Access to Treatment for Individuals with Opioid Use Disorder

Corey S. Davis, JD, MSPH, Harm Reduction Legal Project, Network for Public Health Law; Amy Judd Lieberman, JD, Harm Reduction Legal Project, Network for Public Health Law

SUMMARY. Highly effective medications to treat opioid use disorder (OUD) have existed for decades. Despite their proven efficacy, federal and state laws severely limit access to these medications, limitations that disproportionately impact those who are made particularly vulnerable by factors including economic injustice and structural racism. In response to the COVID-19 epidemic, the U.S. Drug Enforcement Administration (DEA) and other federal agencies have taken steps to temporarily remove some legal and regulatory barriers to these medications. Most of these changes are set to expire with the COVID-19 public health emergency declaration, although the epidemic of opioid-related harm will not end when the novel coronavirus is controlled. Indeed, data from many states show a sharp increase in opioid-related harm since the beginning of the COVID-19 pandemic. This Chapter highlights the positive impact of OUD treatment, recent changes to increase access to that treatment, and recommendations for permanently reducing legislative and regulatory barriers to effective, evidence-based interventions for OUD.

Introduction

Opioids, either alone or in combination with other substances, killed nearly 47,000 people in 2018, the latest year for which full data are available. Provisional data show that overdose-related deaths have accelerated since then, with more deaths recorded in the 12-month period ending May 2020 than in any other 12-month period on record. The number of Americans who use heroin more than doubled from 2002 to 2016, and an estimated two million Americans meet the criteria for opioid use disorder (OUD).

Laws at the federal, state, and local levels often act as structural barriers to evidence-based prevention and treatment, and in many cases perpetuate and amplify stigma-driven responses to people with OUD. This is particularly true for individuals made vulnerable by economic deprivation, structural racism, and other social determinants of health. Outside of the criminal justice system, which systematically harms and disenfranchises already vulnerable individuals, legal barriers to OUD treatment are the most poignant example of the negative impact of law on the health of people who use drugs (PWUD).

Medications for OUD have existed for decades. The most effective of these medications, methadone and buprenorphine, are referred to as opioid agonist treatment (OAT) because they activate or partially activate opioid receptors. These medications significantly reduce many of the potential harms associated with OUD, including relapse and bloodborne disease risk. Perhaps most importantly, treatment with either medication reduces both overdose-related and all-cause mortality risk in opioid-dependent individuals by approximately 50% (Sordo et al., 2017).

Because of their effectiveness and relative safety, the National Academies of Sciences, Engineering, and Medicine has declared that “[w]ithholding or failing to have available all classes of FDA-approved medication for the treatment of opioid use disorder in any care or criminal justice setting is denying appropriate medical treatment” (Leshner & Dzau, 2019). Alex Azar, the former secretary of Health and Human Services (HHS), has noted that attempting to treat OUD without OAT is “like trying to treat an infection without antibiotics” (Roubein, 2018).

Despite this rhetorical support from expert organizations and federal officials, unduly restrictive federal, state, and local laws and policies significantly impede access to OAT. While these legal and policy barriers are harmful in normal times, COVID-19 has compounded the risks to people with OUD, particularly for high-risk individuals. Preliminary CDC data show that more than 19,000 people died from a drug overdose in the first quarter of 2020, almost 3,000 more than the first quarter of 2019, and more than 40 states have reported an increase in opioid-related mortality as of December 2020.

This trend has been exacerbated by the COVID-19 crisis. The offices of many clinicians, treatment programs, and harm reduction services have had to close or significantly reduce their hours due to lockdowns and social distancing requirements, and disruptions to normal routines and increased social isolation increase the risk of returning to drug use for people in recovery. Many people who previously used drugs with other individuals who would be able to respond in an overdose emergency are now using alone, dramatically increasing the risk of fatal overdose.
Further, patients with OUD are at a significantly increased risk for COVID-19, and COVID-19 patients with OUD have significantly worse outcomes than those without OUD. This increased risk is especially pronounced in Black patients (Wang et al., 2020).

Legal Barriers to Opioid Agonist Treatment

Legal barriers to OAT are many and varied. Although methadone prescribed for pain is subject only to the restrictions that apply to all controlled substances, federal law imposes numerous additional limitations when it is used for OUD treatment. These restrictions begin with limits on which patients may receive the medication. To be considered for treatment, most individuals must have had OUD for at least one year and have received a full medical evaluation prior to receiving treatment. Federal law also limits the dosage that patients can receive, regardless of the prescriber’s determination of their clinical need (Davis & Carr, 2019).

Moreover, while most drugs can be dispensed at any licensed pharmacy, only federally certified opioid treatment programs (OTP) may dispense methadone for OAT, and practitioners providing it must obtain an annual registration from the federal Drug Enforcement Agency (DEA). OTPs may provide methadone only in oral form, and patients generally must ingest it under the supervision of OTP staff. Although “take-home” doses are permissible, the terms under which patients are trusted with medication prescribed to them are set not by the prescriber but by federal law. Requirements for daily dosing disproportionately harm individuals without reliable transportation and make it nearly impossible for individuals who work non-standard shifts to access methadone treatment. For example, one study found that 20% of people in treatment reported difficulty getting to or from treatment as a reason for nonattendance, and another study found that 26% of patients traveled more than 15 miles to their OTP, and 6% traveled more than 50 miles (Network, 2020).

Several states, including many of those with a considerable population of people with OUD, have created additional barriers to accessing methadone for OAT. For example, Georgia limits each region of the state to a maximum of four licensed methadone programs, and West Virginia has a blanket moratorium on the establishment of new OTPs (Davis & Carr, 2019). Although several federal appellate courts have ruled that some laws that restrict the siting of OTPs violate the Americans with Disabilities Act, many states and localities implicitly or explicitly limit where they can be located — often pushing them far away from where most people live and into areas that are difficult to access via public transportation.

Federal restrictions on buprenorphine prescribed for OUD, while less severe than those imposed on methadone, also serve to ensure that some people who would benefit from the medication are left to suffer without (Davis & Carr, 2017). Perhaps the most important of these is that only health professionals who have received a federal “waiver” are permitted to prescribe buprenorphine for OUD. To qualify for a waiver, physicians must either hold a certification in addiction medicine or complete specific training, which usually includes an eight-hour series of instruction. Non-physicians must complete 24 hours of training. Federal law also limits the number of patients a waivered provider may treat.

These limitations conspire to artificially reduce the number of providers who offer buprenorphine, as well as the patients who can benefit from it. In 2016, nearly half of America’s 3,100 counties, including more than 75% of rural counties, were without a single physician authorized to prescribe the medication (Andrilla et al., 2017). In fact, only 2% of waivered physicians practice in remote rural areas, even though as of 2018 the rate of non-medicinal use of opioids was greater in rural areas than urban areas, and the per capita overdose rate was nearly 45% higher in rural communities (Weintraub et al., 2018). Even when patients can access buprenorphine providers, they may have difficulty obtaining the medication from pharmacies. A recent survey of pharmacies in a rural area with high opioid overdose rates found that 80% limited buprenorphine dispensing, often because of concerns regarding potential violations of federal law (Cooper et al., 2020).

Similarly, the majority of methadone clinics are clustered in large urban centers, causing people in rural areas to have to drive large distances to access care. One study of the five states with the highest rates of opioid-related fatal overdose found that the average drive time to an OTP was 49 minutes for rural counties compared to approximately eight minutes in large central metro areas (Joudrey, P. J., et al., 2019). Legal limitations on OAT also contribute to severe racial disparities in treatment access. Despite similar prevalence of OUD among Black and white adults, from 2012 to 2015 white patients were almost 35 times more likely to have a buprenorphine-related office visit compared to Black patients (Lagisetty et al., 2019). While patients should be free to choose which treatment they prefer, Black patients are often limited to methadone as their only option due to their location, despite an increase in opioid overdoses in Black communities (Nguemeni Tiako, M.J., 2020). In some programs, Black patients are subjected to tighter regulations including lower methadone dose limits and decreased likelihood of take-home doses.

Access to buprenorphine is also limited by the Ryan Haight Act, which permits controlled substances to be initially prescribed, in most instances, only after the prescriber has conducted an in-person examination of the potential patient. This requirement, which was designed to target illicit internet pharmacies, creates nearly insurmountable barriers for individuals who would benefit from buprenorphine treatment but are unable to meet with a waivered provider in person to begin therapy. Its effects fall particularly hard on individuals with OUD in rural areas, those without reliable transportation, and individuals with disabilities.

Although the DEA is charged with balancing the needs of ensuring access to controlled medications while limiting diversion, these restrictions all favor diversion control over medically indicated access. Diversion — that is, use of medications for OUD by someone other than the person to whom it was prescribed — is often raised as a justification for the limits imposed on OUD. However, studies evaluating the use of non-prescribed buprenorphine have demonstrated that it is primarily used for the purpose for which it was intended — helping people with OUD reduce use of other opioids and to treat symptoms of withdrawal (Chilcoat et
al., 2019). Indeed, among adults with OUD, greater frequency of non-prescribed buprenorphine use is significantly associated with lower risk of overdose (Carlson et al., 2020). Improving access to treatment would likely reduce this concern by reducing the demand for non-prescribed buprenorphine.

Changes during the COVID-19 Emergency

Federal agencies have temporarily removed some barriers to OAT during the COVID-19 pandemic. In the methadone context, the Substance Abuse and Mental Health Services Administration (SAMHSA) issued guidance in late March 2020 that allows states to permit all patients who are on a stable methadone dose to receive 28 days of take-home medication, and for patients who are less stable to receive 14 days of take-home medication (SAMHSA, 2020). It is up to states to request this ability, however, and individual programs to implement the change.

Further, in consultation with SAMHSA, DEA has temporarily permitted OTPs to provide patients who are otherwise permitted to receive take-home doses of methadone to obtain those doses from temporary off-site locations, provided they are in the same state in which the OTP is registered and meet certain other conditions. DEA also temporarily permits authorized OTP employees to personally deliver methadone to patients who cannot travel to the OTP to obtain the medication themselves and has authorized law enforcement and National Guard personnel to deliver methadone to patients as well. However, an individual must still present in-person to an OTP to begin methadone treatment.

In the buprenorphine context, the HHS secretary, in coordination with the attorney general, has used existing statutory authority to waive the Ryan Haight Act’s in-person examination requirement, thereby permitting the initial consultation for buprenorphine treatment to be held via telemedicine. While this authority was initially limited to communication conducted via a real-time, two-way interactive audio-visual communication system, DEA used its enforcement discretion to authorize audio-only consultation as well. This innovation is key, as it permits “tele-bupe” services whereby an individual with OUD can quickly and easily contact a waivered physician who conducts a phone consultation and, where appropriate, prescribes buprenorphine and schedules appropriate follow-up. This is especially vital to the 21.3 million Americans who live in “digital deserts” and have no fixed broadband service, including almost half of low-income Americans and one-third of rural Americans (Khatri et al., 2020).

Further, the HHS Office for Civil Rights, which enforces the Health Insurance Portability and Accountability Act of 1996 (HIPAA) regulations, has issued a formal notice that it will “exercise its enforcement discretion and will not impose penalties for noncompliance with the regulatory requirements under the HIPAA Rules against covered health care providers in connection with the good faith provision of telehealth during the COVID-19 nationwide public health emergency,” and that “[a] covered health care provider that wants to use audio or video communication technology to provide telehealth to patients during the COVID-19 nationwide public health emergency can use any non-public facing remote communication product that is available to communicate with patients” (HHS, 2020). While the office notes that many audio-visual tools are HIPAA compliant, this use of enforcement discretion will permit providers to interact with patients who may not have access to professional software, including via programs that are regularly used on cell phones.

In acknowledgement of the fact that some prescribers may be responding to the crisis outside of the state in which they normally practice, DEA has waived the requirement that a DEA-registered provider obtain a separate registration in each state in which they practice, if they are practicing in a state that has granted reciprocity to providers licensed in other states during the public health emergency. Since DEA considers a provider to be practicing in the state in which their patient is located, this change may further improve the ability of providers to prescribe buprenorphine via telemedicine, particularly in rural areas and in smaller states.

Implementation of these changes has been uneven. Many states impose their own restrictions on methadone for OAT, and modifications to those restrictions are necessary to fully implement the modifications to federal law. For example, New York has implemented delivery of methadone to high-risk patients who are more than 50 years old who are permitted at least seven days of take-home doses, and Oregon has issued guidance for OTPs that closely mirrors that from SAMHSA. Virginia’s Medicaid program has provided guidance to OTPs that includes eliminating penalties for missed urine drug screens, and West Virginia has suspended counseling requirements for OTP patients during the COVID-19 emergency.

Federal flexibility regarding the use of telehealth seems to have been more widely implemented, likely due to the fact that telehealth for all fields of medicine has been expanded in the COVID-19 response. Many states have expanded their telehealth rules to include changes such as the approval of mental health providers’ use of telehealth, payment parity with in-person visits, and authorized use of audio-only communication if necessary. However, some continue to impose limitations that exceed those in federal law.

Organizations in several states have begun offering buprenorphine hotlines, whereby individuals who want to begin buprenorphine treatment can connect with a waivered provider over the phone. The provider then conducts an intake with the patient, prescribes buprenorphine if medically indicated, and schedules follow-up appointments. These programs can greatly reduce barriers to care for individuals who live in rural areas or who otherwise have difficulty accessing a waivered provider. However, they are typically limited to individuals in certain geographical areas; there is no nationwide hotline to initiate buprenorphine treatment.

In December 2020, Congress passed the Coronavirus Response and Relief Supplemental Appropriations Act. Unfortunately, the Act did not contain any significant legal or regulatory changes regarding access to OAT. Early drafts included language that would have eliminated the buprenorphine waiver requirement, which would likely have greatly expanded the availability of OAT and helped to ameliorate the racial and socioeconomic disparities plaguing
access to OAT. However, the final text of the bill did not include this language. Instead, the law provides $4.25 billion for SAMHSA to provide increased mental health and substance abuse services and support, including $1.65 billion in funds for Substance Abuse and Prevention Treatment Block Grants, among other general mental health services funding.

Despite the changes made in response to the COVID-19 crisis, overdose deaths continue to rise. Further, all these legal changes are in effect only during the COVID-19 emergency, and many require action on the part of states and other agencies to fully implement. Once the pandemic is resolved and the new coronavirus-related emergency declarations have expired, the older restrictions are set to resume. Such an outcome would be contrary to common sense and evidence-based practice and should not be permitted to occur. Both federal and state governments should make these legislative and regulatory changes permanent to remove barriers to evidence-based OUD treatment. Congress should also act to remove barriers to OAT, such as the requirement that providers who prescribe buprenorphine for OAT receive a “waiver” before doing so, that have not been waived during the COVID-19 outbreak, to increase access to care.

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**Recommendations for Action**

### Federal government:

- To remove barriers to buprenorphine, Congress should remove or modify the waiver requirement and allow prescribing without an initial in-person evaluation:
  - Amend 21 U.S.C. § 829(e) to permit clinicians to prescribe buprenorphine for OUD treatment without an initial in-person evaluation, including through audio-only interactions where necessary, greatly increasing access to OAT to those in rural areas or without transportation;
  - Amend 21 U.S.C. § 823(g)(2) to permit all prescribers registered with the DEA to prescribe buprenorphine for OUD treatment without first obtaining a “waiver;”
  - Amend 21 U.S.C. § 823(g)(2)(B)(iii) to remove or increase the cap on the number of patients a waivered provider may treat with buprenorphine.

- To remove barriers to all opioid agonist medications, the Secretary of Health and Human Services (HHS), should permit treatment to be initiated via telehealth, remove restrictions on who can receive treatment, permit the prescribing physician to determine methadone dosing, and permit methadone to be dispensed outside of OTP:
  - In coordination with the Attorney General, use the statutory authority provided by 21 U.S.C. § 54(D) to waive the Ryan Haight Act’s in-person examination requirement for the duration of the federally declared opioid emergency, greatly increasing access to OAT to those in rural areas or without transportation;
  - Remove restrictions on which patients may receive methadone for OUD by repealing 42 C.F.R. § 8.12(e);
  - Repeal the requirement in 42 C.F.R. § 8.12(f)(2) that a prospective OTP patient undergo a “complete, fully documented physical evaluation” before admission;
  - Repeal 42 C.F.R. § 8.12(h)(3)(ii) to remove initial dosing limitations on methadone treatment;
  - Modify 42 C.F.R. § 8.12(i) to liberalize limitations on take-home methadone dosing;
  - Modify 42 C.F.R. § 8.11(a)(1) to permit facilities such as pharmacies that do not meet all the requirements of 42 C.F.R. § 8.12 to dispense methadone for OUD treatment.

- The Attorney General should comply with the requirements of 21 U.S.C. § 831(h)(2) and promulgate regulations that permit all waivered clinicians to prescribe buprenorphine without conducting an in-person examination of the prospective patient.

- Federal agencies that provide funding to graduate medical education, particularly the Centers for Medicare
and Medicaid Services, should condition federal funding of residency programs on clinicians having received evidence-based instruction in OUD prevention, care, and treatment.

**State governments:**

- To remove barriers to opioid agonist treatment, legislators and regulatory agencies should remove restrictions on OTP siting, authorize provision of treatment via telehealth and implement a “hotline” for buprenorphine initiation, remove payment barriers to OAT, require newly licensed physicians to obtain a buprenorphine waiver, and require correctional facilities to offer OAT.
  - Remove restrictions on OTP siting and forbid localities from imposing same;
  - Authorize the provision of buprenorphine via telehealth where applicable;
  - Remove prior authorization and other payment barriers to OAT;
  - Ensure that state Medicaid programs cover methadone and buprenorphine as well as transportation to and from provider appointments;
  - Require state and local correctional facilities to screen for OUD and offer OAT as appropriate;
  - Require all newly licensed physicians to obtain a waiver to prescribe buprenorphine for OAT so long as the waiver requirement exists;
  - Legislators should reform criminal and child protection laws that serve as barriers to treatment access;
  - Regulatory agencies should enable individuals with OAT to access a waivered prescriber by calling a single, toll-free number.

**Local governments:**

- Local governments should remove legal and financial barriers to OTPs and other treatment programs.
  - Modify zoning and licensing laws that create barriers to the establishment of and access to methadone treatment facilities;
  - Fully fund prevention and treatment initiatives.
REFERENCES


CHAPTER 18 • ACCESS TO TREATMENT FOR INDIVIDUALS WITH OPIOID USE DISORDER

