

Increasing Access to Medications for Opioid Use Disorder: Policy Strategies During and After COVID-19 Pandemic

By Caroline M. Au-Yeung, Lynn A. Blewett, and Tyler N.A. Winkelman

Policy Points

- Policymakers should make permanent important policy changes put in place during the COVID-19 pandemic that have improved access to medications for opioid use disorder
- Policymakers should maintain COVID-19 policies that have increased access to medication for opioid use disorder by addressing service delivery, medication-prescribing authority, dispensing rules, prescriptions and refill parameters, and more

ABSTRACT

A number of federal and state policy changes have been put in place during the COVID-19 pandemic to improve access to medications for opioid use disorder (MOUD), including methadone, buprenorphine, and naltrexone. In this brief, we explore these policy changes and recommend that policymakers keep particular changes in place beyond the emergency period. Specifically, policymakers should make permanent (1) federal policies allowing buprenorphine initiation via telemedicine and state policies lifting buprenorphine prescribing restrictions that go beyond federal requirements; (2) federal policies allowing opioid treatment programs to dispense more doses of methadone and state policies lifting methadone dispensing restrictions; and (3) the prohibition of Medicaid prior authorization requirements for MOUD.

INTRODUCTION

Evidence indicates that opioid use disorders (OUDs), overdoses, and overdose deaths escalated as a result of COVID-19-related isolation and economic anxiety; opioid overdose deaths in particular reached record levels in 2020.¹⁻³ At the same time, medications for opioid use disorder (MOUD)—traditionally administered in person through frequent visits (as many as six per week) in clinical settings—became challenging to access during the pandemic because high-frequency clinic visits put patients at increased risk of COVID-19.

MOUD—sometimes referred to as medication—assisted treatment, or MAT—is the use of medications to treat OUD, reduce opioid use, and lower the risk of overdose mortality.⁴ Frequently coupled with counseling and behavioral therapies, MOUD is the most effective OUD treatment and the standard of care for OUD.⁵

The US Food and Drug Administration has approved three drugs to treat OUD: methadone, buprenorphine, and naltrexone. Methadone and buprenorphine are opioids that reduce withdrawal symptoms and cravings while blocking other opioids, like heroin, that can cause overdose. Naltrexone is a nonopioid antagonist that blocks opioids and reduces cravings but cannot treat withdrawal symptoms.⁶

Even in the year prior to the pandemic, less than 20% of people with OUD received MOUD, despite research showing that medications used to treat OUD are effective. To make MOUD more accessible during the COVID-19 pandemic, federal and state policymakers implemented a number of changes to address long-standing legal and regulatory barriers to obtaining MOUD.

MOUD LAWS AND REGULATIONS: BEFORE AND AFTER COVID-19

Service Delivery

Under federal regulations, the initiation of methadone treatment for OUD must take place in a specially licensed clinic called an opioid treatment program (OTP), while buprenorphine and naltrexone can be initiated in a qualified provider's office or an OTP.8 In either case, the federal Ryan Haight Act of 2008 requires an in-person medical examination before medication therapy can begin.9 Some states exceed these federal requirements and specify a required schedule of subsequent visits as well. In Tennessee, for example, patients must attend weekly office visits during the induction phase of buprenorphine (although these visits are not required to be in person), with additional office visits at two- to four-week intervals for the first year of treatment. 10,11

Federal regulatory agencies have made a number of changes to facilitate the delivery of MOUD via telemedicine during the COVID-19 emergency in order to prevent the spread of the virus. Most notably, the Drug Enforcement Agency (DEA) and the Substance Abuse and Mental

Health Services Administration (SAMHSA) waived the requirement for an in-person examination for individuals who are beginning buprenorphine if an evaluation can be reasonably conducted via telemedicine, including by telephone. 12 Methadone still cannot be initiated via telemedicine, but subsequent methadone appointments for established patients can be conducted through telemedicine. 13 Some states, such as Indiana and Ohio, that have their own laws in place prohibiting or restricting the prescribing of controlled substances (including buprenorphine) via telemedicine, announced public health emergency exceptions to these state-level rules as well. 14,15 Other states, such as Tennessee, have gone a step further, stating that clinicians are "expected" to conduct buprenorphine assessments and follow-ups via telehealth during the public health emergency. 16

Federal COVID-19-related telemedicine guidance for MOUD does not address the delivery of accompanying counseling services. However, individual states have issued guidance permitting the use of telemedicine to deliver counseling by OTPs. Pennsylvania issued a statement declaring that OTP substance use disorder (SUD) counselors may provide counseling services through telehealth, including via telephone. To Similarly, New Jersey's Department of Mental Health and Addiction Services announced that OTP counseling should be curtailed or provided through telehealth, although telephonic delivery was not addressed.

Prescribing

Under federal law, naltrexone can be prescribed by any licensed health care provider with prescribing authority, but the prescribing rules are stricter for methadone and buprenorphine, which are opioids and therefore controlled substances under the Controlled Substances Act of 2016: A physician must have a DEA registration in any state in which he or she dispenses methadone, and a physician or other qualifying practitioner must receive a DEA waiver (known as an "X waiver") to prescribe buprenorphine.¹⁹

While federal law allows qualified nurse practitioners (NPs) and physician assistants (PA) to receive an X waiver to prescribe buprenorphine, ²⁰ scope of practices laws in roughly half of states prohibit NPs from prescribing buprenorphine unless they are working in collaboration

with a waivered physician, and several states explicitly prohibit NPs from prescribing buprenorphine. One state, Kentucky, prohibits PAs from prescribing the drug as well.²¹

Federal prescribing authority for methadone remains unchanged under COVID-19, but the Department of Health and Human Services (HHS) issued new guidelines in April 2021 for the treatment of OUD with buprenorphine, such that eligible physicians and other qualifying practitioners are exempt from federal certification requirements related to training, counseling, and other ancillary services that are part of the process for obtaining a buprenorphine waiver and can treat up to 30 patients with buprenorphine under this exemption. ²² Clinicians must, however, pursue an X waiver under established protocols (i.e., with training) in order to treat more than 30 patients at a time. ²³

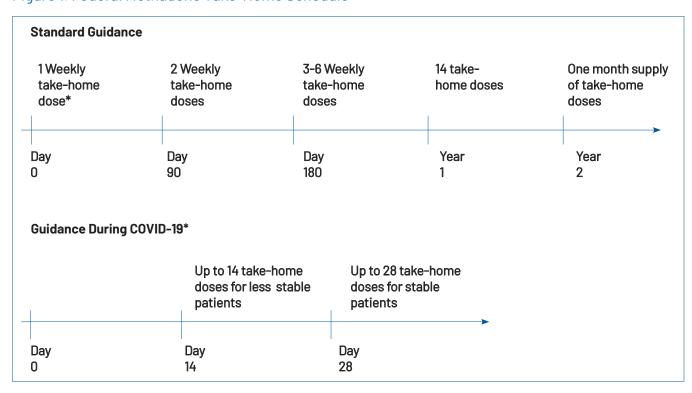
In addition to federal action to expand the number of X-waivered clinicians through training exemptions, some

states are encouraging clinicians to apply for an exempt X waiver to prescribe buprenorphine in order to enhance access to treatment during the pandemic. California, for example, is promoting the new exemption to qualified practitioners through its CA Bridge program.²⁴

Dispensing and Refills

Federal law specifies that methadone, when prescribed for OUD, can be dispensed only by an OTP and limits unsupervised, or "take-home," doses of methadone to reduce the risk of misuse and diversion. The federal take-home schedule for methadone permits OTP patients to receive one weekly take-home methadone dose for the first 90 days of treatment (in addition to take-home doses allowed during days of clinic closure). A patient may then take home two doses per week after 90 days in treatment, three doses per week after 180 days, a maximum of six doses for the remainder of the first year, a maximum of 14 doses during the second year, and a one-month maximum supply thereafter.

Figure 1. Federal Methadone Take-Home Schedule



^{*}Counts do not include any take-homes doses allowed during days of clinic closure.

Sources: Federal Opioid Treatment Standards, 42 CFR § 8.12 (2015). https://www.govregs.com/regulations/expand/title42_chapterl_part8_sub-partC_section8.12#title42_chapterl_part8_subpartC_section8.12. Accessed September 30, 2021; Substance Abuse and Mental Health Services Administration (SAMHSA). Opioid Treatment Program (OTP) Guidance. March 19, 2020. https://www.samhsa.gov/sites/default/files/otp-guidance-20200316.pdf. Accessed September 30, 2021.

Some states uphold stricter methadone take-home parameters than the federal schedule. Wisconsin allows no take-home methadone doses for the first 90 days of treatment except the single dose allowed each week for clinic closure. A patient may then take home one dose per week after 90 days in treatment, two doses after 180 days, a maximum of four doses during the remainder of the first year, a maximum of six doses after one year, and a 13-day maximum supply after two years. ²⁵

Unlike methadone, buprenorphine for MOUD can, under federal law, be provided through a range of non-OTP service settings, including outpatient clinics, treatment facilities, correctional facilities, and hospitals, all of which can dispense buprenorphine directly to patients or issue prescriptions to be filled by pharmacies—with most clinicians prescribing no more than a 30-day supply. Federal regulations stipulate that a prescription for buprenorphine cannot be refilled more than five times, or filled or refilled more than six months after the date on which the prescription was issued.¹⁹

States sometimes impose additional prescription limitations on buprenorphine. In Missouri, for example, midlevel practitioners may issue only a 30-day prescription of buprenorphine and cannot include refills on their prescriptions. In addition, the state limits all patients receiving MOUD to a 90-day supply.²⁶

In response to COVID-19, SAMHSA relaxed the standard federal take-home schedule for methadone in March 2020, informing states that OTPs may dispense up to 28 days of take-home methadone doses to any stable patients (a supply that would have previously required two years of OTP enrollment) and up to 14 days of take-home doses to any patients who are "less stable" but deemed by the OTP to be able to safely handle this number of take-home doses. ²⁷ Patients may also receive up to 14 take-home doses of methadone if they have lab-confirmed COVID-19. Further, states may choose to allow OTPs to deliver medications to quarantined or otherwise homebound patients who cannot travel, as Ohio and New York have done (Figure 1). ^{28,29}

Although methadone take-home restrictions have been loosened under COVID-19, federal refill restrictions affecting buprenorphine and naltrexone remain unchanged. Some states have, however, loosened their

own prescription refill and supply restrictions during the COVID-19 emergency. New Hampshire, for example, is allowing pharmacies to dispense refills of up to a 90-day supply of medication, including controlled substances such as buprenorphine, without the authorization of the prescribing provider.³⁰ Similarly, pharmacists in Nevada are authorized to issue emergency refills of up to a 30-day supply of a controlled substance when prescriber authorization cannot be obtained.³¹

Drug Screening

Federal law requires that patients receiving methadone or buprenorphine at an OTP complete a minimum of eight drug tests per year. SAMHSA believes that these toxicology tests are an important component in decision-making around take-home medication privileges, but cautions that treatment decisions should not be based solely on toxicology results.³²

Although more than half of states adhere to federal minimums for MOUD toxicology screening, some require more than eight drug tests annually. Most such states require 12 tests, but there are more stringent exceptions. Massachusetts, for example, requires a minimum of 15 tests per year, and Arkansas goes so far as to mandate weekly testing for the first three months of treatment, with patients graduating to a monthly testing schedule only after three months of tests showing no indication of drug abuse. 33,34

The DEA has not authorized a suspension of drug testing for OTP patients during the COVID-19 pandemic. Instead, practitioners must exercise clinical judgment to determine whether drug testing is indicated for a given individual, balancing this requirement against the risks of COVID-19. In many cases, providers did not administer tests during the early phase of the pandemic with the intent to administer required tests later in the year when revised care processes had been established. Indeed, the American Society of Addiction Medicine (ASAM) advises that "during a public health emergency, access to life-saving addiction treatment should not be conditional on urine drug testing," and "requiring patients to present to a health care facility to provide urine samples for urine drug testing may be more harmful than beneficial."23 Accordingly, ASAM suggests that OTPs in areas or settings where community spread of COVID-19 is occurring

consider pausing drug testing altogether, limiting drug testing in cases where testing is still warranted (e.g., patients with unstable OUD), and/or using alternative testing protocols (e.g., collecting specimens outside the treatment facility). 23

In a few cases, states have issued their own guidance regarding toxicology screening during the COVID-19 emergency. For example, Washington State Health Care Authority notified the state's Medicaid program that toxicology testing is not necessary to initiate or continue an individual on buprenorphine, and such testing should be a clinical decision "balancing unnecessary exposure for patients and providers with concerns about persistent use and diversion."

Counseling

Under federal law, OTPs must provide substance abuse counseling "as clinically necessary," although federal law does not dictate how often counseling must be delivered or the type of counseling that should be offered, and evidence that counseling requirements are efficacious is lacking.8 There are no federal counseling requirements for receiving MOUD outside of an OTP; however, it is recommended that office-based outpatient treatment providers establish linkages within their communities with relevant resources and/or medical subspecialties (e.g., behavioral health). ³⁶ ASAM guidance states that refusal to participate in counseling should not preclude or delay starting MOUD. ³⁷

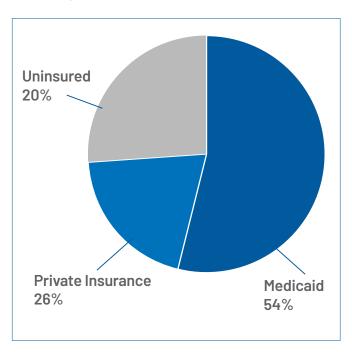
State requirements for counseling that accompanies MOUD may be more stringent than federal minimums. Utah exceeds federal requirements, specifying that patients in OTPs must participate in counseling for at least one hour per week for the first 90 days of treatment, for at least two hours per month for the subsequent six months, and once monthly thereafter. Indiana law goes one step further, not only specifying a counseling schedule but also stipulating that counseling sessions must include individual counseling in particular. The state of Virginia allows individual or group counseling but requires that these sessions be conducted in person.

The federal government has not made any COVID-19related modifications to its requirement that OTPs provide counseling in conjunction with MOUD. However, some states with their own counseling specifications have modified these rules due to the pandemic. California is allowing OTPs to make exceptions to the state's once-monthly counseling requirements as long as the OTP is complying with federal rules. 41 West Virginia suspended its counseling requirements altogether for the duration of the federal COVID-19 emergency declaration. 42

FEDERAL AND STATE MEDICAID POLICY AND MOUD ACCESS

In all, 54% of nonelderly adults treated for OUD in 2017 were covered by Medicaid (Figure 2), and Medicaid-insured nonelderly adults with OUD were more likely than those with other coverage to receive treatment during this time. 43 As the majority payer for OUD treatment, Medicaid has a significant role in determining access to MOUD through coverage and benefit design. The federal SUPPORT Act of 2018 leveraged the ability of the Medicaid program to improve MOUD

Figure 2. Insurance Status of Nonelderly Adults (18–64 Years) Treated for Opioid Use Disorder, 2017



Source: Kaiser Family Foundation analysis of 2017 National Survey on Drug Use and Health. From Orgera K, Tolbert J. The Opioid Epidemic and Medicaid's Role in Facilitating Access to Treatment. San Francisco, CA: Kaiser Family Foundation; 2019. https://files.kff.org/attachment/Issue-Brief-The-Opioid-Epidemic-and-Medicaids-Role-in-Facilitating-Access-to-Treatment.

access by requiring all state Medicaid programs to cover methadone, buprenorphine, and naltrexone, as well as adjunctive counseling services, effectively ensuring consistent coverage across the country. 44 However, the SUPPORT Act did leave open the question of utilization management policies—such as prior authorization rules—around MOUD, which can vary widely from state to state and which may make it more difficult for OUD patients to access these medications when they are ready to seek treatment. 45

Prior Authorization

A 2018 SAMHSA analysis noted that in some states, Medicaid-covered medications for OUD treatment-most commonly buprenorphine—require prior authorization from members' fee-for-service (FFS) pharmacy benefit plans, a process that can prevent timely access to treatment. 46 A subsequent 2019 Kaiser Family Foundation survey found that 21 states either had already relaxed or removed FFS prior authorization requirements to expand access to MOUD and/or planned to do so in fiscal year (FY) 2020.⁴⁷ However, Medicaid managed care plans (in contrast to FFS plans) are not required to adhere to prior authorization restrictions unless explicitly directed by regulation to do so. Accordingly, more than 40% of Medicaid managed care plans across the country required prior authorization in order to reimburse for methadone, buprenorphine, and naltrexone in 2018.48

Regardless of an emergency declaration, states have the flexibility to establish and manage pharmaceutical prior authorization processes without approval from Centers for Medicare and Medicaid Services. During an emergency, states can also temporarily suspend prior authorization requirements, extend prior authorizations through the emergency declaration period, and expedite prior authorizations by requiring flexibility in documentation (e.g., optional physician signatures). 49 Individual states have leveraged this flexibility to ensure access to prescription medications, including medications for OUD, among Medicaid beneficiaries during the pandemic. Ohio is one such state: its Medicaid program temporarily suspended all prior authorization requirements and extended all existing prior authorization approvals for six months from the renewal or expiration date. 50

Medicaid Coverage of Telehealth

During the COVID-19 emergency, all 50 states and the District of Columbia have modified their Medicaid policies regarding telehealth to allow for more virtual visits so that in-person interactions are minimized while maintaining access to care. 51 States are, variously, offering Medicaid reimbursement for telehealth services at the same payment rates as for in-person visits and extending telehealth policies to cover a wider array of providers than are usually covered by telehealth. North Carolina, for example, offers Medicaid reimbursement for counseling services provided by licensed clinical addiction specialists and peer counselors in conjunction with MOUD. 52 Additionally, as of July 2020, all 50 state Medicaid agencies issued guidance to expand "telehealth" to include some form of audio-only interactions so Medicaid can be used to cover telephonic visits. This is a critical benefit for many people with OUD (especially low-income individuals who are homeless or leaving incarceration) who do not have access to laptops and smartphones, and it enhances the already expanded accessibility of buprenorphine treatment in particular, as buprenorphine for OUD can be administered entirely by telehealth during the COVID-19 emergency. 51,53

CONCLUSION

A number of federal and state policy changes have been put in place to improve access to MOUD during the COVID-19 pandemic by modifying the treatment and reimbursement landscape (Table 1). These changes have addressed service delivery, medication-prescribing authority, dispensing rules, prescriptions and refill parameters, counseling requirements, and drug-screening rules. The number and speed of these changes is unprecedented.

The need to expand access to MOUD will not end with the COVID-19 emergency, as the number of individuals in need of treatment far exceeds the capacity of MOUD providers and facilities. Some of the policy changes that have made MOUD more accessible during the pandemic have already been made permanent at the state level (e.g., expanding the definition of "telehealth"). The continuation of other changes will require ongoing support from state and national policymakers. We recommend

continued efforts around three regulatory strategies in particular:

- Moving forward, national and state policymakers should encourage the continuation of federal policies allowing buprenorphine initiation via telemedicine and the removal of state-level restrictions that go beyond federal requirements. This would promote equity for individuals with SUD living in areas with insufficient numbers of waivered providers as well as for individuals facing transportation barriers and other obstacles to receiving treatment in person.
- 2. National and state policymakers should also promote the continuation of federal policies allowing OTPs to dispense more doses of methadone and the removal of any additional state-level methadone dispensing restrictions that exist. Allowing patients to take home more doses reduces the burden on them to

- travel to and spend time at the OTP in order to maintain treatment. OTP experiences during the pandemic indicate that allowing patients to have more take-home doses has gone well, with few diversion and overdose problems. 54,55
- Policymakers should work to prohibit Medicaid prior authorization requirements for MOUD and to make permanent any temporary suspensions of prior authorization requirements for these medications that were implemented during the COVID-19 emergency.

Although there are other policy avenues for expanding access to MOUD, these three areas are particularly relevant for reducing logistical barriers to treatment. Evidence and testimony from providers and patients indicates that these mechanisms have been safe and effective during the COVID-19 pandemic and that continuing them beyond the pandemic period is warranted.

Table 1. Accessing Medications

Accessing Medications for Opioid Use Disorder (MOUD) During the COVID-19 Pandemic: Policy Solutions

Service Delivery

- Federal in-person exam requirement for buprenorphine has been removed.
- · An in-person exam is still required for methadone initiation, but subsequent visits can be conducted via telemedicine.
- Some states (e.g., Indiana, Ohio, and Tennessee) have loosened their own restrictions on prescribing controlled substances via telemedicine and/or are requiring clinicians to conduct buprenorphine assessments via telehealth.
- Individual states (e.g., Pennsylvania and New Jersey) have issued guidance permitting the use of telemedicine to deliver counseling by OTPs or allowing OTPs to curtail counseling.

Prescribing Rules

• The US Department of Health and Human Services issued new guidelines in April 2021 exempting eligible physicians and other qualified practitioners from federal training requirements to obtain an X waiver to treat up to 30 patients at a time with buprenorphine.

Dispensing and Refill Rules

- The Substance Abuse and Mental Health Services Administration (SAMHSA) relaxed the standard federal take-home schedule for methadone in March 2020.
- Some states (e.g., Ohio and New York) have chosen to allow OTPs to deliver medications to quarantined or otherwise homebound patients who cannot travel.
- Some states (e.g., New Hampshire and Nevada) have loosened their own prescription refill and supply restrictions during the COVID-19 emergency.

Drug-Testing Requirements

- Practitioners must exercise clinical judgment to determine whether drug testing is indicated for a given individual, balancing the requirement of a minimum of eight tests a year against the risks of COVID-19.
- The American Society for Addiction Medicine suggests that OTPs in areas or settings where community spread of COVID-19 is occurring consider pausing drug testing altogether, limiting drug testing in cases where testing is still warranted (e.g., patients with unstable OUD), and/or using alternative testing protocols (e.g., collecting specimens outside the treatment facility).
- Some states (e.g., Washington) have issued their own quidance regarding toxicology screening during the COVID-19 emergency.

Counseling Requirements

• Some states have modified their own counseling rules due to the pandemic, with some states (e.g., California) allowing OTPs to make exceptions to state requirements as long as federal requirements are met; and others (e.g., West Virginia) suspending their counseling requirements altogether.

Medicaid Prior Authorization Rules

• Individual states (e.g., Ohio) have leveraged their authority to temporarily suspend prior authorization requirements, extend prior authorizations through the emergency declaration period, and expedite prior authorizations by requiring flexibility in documentation.

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ABOUT THE AUTHORS

Caroline Au-Yeung, MPH, is a research fellow at the State Health Access Data Assistance Center (SHADAC) in the University of Minnesota School of Public Health and specializes in qualitative evaluations. She was part of a team that conducted Medicaid eligibility, enrollment, and renewal case studies for the Medicaid and CHIP Payment and Access Commissions (MACPAC). Ms. Au-Yeung also co-led an analysis of Minnesota's Accountable Communities for Health, each of which aimed to meet the clinical and social needs of a defined population through person-centered, coordinated care across a range of medical and community providers. Most recently, Ms. Au-Yeung supported an evaluation of the Rural Health Network Development program, a Health Resources and Services Administration initiative that aims to support integrated rural health care networks with an emphasis on social determinants of health. She holds a bachelor's degree in English from Macalester College and a Master of Public Health from the University of Minnesota.

Lynn A. Blewett, PhD, MPA, is a professor in the Division of Health Policy and Management at the University of Minnesota School of Public Health, where she teaches graduate courses on the US health care system and international health systems. In addition to being the founding director of the State Health Access Data Assistance Center (SHADAC), Dr. Blewett has served as chair of the National Center for Health Statistics (NCHS) Scientific Advisory Board and as a member of the National Committee on Vital and Health Statistics (NCVHS). Dr. Blewett has a committed history leading applied policy research, analyzing state and federal data resources, and translating research to inform health policy, access to care, Medicaid coverage, and payment policy at both state and national levels. Dr. Blewett holds a PhD in Health Services Research, Policy and Administration and a Master of Public Affairs from the University of Minnesota.

Tyler Winkelman, MD, MSc, is an internist, pediatrician, and health services researcher at Hennepin Healthcare in Minneapolis; an assistant professor in the Departments of Internal Medicine and Pediatrics at the University of Minnesota; and a staff physician at the Hennepin County jail. He is also the codirector of the Health, Homelessness, and Criminal Justice Lab and associate director of the Virtual Data Warehouse at Hennepin Healthcare Research Institute. Dr. Winkelman completed his medical school and internal medicine/pediatrics residency training at the University of Minnesota Medical School. He obtained a master's degree in health and health care research at the University of Michigan through the Robert Wood Johnson Foundation Clinical Scholars Program.

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