



Developing a Buprenorphine Treatment Program for Opioid Use Disorder in Primary Care

This document has been designed to help guide primary care organizations as they develop a buprenorphine treatment program for opioid use disorder (OUD). It provides a checklist of key components that are either required for a health care system when providing buprenorphine treatment for OUD or are considered critical best practices. Buprenorphine treatment for OUD is evolving, and this document's recommendations reflect the national standard of care as of Spring 2020.

Guiding Principles

Primary care is an effective and important setting in which to deliver medication for the treatment of OUD. Primary care clinicians are on the front lines of the health care system and the opioid epidemic. People with OUD are part of our practices and our communities. By offering treatments such as buprenorphine, primary care clinicians provide evidence-based care for patients with OUD. Although this guide supports primary care organizations in developing a buprenorphine treatment program for OUD, [it is important to note that naltrexone is another treatment option for OUD that can be prescribed by primary care clinicians, though there is much less evidence to support its use.](#)¹²

Establishing the Basics of an Office-based Buprenorphine Treatment Program for OUD

Office systems should be structured and organized to support best practices in buprenorphine treatment for OUD. The eight sections below – 1) *Staffing*, 2) *Training*, 3) *Billing*, 4) *Supporting clinicians in providing consistent care for patients with OUD*, 5) *Psychosocial treatment & recovery support services*, 6) *Urine Drug Testing*, 7) *Mitigating Diversion*, and 8) *Administration* – highlight critical best practices for buprenorphine treatment programs in primary care. Call-out boxes share program elements that can enhance support of an office-based buprenorphine treatment program. Although this document uses the term “buprenorphine” treatment throughout, combined buprenorphine/naloxone is the preferred medication formulation and standard of practice unless clinically contraindicated (e.g., in pregnancy).

¹ Substance Abuse and Mental Health Services Administration. Medications for Opioid Use Disorder. Treatment Improvement Protocol (TIP) Series 63. Publication No. PEP20-02-01-006. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2020.

² Wakeman SE, Larochelle MR, Ameli O, et al. Comparative Effectiveness of Different Treatment Pathways for Opioid Use Disorder. JAMA Netw Open. 2020;3(2):e1920622. doi:10.1001/jamanetworkopen.2019.20622



1. Staffing

Providing medication treatment such as buprenorphine for OUD is best managed by a team of clinicians and staff, each with clear roles and responsibilities.

Key Points

- Identify both an administrative and clinical program champion to oversee implementation and integration of the medication treatment program. The program champions will be responsible for leadership, consultation/oversight, coordination, and reporting to clinic leadership and staff.
- Make sure that clinicians, persons responsible for administration, regulatory affairs, risk management, pharmacy, lab, billing and coding, information technology (IT), privacy, medical records, social services, and reception are well-informed about the medication treatment program for OUD, and their roles and responsibilities within the program.
- Define team roles (e.g., phone screening, relaying program information, obtaining consent, appointment tracking, maintaining logs) and ensure that written workflows are available that document these roles and their responsibilities.
- Identify physician(s), nurse practitioner(s), and/or physician assistant(s) who have or are interested in obtaining the Drug Addiction Treatment Act of 2000 (DATA 2000) waiver who are able to prescribe buprenorphine products for treatment of OUD. The Substance Abuse and Mental Health Services Administration ([SAMHSA pharmacist verification tool](#)) can be used to verify practitioner waiver status.
- If possible, ensure that there is more than one waived and prescribing clinician at your site to ensure cross-coverage of patients and avoid undue burden on one clinician. Establish formalized after-hours and cross-coverage plans.
- For clinicians with the DATA 2000 waiver, verify the number of patients they are authorized to treat and the current number of patients that they are treating with buprenorphine (e.g., 30-100 for the first year, with ability to apply for an increase after one year).
- Make sure prescribing clinicians' schedules are set up to accommodate patients with OUD so that they can see them at the more frequent intervals required, and that they can schedule adequate time slots to manage both OUD treatment and other chronic or acute conditions.
- Store a hard or electronic copy of each waiver, and a list of active patients, so they are easily accessible should the Drug Enforcement Agency (DEA) request

ADDED FEATURE

Consider adding a social worker, nurse care manager, peer community health worker, and/or substance use disorder (SUD) professional to the treatment team. These resources can provide care management and care coordination support for the clinician.

RESOURCE

The [PCSS website](#) is a great tool for individuals to become waived (and has [other resources](#) for those already waived). They provide access to the 8- (physician) and 24-hour (NP and PA) waiver course for free. In addition, Washington State DOH provides ½ and ½ training, where a person can receive the first 4 hours of training in person and the remaining online.

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them. The American Society of Addiction Medicine’s (ASAM’s) [DEA Office Inspection Tips](#) is helpful to review for an audit.

- Verify that malpractice insurance covers each clinician at the locations where prescriptions for buprenorphine will be written.
- Verify that clinicians and support staff can access the state Prescription Drug Monitoring Program (PDMP).

Resources

For waiver training:

- Provider Clinical Support System (PCSS): <https://pcssnow.org/medication-assisted-treatment/>
- American Society of Addiction Medicine e-Learning Center: <https://elearning.asam.org/buprenorphine-waiver-course>

2. Training

It is important that staff and clinicians have on-going access to training, mentorship, current literature, and other resources to provide competent and compassionate medication treatment to patients with OUD.

Key Points

- Provide time and opportunities for clinicians and staff to receive training on caring for patients with OUD and other substance use disorders.
- Encourage non-prescribing staff to complete at least 8 hours of DATA 2000 waiver training to gain a foundational understanding of OUD and treatment options.
- Provide staff and clinician training on motivational interviewing and trauma-informed care.
- Practice “run-throughs” of workflows related to medication treatment for OUD.
- Provide scripts and training in effective communication with patients with OUD.

Resources

For general mentorship related to OUD treatment:

- Opioid Response Network: <https://opioidresponsenetwork.org>
- PCSS: <https://pcssnow.org/resources/>

LOCAL RESOURCES

Look for local or state initiatives that provide an honorarium for clinicians to get waived. For example, King County Washington has had a \$500 honorarium program to support clinicians in getting DATA 2000 waived.

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For motivational interviewing:

- Substance Abuse and Mental Health Services Administration Treatment Improvement Protocol (TIP) 35: <https://store.samhsa.gov/product/TIP-35-Enhancing-Motivation-for-Change-in-Substance-Use-Disorder-Treatment/PEP19-02-01-003>
- Motivational Interviewing Network of Trainers: <https://motivationalinterviewing.org/>

For trauma-informed care:

- Substance Abuse and Mental Health Services Administration TIP 57: <https://store.samhsa.gov/product/TIP-57-Trauma-Informed-Care-in-Behavioral-Health-Services/SMA14-4816>
- Texas Department of Family and Protective Services Trauma-Informed Care Training: https://www.dfps.state.tx.us/Training/Trauma_Informed_Care/default.asp
- Oregon Health Authority: <https://www.oregon.gov/oha/PH/DISEASES/CONDITIONS/HIVSTDVIRALHEPATITIS/HIVCARE/TREATMENT/Pages/Trauma-Informed-Care.aspx>

3. Billing

Health plans have different eligibility requirements and coverage policies for OUD treatments such as buprenorphine. Understanding these requirements and policies and communicating these to clinicians and patients is a critical element of your OUD medication treatment program. Make sure clinicians know what facilities serve and can provide medication to un/underinsured individuals in your locality. Many federally qualified health centers (FQHCs) have contracts to provide OUD treatment/medication to un/underinsured individuals.

Key Points

- Generally, buprenorphine treatment visits should be billed like any other medical visit. Check with payers to see if there are any enhanced billing rates for buprenorphine treatment services.
- Contact payers to verify patient eligibility and payer coverage for buprenorphine. Many payers do not require pre-authorization or time-based benefit restrictions.

Resources

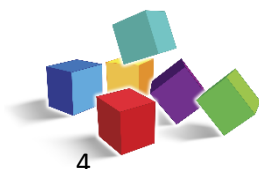
For Washington State's Medicaid-insured population:

- Washington State Health Care Authority: https://www.hca.wa.gov/assets/billers-and-providers/MAT_buprenorphine_products.pdf (information on the clinical care for OUD using buprenorphine that the Medicaid program will cover).

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4. Supporting Clinicians in Providing Consistent Care for Patients with OUD

Providing consistent evidence-based care across your organization can increase quality of care and your team's comfort in caring for patients with OUD. This involves all clinicians and other clinicians following the same protocols for patients with OUD.

Key Points

- Develop aligned, standard policies and protocols, patient agreements, and workflows for OUD care that meet [best practices](#).
- Create electronic health record (EHR)-based templates and tools (e.g., for medication refills, monitoring visits, patient education for after visit summaries) that support care processes.
- Conduct screening for OUD for all adult patients. Consider implementing an evidence-based OUD screening instrument (e.g., Tobacco, Alcohol, Prescription medication, and other Substance use [TAPS], Drug Abuse Screening Test [DAST]).
- Monitor treatment outcomes such as retention in treatment.
- Create a system that allows clinicians or their designees to track the patients for whom they are prescribing buprenorphine (e.g., simple spreadsheet, EHR data pull).
- Create a referral pathway to a methadone treatment program and to behavioral health centers and inpatient and residential OUD treatment programs that can be used if clinically indicated.

EXPERT TIP

Consider providing opportunities for clinicians and support staff to discuss challenging cases, such as regular case consultation meetings.

Resources

- PCSS clinical tools: <https://pcssnow.org/resources/clinical-tools/>
- Guidelines for the Psychosocially Assisted Pharmacological Treatment of Opioid Dependence. Geneva: World Health Organization; 2009. Annex 12, Prescribing guidelines. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK143167/#>

5. Psychosocial Treatment and Recovery Support Services

To maintain a buprenorphine waiver, the clinician must be capable of referring patients for counseling and other ancillary services.

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Key Points

- Identify internal clinic-based behavioral health and substance use disorder (SUD) treatment services.
- Create a local resource directory of SUD- related resources (e.g., Alcoholics Anonymous, Narcotics Anonymous or other support groups, peer recovery services, needle exchange, housing services, addiction medicine consultation, psychiatric services, inpatient and residential treatment services), both for clinical care teams and as a patient handout.
- Develop clear referral pathways for internal and community-based behavioral health resources and social services that address the social determinants of health.

HELPFUL OPTION

Collaborating with a behavioral health agency (BHA) or providing services within a BHA can help provide added support to the patient and clinician.

Resources

For national resources:

- SAMHSA Behavioral Health Treatment Services Locator: <https://findtreatment.samhsa.gov/>

For community resources in Washington State:

- Washington Recovery Helpline: 1-866-789-1511 : <http://www.warecoveryhelpline.org>
- Washington 211 Dial 2-1-1 : <https://wa211.org>

6. Urine Drug Testing

Urine drug testing (UDT) is a tool for discussing a patient’s progress around their personal recovery goals. Since OUD is a chronic relapsing condition and individuals might have differing goals, complete abstinence from non-prescribed opioids or other drugs (e.g., stimulants) should not be expected; UDT should not be used as the sole marker of a patient’s “success.”

Key Points

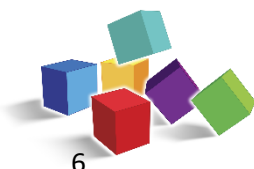
- Provide point-of-care UDT if possible and develop protocols regarding frequency of testing. Make sure your lab meets Clinical Laboratory Improvement Amendments (CLIA) ‘88 requirements in providing this [testing](#) (e.g., by using a CLIA-waived point-of-care UDT).
- A UDT positive result for substances other than buprenorphine (e.g. opioids, stimulants, benzodiazepines) should not prevent access to buprenorphine. [Withholding buprenorphine based on use of other substances](#) is more dangerous than any potential medication interactions.

Resources

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For clinical drug testing in primary care:

- Substance Abuse and Mental Health Services Administration Technical Assistance Publication (TAP) 32: <https://store.samhsa.gov/sites/default/files/d7/priv/sma12-4668.pdf>

7. Mitigating Diversion

Buprenorphine, like any other medication, can be given or sold to people who are not prescribed the medicine. However, concerns about diversion should not prevent clinicians from prescribing medications for OUD treatment. Studies consistently show that most diverted buprenorphine is used to alleviate withdrawal or maintain abstinence rather than to become intoxicated.³ Lack of access to prescribed buprenorphine is believed to be a prime factor in diversion of the medication.⁴

Key Points

- Strive to minimize diversion, while recognizing that 1) there is no way to definitively determine whether a patient is fully adherent to any medication, 2) diversion is not unique to opioids—antibiotics are diverted at similar rates to buprenorphine, 3) treatment need is far greater than diversion risks, and 4) the vast majority of [diverted buprenorphine is used to self-treat OUD](#).
- Develop a diversion mitigation policy to minimize [diversion](#). Recommended strategies include urine drug testing, medication counts, and/or providing a limited medication supply. This policy should not be overly burdensome to prevent patients from engaging in care.
- Provide prescriptions to last from appointment to appointment. Limit initial medication supply to 3-7 days; length of prescription may then be extended depending on patient stability. Be mindful of potential financial and logistical burdens that frequent appointments may impose on patients.

Resources

Medications for Opioid Use Disorder:

- Substance Abuse and Mental Health Services Administration TIP 63: https://medicine.yale.edu/edbup/resources/TIP_63_338482_284_42920_v1.pdf
- Suboxone: Rationale, Science Misconceptions: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5855417/>

³ Lofwall MR, Walsh SL. A review of buprenorphine diversion and misuse: the current evidence base and experiences from around the world. *J Addict Med.* 2014;8(5):315-326. doi:10.1097/ADM.0000000000000045

⁴ Carroll JJ, Rich JD, Green TC. The More Things Change: Buprenorphine/naloxone Diversion Continues While Treatment Remains Inaccessible. *J Addict Med.* 2018;12(6):459-465. doi:10.1097/ADM.0000000000000436

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8. Administration

[Federal 42 Code of Federal Regulations \(CFR\) Part 2](#) regulations have been put in place to protect patient confidentiality related to treatment for SUD. If applicable to your organization, it is critical that clinic administration puts systems in place to ensure that these regulations are followed.

Key Points

- Determine whether your practice is a 42 CFR Part 2 covered organization. SAMHSA provides a [decision guide](#) to identify if your organization or practice needs to be compliant.
- Ensure all clinic staff and clinicians understand the confidentiality policies that are adherent to 42 CFR Part 2.
- Ensure that your permission for record disclosure form is compliant with 42 CFR Part 2.

Resources

For substance abuse confidentiality regulations:

- SAMHSA's FAQs and Fact Sheets: <https://www.samhsa.gov/newsroom/press-announcements/202007131330>
- Health and Human Services (HHS) 42 CFR Part 2 Proposed Rule Fact Sheet: <https://www.hhs.gov/about/news/2020/07/13/fact-sheet-samhsa-42-cfr-part-2-revised-rule.html>

Overall Resources

- [American Society of Addiction Medicine](#) (ASAM) developed the National Practice Guideline to provide information on evidence-based treatment of opioid use disorder and address all of the Food and Drug Administration (FDA)-approved medications available to treat addiction involving opioid use and opioid overdose.
- [ASAM Treatment of Opioid Use Disorder Course](#) covers all forms of medications and treatments of opioid use disorder, and provides the required education needed to obtain the waiver to prescribe buprenorphine. ASAM is an approved clinician by the Center for Substance Abuse Treatment (CSAT)/SAMHSA of DATA 2000 training.
- [Bup.ClinicalEncounters.com](#) is a collection of tools and resources to support primary care physicians in setting up and providing office-based treatment for opioid dependence and to aid those who manage and refer patients being maintained on buprenorphine. Also includes [informational resources for patients](#).
- [Clinical Opiate Withdrawal Scale \(COWS\)](#) a tool to assess opiate withdrawal.

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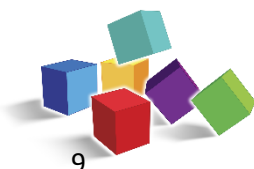


- [Disclosure of Substance Use Disorder Patient Records: Does Part 2 Apply to Me?](#) SAMHSA decision guide on how to identify if your organization or practice needs to be compliant with HHS 42 CFR Part 2.
- Guidelines for the Psychosocially Assisted Pharmacological Treatment of Opioid Dependence. Geneva: World Health Organization; 2009. Annex 12, Prescribing guidelines. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK143167/#>
- [HHS 42 CFR Part 2 Proposed Rule Fact Sheet](#). The 42 CFR Part 2 regulations serve to protect patient records created by federally funded programs for the treatment of SUD.
- Health Resources and Services Administration ([HRSA Substance Abuse Expansion Technical Assistance](#)) supports the improvement and expansion of substance abuse services provided by existing health center program award recipients (those currently funded under section 330 of the Public Health Service Act), with a focus on medication-assisted treatment for opioid use disorders.
- [Information](#) on CLIA'88 requirements.
- [Motivational interviewing](#) resources for those seeking information on motivational interviewing.
- [Next Stage of Buprenorphine Care for Opioid Use Disorder](#) is an article in the Annals of Internal Medicine, November 6, 2018.
- [Oregon Health Authority](#) provides resources for ensuring delivered services are trauma informed.
- [Providers Clinical Support Systems \(PCSS\)](#) is a program funded by SAMHSA to train primary care clinicians in the evidence-based prevention and treatment of opioid use disorders and treatment of chronic pain.
- [PCSS Clinical Tools](#) provides clinical guidelines, forms, and useful links.
- [PCSS Resources for Health Professionals, Patients and Community](#) for treating OUD and chronic pain were developed for health professionals, patients, family members and significant others of patients and the general community to learn more about the evidence-based treatment of opioid use disorders and the treatment of chronic pain.
- [PCSS-MAT](#) offers free, tailored mentoring options, online modules, webinars, small group discussions, clinical guidelines, coaching, and waiver training.
- [Prescription waiver information](#) from SAMHSA on how to apply for a clinician waiver to prescribe or dispense buprenorphine under the DATA 2000.
- [SAMHSA publications and resources on medication-assisted treatment](#) is a comprehensive website with publications and related resources about medication-assisted treatment.

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- [SAMHSA Clinical Drug Testing in Primary Care](#). Technical Assistance Publication (TAP) 32. HHS Publication No. (SMA) 12-4668. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2012.
- [SAMHSA Frequently Asked Questions \(FAQs\) and Fact Sheets](#) regarding the Substance Abuse Confidentiality Regulations.
- [SAMHSA verification tool for pharmacists](#) provides information to verify practitioner waivers to prescribe or dispense buprenorphine under the DATA 2000.
- [Trauma-Informed Care Training](#) from the Texas Department of Family and Protective Services provides this training to assist families, caregivers and other social service clinicians in fostering greater understanding of trauma informed care and child traumatic stress.
- [Treatment Improvement Protocol \(TIP 63\)](#) is a resource for healthcare and addiction professionals, policymakers, patients, and families. It reviews three FDA-approved medications for opioid use disorder treatment—methadone, naltrexone, and buprenorphine—and other strategies and services needed to support people in recovery.
- [Treatment Improvement Protocol \(TIP 35\)](#) includes the latest evidence on motivation-enhancing approaches and strategies. It describes how SUD treatment clinicians can use these approaches and strategies to increase participation and retention in SUD treatment.
- [Treatment Improvement Protocol \(TIP 57\)](#) helps behavioral health professionals understand the impact of trauma on those who experience it. The manual discusses patient assessment and treatment planning strategies. These strategies support recovery and the development of a trauma-informed care workforce.
- [U.S. Food & Drug Administration \(FDA\) Drug Safety Communication](#) urging caution about withholding opioid addiction medications from patients taking benzodiazepines or CNS depressants.
- [Washington State Healthcare Authority](#) is a resource on Medication Treatment Guidelines for SUDS - Buprenorphine Containing Products.
- [Washington Recovery Help Line](#) is a program of Crisis Connections that offers an anonymous, confidential 24-hour help line for Washington State residents. This help line is for those experiencing SUDs, problem gambling, and/or a mental health challenge. Their professionally-trained volunteers and staff provide emotional support. They can also connect callers with local treatment resources or more community services.
- [Washington 2-1-1](#) connects callers, at no cost, to critical health and human services in their community.

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