, observed dosing, and increased psychosocial support.

- **Intensify treatment or level of care, if needed.** Some patients may require an alternative treatment setting or change in pharmacotherapy, such as methadone. The clinician should discuss these alternatives with the patient to assure optimal patient outcome. This should be discussed at treatment onset so that patient is aware of consequences of misuse/diversion.

- **Document and describe the misuse/diversion incident, clinical thinking that supports the clinical response that should be aimed at minimizing risk of diversion and misuse and treating the patient's opioid use disorder at the level of care needed.**

[1] Lofwall, Michelle, and Walsh, Sharon. "A Review of Buprenorphine Diversion and Misuse: The Current Evidence Based and Experiences from Around the World." Journal of Addiction Medicine, Volume 8, Number 5. P. 316.

[2] Ibid, p. 31

# Reference List

American Society of Addiction Medicine. (2021). *XYZ Medical Practice Sample Office- Based Opioid Use Disorder Policy and Procedure Manual.* Retrieved August 5, 2021, from https://www.asam.org/docs/default-source/advocacy/sample-diversion-policy-may2021.pdf?sfvrsn=53e15cc2_2

## Appendix G.

# Comprehensive Clinical Assessment Adapted from BMC and SAMHSA Resources

1. **Assess substance use**
    a. Current opioid use patterns, including severity and duration of use, type and amount used, level of tolerance, method of administration, and time of last use
    b. Patient's physical presentation, including possible substance intoxication, indication of drug or needle use, or severity of opioid withdrawal symptoms.
    c. Prior treatment experiences including with opioid agonists patient response, side effects, and perceived effectiveness.
    d. Other substance use, including tobacco, alcohol, benzodiazepines, and other drugs
        i. It is very important to note that alcohol and sedatives such as benzodiazepines, in combination with buprenorphine, have been associated with opioid overdose.
2. **Assess/review medical and mental health history**
    a. Comorbid medical conditions and psychiatric disorders, including suicidality
    b. Communicable diseases (e.g., viral hepatitis, human immunodeficiency virus (HIV), tuberculosis (TB), syphilis)
    c. Active medication list and allergies
3. **Identify other needs**
    a. Need for and access to social support
    b. Employment status
    c. Housing stability
    d. Financial needs
    e. Need for legal assistance
4. **Conduct mandatory screening**
    a. Toxicology screening
    b. Pregnancy testing for female patients of childbearing age
    c. HIV testing (strongly recommended)
    d. Purified protein derivative (PPD) screen up to date
    e. Laboratory tests as clinically needed. Consider: complete blood count, comprehensive metabolic panel, hepatic function, rapid plasma reagin (RPR), hepatitis A, B and C serologies
5. **Conduct physical examination (if no recent exam, or records are not available)**
    a. Physical signs of opioid use, opioid intoxication, or withdrawal
    b. Medical consequences of opioid use

6. **Review prescription drug use history**
    a. State's Prescription Drug Monitoring Program (PDMP), where available, provides a resource to detect unreported use of other medications, such as sedative-hypnotics or other controlled substances, that may interact adversely with the treatment medications

7. **Educate the patient**
    a. How the medication works and associated risks/benefits
    b. Harm reduction
    c. Naloxone prescription recommended

# Reference List

LaBelle, C. T., Bergeron, L. P., Wason, K. W., and Ventura, A. S. (2016). *Policy and Procedure Manual of the Office Based Addiction Treatment Program for the use of Buprenorphine and Naltrexone Formulations in the Treatment of Substance Use Disorders. Unpublished treatment manual.* Boston Medical Center.

Substance Abuse and Mental Health Services Administration. (2020). Medications for Opioid Use Disorder. *Treatment Improvement Protocols (TIPs)*. Rockville, MD.

Substance Abuse and Mental Health Services Administration. (n.d.). *Buprenorphine Quick Start Guide.*

Appendix H.

# BMC Consent for Release of Information

# CONSENT FOR RELEASE OF INFORMATION

I,_____, BORN ON _____
(PATIENT NAME) (PATIENT BIRTH DATE)

SSN_____, AUTHORIZE_____TO
(PATIENT SOCIAL SECURITY #) (CLINIC OR DOCTOR'S NAME)

DISCLOSE TO _____
(NAME AND LOCATION OF PERSON/ORGANIZATION TO RECEIVE INFORMATION)

THE FOLLOWING INFORMATION: _____.

THE PURPOSE OF THIS DISCLOSURE IS:_____.

THIS AUTHORIZATION EXPIRES ON: _____, OR WHENEVER _____ IS NO LONGER PROVIDING ME WITH SERVICES.

**CONFIDENTIALITY OF SUBSTANCE USE DISORDER PATIENT RECORDS**

THE CONFIDENTIALITY OF SUBSTANCE USE DISORDER PATIENT RECORDS MAINTAINED BY THIS PRACTICE/PROGRAM IS PROTECTED BY FEDERAL LAW AND REGULATIONS. GENERALLY, THE PRACTICE/PROGRAM MAY NOT SAY TO A PERSON OUTSIDE THE PRACTICE/PROGRAM THAT A PATIENT ATTENDS THE PRACTICE/PROGRAM, OR DISCLOSE ANY INFORMATION IDENTIFYING A PATIENT AS HAVING OR HAVING HAD A SUBSTANCE USE DISORDER UNLESS:

1. THE PATIENT CONSENTS IN WRITING;
2. THE DISCLOSURE IS ALLOWED BY A COURT ORDER, OR
3. THE DISCLOSURE IS MADE TO MEDICAL PERSONNEL IN A MEDICAL EMERGENCY OR TO QUALIFIED PERSONNEL FOR RESEARCH, AUDIT, OR PRACTICE/PROGRAM EVALUATION.

VIOLATION OF THE FEDERAL LAW AND REGULATIONS BY A PRACTICE/PROGRAM IS A CRIME. SUSPECTED VIOLATIONS MAY BE REPORTED TO APPROPRIATE AUTHORITIES IN ACCORDANCE WITH FEDERAL REGULATIONS. THE REPORT OF ANY VIOLATION OF THESE REGULATIONS MAY BE DIRECTED TO THE ATTORNEY GENERAL FOR YOUR STATE.

FEDERAL LAW AND REGULATIONS DO NOT PROTECT ANY INFORMATION ABOUT A CRIME COMMITTED BY A PATIENT, EITHER AT THE PRACTICE/PROGRAM OR AGAINST ANY PERSON WHO WORKS FOR THE PRACTICE/PROGRAM OR ABOUT ANY THREAT TO COMMIT SUCH A CRIME.

FEDERAL LAWS AND REGULATIONS DO NOT PROTECT ANY INFORMATION ABOUT SUSPECTED CHILD ABUSE OR NEGLECT FROM BEING REPORTED UNDER STATE LAW TO THE APPROPRIATE STATE OR LOCAL AUTHORITIES.

I understand that my records are protected under the Federal regulations and cannot be disclosed without my written consent unless otherwise provided for in the regulations. I also understand that I may revoke this consent at any time except to the extent that action has been taken in reliance on it.

| | |
|---|---|
| Signature of patient | Date |
| Signature of parent/guardian/authorized signer (if applicable) | Date |
| Signature of witness | Date |

**ATTENTION RECIPIENT: Notice Prohibiting Re-disclosure**

This information has been disclosed to you from the records protected by Federal confidentiality rules (42 C.F.R. Part 2). The Federal rules prohibit you from making any further disclosure of this information unless further disclosure is expressly permitted by the written consent of the person to whom it pertains or as otherwise permitted by 42 C.F.R. Part 2. A general authorization for the release of medical or other information is NOT sufficient for this purpose. The Federal rules restrict any use of this information to criminally investigate or prosecute any patient with alcohol or drug use disorder.

**After completion, scan form into patient record and provide a copy to the patient.**

# Reference List

LaBelle, C. T., Bergeron, L. P., Wason, K. W., and Ventura, A. S. (2016). *Policy and Procedure Manual of the Office Based Addiction Treatment Program for the use of Buprenorphine and Naltrexone Formulations in the Treatment of Substance Use Disorders Unpublished treatment manual.* Boston Medical Center. Retrieved August 5, 2021, from https://www.bmcobat.org/resources/index.php?filename=45_87_Consent%252Bfor%252BRelease%252Bof%252BInformation.pdf

Appendix I.

# BMC Appointed Pharmacy Consent

# APPOINTED PHARMACY CONSENT

(buprenorphine HCl/naloxone HCl dihydrate) sublingual tablet or film
(buprenorphine HCl) sublingual tablet, naltrexone (oral or extended-release injectable)

I_____ do hereby: (**check all that apply**)
Patient Name (Print)

☐ Authorize_____at the above address to disclose my treatment for opioid use disorder to employees of the pharmacy specified below. Treatment disclosure most often includes, but may not be limited to, discussing my medications with the pharmacist, and faxing/calling in my buprenorphine/naloxone prescriptions directly to the pharmacy.

☐ Agree to purchase all buprenorphine/naloxone, and any other medications related to my treatment from the pharmacy specified below.

☐ Agree not to use any pharmacy other than the one specified below for the duration of my treatment with the physician specified above, unless specific arrangements have been made with the physician.

☐ Agree to make payment arrangements with the pharmacy specified below in advance of treatment, so that my buprenorphine/naloxone prescriptions can be filled and either delivered to the physician's office address given above or picked-up by employees of the same.

☐ I understand that I may withdraw this consent at any time, either verbally or in writing, except to the extent that action has been taken in reliance on it. This consent will last while I am being treated for opioid use disorder by the physician specified above, unless I withdraw my consent during treatment. This consent will expire 365 days after I complete my treatment, unless the provider specified above is otherwise notified by me.

I understand that the records to be released may contain information pertaining to psychiatric treatment and/or substance use disorder treatment. These records may also contain confidential information about communicable diseases including HIV/AIDS or related illness. I understand that these records are protected by the Code of Federal Regulations Title 42 Part 2 (42 CFR Part 2), which prohibits the recipient of these records from making any further disclosures to third parties, without the express written consent of the patient.

I acknowledge that I have been notified of my rights pertaining to the confidentiality of my treatment information/records under 42 CFR Part 2, and I further acknowledge that I understand those rights.

_____

Signature of patient Date

Signature of parent/guardian/authorized signer (if applicable) Date

Signature of witness Date

**APPOINTED PHARMACY:**

NAME:_____ PHONE: _____

ADDRESS: _____

**CONFIDENTIALITY OF SUBSTANCE USE DISORDER PATIENT RECORDS**

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1. THE PATIENT CONSENTS IN WRITING;
2. THE DISCLOSURE IS ALLOWED BY A COURT ORDER, OR
3. THE DISCLOSURE IS MADE TO MEDICAL PERSONNEL IN A MEDICAL EMERGENCY OR TO QUALIFIED PERSONNEL FOR RESEARCH, AUDIT, OR PRACTICE/PROGRAM EVALUATION.

VIOLATION OF THE FEDERAL LAW AND REGULATIONS BY A PRACTICE/PROGRAM IS A CRIME. SUSPECTED VIOLATIONS MAY BE REPORTED TO APPROPRIATE AUTHORITIES IN ACCORDANCE WITH FEDERAL REGULATIONS. THE REPORT OF ANY VIOLATION OF THESE REGULATIONS MAY BE DIRECTED TO THE ATTORNEY GENERAL FOR YOUR STATE.

FEDERAL LAW AND REGULATIONS DO NOT PROTECT ANY INFORMATION ABOUT A CRIME COMMITTED BY A PATIENT, EITHER AT THE PRACTICE/PROGRAM OR AGAINST ANY PERSON WHO WORKS FOR THE PRACTICE/PROGRAM OR ABOUT ANY THREAT TO COMMIT SUCH A CRIME.

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**After completion, scan form into patient record and provide a copy to the patient.**

# Reference List

LaBelle, C. T., Bergeron, L. P., Wason, K. W., and Ventura, A. S. (2016). *Policy and Procedure Manual of the Office Based Addiction Treatment Program for the use of Buprenorphine and Naltrexone Formulations in the Treatment of Substance Use Disorders. Unpublished treatment manual*. Boston Medical Center. Retrieved August 5, 2021, from https://www.bmcobat.org/resources/index.php?filename=44_86_Appointed%252BPharmacy%252BConsent.pdf.

Appendix J.

# BMC Treatment Agreement for Buprenorphine

## Office Based Addiction Treatment (OBAT) Program

As a patient in the Office Based Addiction Treatment (OBAT) program, I freely and voluntarily agree to accept this treatment agreement, as follows. I understand the OBAT program includes providers, nurses, care coordinators, medical assistants, and administrative support personnel.

**I agree to do my best to arrive on time to all my scheduled appointments. I will call the clinic if I will be late/early or need to reschedule my appointment.**

When I am in the clinic, I agree to conduct myself in a courteous and respectful manner.

**I agree not to sell, share or give any of my medication to others. I understand that any mishandling of my medication may result in a change of my treatment plan including referral to a higher level of care or discharge.**

I agree not to conduct any illegal, threatening, or disruptive activities in the clinic or on BMC campus. I will be discharged or referred to a higher level of care for behaviors that are unsafe or inappropriate.

**I agree that it is my responsibility to keep my medication safe and secure at all times. I understand that any lost medication will require an assessment and plan with my team. My medication should not be kept in public places (like a bathroom medicine cabinet, vehicles), and should be out of the reach and sight of children at all times. I will keep my medication in a container that displays a prescription label. If I carry sealed films on my person, I will do so with a pharmacy label.**

I agree to inform my provider and/or OBAT nurse immediately about prescriptions or over the counter medications from any prescribers, pharmacies, or other sources (such as the dentist, emergency department, or psychiatrist).

**Per Massachusetts law, BMC OBAT will routinely access the Prescription Drug Monitoring Program (PDMP) to review medication profiles. If I am found to be obtaining prescriptions from other providers, the OBAT team will address the circumstances with me, and if necessary, adjust my treatment plan.**

I understand that mixing buprenorphine with other substances, especially those that can cause sedation such as benzodiazepines, gabapentin, alcohol, etc. can be dangerous and can increase my risk of overdose and even death.

**I agree to take my medication as the provider has instructed and not to adjust the way I take it without first consulting my nurse or provider.**

I agree to random call back visits that include urine toxicology screens and medication counts. I understand that I need to have a working telephone. When called by the OBAT team, I will respond within 24 hours by telephone.

**I agree not to eat poppy seeds while in treatment. Poppy seed consumption may result in a positive opioid screen.**

I understand that if I misuse other substances or medications, the OBAT team will assist me by changing or intensifying my treatment plan. If I continue to struggle with ongoing substance use, I may be transferred to a more intensive setting to meet my treatment needs.

**I agree to urine toxicology screenings. I will not tamper with testing. I understand that it is best to be honest with my treatment team if I am struggling and understand the team is here to assist me in my treatment.**

Urine screens that are negative for buprenorphine will be evaluated by the OBAT team and toxicologist.

**I understand that the BMC OBAT does not maintain a chain of custody over urine toxicology screens. BMC OBAT collects urine toxicology tests as medically necessary. Testing that requires chain of custody must occur outside of the OBAT program.**

If I am female and of childbearing age and do not plan on becoming pregnant, it is strongly recommended that I utilize contraceptives. If I become pregnant while in treatment, I will alert my OBAT team immediately so they can assist me in connecting with an OB/GYN provider who understands addiction. I will not be discharged from the program.

**If I participate in a higher level of treatment or am discharged from OBAT, I may be readmitted at a future time.**

I agree to participate in patient education, counseling and relapse prevention programs to assist me in my treatment.

**I understand that my records, course of treatment and medical care is in an electronic medical record. These notes will be visible to any healthcare professional involved in my care at Boston Medical Center. The healthcare providers will only access your medical record if they are involved in your care.**

_____ _____

Printed Name Signature

_____

Date

_____ _____

Witness Signature

_____

Date

# Reference List

Boston Medical Center's Office Based Addiction Treatment Training and Technical Assistance +. (2021). *Resources: OBAT Clinical Tools and Forms.* Retrieved August 5, 2021, from https://www.bmcobat.org/resources/?category=4

Appendix K.

# ASAM Sample Treatment Agreement

*This form is provided for educational and informational purposes only. It is not intended to establish a legal or medical standard of care. Physicians should use their personal and professional judgment in interpreting this form and applying it to the particular circumstances of their individual patients and practice arrangements. The information provided in this form is provided "as is" with no guarantee as to its accuracy or completeness. ASAM will strive to update this form from time to time, but cannot ensure that the information provided herein is current at all times.*

# Sample Treatment Agreement

I agree to accept the following treatment contract for buprenorphine office-based opioid addiction treatment:

1. I will keep my medication in a safe and secure place away from children (e.g., in a lock box). My plan is to store it (describe where and in what)?

   _____
2. I will take the medication exactly as my doctor prescribes. If I want to change my medication dose, I will speak with the doctor first. Taking more than my doctor prescribes OR taking it more than once daily as my doctor prescribes is medication misuse and may result in supervised dosing at the clinic. Taking the medication by snorting or by injection is also medication misuse and may result in supervised dosing at the clinic, referral to a higher level of care, or change in medication based on the doctor's evaluation.
3. I will be on time to my appointments and be respectful to the office staff and other patients.
4. I will keep my doctor informed of all my medications (including herbs and vitamins) and medical problems.
5. I agree not to obtain or take prescription opioid medications prescribed by any other doctor.
6. If I am going to have a medical procedure that will cause pain, I will let my doctor know in advance so that my pain will be adequately treated.
7. If I miss an appointment or lose my medication, I understand that I will not get more medication until my next office visit. I may also have to start having supervised buprenorphine dosing.
8. If I come to the office intoxicated, I understand that the doctor will not see me, and I will not receive more medication until the next office visit. I may also have to start having supervised buprenorphine dosing.
9. I understand that it is illegal to give away or sell my medication – this is diversion. If I do this, my treatment will no longer include unsupervised buprenorphine dosing and may require referral to a higher level of care, supervised dosing at our clinic, and/or a change in medication based on the doctor's evaluation.
10. Violence, threatening language or behavior, or participation in any illegal activity at the office will result in treatment termination from our clinic.
11. I understand that random urine drug testing is a treatment requirement. If I do not provide a urine sample, it will count as a positive drug test.
12. I understand that I will be called at random times to bring my medication bottle into the office for a pill count. Missing medication doses could result in requirement for supervised dosing or

referral to a higher level of care at this clinic or potentially at another treatment provider based on your individual needs.

13. I understand that initially I will have weekly office visits until I am stable. I will get a prescription for 7 days of medication at each visit.
14. I can be seen every two weeks in the office starting the second month of treatment if I have two negative urine drug tests in a row. I will then get a prescription for 14 days of medication at each visit.
15. I will go back to weekly visits if I have a positive drug test. I can go back to visits every two weeks when I have two negative drug tests in a row again.
16. I may be seen less than every two weeks based on goals made by me and my doctor.
17. I understand that people have died by mixing buprenorphine with other drugs like alcohol and benzodiazepines (drugs like Valium®, Klonopin® and Xanax®).
18. I understand that treatment of opioid addiction involves more than just taking my medication. I agree to comply with my doctor's recommendations for additional counseling and/or for help with other problems.
19. I understand that there is no fixed time for being on buprenorphine and that the goal of treatment is to stop using all illicit drugs and become successful in all aspects of my life.
20. I understand that I may experience opioid withdrawal symptoms when I go off buprenorphine.
21. I have been educated about the other two FDA-approved medications for opioid dependence treatment, methadone and naltrexone.
22. If female, I have been educated about the increased chance of pregnancy when stopping illicit opioid use and starting buprenorphine treatment and offered methods for preventing pregnancy.
23. If female, I have been educated about the effects of poor diet, illicit opioid use, use of dirty needles/sharing injection equipment, physical and mental trauma, and lack of pre-natal medical, substance use and mental health care during pregnancy and how these things can adversely affect my health and my current or future fetus/newborn's health. I understand that neonatal abstinence syndrome can occur when taking illicit opioids and that neonatal abstinence syndrome (NAS) is less severe, but can still occur, when pregnant women take methadone or buprenorphine as prescribed/dispensed in substance use disorder treatment. Cigarette smoking can make the severity of NAS worse and cause pre-term birth and small babies. Alcohol use can cause significant cognitive/brain damage in fetuses and newborns.
24. Other specific items unique to my treatment include:

| Patient name (print) | Patient signature | Date |
|---|---|---|

# Reference List

American Society of Addiction Medicine. (n.d.). *Sample Treatment Agreement.* Retrieved August 5, 2021, from https://www.asam.org/docs/default-source/advocacy/sample-treatment-agreement30fa159472bc604ca5b7ff000030b21a.pdf

Appendix L.

# BMC Checklist Prior to Induction

# CHECKLIST: PRIOR TO BUPRENORPHINE/NALOXONE INDUCTION

Patient Name: _____ Date: _____

☐ Review and sign treatment agreement and consents.

☐ Reinforce to patient the need for frequent appointment adherence, and establish whether this is realistic. If patient states that it is not manageable, address with the team prior to initiating treatment.

☐ Put counseling services in place prior to the patient starting treatment.

☐ Ensure that UTS is negative for all illicit substances, other than opioids.

☐ Ensure negative pregnancy test for women of child-bearing age.

- If positive hCG, OBAT team will immediately assist patient engagement with appropriate OB providers.

☐ If patient is referred or presents from detox, ensure he/she has discharge paperwork with medication protocol. Confirm what was prescribed (benzodiazepines or methadone) while in detox. These substances may be present in UTS if induction occurs shortly after discharge from detox.

☐ Consult with waivered provider after initial visit, and obtain the prescription from the prescriber.

☐ After OBAT team review, schedule induction per protocol in collaboration with patient and team: date, time, prescription, and clinic schedule.

☐ Telephone patient to review induction plan, and fax prescription to pharmacy for patient to pick up on the day of induction.

☐ Patient presents to clinic for induction.

_____

Nurse Case Manager (Print Name) Signature Date

_____

Witness (Print Name) Signature Date

# Reference List

LaBelle, C. T., Bergeron, L. P., Wason, K. W., Ventura, A. S., and Beers, D. (2018). *Clinical Guidelines of the Office Based Addiction Treatment Program for the use of Buprenorphine and Naltrexone Formulations in the Treatment of Substance Use Disorders. Unpublished treatment guidelines.* Boston Medical Center. Retrieved August 5, 2021, from https://www.bmcobat.org/resources/index.php?filename=23_Clinical_Guidelines_National.pdf

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Any person depicted in a photo is a model.

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SAMHSA
Substance Abuse and Mental Health Services Administration

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