

Access to Treatment for Individuals with Opioid Use Disorder

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SUMMARY. The United States is currently facing two severe public health emergencies: COVID-19 and the continuing epidemic of preventable opioid-related harm. While these epidemics share some similarities, there is one key difference: while there are currently no approved pharmaceutical treatments for the novel coronavirus, highly effective medications to treat opioid use disorder (OUD) have existed for decades. Despite their proven efficacy, access to these medications has long been limited by federal and state laws, limitations that disproportionately impact those who are made particularly vulnerable by structural factors including economic injustice and structural racism. In response to the COVID-19 epidemic, the U.S. Drug Enforcement Administration and other federal agencies have taken steps to temporarily remove some legal and regulatory barriers to these medications. These changes are not comprehensive, and most are tied to the COVID-19 public health emergency declaration. The epidemic of opioid-related harm will not end when the new coronavirus is controlled or the related emergency declaration expires. Indeed, it seems likely that steps taken to attempt to control the virus' spread may result in an even more unhealthy risk environment for people with OUD, with a resulting increase in treatment need. This Chapter briefly highlights the potential positive impact of increased access to OUD treatment, current changes to increase access to that treatment, and recommendations for making those changes permanent.

Introduction

Opioids, either alone or in combination with other substances, have killed over half a million Americans over the past 15 years – including nearly 48,000 in 2018 alone (Wilson et al., 2020). 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).

Federal and state laws, even those facially designed to provide support for individuals with OUD, often act as structural barriers to evidence-based prevention and treatment, and in many cases perpetuate and amplify stigma-driven responses to addiction and people with OUD. This is particularly true for individuals made vulnerable by economic deprivation, structural racism, and related social determinants of health. Outside of the criminal context, which systematically harms and disenfranchises already vulnerable individuals, the most poignant example of the negative impact of law on the health of people who use drugs (PWUD) is barriers to OUD treatment.

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), and the 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. Overdose rates appear to be increasing, likely due to

complications arising from the novel coronavirus and efforts taken to contain it. 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 may 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.

Legal Barriers to Opioid Use Disorder 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 a number of additional limitations when it is used for OUD treatment. These restrictions begin with limits on which patients may receive the medication. Instead of deferring to the expertise of the prescriber, as is done with nearly every other medication, federal law limits the pool of patients who may receive methadone for OAT. To be considered for treatment, most individuals must have been addicted to an opioid 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, federal law strictly regulates the provision of the medication itself. Unlike most drugs, which 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 their own prescribed medication are set not by the treatment team but by federal law. These restrictions persist despite little evidence they reduce harm, and some evidence that they increase it. For example, 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.

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 law 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). Localities often impose additional restrictions on OTPs, most notably through the use of zoning restrictions. 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 physicians and certain other 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. The non-physician prescribers who can become waived (not all may do so; that too is limited by federal law) must complete 24-hours of training. Federal law also limits the number of patients a waived provider may treat. Most providers are limited to 30 or 100 patients, although some may treat up to 275.

These limitations conspire to artificially reduce the number of providers who offer the medication, as well as the patients who can benefit from it. In 2016, fewer than 30,000 doctors were waived, leaving nearly half of America's 3,100 counties, including over 60% of rural counties, without a single physician authorized to prescribe the medication (Andrilla et al., 2017). They 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).

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 ("Controlled Substances Dispensed by Means of the Internet," 2020). 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 waived provider in person to begin therapy. This restriction falls 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, research shows that "diverted" buprenorphine has the same positive health impacts as buprenorphine that was prescribed to the individual using it. Studies evaluating 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 Made in Light of COVID-19

Several federal agencies have temporarily removed some barriers to the delivery of OAT during the COVID-19 pandemic. In the

methadone context, the Substance Abuse and Mental Health Services Administration (SAMHSA) issued guidance in late March 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 located 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. Due to other federal requirements, however, an individual must present in-person to an OTP to begin methadone treatment.

In the buprenorphine context, the HHS secretary, in coordination with the attorney general, have 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 an "audio-visual, real-time, two-way interactive communication system," DEA has recently used its enforcement discretion to authorize audio-only consultation as well (Prevoznik, 2020). This innovation is key, as it permits "tele-bupe" services whereby an individual with OUD can quickly and easily contact a waived physician who conducts a phone consultation and, where appropriate, prescribes buprenorphine and schedules appropriate follow-up.

Further, the HHS Office for Civil Rights, which enforces 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, in some circumstances, the requirement that a DEA-registered provider obtain a separate DEA registration in each state in which they practice. In states that have granted reciprocity to providers licensed in other states during the public

health emergency, DEA will permit them to do so without obtaining a separate DEA registration for that state. The Agency explicitly notes that this waiver applies to the practice of telemedicine with patients located in states where the prescriber is not DEA-registered. 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 over 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 on this modality that exceed those in federal law (Augenstein et al., 2020).

Organizations in several states have begun offering buprenorphine hotlines, whereby individuals who want to begin buprenorphine treatment can connect with a waived 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 waived provider. However, they are typically limited to individuals in certain geographical areas; there is no nationwide hotline to initiate buprenorphine treatment.

These modifications at the federal and state level likely will temporarily reduce the impact of the COVID-19 crisis on people with OUD and may help reduce some of the racial disparities exacerbated by both epidemics. However, all 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 policies will 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 legislative and regulatory changes that permanently remove barriers to evidence-based OUD treatment. Congress should also act to remove barriers to OAT treatment, 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. 🦠

Recommendations for Action

Federal government:

- Congress should:
 - o 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;
 - o 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;”
 - o Amend 21 U.S.C. § 823(g)(2)(B)(iii) to remove or increase the cap on the number of patients a waived provider may treat with buprenorphine.
- The Secretary of Health and Human Services (HHS), should:
 - o 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;
 - o Remove restrictions on which patients may receive methadone for OUD by repealing 42 C.F.R. § 8.12(e);
 - o 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;
 - o Repeal 42 C.F.R. § 8.12(h)(3)(ii) to remove initial dosing limitations on methadone treatment;
 - o Modify 42 C.F.R. § 8.12(i) to liberalize limitations on take-home methadone dosing;
 - o 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 waived 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:

- Legislators and regulatory agencies should:
 - o Remove restrictions on OTP siting and forbid localities from imposing same;
 - o Authorize the provision of buprenorphine via telehealth where applicable;
 - o Remove prior authorization and other payment barriers to OAT;
 - o Require state and local correctional facilities to screen for OUD and offer OAT as appropriate;
 - o Require all newly licensed physicians to obtain a waiver to prescribe buprenorphine for OAT.
- 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 waived prescriber by calling a single, toll-free number.

Local governments:

- Local governments should
 - o Modify zoning and licensing laws that create barriers to the establishment of and access to methadone treatment facilities.
 - o Fully fund prevention and treatment initiatives.



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