

BACKGROUND

- An estimated 11.4 million Americans ages 12 and older misuse opioids, the majority of whom misused prescription pain relievers.¹
- About 2.1 million Americans (0.8% of people aged 12 and older) have dependence to opioid pain relievers and 700,000 to heroin.¹
- Only a fraction of Americans actually receives maintenance therapy for their opioid addiction: 356,843 with methadone and 48,148 with buprenorphine.²
- More Americans die from overdoses of prescription opioids than from all other drugs combined, including heroin and cocaine.³
- U.S. deaths involving prescription opioids tripled from 2001 to 2013; deaths involving heroin increased 5-fold.⁴
- HRSA Health Centers provides access to treatment and recovery services for opioid use disorder within urban and rural communities.

Opiates include opium derivatives ranging from heroin to prescription pain relievers such as codeine, morphine, oxycodone, and hydrocodone. Opioids originally referred to synthetic derivatives of opium, such as prescription drugs. In new uses, these terms are often interchangeable. Opioid use disorder has increasingly become a public health crisis in many communities across the country. Communities are challenged to manage the impact: poor health outcomes, increased needs related to the social determinants of health, and spread of communicable diseases such as HIV, Hepatitis C, and other infectious diseases.

ROLE FOR HEALTH CENTERS

Buprenorphine-naloxone (hereafter referred to as “buprenorphine” for simplicity) is an office-based therapy that can be prescribed at health centers by MDs/DOs who have completed an [8-hour training](#) and have applied for and been granted a waiver under the Drug Addiction Treatment Act of 2000 (DATA 2000). Under Section 303 of the Comprehensive Addiction and Recovery Act (CARA), nurse practitioners (NPs) and physician assistants (PAs) can also be granted a waiver to prescribe buprenorphine products for opioid use disorders after completing 24 hours of training.

- 1 Health centers should consider periodic, regular screening of all adult and teenage patients for substance use as recommended in the Substance Abuse and Mental Health Services Administration’s (SAMHSA) [Medications for Opioid Use Disorder](#).
- 2 Screening can be conducted by any trained clinical team member using validated [screening tools as brief as one question](#) as part of routine clinical workflow. Screening, Brief Intervention, and Referral to Treatment (SBIRT) and Motivational Interviewing can be integrated into workflows.
- 3 Individuals meeting DSM-5 criteria for opioid use disorder may be offered or referred for opioid substitution therapy (OST) with buprenorphine or methadone. OST is the best evidence-based treatment for opioid use disorder. OST, including the use of buprenorphine, falls under the larger pharmacologic strategy of medication-assisted treatment (MAT), which may include non-opioid medication classes for treating substance use disorders as well as behavioral health therapy.⁵ Special training may be added for special populations, including but not limited to use during pregnancy, adolescent patients, geriatric patients, patients with chronic pain, and patients with multiple medical co-morbidities.

KEY CLINICAL CHALLENGES & STRATEGIES

Health centers wishing to integrate buprenorphine therapy into their primary care practice can consider the following strategies to address common clinical challenges.

- 1 **Physician Recruitment and Retention:** Educate and identify interested MDs/DOs as well as NPs/PAs; offer training time and cost of waiver; establish team-based program to support prescribers with potential members to include nurse, medical assistant, substance misuse counselor, mental health clinician, and front desk staff; provide support through long distance learning models and mentorship programs. The [Providers Clinical Support System](#) (PCSS) offers an exemplary long distance mentorship model as well as free training courses. Telehealth practitioners are exempt from the requirement of one in-person medical evaluation of the patient if the practitioner is engaged in the practice of telemedicine and is acting in accordance with the requirements of [21 U.S.C. § 802](#).
- 2 **Clinical Time Constraints:** Map out workflow including how referrals, intakes, in-office and home inductions, maintenance visits, toxicology screenings, prescriptions, and patient adherence to treatment plan will be handled; use team members to accomplish many clinical tasks, e.g., nursing visits, groups, care management to improve treatment efficacy; to ensure patient attendance and to empower clinical team members, consider use of vouchers that can be issued by any team member to patients to allow them to pick up the buprenorphine prescription at the pharmacy.

KEY CLINICAL CHALLENGES & STRATEGIES *(continued)*

- 3 Limited Resources:** Identify, list, and form internal and external alliances, especially mental health, substance misuse, and pharmacy. Others may include methadone clinics, residential programs, case management, social work, support groups, housing, and correctional programs.
- 4 Cross-coverage:** Clarify coverage when prescribers or team members are absent; communicate plan to all affected staff and disclose in treatment contracts.
- 5 Diversion (diverting prescribed drugs for illicit purposes):** Establish or improve baseline controlled prescription policies to standardize practice and set expectations for prescribers and patients. Conduct toxicology screens and medication counts, obtain patient consents to work with select pharmacies, consult state prescription monitoring programs. Establish expectations for how prescription monitoring programs will be integrated into health record and used clinically. Remote patient monitoring and controlled pill dispensers may be considered.
- 6 Communication and Education:** Communicate regularly with team, staff, leadership, pharmacy, lab, and external partners; educate around potential conflicts among team and staff regarding treatment philosophy and approach; have patient review and sign an agreement that educates patient on buprenorphine use and the program. Translate agreement to major languages of the service area. Keep in mind that patients may receive treatment and recovery support from their family or their definition of family, which may include friends, sponsors, and other close supports.
- 7 Stigma:** Patients and staff may have conscious or non-realized prejudices toward substance use disorder and those affected by it. Consider trainings on recognizing stigmatizing behaviors, being mindful of language, and recognizing bias. “Adherence” and “recovery” may be more supportive language than “compliance” and “relapse.”
- 8 Co-occurring Behavioral Health Disorders:** Untreated or co-morbid mental health challenges may exacerbate substance use and vice-versa. Likewise, treatment of one is likely to improve outcomes for the other.
- 9 Overdose Risk:** Patients and staff need to be cognizant of drug overdose risk both during treatment and in lapses from treatment.

SPECIAL CONSIDERATIONS

Health centers will find that the integration of buprenorphine therapy into primary care has implications for different aspects of their clinical and financial operations.

- 1 Implications for Access and Scheduling:** Patients engaged in OST typically require multiple visits per month to the health center whether for group counseling, labs, pharmacy, and/or to see a member of the clinical team, affecting both clinic capacity and revenue.
- 2 Implications on Cost Coverage:** State Medicaid and other third-party insurers have different coverage requirements regarding preferred buprenorphine formulations and prior authorizations. Patient Assistance Programs may exist for eligible, uninsured patients through pharmaceutical companies. Discounted pricing can be accessed by eligible organizations and covered entities through the [340B Drug Pricing Program](#). Toxicology screening can be costly for uninsured patients, and point-of-care testing may be more cost-effective than send-out labs. Arrangements with laboratories can be negotiated to cover the uninsured.
- 3 Implications for Public Health:** Opioid use disorder treatment reduces infectious transmissions, complications from injection practices, and hospitalizations; increases retention in care; improves poverty, employment and social integration.
- 4 Implications for Protecting Patient Confidentiality:** [Title 42 of the Code of Federal Regulations \(CFR\) Part 2: Confidentiality of Substance Use Disorder Patient Records \(“Part 2”\)](#) protects the confidentiality of certain substance use disorder (SUD) records by restricting the circumstances under which Part 2 Programs or other lawful holders can disclose SUD records. Further info can be found at: <https://www.samhsa.gov/health-information-technology/laws-regulations-guidelines>.
- 5 Licensing:** Prescribers wishing to use buprenorphine products for outpatient treatment of opioid use disorders require a DATA 2000 Waiver, commonly referred to as a DEA “X number”; the number of active patients must be maintained by provider (MDs or DOs: maximum 30 in year 1; 100 in year 2; 275 in years 3+ with waiver; PAs/NPs: maximum of 30 active patients simultaneously in years 1+). [Prescribers must request](#) increases in their active patient census; it is not automatically increased.
- 6 Data of Potential Interest:** Patient characteristics and co-morbidities; number of patients enrolled; number of clinic visits; retention time in program; toxicology results; engagement in mental health and substance use counseling; primary care prevention and chronic disease management outcomes; emergency room use; timeline of recovery progression; trends in recovery attainment.

KEY STRATEGIC DOCUMENTS, WEBSITES, & INFORMATION

- › Web-based Waiver Training: <https://www.samhsa.gov/medication-assisted-treatment/training-resources/buprenorphine-physician-training>
- › [MAT Business Plan](#): NACHC and PCSS
- › [Documentation and Charge Capture Process: Medication-Assisted Treatment](#): NACHC and PCSS
- › DATA 2000 Waiver Notification Forms (new request and patient limit increase): <https://www.samhsa.gov/medication-assisted-treatment/buprenorphine-waiver-management/apply-for-physician-waiver>
- › Medications for Opioid Use Disorder, Treatment Improvement Protocol (TIP) 63, Substance Abuse and Mental Health Services Administration: <https://store.samhsa.gov/product/TIP-63-Medications-for-Opioid-Use-Disorder-Full-Documents-Including-Executive-Summary-and-Parts-1-5-/SMA18-5063FULLDOC>
- › Screening and Assessment Tools (e.g., DAST-10, AUDIT, AUDIT-C): Part 5 in TIP 63
- › Treatment Agreement/Pharmacy Consent: Samples in Part 5 in TIP 63
- › Single-Question Drug Screen: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2911954>
- › DSM-5 Criteria for Opioid Use Disorder: <https://www.aoaam.org/resources/Documents/Clinical%20Tools/DSM-V%20Criteria%20for%20opioid%20use%20disorder%20.pdf>

KEY STRATEGIC DOCUMENTS, WEBSITES, & INFORMATION

- › ICD-10 Diagnostic Codes: <https://icd.codes/icd10cm/F112>
- › Providers Clinical Support System: <https://pcssNOW.org>
- › Billing codes: V58.69 for drug toxicology screening
- › Agency for Healthcare Research and Quality's Provider- and Practice-Level Competencies for Integrated Behavioral Health in Primary Care: https://integrationacademy.ahrq.gov/sites/default/files/AHRQ_AcadLitReview.pdf
- › Bureau of Primary Health Care's Behavioral Health and Primary Care Integration Resources: <https://bphc.hrsa.gov/qualityimprovement/clinicalquality/behavioralhealth/index.html>
- › Centers for Disease Control and Prevention's Guideline for Prescribing Opioids for Chronic Pain and Related Resources: <https://www.cdc.gov/drugoverdose/prescribing/qi-cc.html>
- › Milbank Memorial Fund's Evolving Models of Behavioral Health Integration: Evidence Update 2010-2015: <https://www.milbank.org/wp-content/uploads/2016/05/Evolving-Models-of-BHI.pdf>

ORGANIZATIONS FOR MORE INFORMATION

- › American Academy of Addiction Psychiatry — <https://www.aaap.org/>
- › American Society of Addiction Medicine — <https://www.asam.org/>
- › National Institute on Drug Abuse — <https://www.drugabuse.gov/nidamed-medical-health-professionals>
- › Substance Abuse and Mental Health Services Administration — <https://www.samhsa.gov/medication-assisted-treatment/treatment/buprenorphine>

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- ¹ Substance Abuse and Mental Health Services Administration. (2018). Key substance use and mental health indicators in the United States: Results from the 2017 National Survey on Drug Use and Health (HHS Publication No. SMA 18-5068, NSDUH Series H-53). Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. Retrieved from <https://www.samhsa.gov/data/sites/default/files/cbhsq-reports/NSDUHF2017/NSDUHF2017.htm> on January 24, 2019
- ² Substance Abuse and Mental Health Services Administration. Behavioral Health Barometer: United States, Volume 4: Indicators as measured through the 2015 National Survey on Drug Use and Health and National Survey of Substance Abuse Treatment Services. HHS Publication No. SMA-17-BaroUS-16. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2017.
- ³ National Institute on Drug Abuse. Prescription and Over-the-Counter Medications. Retrieved from <https://www.drugabuse.gov/publications/drugfacts/over-counter-medicines> on January 24, 2019.
- ⁴ National Institute on Drug Abuse. Overdose Death Rates. Retrieved from <https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates> on January 24, 2019.
- ⁵ Mattick RP, Kimber J, Breen C, Davoli M. Buprenorphine maintenance versus placebo or methadone maintenance for opioid dependence. Cochrane Database Syst Rev. 2008;CD002207. [PubMed:18425880]

This publication was supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) as part of an award totaling \$6,375,000 with 0 percent financed with non-governmental sources. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by HRSA, HHS, or the U.S. Government. For more information, please visit [HRSA.gov](https://www.hrsa.gov).