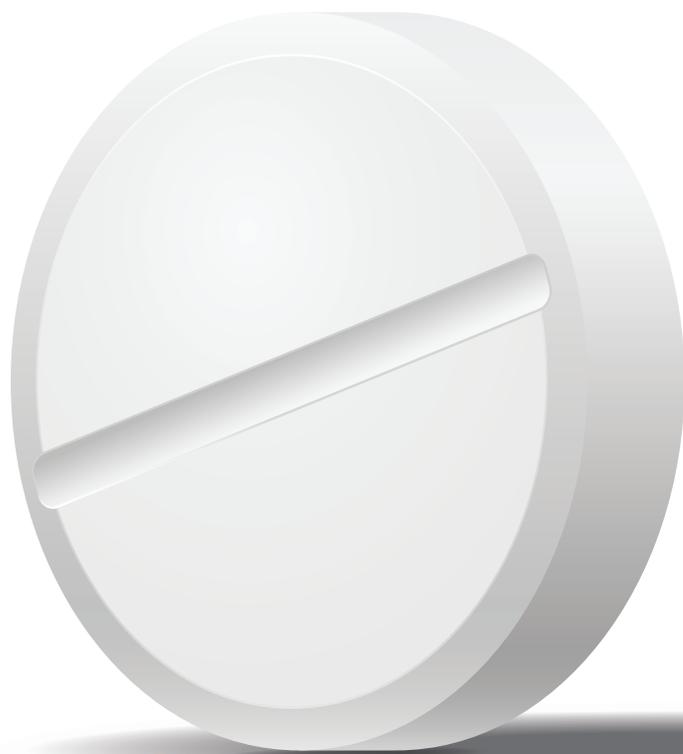


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Preparations for Treating Opioid Use Disorder in the Office

Use this guide to plan for offering medication-assisted treatment with buprenorphine.



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Opioid use disorder (OUD) affects all segments of the U.S. population.^{1,2} The impacts of OUD and opiate misuse are severe, leading to dramatic declines in public health and quality of life, including increased rates of overdose and death. In 2016, more than 11.5 million people in the United States age 12 or older misused opiates in the past year, and approximately 2.1 million people age 12 or older had an opioid use disorder.² From 1999 to 2016, approximately 632,000 Americans died of drug overdose, and more than half of those deaths were due to opioid overdose.³ From 2015 to 2016, opioid overdoses accounted for two-thirds of all drug overdose deaths.³ ▶

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The *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition* (DSM-5) in 2013 updated the diagnostic criteria and terminology for OUD⁴ and replaced the more stigmatizing terms of “opioid abuse” and “opioid dependence” with “opioid use disorder.” Describing the problem as a dis-

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order empowers patients, providers, and payers to focus on treatment options in the clinical domain.

Prescription opioids are a key contributing factor to the rise of OUD in the United States. The Centers for Disease Control and Prevention (CDC) estimates that physicians wrote 259 million opioid prescriptions in 2012, enough for each U.S. adult to have a prescription.⁵ Additionally, the emergence of synthetic opioids such as illicit fentanyl has resulted in a recent and dramatic surge of overdose deaths.^{6,7}

The opioid crisis calls for physicians not only to follow best practices for the responsible prescribing of opioid painkillers⁵ but also to provide treatment options where prevention has failed. Medication-assisted

treatment (MAT) is an important part of the solution. MAT improves outcomes, reducing OUD morbidity and mortality, as well as societal problems associated with untreated OUD.⁸ Family physicians write more opioid prescriptions by volume than any other specialty,⁹ yet most family physicians don't prescribe MAT and feel ill equipped to address OUD.¹⁰ Recent policy developments and advances in MAT offer family physicians the opportunity to rise to the challenge of treating OUD in the office. The authors collectively have more than 14 years of experience providing OUD MAT treatment services with buprenorphine in practice and, along with other family physicians,¹¹ have found this work to be humbling, gratifying, and an antidote to burnout. This article will present a guide to integrating MAT with buprenorphine into your practice.

MEDICATION-ASSISTED TREATMENT: WHY BUPRENORPHINE?

Two agonist medications – methadone and buprenorphine – are approved by the U.S. Food and Drug Administration (FDA) to treat OUD. Methadone, a full agonist on the mu-opioid receptor, has been used for decades with well-established efficacy.¹² However, when prescribed for the treatment of OUD, methadone can only be dispensed through an opioid treatment program certified by the Substance Abuse and Mental Health Services Administration (SAMHSA). SAMHSA-certified programs may be geographically isolated from patients, especially patients in rural areas. Buprenorphine can be prescribed for the treatment of OUD by certified providers, widening the availability of MAT to primary care practices.

Buprenorphine, a partial agonist, is an effective alternative with several pharmacokinetic features that favor its use over methadone.¹³ When prescribed at doses of 7 mg or more daily, buprenorphine is equally effective as methadone at retention in treatment and reducing opioid use.¹⁴ It has a ceiling effect as doses increase, which, relative to methadone, reduces the risk of misuse and side effects such as respiratory depression leading to overdose.^{13,15,16} Its long half-life allows for once-daily dosing for suppression of craving and withdrawal.^{13,16} A medication that combines buprenorphine

KEY POINTS

- Family physicians write more opioid prescriptions by volume than any other specialty, yet most family physicians don't provide medication-assisted treatment (MAT) for patients with opioid use disorder.
- MAT with buprenorphine is an effective alternative to methadone that can be provided in primary care practices by family physicians who complete eight hours of training and obtain a waiver from the Substance Abuse and Mental Health Services Administration.
- Preparing the office and the clinical team for offering MAT with buprenorphine requires identifying a practice champion; assessing practice readiness; setting up office protocols; securing pharmacy, laboratory, and counseling services; and establishing a clinical workflow.

with naloxone, an opioid antagonist, is preferred over buprenorphine monotherapy for most treatment options (except pregnancy and lactation) because of lower diversion risk.^{17,18} When the buprenorphine/naloxone combination is taken sublingually, it acts as if it was buprenorphine alone, with no apparent effect from the naloxone because of naloxone's poor enteral and transmucosal bioavailability. However, if the combined preparation is injected, naloxone will have a substantial effect and precipitate opioid withdrawal.

Every family medicine practice is unique and has its own opportunities, challenges, and demand for OUD treatment. The following steps will help you to assess your practice needs and readiness to provide OUD MAT services, identify barriers, and plan for implementation.

1. IDENTIFY A PRACTICE CHAMPION

The practice champion will help spearhead the effort to offer OUD MAT in the practice, beginning by leading an assessment of the practice's readiness. This may be a provider who already has a waiver to treat OUD with buprenorphine or who will be the first to receive training and organize training for others. The practice champion may also serve as an ongoing resource by sharing information and helping team members keep their OUD MAT knowledge and skills current.

2. ASSESS YOUR PRACTICE

Practice models for delivering OUD MAT in primary care vary according to the practice's readiness for implementation. To identify the structure that works best, the practice should ask assessment questions including the following:¹⁹

- What medications do you plan to use for MAT (e.g., buprenorphine, naltrexone, or both)?
- What kind of behavioral health services are available to your patients (e.g., counseling on site or by referral)?
- For patients who require more complex care, can you offer a team-based approach for coordination of services (e.g., collaboration with specialized drug treatment centers or telehealth)?
- Are there opportunities for community engagement (e.g., educational activities or advertisement)?

RESOURCES

Application Forms

Drug Enforcement Administration Registration Form

<https://apps.deadiversion.usdoj.gov/webforms/jsp/regapps/common/newAppLogin.jsp>

Substance Abuse and Mental Health Services Administration (SAMHSA) Buprenorphine Waiver Application

<https://www.samhsa.gov/medication-assisted-treatment/buprenorphine-waiver-management/apply-for-physician-waiver>

Patient Forms and Contracts

Sample Treatment Agreement/Contract from SAMHSA

<https://www.ncbi.nlm.nih.gov/books/NBK64238>

Informed Consent Form from the California Society of Addiction Medicine

https://www.csam-asam.org/sites/default/files/pdf/misc/Consent_form_sample_5.doc

Screening and Assessment Tools

Single-Question Screening Test

<https://cde.drugabuse.gov/instrument/e905cd64-decf-7783-e040-bb89ad4362ad>

Clinical Opiate Withdrawal Scale (COWS)

<https://www.drugabuse.gov/sites/default/files/files/ClinicalOpiateWithdrawalScale.pdf>

When assessing your patient base, remember that patients needing OUD treatment may come from within your practice or from community referral. The patients you treat with buprenorphine in the family medicine office should be medically and behaviorally stable with minimal comorbidities and a supportive, drug-free home environment. Patients with unstable environments, other comorbidities, or poly-drug use may require referral to more specialized care.

The practice assessment should also include identifying staffing needs and outlining roles. In the process, it is important to address and alleviate employee fears and stigma regarding OUD, as common biases may impede patient care.²⁰ Although some staff may initially be concerned about the possibility of disruptive or violent patient behavior, in the authors' experience, only one patient incident prompted clinic security intervention. ➤

3. OBTAIN A WAIVER TO TREAT OUD WITH BUPRENORPHINE

The Drug Addiction Treatment Act of 2000 (DATA 2000) allows qualified clinicians to obtain a waiver to treat OUD with buprenorphine in any clinical setting where they are licensed to practice. According to SAMHSA, to qualify for and receive a waiver, each clinician must meet the following requirements:

- Have an active and valid state medical license and, if required by your state, a state controlled substance license. Nurse practitioners (NPs) and physician assistants (PAs) are required to be licensed under state law to prescribe schedule III, IV, or V medications for the treatment of pain. If NPs or PAs work in a state that requires that they prescribe under the supervision of or in collaboration with a qualifying physician, the physician doesn't need to apply for a waiver to treat OUD with buprenorphine but does need to be qualified to do so.
- Register with the Drug Enforcement Administration (DEA). If you are not already registered with the DEA to prescribe controlled substances, you will need to complete the DEA's online registration form and pay the registration fee (\$731 for three years of registration). (See "Resources," page 23, for more information about this form and other resources mentioned throughout the article.)
- Complete MAT training or certification. Physicians need to complete at least eight hours of MAT waiver training or certification by an appropriate organization; free online and in-person training options are available.²¹ NPs and PAs are required to complete 24 hours of MAT training.
- Complete the SAMHSA waiver notification form. This online form serves as a notification of your intent to provide MAT with buprenorphine. Once you submit the form, you will also need to fax a copy of your training certificate to SAMHSA's Center for Substance Abuse Treatment. In the first year following acquisition of the waiver, physicians may provide buprenorphine treatment to 30 patients. Thereafter, physicians can use the waiver notification form to apply to increase their patient capacity to 100 patients in the second year and 275 patients in the third year.²¹
- Be capable of referring patients to counseling services.

4. SET UP OFFICE PROTOCOLS

Preparing to provide MAT with buprenorphine also requires creating some infrastructure to support documentation, coding, and billing for the new services. Here are several key components to consider.

- **Patient forms.** To help establish the ground rules for treatment, identify which treatment contracts, informed consent forms, and other documents you will ask the patient or guardian to review and sign.
- **Medical records.** For a successful operation, electronic health record templates, prompts, reminders, registries, and referral processes must be created and tested. You'll want to use templates for induction and return visits, and consider incorporating standard screening instruments for substance use disorders, such as the Single Question Drug Screen,¹⁰ the Clinical Opiate Withdrawal Scale (COWS), patient's progress toward life goals, results of the state prescription drug monitoring program (PDMP) check, urine drug testing results, medication counts, counseling referral, and pharmacy resources. Records must be accurate to document treatment and provide legal protection. If buprenorphine is dispensed in the office, logs must be maintained and readily available for review. Maintaining the confidentiality of patient records requires special consideration to ensure that they are released only with patient consent or a court order.
- **Malpractice insurance.** Waivered clinicians may want to notify their malpractice insurer of their expanded scope of practice, but they should not expect a significant increase in coverage cost.
- **Insurance requirements.** Prior authorization requirements vary by payer but typically fall into one of the following categories: 1) no prior authorization required, 2) authorization required only if a daily dosage limit is exceeded or a specific buprenorphine product requested, or 3) quarterly authorization required.
- **Coding and billing.** Pre-induction visits may be billed using an E/M office visit code selected based on the extent of the history, exam, or medical decision making.²² A properly documented comprehensive evaluation of a new patient or established patient for suitability for buprenorphine treatment could qualify as a level IV or V service on

this basis. Induction visits could be coded similarly, and since induction services typically exceed routine visit times, direct prolonged service codes 99354-99355 may be used in addition to the E/M office visit codes.

For maintenance visits, an E/M office visit code may be selected based on the key components or, if more than half of the face-to-face time is devoted to counseling or coordination of care, based on time. ICD-10 code F11.20 for opioid dependence or a related code may be used to support the CPT codes.

5. SECURE PHARMACY, LABORATORY, AND COUNSELING SERVICES

The practice must decide whether to stock buprenorphine medications for in-office inductions, which streamlines the induction process, or to allow time in the induction protocol for patients to first get a buprenorphine prescription filled at an outside pharmacy, which eliminates the need for the practice to stock buprenorphine induction doses. Buprenorphine stock must be monitored and securely stored in a double-locked medicine cabinet or safe.

Urine drug testing with real-time results should be available on site. Additionally, the state PDMP database should be accessible for queries just prior to or during visits.

Although primary care settings with fully integrated behavioral health services are ideally positioned to provide the counseling component of OUD treatment, more traditional offices can refer patients to community behaviorists for this important aspect of their care. We suggest establishing referral relationships with providers who have experience working with clients who have substance use disorders and are open to OUD recovery supported by MAT.

6. ESTABLISH A CLINICAL WORKFLOW, AND GO LIVE

Buprenorphine MAT occurs in three phases: induction, stabilization, and maintenance. The goal of the induction phase is to help the patient transition to a dose of buprenorphine to manage withdrawal and cravings.¹¹ Various office and clinical protocols are appropriate. However, we recommend a team-based approach that includes front office, medical records/billing, and administrative staff along with the

clinician and nursing staff. For example, in the induction phase, front-office staff provide screening forms for the patient to complete prior to being roomed. Nursing staff room the patient, review the screening results, and have urine drug testing and diagnostic forms completed. The clinician then sees the patient, confirms the diagnosis, completes the informed consent process, and decides on an induction approach. For in-office induction, some practices have nursing staff assess, monitor, and reas-

As with any other practice change, staff may require new skills and training, along with some adjustment time, incentives, and feedback loops.

sess the patient using the COWS, and the clinician sees the patient briefly after each assessment to adjust dosing as needed.²² Other practices have the clinician complete the patient monitoring and assessments. For return visits, protocols ensure that urine drug testing results, medication counts, and PDMP reviews are completed prior to the clinician's time with the patient.

As with any other practice change, staff may require new skills and training, along with some adjustment time, incentives, and feedback loops. Medication protocols in particular may be new to many staff. The practice champion should provide a brief overview of OUD and MAT during a routine practice meeting for all personnel, and additional training should be tailored to specific staff and clinician roles in the workflow.

To help counter the stigma around OUD and MAT, training should also focus on using nonjudgmental, medically accurate language.²⁰ Consider these examples:

- UDT results should be referred to as expected or unexpected, or positive or negative for a particular substance. Avoid referring to a test result as clean or dirty.
- Buprenorphine-based treatments should be referred to as medication therapies or simply medications. Avoid referring to them as substitution or replacement therapies. ►

• Patients who have OUD should not be referred to as opioid abusers or junkies.

For a full discussion of the clinical considerations of providing MAT with buprenorphine, please see the authors' recent article "Buprenorphine Therapy

Buprenorphine MAT in primary care practices is an important and impactful part of the solution to the opioid crisis.

for Opioid Use Disorder," *American Family Physician*, March 1, 2018, <https://www.aafp.org/afp/2018/0301/p313.html>.

NEXT STEPS

Treating patients with OUD using buprenorphine MAT in primary care practices is an important and impactful part of the solution to the opioid crisis. It is also a clinically rewarding experience for the family physician. Getting trained and obtaining a waiver to prescribe buprenorphine is the first step. We hope this brief article helps more physicians to take the next step of implementing this vital treatment in their practices. **FPM**

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