Opioid Agonist Treatment (OAT)
The Gold Standard for Opioid Use Disorder Treatment

We are the Drug Policy Alliance.

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Opioid-Involved Overdose Deaths are at Crisis Levels and Continue to Rise

Overdose deaths involving opioids, like heroin and many prescription pain medications, have risen sharply over the past decades.[1] In 2019, nearly 60,000 people died of an opioid-involved overdose.[2] Overdose deaths during the COVID-19 pandemic have accelerated, leading to the highest number ever recorded in a 12-month period.[3] Federal and state policymakers must act now to increase access to lifesaving interventions, including opioid agonist treatment.

What is Opioid Agonist Treatment (OAT)?

Opioid Agonist Treatment (OAT) is the safest and most effective method for treating opioid use disorders.* OAT uses medications to activate the opioid receptors, preventing withdrawal and reduce cravings for opioids like heroin and prescription pain medications. Two opioid agonists are approved by the Food and Drug Administration for treating opioid use disorder – methadone and buprenorphine. Despite OAT's effectiveness, federal and state laws severely restrict access.

Methadone is a long-acting full opioid agonist, classified as a Schedule II controlled substance. Buprenorphine is a long-acting partial opioid agonist, meaning it does not activate opioid receptors as must as full agonists like methadone. Buprenorphine is classified as a Schedule III controlled substance. When used in proper doses, both methadone and buprenorphine block opioids like heroin from producing their effects, relieve withdrawal, and reduce opioid cravings.

What are the benefits of OAT?

A 2019 National Academy of Sciences consensus study stated, "The verdict is clear: effective agonist medication used for an indefinite period of time is the safest option for treating [opioid use disorder]."[4] Over five decades of research has consistently demonstrated that OAT reduces:

- Risk of death, including by fatal overdose;
- Use of opioids like heroin;
- Injection drug use;
- Risk of HIV and Hepatitis C transmission; and
- Involvement in the criminal legal system.[5]

OAT also leads to improvements in social functioning and quality of life.[6]

Opioid agonist treatment is estimated to reduce risk of death from all causes, including overdose, by half.[7]

How can people access OAT?

OAT is strictly regulated by federal and state laws. Buprenorphine and methadone are regulated differently. Methadone is only available through Drug Enforcement Administration-registered and Substance Abuse and Mental Health Services Administration (SAMHSA)-approved opioid treatment programs (OTPs).[8] Treatment at OTPs is highly restrictive, requiring, among other things, that patients demonstrate a minimum of one year of addiction to opioids, complete a full medical evaluation prior to treatment, travel daily to receive medication, and submit to frequent drug tests.[9]

Patients may access buprenorphine through an OTP or through a medical provider who has obtained special approval to prescribe buprenorphine outside of an OTP (known as an "X waiver"). To obtain an X waiver, physicians must either have certification in addiction medicine or complete an 8-hour course, while

* Although long-acting injectable naltrexone (i.e., Vivitrol) is often discussed with OAT, it is not an opioid agonist. It is an opioid antagonist, meaning it blocks opioids from producing their effects. Long-acting injectable naltrexone does not have the same robust evidence of effectiveness as OAT.

other practicitioners† must complete a 24-hour course.[10] Federal law also limits the number of patients a clinician may prescribe buprenorphine to at one time: most are only authorized to prescribe to a maximum of 30 patients.[11]

What are barriers to accessing OAT?

Federal laws severely limit access to OAT, particularly methadone. Requirements to travel daily to an OTP to receive methadone prevent many people in need from receiving treatment due to time, cost, and interference with other obligations, including work and child care.[12] This is particularly problematic for those in rural areas where OTPs are scarce. For example, as of January 2021, there are no OTPs in Wyoming and only one in South Dakota.[13] Patients can only "earn" take-home medication privileges after at least three months of daily attendance, and even then, it remains restrictive.[14] Even though federal OTP regulations are stringent, many states further restrict access with additional legal limitations.[15]

Buprenorphine can be prescribed by X waivered providers outside of an OTP, but there is still a dire shortage of these providers. A 2018 survey found that 40 percent of U.S. counties do not have a single X waivered provider, and two-thirds of counties had low or no provider capacity.[16] Further, most X waivered providers are only permitted to prescribe to 30 patients.[17] The Government Accountability Office found that regulatory restrictions on X waivered providers like patient limits and stigma related to OAT contribute to provider shortages.[18]

Private and public health insurance restrictions also hinder OAT access. These include prior authorization requirements, which force patients and providers to obtain approval from the insurance company before treatment will be covered, "fail first" requirements that mandate patients to try alternative medications or non-medication treatments before OAT is covered, minimum counseling requirements, and lifetime or annual limits on amounts of medications.[19] Even though prior authorizations delay access to treatment and result in patients falling out of care, over half of the state Medicaid plans require prior authorization for at least one form of OAT.[20] Many require the patient to comply with minimum counseling requirements despite evidence showing that OAT is equally effective with or without counseling.[21]

Racial disparities also impact OAT access. White people are significantly more likely to receive a buprenorphine prescription than people of color, due in part to many providers only accepting private insurance or cash.[22] A shortage of providers of color with X waivers also contributes to these disparities.[23]

Recommendations to increase OAT access

Policymakers must prioritize the following actions to increase OAT access.

Remove burdensome OTP restrictions

The federal government should amend statutes and regulations to allow for methadone access outside of OTPs and without the burden of daily attendance. Access would be significantly improved if providers could prescribe methadone in an office- or community-based setting and community pharmacies could dispense the medication. Community pharmacies are much more accessible than OTPs, especially in rural areas.[24] Eliminating OTP requirements would allow reduce transportation issues, improve patient choice in providers, and likely lead to increased insurance coverage for methadone. It would also help to reduce stigma associated with methadone by allowing integration into community healthcare.

Short of repealing the requirement to receive methadone through an OTP, the federal government could increase access to take-home medications, as it has temporarily done in response to the COVID-19 pandemic without issue.[25] It could also allow for patients to access methadone through a community pharmacy, even if still required to periodically attend an OTP for other services.

† Other practitioners include nurse practitioners, physician assistants, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwifes.

States should also repeal any laws that impose more stringent burdens than required by federal law. States could enact laws that tie their OTP standards to federal law and require consistent review to ensure compliance with changes to federal law.

Repeal the X waiver requirement

The X waiver is an unnecessary burden for providers that stigmatizes buprenorphine and limits the number of providers able to prescribe the medication. No other health condition is subject to patient limits, and no other medication requires a special waiver to prescribe. Both SAMHSA and the Government Accountability Office have stated that the X waiver structure has contributed to low numbers of providers able to prescribe buprenorphine.[26]

Congress should repeal the X waiver requirement, allowing all otherwise qualified providers to prescribe buprenorphine without a patient cap.[27] The Department of Health and Human Services and the Drug Enforcement Administration (DEA) can and should take regulatory action to create exemptions to the X waiver requirement and eliminate (or at least increase) patient caps. This will help reduce stigma and increase access to providers.

States can also remove any barriers to buprenorphine access in state law, including ensuring prescribing power is within the scope of practice of nurse practitioners, physician assistants, and other qualified providers.

Even if the X waiver requirement is repealed or reformed, education and outreach to providers should continue in an effort to increase the number of providers actually prescribing and pharmacies distributing buprenorphine.

Increase OAT access points

Removing requirements to access OAT through OTPs would open more avenues for OAT access, but policymakers can and should do more to increase OAT access points. Emergency departments should initiate OAT services for people who want it and connect them with ongoing OAT services.‡ Massachusetts law requires emergency departments to have the capacity to initiate OAT and connect to ongoing services for patients who experience an opioid-related overdose.[28] Both California and New York have invested in programs to provide training and technical assistance to make buprenorphine accessible in emergency departments across the states.[29]

OAT should also be readily available in jails and prisons. Research demonstrates that providing OAT during incarceration improves health and criminal legal system outcomes.[30] Currently, only a handful of jails and prisons across the country allow access to OAT, even for people who had been accessing OAT prior to incarceration. A model program in Rhode Island provides OAT access in the state's unified jail and prison system and has been credited with dramatically reducing overdose deaths after release.[31] Federal, state, and local governments should ensure access to OAT for people in jails and prisons.

OAT should be available through mobile services. This will help alleviate transportation barriers and increase reach in rural areas. However, only 19 mobile methadone sites currently operate in the entire country due to DEA restrictions.[32] The DEA should revise regulations to facilitate additional mobile OAT access. Federal, state, and local governments should fund mobile OAT access and remove regulatory barriers.

Telehealth is an important way to increase OAT access, but legal barriers persist. Generally, providers cannot prescribe OAT to new patients until they conduct an in-person examination.[33] During the COVID-19 pandemic, providers may prescribe buprenorphine to new patients following an evaluation over the telephone, without completing an in-person examination.[34] The Rhode Island Department of Health responded by establishing a statewide buprenorphine hotline, where people can call to be connected to a provider who can perform a

‡ Providers in emergency departments have the capability to administer OAT for 72 hours without being registered as an OTP or having an X waiver. 21 C.F.R. § 1306.07(b).

telephonic assessment.[35] Access to buprenorphine via telephonic assessment should continue beyond the COVID-19 pandemic. Federal agencies, including SAMHSA and the DEA, should permit providers to prescribe methadone after an evaluation via telehealth, including by telephone. States should remove any regulatory barriers to OAT via telehealth to accommodate federal changes, and they should ensure adequate reimbursement for telehealth services through Medicaid programs.

Remove Health Insurance Barriers to OAT

A 2020 expert consensus report recommended that "states should remove prior authorization for all Food and Drug Administration-approved medications to treat opioid use disorder… [and] restrictions such as concurrent psychosocial therapy, step therapy, or lifetime limits."[36] The American Medical Association calls for the elimination of prior authorization requirements, and some major insurers have announced plans to eliminate prior authorization requirements for OAT.[37]

Seven states currently prohibit public and/or private insurance from imposing prior authorizations for at least some forms of OAT.[38] More states should follow suit and prohibit prior authorizations as well as other barriers like counseling requirements, step therapy, and lifetime limits, in public and private insurance.

Conclusion

Sweeping actions are needed to address the major public health crisis of opioid-involved overdose deaths. Without prompt action, hundreds of thousands of people will continue to die from opioid-involved overdoses. Policymakers must increase access to lifesaving OAT now.

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