Overview

Some 1.6 million Americans have opioid use disorder (OUD), and the overdose crisis has worsened over the past several years, with preliminary data from 2019 and 2020 indicating that opioid overdose death rates are climbing.\(^1\) FDA-approved medications—specifically, buprenorphine and methadone—have been shown to reduce the risk of overdose, illicit opioid use, and the transmission of infectious disease that can accompany injection drug use. Unfortunately, only 18% of people with OUD in the United States received any of the three FDA-approved lifesaving treatments in 2019: buprenorphine, methadone, and naltrexone.\(^2\)

Unlike naltrexone, which can be dispensed like any other prescription medication, methadone and buprenorphine have more regulations for prescribing. Although methadone can be provided only through specialized opioid
treatment programs (OTPs), buprenorphine can be prescribed by health care providers outside of OTP settings if providers complete training by the U.S. Substance Abuse and Mental Health Services Administration (SAMHSA) and obtain a waiver from the Drug Enforcement Administration (DEA). Although the buprenorphine regulations were intended to increase access to medications in additional health care settings, in practice these federal requirements narrow the pool of eligible prescribers and also limit the number of patients each waivered provider is allowed to treat. As a consequence, many patients struggle to identify a buprenorphine provider and access the medication. For instance, in 2018, 40% of U.S. counties did not have a single waivered provider. This treatment gap is amplified among communities of color, with Black patients less likely to receive a buprenorphine prescription than White ones.

In response to these structural issues, some state agencies, policymakers, and waivered providers have taken steps to reduce barriers to buprenorphine treatment, an approach referred to as “low-threshold buprenorphine.” This approach can be applied in a variety of care settings—such as federally qualified health centers (FQHCs), primary care clinics, opioid treatment programs, specialty substance use disorder treatment facilities, hospital emergency departments, syringe services programs, and mobile treatment vans—and includes prescribing buprenorphine as soon as a patient is interested in treatment; providing medication without requiring concurrent services, such as counseling; eliminating the clinical practice of terminating treatment as a consequence of continued substance use; and offering low-cost or no-cost initiation of treatment. Recent evidence suggests that low-threshold treatment can increase the number of patients who initiate buprenorphine treatment, and also engage marginalized populations less able to access care in traditional settings—including people who are involved in the justice system, experiencing homelessness, or uninsured.

However, providers face barriers to implementing low-threshold treatment approaches, including billing and reimbursement (because specialty programs have historically required counseling in addition to medication). And some primary care providers may be unfamiliar with treatment options for patients with OUD, in part because of stigma against patients and medication treatment.

Fortunately, federal and state policymakers can move to amend reimbursement policies, treatment guidelines, and regulations to ensure that providers are equipped to deliver timely and effective patient care. They can support low-threshold buprenorphine prescribing via the following steps:

- Encourage timely and convenient initiation of buprenorphine treatment:
  - Remove prior authorization requirements for initial buprenorphine prescriptions with Medicaid and commercial insurers.
  - Amend state billing requirements and allow buprenorphine to be prescribed prior to a completed initial intake assessment, so as not to delay the start of treatment.
  - Fund the initiation of buprenorphine through emergency departments, using federal grants or state funds.
  - Make permanent the federal regulatory flexibilities, enacted as a result of the COVID-19 pandemic, that temporarily suspended the required in-person consultation for initiation of buprenorphine—allowing more patients to begin treatment via consultation by telephone.

- Support patient retention in buprenorphine treatment:
  - Remove state regulations that require clinicians to taper buprenorphine doses over time, and consider increasing daily dose limits.
Eliminate requirements that patients on buprenorphine receive counseling, and evaluate Medicaid payment structures and state contracts with providers to ensure that providers can bill for medication treatment without concurrent counseling services.

Prohibit the discharge, from publicly funded OUD treatment programs, of patients who continue to use substances.

- Fund supplemental health and social services that facilitate the initiation and continuation of low-threshold buprenorphine treatment:
  - Allow Medicaid reimbursement for services that support patients in their varying treatment needs (e.g., social work, recovery coaching, peer and outreach work).
  - Dedicate federal and state grant money to services that facilitate low-threshold prescribing (e.g., outreach, transportation, case management).

**Encourage the timely and convenient initiation of buprenorphine treatment**

States should make policy changes that enable people to access buprenorphine treatment for OUD as soon as they are ready. Delays in the initiation of medication, such as waitlists for treatment, have been demonstrated to increase a patient’s risk for morbidity and mortality—particularly for overdose in patients who stopped using illicit opioids in preparation for treatment.9

First, states should remove Medicaid prior authorization requirements for buprenorphine, which as of 2018 remains the law of the land in 39 states and the District of Columbia for buprenorphine, and in 30 states for buprenorphine-naloxone (the combined formulation of the drug).10 Under the current policy, providers must justify the need for a specific treatment to ensure its appropriate use, and to prevent wasteful spending or misuse, before Medicaid pays for the prescription.11

However, this process often delays treatment unnecessarily. The evidence is clear that medications for OUD reduce illicit opioid use, risk of overdose, and patient use of costly hospital and emergency care.12 More states should adopt what is known as a “Medication First” approach to treatment, which prioritizes access to pharmacotherapy as quickly as possible, for as long as is therapeutically beneficial, and without strict program requirements for patients. Missouri’s Medicaid program has removed prior authorization requirements for initial buprenorphine prescriptions as part of the state’s Medication First initiative,13 and 17 other states enacted legislation precluding state-regulated commercial insurance plans from placing prior authorizations on FDA-approved medications for OUD.14

Second, Medicaid and the state agencies responsible for administering SAMHSA Substance Abuse Block Grant (SABG) funds to treatment programs should amend payment policies that require providers to conduct comprehensive patient intake assessments prior to prescribing buprenorphine. Although assessments help providers diagnose and identify the severity of OUD, they, too, can cause delays in medication treatment.15 Under Missouri’s Medication First approach, the state’s Department of Mental Health amended its billing requirements to allow providers up to 30 days to complete an intake assessment after prescribing buprenorphine.16
Box 1. Featured Program: Missouri Medication First Approach

To increase buprenorphine access for uninsured patients, the Missouri Department of Mental Health partnered with the University of Missouri, St. Louis to develop the Medication First treatment approach for publicly funded substance use disorder treatment programs. The core components of this approach are providing patients with timely access to buprenorphine prior to assessment and treatment planning, ongoing buprenorphine maintenance without limits or dosage tapering, and offering—but not requiring—psychosocial services.

The state used grant money from the State Targeted Response to the Opioid Crisis (STR) allotment to fund 38 treatment sites across 14 agencies. This allowed for the implementation of Medication First by training staff, reforming clinical protocols, and partnering with providers waivered to prescribe buprenorphine. Missouri then compared treatment outcomes from the nine months before (July 2016 through March 2017) and nine months during the grant funding period (July 2017 through March 2018). Officials found that utilization of buprenorphine increased from 44.8% to 85.3%; time to receipt of buprenorphine improved from eight days to zero days; and treatment retention improved at one-, three-, and six-month intervals. Additionally, the average monthly costs of treatment dropped 21% after the approach was implemented.

Third, states should fund innovative models to offer buprenorphine treatment without requiring referrals and appointments. For example, when patients come to the emergency department with an opioid-related illness or injury, physicians should begin buprenorphine treatment while waiting to connect them with a provider for ongoing care.17

Yet many emergency physicians feel they do not have the funding, systems, or staff in place to fully serve the health and social needs of OUD patients.18 To overcome this barrier, the Kentucky Cabinet for Family and Health Services used federal grant money to partner with emergency departments and create a special clinic to provide a bridge to ongoing community treatment.19 This effort, launched in 2018, provides buprenorphine to discharged patients until they can be connected to care in the community, and it also provides counseling, care navigation, peer supports, and education on overdose prevention.20 In its first year, the bridge clinic started buprenorphine treatment for about 100 patients from among 300 referrals.21 Although many patients are referred from the hospital, the clinic also accepts walk-ins.

Fourth, states should issue clinical guidelines for unobserved initiation of buprenorphine, also called at-home induction. Currently, state guidelines tend to focus on and encourage office induction, an approach that is resource-intensive for health care facilities, and one that can make same-day treatment less feasible.22 Patients may be more comfortable with a home induction because the process can be time-consuming and include uncomfortable withdrawal symptoms, as prior to their first dose, patients need to stop using other opioids for a short period of time, which causes mild to moderate withdrawal.23 Studies show at-home initiation does not increase serious adverse medical events or interfere with successful treatment initiation or retention.24 States should publish guidance to encourage this low-threshold approach to care. For example, the New York State Department of Health’s clinical guidance for buprenorphine describes home initiation as feasible and safe, and outlines steps prescribers should take to ensure that patients have the information they need to succeed.25

Typically, a clinician must see a patient in an office visit before prescribing buprenorphine for in-home initiation, but the federal government temporarily lifted this requirement during the COVID-19 public health emergency,
through guidance from federal agencies, to reduce the number of patients visiting health facilities. Early data indicates that this change has not resulted in adverse or unintended outcomes, and has led to innovative methods for increasing access to treatment, such as the Rhode Island Buprenorphine Hotline, which connects people seeking treatment to a waivered buprenorphine provider who can assess the patient over the phone and prescribe the medication, if appropriate, essentially acting as a “tele-bridge” to outpatient treatment. Until the requirement for an in-person office visit is permanently lifted, the federal government should use the authority of the ongoing opioid crisis public health emergency (first declared in 2017) to continue to waive this rule.

Support patient retention in buprenorphine treatment

There are several policies—such as limits on prescriptions, requirements for concurrent counseling, and penalties for continued illicit drug use—that can disrupt the course of treatment once a patient starts medication for OUD. To support treatment retention in a low-threshold approach, states should remove such unnecessarily burdensome policies.

First, Medicaid programs should remove rules that require clinicians to gradually lower buprenorphine doses over a period of time, known as tapering. Some Medicaid programs limit the dosages and length of time that patients can receive buprenorphine. But like other chronic illnesses, OUD is a long-term medical condition that requires ongoing treatment. Requirements to taper prescribing or reduce dosage over time can interfere with the effectiveness of treatment and recovery. Some states, including Tennessee, require providers to submit tapering plans to obtain prior authorization. By contrast, Missouri’s Medication First program removed such requirements.

States should also consider increasing dose limits on buprenorphine. The American Society of Addiction Medicine (ASAM) guidelines suggest that 24 milligrams should be the maximum daily dose; however, some state Medicaid programs, such as Tennessee’s, still cap the dose at 16 milligrams per day. No Medicaid program should limit buprenorphine dosage below clinical guidelines. States should consider exceeding the suggested 24-milligram maximum to account for higher doses that may be needed for patients with higher opioid tolerance, especially because fentanyl—a potent synthetic opioid—dominates the drug market. For example, Washington state permits providers to prescribe 32 milligrams per day, with flexibility for higher doses with prior authorization. Such flexible policies can help keep patients in treatment.

Second, Medicaid and state agencies administering SABG funds to treatment programs should eliminate requirements that patients on buprenorphine receive counseling. Although federal rules require that practitioners have the capacity to refer patients to behavioral health services, there is no obligation for patients to use them. Moreover, ASAM practice guidelines specify that a patient’s decision about whether to engage in counseling should not interfere with receiving medication treatment. Still, in some Medicaid programs, health care providers are reimbursed for providing buprenorphine treatment only if the patient also receives counseling services from that same provider or another practitioner. Although counseling provides a benefit to many patients and should be available to those interested, evidence shows that people taking only buprenorphine do not have significantly different treatment outcomes from patients who also receive psychosocial services. Furthermore, some people cite the requirement to attend counseling sessions as an impediment to staying in treatment due to inflexibility in available appointments that interfere with other aspects of everyday life (e.g., employment). Therefore, states should evaluate and amend their state agency and Medicaid payment bundles (i.e., payment for a predetermined set of services) and reimbursement rates so that prescribing low-threshold buprenorphine separate from counseling is financially practical for providers. For example, prior to implementing Medication First, Missouri’s Department of Mental Health increased administrative reimbursement rates for prescribing buprenorphine for providers in participating treatment programs.
States should also consider separating counseling from medication in treatment payment bundles, as Maryland did in its opioid treatment programs.\textsuperscript{41} Maryland rebundled payments to include managing the care plan, dosing, dispensing, and administering medication, drug screens, and coordination with other services; and individual and group counseling became separately billable services.\textsuperscript{42} Additionally, because medication alone is an effective treatment, states should not require that facilities licensed to offer buprenorphine also furnish behavioral health services.\textsuperscript{43} State can decouple these services through regulatory language; for example, while some states define “medication-assisted treatment” as medications in combination with behavioral therapies, New York defines it as treatment of a substance use disorder with medication alone.\textsuperscript{44}

Third, states should prohibit publicly funded treatment programs from discharging patients for continued illicit drug use. Patients in low-threshold buprenorphine treatment programs sometimes continue using illicit opioids or stimulants, especially those also experiencing homelessness or other issues.\textsuperscript{45} Although some programs cite continued drug use as grounds for involuntary termination—a practice commonly called administrative discharge—evidence shows that it is safer for patients to continue prescribed medications for OUD than to be put at high risk for overdose by suddenly stopping treatment.\textsuperscript{46} Federal guidelines recommend that programs avoid administrative discharge and instead re-evaluate patients if the current treatment plan proves ineffective.\textsuperscript{47} Accordingly, regulators should explicitly prohibit the practice when licensing and certifying substance use treatment programs; for example, Maine’s regulations for opioid treatment programs bar the use of administrative discharge “to discipline clients for minor infractions of program policy.”\textsuperscript{48}

**Paying for nonclinical aspects of low-threshold care**

Low-threshold buprenorphine approaches reach populations that tend to be underserved and socially and economically disadvantaged. Patients are often uninsured and face housing insecurity, lack of transportation, and unemployment—all of which can interfere with their ability to start and remain in treatment. Offering support services that facilitate access to medication treatment can help patients overcome barriers and achieve long-term recovery.\textsuperscript{49}

States should use Medicaid or grant funding to address this multitude of needs for patients who seek additional services. For example, REACH, a low threshold and harm reduction focused facility in New York state, has recently become a certified outpatient treatment center. This will allow REACH to receive enhanced Medicaid reimbursement for its full range of services—including integrated primary care, medication for opioid use disorder, testing and treatment for hepatitis C and HIV, community health worker and behavioral health services, and peer and outreach work—all of which allow REACH to support patients in their varying health care and social needs.\textsuperscript{50}

In the Massachusetts Collaborative Care Model, nurse care managers (NCMs) are integrated into FQHCs and can bill at the same rate as other clinicians for buprenorphine initiation visits while buprenorphine prescribers are responsible for diagnosing OUD and prescribing the medication. NCMs can offer to help address patients’ nonmedical challenges, such as insurance or pharmacy problems, legal issues, and housing.\textsuperscript{51} Five years after this model began in 14 community health centers, buprenorphine treatment admissions had increased nearly seven-fold, and two-thirds of patients stayed in treatment for more than one year.\textsuperscript{52}

States can also direct federal grants, including State Targeted Response to the Opioid Crisis (STR) and State Opioid Response funding, to cover nonclinical aspects of care. Missouri used STR funds to pay for patient transportation to participating treatment providers, and Kentucky used the grant to integrate peer support specialists into emergency departments as part of its bridge clinic initiative.\textsuperscript{53}
Challenges to the adoption of low-threshold treatment approaches

Even if state policies change to permit and encourage low-threshold buprenorphine prescribing, access to care can still be complicated by the metrics used to determine treatment success, concerns about medication diversion to people who would use it without a prescription, and a shortage of buprenorphine providers.

State grant funding is often paired with reporting requirements; however, because low-threshold treatment does not place the same requirements on patients as traditional treatment, distinct performance measures are necessary for these two types of treatment. For example, low-threshold treatment is less likely than standard OUD treatment to result in the cessation of drug use. Still, low threshold treatment can reduce illicit drug use, which in turn prevents overdose deaths. Accordingly, an appropriate success metric for low threshold treatment would be the reduction of drug use. Another common measure is treatment retention for an uninterrupted period of time, but this metric may not be appropriate for populations receiving low-threshold buprenorphine because they are more likely to experience disruptions to care such as homelessness. Instead, evaluations of patient success could measure the number of days covered by medication treatment in a given time period, even if they are not consecutive.\(^5\)\(^4\)

Some state officials and providers are also concerned that low-threshold buprenorphine could lead to diversion of the medication to people who would use it without a prescription. Although that is a risk with most prescription drugs, evidence suggests that people use nonprescribed buprenorphine to self-treat or prevent withdrawal, and diversion could be the result of a lack of access to treatment.\(^5\)\(^6\) One study even suggested that better access to buprenorphine from a doctor could reduce diversion of this medication.\(^5\)\(^6\) Furthermore, surveys of patients receiving low-threshold treatment find that they have prior experience using buprenorphine, often not prescribed, prior to entering treatment.\(^5\)\(^7\) This finding may indicate that low-threshold programs have the ability to reach a population interested in trying the medication but who otherwise lack access to a clinician who could prescribe it.\(^5\)\(^8\)

Finally, many states and rural jurisdictions do not have enough providers who can offer buprenorphine because of the federal requirement for a DEA waiver to prescribe it.\(^5\)\(^9\) Some physicians see the waiver process as a barrier to offering treatment; others do not seek a waiver because they feel they don’t have the capability to treat patients with OUD who may have complex health or social issues.\(^6\)\(^0\) To address these challenges, some states have offered support for practitioners to get waivered. For example, New Mexico implemented Project ECHO (Extension for Community Healthcare Outcomes) to link primary care providers to mentors and training on treating substance use disorders to help them to become waivered; after the start of the project, the number of waivered providers in the state increased more than tenfold from 2006 to 2016.\(^6\)\(^1\) The federal government could also remove the waiver requirement altogether.\(^6\)\(^2\) Recently, experts in the field have argued that the process is unnecessarily burdensome, citing the urgency of the opioid overdose crisis and the fact that there are no restrictions on prescribing other types of opioids for pain.\(^6\)\(^3\) Increasing the number of buprenorphine prescribers is critical to expanding care for OUD, including low-threshold treatment approaches.

**Conclusion**

Low-threshold prescribing can play a crucial role in expanding access to buprenorphine, particularly among marginalized populations and individuals separated from the traditional health care system. As states and localities continue to explore providing low-threshold treatment, policymakers should look to innovations and initiatives to ensure increased access to this lifesaving medication for people with OUD.
Endnotes


11. Ibid.


16 Winograd et al., “Implementation and Evaluation of Missouri’s Medication First Treatment Approach.”


20 Ibid.

21 M. Binkley et al., “Bridge to Life: Connecting Individuals Presenting to the Hospital With Complications From Opioid Use Disorder to Evidence-Based Care” (presentation, Rx Drug Abuse and Heroin Summit, Atlanta, Georgia, April 23, 2019), https://www.eventscribe.com/2019/RxSummit/fsPopup.asp?fp=SUIESthPV14MyYJ3&PresentationID=491212&rnd=0.9485711&mode=presinfo.


35 Fareed et al., “Effect of Buprenorphine Dose on Treatment Outcome.”

36 Substance Abuse and Mental Health Services Administration, “Become a Buprenorphine Waivered Practitioner.”

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40 Winograd et al., “Implementation and Evaluation of Missouri’s Medication First Treatment Approach.”


42 Ibid.

43 Sigmon et al., “Bridging Waitlist Delays With Interim Buprenorphine Treatment: Initial Feasibility.”

definitions.


56. Lofwall and Havens, “Inability to Access Buprenorphine Treatment.”


58. Ibid.

59. Grimm, “Geographic Disparities Affect Access to Buprenorphine Services for Opioid Use Disorder.”


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