



Improving Access to Medications for Opioid Use Disorder: Lessons from the COVID-19 Pandemic

By Stacey McKenna

Decreasing regulations would allow for the development and implementation of innovative, community-based programs that would support patient safety, autonomy and well-being.

Executive Summary

Opioid use disorder (OUD) affects millions of people in the United States, and more than 200 people died each day of an opioid-involved overdose in 2021. Medication for opioid use disorder (MOUD) is an evidence-based approach that can cut the risk of overdose in half and improve a range of health and social outcomes. Nonetheless, a minority of those living with OUD are engaged in MOUD-based recovery. A diverse swathe of experts—including scholars, on-the-ground harm reductionists and treatment providers—agree that one of the most important barriers to accessing MOUD is overly restrictive policy. Indeed, the two most effective and widely used MOUDs (methadone and buprenorphine) are controlled substances and, as such, are subject to tight, multiagency restrictions that affect who can prescribe them, how they may be dispensed, and the conditions around patient possession and consumption.

Beginning in March 2020, the unique context of the COVID-19 pandemic led government agencies to relax some of these restrictions with the aim of ensuring that MOUD would remain accessible. This study reviews the pre- and post-COVID MOUD policy environments and synthesizes the literature on health and social outcomes to identify key ways in which these changes affected MOUD access and use, as well as patient treatment experiences.

Table of Contents

Executive Summary	1
Introduction	2
Background: Harm Reduction and MOUD	3
MOUD and Policy	5
MOUD Policy and Access Before COVID-19	5
Pandemic-Era Policy Changes	8
Health and Safety Outcomes of COVID-19-Related Policy Changes	9
MOUD-Involved Overdose	9
Treatment Success	11
Policy Takeaways	13
Conclusion	15
About the Author	15

Our research indicates that the MOUD policy changes, while not uniformly applied, had net positive effects. Although the inconsistent adoption of the policy changes and the complexity of COVID-19-era circumstances made it difficult to assess population-level impacts, the key health and safety outcomes among patients who received buprenorphine via telehealth or increased take-home doses of methadone were that: (1) MOUD-involved overdoses did not significantly increase and (2) treatment outcomes and patient acceptance remained on par with or superior to pre-pandemic baselines. As such, while individual experiences with and preferences for specific pandemic-era protocols varied, patients and providers were generally supportive of continuing with the relaxed restrictions.

Despite these successes, our research indicates that the rule changes were not sufficient to close gaps in MOUD treatment. In particular, several persistent structural and sociocultural barriers require attention to maximize the benefits of relaxed regulation. Stigma; economic and geographic disparities in access to digital technology; and complicated payment and reimbursement systems all contributed to inequities in MOUD access and outcomes, even in a more permissive policy environment. Based on these findings, we recommend extending and expanding upon the COVID-era changes, and we call on states to recognize and follow the evidence-based loosening of regulations with the understanding that continued work will be necessary to address additional barriers to equitable access.

Introduction

In 2021, a record 107,622 people in the United States died of a drug overdose; three-quarters of those deaths—80,816, or more than 200 per day—involved an opioid.¹ Unfortunately, there is no silver bullet to combat these deaths. History has taught us that abstinence is not achievable on a population level and leaves many people behind.² Harm reduction, on the other hand, meets people where they are and provides a diverse set of resources that empower them to make healthier, often life-saving choices.³

Thus, in the United States—where an estimated 2.7 million to 7.6 million people are living with an OUD—harm reduction has the potential to save tens of thousands of lives and improve far more.⁴ Like increasingly familiar resources such as fentanyl test strips and the overdose reversal drug naloxone, MOUD dramatically reduces overdose risk and improves other health and social outcomes.⁵ And although MOUD

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1. National Center for Health Statistics, "U.S. Overdose Deaths In 2021 Increased Half as Much as in 2020 – But Are Still Up 15%," Centers for Disease Control and Prevention, May 11, 2022. https://www.cdc.gov/nchs/pressroom/nchs_press_releases/2022/202205.htm.
2. Susan E. Collins, "Sobriety is just one pathway to recovery. Harm reduction is another," *STAT*, April 11, 2019. <https://www.statnews.com/2019/04/11/harm-reduction-substance-use-disorder>; Scott O. Lilienfeld and Hal Arkowitz, "Why 'Just Say No' Doesn't Work," *Scientific American*, Jan. 1, 2014. <https://www.scientificamerican.com/article/why-just-say-no-doesnt-work>.
3. Substance Abuse and Mental Health Services Administration, "Harm Reduction," U.S. Department of Health & Human Services, Aug. 16, 2022. <https://www.samhsa.gov/find-help/harm-reduction>.
4. "Opioid Use Disorder," Centers for Disease Control and Prevention, Aug. 30, 2022. <https://www.cdc.gov/dotw/opioid-use-disorder/index.html#:~:text=About%202.7%20million%20people%20in%20the%20United%20States%20report%20suffering%20from%20OUD>; Noa Krawczyk et al., "Has the treatment gap for opioid use disorder narrowed in the U.S.? A yearly assessment from 2010 to 2019," *International Journal of Drug Policy* 110 (December 2022). <https://www.sciencedirect.com/science/article/pii/S0955395922002031>.
5. "Detecting Fentanyl. Saving Lives.," Johns Hopkins Bloomberg School of Public Health, last accessed March 15, 2023. <https://americanhealth.jhu.edu/fentanyl/>; "Lifesaving Naloxone," Centers for Disease Control and Prevention, Jan. 25, 2023. <https://www.cdc.gov/stopoverdose/naloxone/index.html#:~:text=Naloxone%20is%20a%20life%20saving,medications%E2%80%9494when%20given%20in%20time.&text=Naloxone%20is%20easy%20to%20use%20and%20small%20to%20carry>; National Institute on Drug Abuse, "Medications to Treat Opioid Use Disorder Research Report: How effective are medications to treat opioid use disorder?," National Institutes of Health, December 2021. <https://nida.nih.gov/publications/research-reports/medications-to-treat-opioid-addiction/efficacy-medications-opioid-use-disorder>.

does represent a form of “recovery” or “treatment,” it is firmly rooted in a harm reduction ethos.⁶ However, despite the approach’s established efficacy, only 13 to 27 percent of those living with OUD are receiving MOUD.⁷

Research suggests that a number of intersecting factors—including stigma, cost, policy and insufficient addiction education among providers—contribute to the relatively poor uptake of MOUD.⁸ Chief among them, experts posit, are overly restrictive federal policies that both reduce clinicians’ provision of this evidence-based care and make it logistically difficult for individuals to access.⁹ The COVID-19 pandemic provided an unusual opportunity to home in on the potential impact of relaxed regulations on the two most effective and frequently used MOUD drugs: methadone and buprenorphine.¹⁰

When the COVID-19 pandemic disrupted health care delivery, it led the U.S. federal government to loosen restrictions and make buprenorphine and methadone more accessible. This policy paper synthesizes lessons learned from several of these COVID-era changes and highlights implications for future policy efforts. The following pages:

- Provide a brief overview of MOUD in the United States
- Review the safety and efficacy of buprenorphine and methadone
- Describe pre- and during-COVID regulations
- Explain key health and safety outcomes associated with the COVID-era changes
- Outline several takeaways for policymakers

Background: Harm Reduction and MOUD

The persistent tragedy of the ongoing overdose crisis in the United States has brought considerable attention to harm reduction, a pragmatic approach that empowers people who use drugs to stay alive and protect their health, even if they are not ready, willing or able to stop using substances.¹¹ The U.S. harm reduction movement began in the 1980s in response to the HIV epidemic, and contemporary conversations often focus on reducing infectious disease transmission through the provision of sterile injection equipment and preventing overdose death by distributing fentanyl test strips or naloxone, a medication that reverses overdoses.¹²



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6. National Institute on Drug Abuse. <https://nida.nih.gov/publications/research-reports/medications-to-treat-opioid-addiction/efficacy-medications-opioid-use-disorder>.
7. “Opioid Use Disorder.” <https://www.cdc.gov/dotw/opioid-use-disorder/index.html#:~:text=About%202.7%20million%20people%20in%20the%20United%20States%20report%20suffering%20from%20OUD;Krawczyk%20et%20al.%20https://www.sciencedirect.com/science/article/pii/S0955395922002031>.
8. Bertha K. Madras et al., “Improving Access to Evidence-Based Medical Treatment for Opioid Use Disorder: Strategies to Address Key Barriers Within the Treatment System,” National Academy of Medicine, April 27, 2020. <https://nam.edu/improving-access-to-evidence-based-medical-treatment-for-opioid-use-disorder-strategies-to-address-key-barriers-within-the-treatment-system>.
9. Jeffrey A. Singer, “If SAMHSA Seriously Wants to Destigmatize People with Substance Use Disorder, It Can Start by Destigmatizing How They Receive Treatment,” Cato Institute, Jan. 23, 2023. <https://www.cato.org/blog/samhsa-seriously-wants-destigmatize-people-substance-use-disorder-it-can-start-destigmatizing>; Zoe Adams, “Doctors, Not Dealers,” *Guernica*, Feb. 27, 2023. <https://www.guernicamag.com/doctors-not-dealers>.
10. Substance Abuse and Mental Health Services Administration, “Methadone Take-Home Flexibilities Extension Guidance,” U.S. Department of Health & Human Services, Jan. 25, 2023. <https://www.samhsa.gov/medications-substance-use-disorders/statutes-regulations-guidelines/methadone-guidance#:~:text=On%20March%2016%2C%202020%2C%20SAMHSA,14%20days%20of%20Take%2DHome;FAQs:Provision%20of%20methadone%20and%20buprenorphine%20for%20the%20treatment%20of%20opioid%20use%20disorder%20in%20the%20COVID-19%20emergency;Substance%20Abuse%20and%20Mental%20Health%20Services%20Administration,2020>. <https://www.samhsa.gov/sites/default/files/faqs-for-oud-prescribing-and-dispensing.pdf>.
11. Joseph P. Williams, “A Fight to Do No Harm,” *U.S. News & World Report*, Jan. 24, 2019. <https://www.usnews.com/news/healthiest-communities/articles/2019-01-24/opioid-crisis-harm-reduction-struggles-for-acceptance-in-us>; “Principles of Harm Reduction,” National Harm Reduction Coalition, last accessed March 15, 2023. <https://harmreduction.org/about-us/principles-of-harm-reduction>.
12. Don C. Des Jarlais, “Harm reduction in the USA: the research perspective and an archive to David Purchase,” *Harm Reduction Journal* 14:51 (July 26, 2017). <https://link.springer.com/article/10.1186/s12954-017-0178-6>.

However, before syringe service programs and overdose prevention centers, some doctors were practicing harm reduction-based treatment as early as the 1960s in the form of methadone maintenance.¹³ By providing legal, regulated, but still opioid-based medications, doctors gave patients suffering from OUD a way to avoid cravings and withdrawal symptoms, thus facilitating their efforts to reduce or cease their use of illicit opioids.¹⁴ Nearly 60 years later, this harm-reduction-based approach remains an important but underused tool for improving the health and lives of people with OUD.

Three medications are currently approved for MOUD by the United States Food and Drug Administration (FDA): methadone, buprenorphine and naltrexone. All three drugs bind to opioid receptors in the brain, but each behaves slightly differently and has consequent strengths and weaknesses.¹⁵

Methadone is a long-acting opioid agonist that attaches to and activates opioid receptors in the brain. This activation makes it an effective therapy for pain, but it can also cause euphoria and respiratory depression, although—when taken as prescribed for OUD—these effects are much less pronounced than those of heroin or fentanyl.¹⁶ Buprenorphine is a partial agonist, which also binds to opioid receptors in the brain, but produces less activation than methadone and therefore even less of a “high.”¹⁷ Both methadone and buprenorphine work by curbing cravings and mitigating or stopping withdrawal symptoms. As such, compared to individuals not receiving treatment or those receiving medication-free treatment for OUD, people who take methadone or buprenorphine are less likely to use illicit opioids and have a substantially diminished risk of overdose. In addition, these MOUDs are associated with lower mortality, improved overall health and fewer interactions with law enforcement.¹⁸

Naltrexone, on the other hand, is an opioid antagonist that blocks opioid receptors in the brain and, rather than suppressing withdrawal symptoms, prevents opioids from producing euphoric effects.¹⁹ Some evidence suggests that once people are successfully inducted, long-acting injectable naltrexone can have similar benefits to methadone and buprenorphine.²⁰ However, given the small body of currently available evidence supporting its use, the need for an initial detoxification from opioids (which frequently fails), high rates of early relapse and an elevated risk



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A long-acting opioid agonist that attaches to and activates opioid receptors in the brain

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Naltrexone

An opioid antagonist that blocks opioid receptors in the brain and, rather than suppressing withdrawal symptoms, prevents opioids from producing euphoric effects

13. H. Joseph et al., “Methadone maintenance treatment (MMT): a review of historical and clinical issues,” *Mount Sinai Journal of Medicine* 67:5-6 (October-November 2000), pp. 347-364. <https://pubmed.ncbi.nlm.nih.gov/11064485>.

14. Ibid.

15. National Institute on Drug Abuse, “How do medications to treat opioid use disorder work?” National Institutes of Health, December 2021. <https://nida.nih.gov/publications/research-reports/medications-to-treat-opioid-addiction/how-do-medications-to-treat-opioid-addiction-work>.

16. Ibid.

17. Ibid.

18. National Institute on Drug Abuse, “How effective are medications to treat opioid use disorder?” <https://nida.nih.gov/publications/research-reports/medications-to-treat-opioid-addiction/efficacy-medications-opioid-use-disorder>; Marguerite Burns et al., “Duration of medication treatment for opioid-use disorder and risk of overdose among Medicaid enrollees in 11 states: a retrospective cohort study,” *Addiction* 117:12 (December 2022), pp. 3079-3088. <https://onlinelibrary.wiley.com/doi/abs/10.1111/add.15959>; Navin Kumar et al., “The role of social network support in treatment outcomes for medication for opioid use disorder: A systematic review,” *Journal of Substance Abuse Treatment* 127 (August 2021). <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9022048/#:~:text=MOUD%20has%20shown%20several%20benefits,et%20al.%2C%202007>; Sarah E. Wakeman et al., “Comparative Effectiveness of Different Treatment Pathways for Opioid Use Disorder,” *JAMA Network Open* 3:2 (Feb. 5, 2020). <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2760032>.

19. National Institute on Drug Abuse, “How do medications to treat opioid use disorder work?” <https://nida.nih.gov/publications/research-reports/medications-to-treat-opioid-addiction/how-do-medications-to-treat-opioid-addiction-work>.

20. National Institute on Drug Abuse, “How effective are medications to treat opioid use disorder?” <https://nida.nih.gov/publications/research-reports/medications-to-treat-opioid-addiction/efficacy-medications-opioid-use-disorder>.

of overdose compared to other MOUDs, many people who use opioids, as well as harm reduction experts, remain wary of considering naltrexone for OUD treatment.²¹ Because of this, and because naltrexone is subject to few regulatory restrictions and therefore saw no substantive restriction loosening due to COVID-19, we do not discuss this agent in the remainder of our analysis.

MOUD and Policy

Although buprenorphine and methadone are widely considered to be gold-standard treatments for OUD, they are underutilized and underprescribed: Only about one in four to one in 10 people living with an OUD actually receive MOUD.²²

Because methadone is an opioid agonist and buprenorphine is a partial opioid agonist, both have the potential to produce euphoria and respiratory depression, and both are scheduled under the Controlled Substances Act.²³ Methadone is classified as a Schedule II substance, defined as having a both an accepted medical use and a high potential for abuse, and buprenorphine is classified as a Schedule III substance, meaning it is deemed to have medical application and a lesser (but still present) potential for abuse.²⁴ As such, both medications are subject to federal drug policies that regulate their possession and distribution.²⁵

MOUD Policy and Access Before COVID-19

As a Schedule II drug, methadone is subject to greater restrictions than buprenorphine. Methadone intended for the treatment of an OUD may be dispensed only through an opioid treatment program (OTP) where the majority of medication doses are administered under supervision.²⁶ These programs must be certified and accredited and are regulated and overseen by several federal agencies: the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Health and Human Services, the Department of Justice and the Drug Enforcement Administration (DEA).²⁷ To open an OTP, the company or nonprofit must demonstrate local need and apply for a state license, which may have additional requirements.²⁸ Once an OTP is established, federal and state

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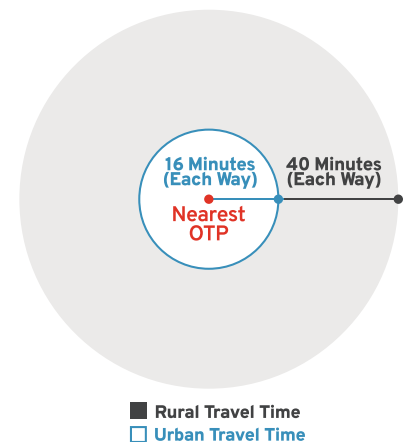
21. "Extended Release Naltrexone (Vivitrol)," Drug Policy Alliance, November 2016. <https://drugpolicy.org/sites/default/files/VivitrolFactSheet.pdf>; National Institute on Drug Abuse, "How effective are medications to treat opioid use disorder?" <https://nida.nih.gov/publications/research-reports/medications-to-treat-opioid-addiction/efficacy-medications-opioid-use-disorder>; "Medication for Opioid Use Disorder (MOUD) Overview," National Harm Reduction Coalition, last accessed March 15, 2023. <https://harmreduction.org/issues/facts>.
22. "Opioid Use Disorder." <https://www.cdc.gov/dotw/opioid-use-disorder/index.html#:~:text=About%202.7%20million%20people%20in%20the%20United%20States%20report%20suffering%20from%20OUD>; Krawczyk et al. <https://www.sciencedirect.com/science/article/pii/S0955395922002031>; Substance Abuse and Mental Health Services Administration, "Facing Addiction in America: The Surgeon General's Spotlight on Opioids," U.S. Department of Health & Human Services, September 2018, p. 2. https://addiction.surgeongeneral.gov/sites/default/files/Spotlight-on-Opioids_09192018.pdf.
23. National Institute on Drug Abuse, "How do medications to treat opioid use disorder work?" <https://nida.nih.gov/publications/research-reports/medications-to-treat-opioid-addiction/how-do-medications-to-treat-opioid-addiction-work>; Drug Enforcement Administration, "Controlled Substances," U.S. Department of Justice, Feb. 15, 2023. https://www.deadiversion.usdoj.gov/schedules/orangebook/c_cs_alpha.pdf.
24. Drug Enforcement Administration, "Controlled Substances." https://www.deadiversion.usdoj.gov/schedules/orangebook/c_cs_alpha.pdf; Drug Enforcement Administration, "Controlled Substance Schedules," U.S. Department of Justice, last accessed March 15, 2023. <https://www.deadiversion.usdoj.gov/schedules/#define>.
25. Substance Abuse and Mental Health Services Administration, "Statutes, Regulations, and Guidelines," U.S. Department of Health & Human Services, last accessed March 15, 2023. <https://www.samhsa.gov/medications-substance-use-disorders/statutes-regulations-guidelines>.
26. Public Health Service, "Title 42 Part 8 – Medication Assisted Treatment for Opioid Use Disorders," U.S. Department of Health & Human Services, last accessed March 15, 2023, pp. 109-110. <https://www.govinfo.gov/content/pkg/CFR-2021-title42-vol1/pdf/CFR-2021-title42-vol1-part8.pdf>.
27. Substance Abuse and Mental Health Services Administration, "Statutes, Regulations, and Guidelines." <https://www.samhsa.gov/medications-substance-use-disorders/statutes-regulations-guidelines>.
28. Christine Vestal, "Long Stigmatized, Methadone Clinics Multiply in Some States," The Pew Charitable Trusts, Oct. 31, 2018. <https://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2018/10/31/long-stigmatized-methadone-clinics-multiply-in-some-states>.

governments dictate how methadone may be distributed, including setting limits on take-home doses and requirements for urine screening schedules.²⁹ Interestingly, many states implement restrictions above and beyond those recommended by federal health agencies, such as encouraging the discontinuation of methadone (against the evidence), mandating additional urine screenings or requiring that urine tests be observed.³⁰ Additionally, individual OTP clinics are permitted to be more—but not less—strict than the federal regulations in their dispensing protocols.³¹

The regulations placed on OTPs and the oversight required to run them may contribute to the relatively scant number of methadone prescribers in the United States. Although the overdose crisis has caused several states to push to expand methadone access, it is far from uniform: Wyoming has no OTPs; South Dakota has one; Nebraska has three; and Mississippi and Hawaii each have only four.³² According to a 2019 report, approximately 80 percent of U.S. counties, home to roughly 77.5 million people, lacked an OTP.³³ Consequently, people in urban areas had to drive an average of 16 minutes to reach the nearest OTP, whereas those in rural areas averaged more than 40 minutes each way.³⁴ For the many methadone patients who must visit a clinic daily or almost daily, this 30- to 90-minute daily commute presents a substantial burden that can disrupt their lives and endanger their recovery.³⁵

In addition to the insufficient number of methadone clinics in the United States, the regulations around dispensing and consuming the medication act as deterrents to care. Research consistently shows that people taking methadone to treat an OUD find that the mandatory frequent, highly regulated and observed clinic visits interfere with work and family obligations, cause them to miss major life events such as weddings and funerals, and contribute to a process that is stigmatizing and dehumanizing.³⁶ In fact, these issues lead many people to relapse or discontinue treatment altogether.³⁷

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29. Public Health Service, pp. 95-121. <https://www.govinfo.gov/content/pkg/CFR-2021-title42-vol1/pdf/CFR-2021-title42-vol1-part8.pdf>; "Overview of Opioid Treatment Program Regulations by State," The Pew Charitable Trusts, Sept. 19, 2022. <https://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2022/09/overview-of-opioid-treatment-program-regulations-by-state>.
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31. Christine Vestal, "As Fentanyl Use Spikes, Feds Urge States to Ease Methadone Rules," The Pew Charitable Trusts, Dec. 19, 2022. <https://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2022/12/19/as-fentanyl-use-spikes-feds-urge-states-to-ease-methadone-rules>.
32. Substance Abuse and Mental Health Services Administration, "Opioid Treatment Program Directory," U.S. Department of Health & Human Services, last accessed March 6, 2023. <https://dpt2.samhsa.gov/treatment/directory.aspx>; Vestal, "Long Stigmatized, Methadone Clinics Multiply in Some States." <https://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2018/10/31/long-stigmatized-methadone-clinics-multiply-in-some-states>.
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34. Paul J. Joudrey et al., "Pharmacy-based methadone dispensing and drive time to methadone treatment in five states within the United States: a cross-sectional study," *Drug and Alcohol Dependence* 211 (Sept. 27, 2021). <https://europepmc.org/backend/ptpmcrender.fcgi?accid=PMC7529685&blobtype=pdf>.
35. Caty Simon et al., "The Methadone Manifesto: Treatment Experiences and Policy Recommendations From Methadone Patient Activists," *American Journal of Public Health* 112:S2 (April 1, 2022), pp. S117-S122. <https://ajph.aphapublications.org/doi/10.2105/AJPH.2021.306665>.
36. David Frank et al., "'It's like 'liquid handcuffs': The effects of take-home dosing policies on Methadone Maintenance Treatment (MMT) patients' lives," *Harm Reduction Journal* 18:88 (Aug. 14, 2021). <https://harmreductionjournal.biomedcentral.com/articles/10.1186/s12954-021-00535-y>; Simon et al. <https://ajph.aphapublications.org/doi/full/10.2105/AJPH.2021.306665>.
37. Frank et al. <https://harmreductionjournal.biomedcentral.com/articles/10.1186/s12954-021-00535-y>; Olivia Randall-Kosich et al., "Comparing Reasons for Starting and Stopping Methadone, Buprenorphine, and Naltrexone Treatment Among a Sample of White Individuals With Opioid Use Disorder," *Journal of Addiction Medicine* 14:4 (July/August 2020), pp. e44-e52. https://journals.lww.com/journaladdictionmedicine/Abstract/2020/08000/Comparing_Reasons_for_Starting_and_Stopping.26.aspx.

The federal government also restricts who can distribute or prescribe buprenorphine. Per the Drug Addiction Treatment Act of 2000, physicians seeking to prescribe the drug had to undergo a minimum of eight hours of addiction training and obtain a waiver from the DEA—commonly referred to as the X-waiver.³⁸ Almost two decades later, the Comprehensive Addictions Recovery Act (2016) and the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (2018) allowed nurse practitioners, physician assistants and others who had completed 24 hours of relevant approved education to apply for an X-waiver.³⁹

In addition, the 2008 Ryan Haight Online Pharmacy Consumer Protection Act restricts how buprenorphine may be prescribed. Specifically, the Act mandates an in-person evaluation for all patients initiating MOUD treatment.⁴⁰

In 2020, fewer than 100,000 health care providers had received the necessary authorization to prescribe buprenorphine.⁴¹ Although this number is double what it was in 2017, it remains insufficient and inequitable. Communities with higher proportions of Black residents are significantly less likely than those with a majority of white residents to have a buprenorphine-waivered provider.⁴² While about 85 percent of urban counties had at least one clinician able to prescribe the drug, only two-thirds of rural counties and fewer than half of those deemed “small and remote” had even one authorized provider.⁴³ Consequently, a substantial number of patients, especially in rural areas, must travel 10 miles or more to access a clinician who can prescribe buprenorphine.⁴⁴ This may be further exacerbated by the fact that pharmacies, especially in rural areas, may limit their buprenorphine dispensing.⁴⁵

The restrictive policies that buprenorphine and especially methadone are subject to are often justified by government authorities as reducing diversion, ensuring “accountability,” and preventing misuse and overdose. However, they likely reduce access to and may hinder the efficacy of MOUD.

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38. H.R. 2634, Drug Addiction Treatment Act, 106th Congress. <https://www.congress.gov/106/bills/hr2634/BILLS-106hr2634pcs.pdf>.

39. “APNA Position: APRNs Prescribing Buprenorphine & Buprenorphine/Naloxone & the Continuing Opioid Crisis,” American Psychiatric Nurses Association, June 10, 2020. <https://apna.org/news/aprns-prescribing-buprenorphine-buprenorphine-naloxone-the-continuing-opioid-crisis>.

40. H.R. 6353, Ryan Haight Online Pharmacy Consumer Protection Act, 110th Congress. <https://www.justice.gov/archive/olp/pdf/hr-6353-enrolled-bill.pdf>.

41. C. Holly A. Andrilla and Davis G. Patterson, “Tracking the geographic distribution and growth of clinicians with a DEA waiver to prescribe buprenorphine to treat opioid use disorder,” *The Journal of Rural Health* 38:1 (January 2022), pp. 87-92. <https://onlinelibrary.wiley.com/doi/epdf/10.1111/jrh.12569>.

42. William C. Goedel et al., “Association of Racial/Ethnic Segregation With Treatment Capacity for Opioid Use Disorder in Counties in the United States,” *JAMA Network Open* 3:4 (April 1, 2020). <https://pubmed.ncbi.nlm.nih.gov/32320038>.

43. Ibid.

44. James R. Langabeer et al., “Geographic proximity to buprenorphine treatment providers in the U.S.,” *Drug and Alcohol Dependence* 213 (Aug. 1, 2020). <https://www.sciencedirect.com/science/article/pii/S0376871620302969>.

45. Hannah L.F. Cooper et al., “Buprenorphine dispensing in an epicenter of the U.S. opioid epidemic: A case study of the rural risk environment in Appalachian Kentucky,” *International Journal of Drug Policy* 85 (November 2020). <https://pubmed.ncbi.nlm.nih.gov/32223985>; Erin G. Major, “Factors in rural community buprenorphine dispensing,” *Exploratory Research in Clinical and Social Pharmacy* 9 (March 2023). <https://www.sciencedirect.com/science/article/pii/S2667276622001032>; Grace Trull et al., “Rural community pharmacist willingness to dispense Suboxone - A secret shopper investigation in South-Central Appalachia,” *Exploratory Research in Clinical and Social Pharmacy* 4 (December 2021). <https://www.sciencedirect.com/science/article/pii/S2667276621000822>; Neda J. Kazerooni et al., “Pharmacy-related buprenorphine access barriers: An audit of pharmacies in counties with a high opioid overdose burden,” *Drug and Alcohol Dependence* 224 (July 1, 2021). <https://www.sciencedirect.com/science/article/abs/pii/S0376871621002246>; Lucas G. Hill et al., “Perceptions, policies, and practices related to dispensing buprenorphine for opioid use disorder: A national survey of community-based pharmacists,” *Journal of the American Pharmacists Association* 63:1 (January–February 2023), pp. 252-260.e6. <https://www.sciencedirect.com/science/article/pii/S1544319122002874>.

Pandemic-Era Policy Changes

In early 2020, the emergence of COVID-19 caused many services across the United States to screech to a sudden halt, including health care. Social distancing mandates and stay-at-home recommendations made it difficult for OTPs and clinicians to continue operating as usual. The health-related, psychological and economic stressors of the pandemic exacerbated the risks associated with OUD and simultaneously made it more difficult to receive treatment. Consequently, the federal government opted to do what activists have been asking of them for years: They relaxed several of the regulations on MOUD.

In mid-March, SAMHSA announced new guidance that gave OTPs substantially increased flexibility when managing their patients, resulting in more opportunities to provide take-home doses of methadone. Rather than strict “time in treatment” guidelines, the new recommendations allowed states to request a change so their providers could classify patients as “stable” or “unstable” and use that criteria to dispense up to 14 or 28 days of take-home doses (Table 1).⁴⁶ In addition, in June 2021, the DEA released a rule that would allow OTPs to operate mobile units to dispense Schedule II to V drugs, including methadone.⁴⁷

While this move was certainly an important shift in federal policy, it was not directive. As a result, states were not required to change their take-home limits, and providers were not required to increase take-home doses or make other adjustments to expand access, so many did not.⁴⁸

Table 1: Federal Guidance Regarding Take-Home Methadone

Time in Treatment	Maximum Take-Home Doses Before COVID-19 Modifications	COVID-Era Take-Home Allowances
First 90 days	1 dose per week	—
Second 90 days	2 doses per week	—
Third 90 days	3 doses per week	—
271 days to 1 year	6 doses per week	—
1 year to 2 years continuous treatment	2-week supply	—
2+ years of continuous treatment	1-month supply, with mandatory monthly visits	—
“Stable”	-	28 days
“Less Stable”	-	14 days

Source: Public Health Service, pp. 110-111. <https://www.govinfo.gov/content/pkg/CFR-2021-title42-vol1/pdf/CFR-2021-title42-vol1-part8.pdf>; “Opioid Treatment Program (OTP) Guidance.” <https://www.samhsa.gov/sites/default/files/otp-guidance-20200316.pdf>.

KEY TAKEAWAY

In mid-March, SAMHSA announced new guidance that gave OTPs substantially increased flexibility when managing their patients, resulting in more opportunities to provide take-home doses of methadone; however, it was not directive. States were therefore not required to change their take-home limits, and providers were not required to increase take-home doses or make other adjustments to expand access, so many did not.



46. “Opioid Treatment Program (OTP) Guidance,” Substance Abuse and Mental Health Services Administration, March 19, 2020. <https://www.samhsa.gov/sites/default/files/otp-guidance-20200316.pdf>.

47. Drug Enforcement Administration, “Registration Requirements for Narcotic Treatment Programs With Mobile Components,” Department of Justice, June 28, 2021. <https://www.federalregister.gov/documents/2021/06/28/2021-13519/registration-requirements-for-narcotic-treatment-programs-with-mobile-components>.

48. Andrew Joseph, “Under new rules, methadone clinics can offer more take-home doses. Will they?,” *STAT*, Dec. 22, 2022. <https://www.statnews.com/2022/12/22/new-rules-methadone-clinics-take-home-doses>; Frank et al. <https://harmreductionjournal.biomedcentral.com/articles/10.1186/s12954-021-00535-y>; Beth E. Meyerson et al., “Nothing really changed: Arizona patient experience of methadone and buprenorphine access during COVID,” *PLoS One* 17:10 (Oct. 25, 2022). <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0274094>.

The key COVID-era policy changes related to buprenorphine were those that expanded access to the medication via telehealth. Specifically, regulations related to the Health Insurance Portability and Accountability Act were relaxed to facilitate the rapid adoption and implementation of telehealth by providers, and the DEA allowed for new buprenorphine patient evaluations via video platforms.⁴⁹ New guidelines in April 2021 also relaxed training requirements to apply for an X-waiver and increased the number of patients waived providers could take on.⁵⁰

Health and Safety Outcomes of COVID-19-Related Policy Changes

The unique circumstances associated with the COVID-19 pandemic complicate drawing absolute, population-level conclusions from this natural experiment. However, by synthesizing findings from national epidemiologic studies and targeted research from states and programs that implemented the policy changes, we are able to evaluate how people were affected by and responded to loosened MOUD regulations and project expectations should the policy changes be widely adopted going forward.

Because of the timing of MOUD-related policy changes and subsequent lack of relevant research—for example, the first mobile methadone van launched in mid-2022—this section primarily focuses on two outcomes related to the expansion of telehealth buprenorphine and take-home methadone: MOUD-involved overdose and markers of treatment success (conceptualized as recovery-related outcomes and patient experience).⁵¹

MOUD-Involved Overdose

Regulators and health care providers often cite concerns about unintended consequences to justify the heavy restrictions placed on MOUD access. Chief among these is the fear that medications will be misused or diverted (i.e., when prescription medications are used in ways other than prescribed or distributed illegally)—and would thereby increase MOUD-involved overdoses.⁵²

Before the 2020 policy changes, research challenged these assertions, generally indicating that increasing access to MOUD decreases the likelihood of the drugs being misused or sold on the illegal market.⁵³ COVID-era studies generally focused on changes in MOUD-involved overdoses and similarly found that reducing



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49. Utsha Khatri et al., “These Key Telehealth Policy Changes Would Improve Buprenorphine Access While Advancing Health Equity,” *Health Affairs Forefront*, Sept. 11, 2020. <https://www.healthaffairs.org/doi/10.1377/forefront.20200910.498716/full>.

50. Joanne Spetz et al., “Changes in US Clinician Waivers to Prescribe Buprenorphine Management for Opioid Use Disorder During the COVID-19 Pandemic and After Relaxation of Training Requirements,” *JAMA Network Open* 5:5 (May 12, 2022). <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2792222>.

51. Alison Knopf, “First methadone van approved under new DEA rules,” *Alcoholism & Drug Abuse Weekly* 34:29 (July 25, 2022), pp. 5-6. <https://onlinelibrary.wiley.com/doi/abs/10.1002/adaw.33507>.

52. Centers for Medicare & Medicaid Services, “Drug Diversion: What Is a Prescriber’s Role in Preventing the Diversion of Prescription Drugs?,” Department of Health & Human Services, February 2016. <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/DrugDiversionFS022316.pdf>; Brandon del Pozo and Josiah D. Rich, “Revising our attitudes towards agonist medications and their diversion in a time of pandemic,” *Journal of Substance Abuse Treatment* 119 (December 2020). <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7505066>; K. Michelle Peavy et al., “Rapid Implementation of Service Delivery Changes to Mitigate COVID-19 and Maintain Access to Methadone Among Persons with and at High-Risk for HIV in an Opioid Treatment Program,” *AIDS and Behavior* 24 (April 28, 2020), pp. 2469-2472. <https://link.springer.com/article/10.1007/s10461-020-02887-1>.

53. Mancher M, Leshner AI, eds., *Medications for Opioid Use Disorder Save Lives*: National Academies Press, 2019). <https://www.ncbi.nlm.nih.gov/books/NBK541389>.

regulations does not lead to a significant rise in diversion, misuse or associated harms.⁵⁴ Perhaps surprisingly, some research even indicates that MOUD diversion can have protective consequences in communities, as the medications make it into the hands of individuals who may otherwise lack access.⁵⁵ For these reasons, rather than looking at diversion, we focus this section on MOUD-involved overdose.

Findings related to buprenorphine are straightforward. A national study demonstrated that although opioid overdose mortality increased in the United States from 2019 to 2021, the proportion of those deaths that involved buprenorphine did not increase.⁵⁶ This is especially meaningful because the total number of people taking buprenorphine increased during this same period.⁵⁷ Thus, it is clear that increasing access to buprenorphine did not lead to an increased likelihood that the medication would be involved in an overdose.

The evidence around population-level impacts of methadone changes is more complex because the policies permitting more take-home doses were spottily adopted, and the total number of people taking methadone for OUD declined.⁵⁸ However, the majority of research still suggests that the changes did not increase harm. In a widely cited national study, researchers found that methadone-involved overdoses, which were declining before COVID, continued to fall at roughly the same rate well into 2021.⁵⁹ The authors did note one exception to this trend—in March 2020, methadone-involved overdoses increased—but close analysis revealed that the jump paralleled a nationwide surge in fentanyl overdoses, indicating that the increase was likely due to external factors such as the pandemic onset and increased quantities of fentanyl in the illicit drug market.⁶⁰ Furthermore, this same study found that methadone-involved overdose numbers rapidly returned to pre-pandemic levels and resumed a similar rate of decline as seen before the pandemic and its associated policy changes.⁶¹ A separate national study, however, had conflicting findings. Looking at the methadone-involved overdose death rate between 1999 and 2020, other researchers found that the medication was involved in more overdoses in 2020 compared to previous years.⁶² However, the authors collected mortality data only



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54. Noa Krawczyk et al., “Synthesizing evidence of the effects of COVID-19 regulatory changes on methadone treatment for opioid use disorder: implications for policy,” *The Lancet* 8:3 (March 2023), pp. E238-E246. [https://www.thelancet.com/journals/lanpub/article/PIIS2468-2667\(23\)00023-3/fulltext#seccestitle60](https://www.thelancet.com/journals/lanpub/article/PIIS2468-2667(23)00023-3/fulltext#seccestitle60); “Flexibilities in Controlled Substances Prescribing and Dispensing During the COVID-19 Pandemic,” *Issue Brief*, Office of Science & Data Policy, Assistant Secretary for Planning and Evaluation, August 2022. <https://aspe.hhs.gov/sites/default/files/documents/8d26dfc6c859795bf2307ae6a845b7f5/ASPE-brief-covid-flexibilities-aug-2022.pdf>.
55. Magdalena Harris and Tim Rhodes, “Methadone diversion as a protective strategy: The harm reduction potential of ‘generous constraints,’” *International Journal of Drug Policy* 24:6 (2013), pp. e43-e50. <https://www.sciencedirect.com/science/article/abs/pii/S0955395912001545>; Ingrid Amalia Havnes et al., “‘Diversion’ of methadone or buprenorphine: ‘harm’ versus ‘helping,’” *Harm Reduction Journal* 10:24 (2013). <https://harmreductionjournal.biomedcentral.com/articles/10.1186/1477-7517-10-24>.
56. Lauren J. Tanz et al., “Trends and Characteristics of Buprenorphine-Involved Overdose Deaths Prior to and During the COVID-19 Pandemic,” *JAMA Network Open* 6:1 (Jan. 20, 2023). <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2800689>.
57. Substance Abuse and Mental Health Services Administration, “National Survey of Substance Abuse Treatment Services (N-SSATS): 2020. Data on Substance Abuse Treatment Facilities,” Department of Health & Human Services, June 2021, p. 49. https://www.samhsa.gov/data/sites/default/files/reports/rpt35313/2020_NSSATS_FINAL.pdf.
58. Joudrey et al. <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2782211>; Substance Abuse and Mental Health Services Administration, 2021, p. 49. https://www.samhsa.gov/data/sites/default/files/reports/rpt35313/2020_NSSATS_FINAL.pdf; Meyerson et al. <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0274094>.
59. Christopher M. Jones et al., “Methadone-Involved Overdose Deaths in the US Before and After Federal Policy Changes Expanding Take-Home Methadone Doses From Opioid Treatment Programs,” *JAMA Psychiatry* 79:9 (July 13, 2022). <https://jamanetwork.com/journals/jamapsychiatry/fullarticle/2793744>.
60. Ibid.
61. Ibid.
62. Daniel E. Kaufman et al., “Examination of methadone involved overdoses during the COVID-19 pandemic,” *Forensic Science International* 344 (2023). <https://europepmc.org/backend/ptpmcrender.fcgi?accid=PMC9886385&blobtype=pdf>; Jones et al. <https://jamanetwork.com/journals/jamapsychiatry/fullarticle/2793744>.

through 2020 and did not break down findings by month; as such, their analysis may have missed the nuance and long-term resilience identified by other scholars.⁶³

Given the inconsistent implementation of COVID-era methadone policies across the United States, program-specific and state-level data help paint a clearer picture. A study of Connecticut's eight OTPs found that the pandemic-era policies led, as intended, to dramatic increases in take-home methadone and substantial decreases in the frequency of urine screenings.⁶⁴ A minority of OTPs reported diversion, but those that reported this noted that it had occurred less than expected. In addition, the increase in take-home methadone doses did not lead to an increase in state-wide overdoses involving the medication.⁶⁵ In a study on the other side of the country, 183 OTP clients in Spokane, Washington, found that although take-home doses increased by nearly 200 percent, patient visits to emergency departments fell, and there was no evidence of increased diversion, assessed through both urine screening and overdose rates.⁶⁶ Taken together, this evidence was sufficient to convince SAMHSA to extend its methadone take-home recommendations for one year beyond the end of the COVID public health emergency.⁶⁷

Treatment Success

Another argument against relaxed MOUD regulations is that in-person assessments and especially the highly structured environment of the OTP hold patients accountable and thus improve recovery outcomes.⁶⁸ However, data on pandemic-era regulatory relaxations indicate that the changes increased access for some populations; generally did not decrease—and in some cases improved—treatment quality; and were well received by many.

Findings related to the impact of MOUD policy changes on treatment access were mixed and muddled by the same pandemic circumstances that reduced health care engagement more broadly. National data indicate that while the number of buprenorphine providers increased during the COVID-19 period, the number of methadone providers able to take new patients declined.⁶⁹ Furthermore, from 2019 to 2020, the number of people taking buprenorphine increased, but the



Data on pandemic-era regulatory relaxations indicate that the changes increased access for some populations; generally did not decrease treatment quality; and were well received by many.

63. Ibid.

64. Sarah Brothers et al., "Changes in methadone program practices and fatal methadone overdose rates in Connecticut during COVID-19," *Journal of Substance Abuse Treatment* 131 (December 2021). [https://www.jsatjournal.com/article/S0740-5472\(21\)00175-6/fulltext](https://www.jsatjournal.com/article/S0740-5472(21)00175-6/fulltext).

65. Ibid.

66. Ofer Amram et al., "The impact of relaxation of methadone take-home protocols on treatment outcomes in the COVID-19 era," *The American Journal of Drug and Alcohol Abuse* 47:6 (Oct. 20, 2021). <https://www.tandfonline.com/doi/full/10.1080/00952990.2021.1979991>.

67. "Methadone Take-Home Flexibilities Extension Guidance," Substance Abuse and Mental Health Services Administration, Jan. 25, 2023. <https://www.samhsa.gov/medications-substance-use-disorders/statutes-regulations-guidelines/methadone-guidance#:~:text=On%20March%2016%2C%202020%2C%20SAMHSA,14%20days%20of%20Take%2DHome>.

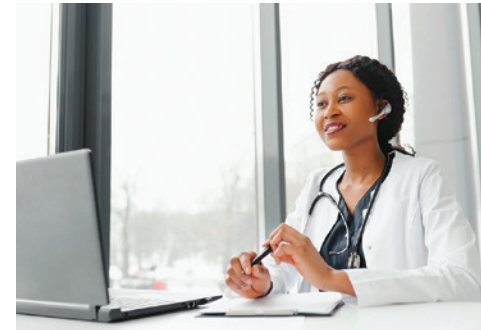
68. Erin Fanning Madden et al., "Treatment provider perceptions of take-home methadone regulation before and during COVID-19," *Drug and Alcohol Dependence* 228 (Nov. 1, 2021). <https://linkinghub.elsevier.com/retrieve/pii/S0376871621005950>.

69. Spetz et al. <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2792222>; Peter C. Treitler et al., "Perspectives of opioid use disorder treatment providers during COVID-19: Adapting to flexibilities and sustaining reforms," *Journal of Substance Abuse Treatment* 132 (January 2022). [https://www.jsatjournal.com/article/S0740-5472\(21\)00240-3/fulltext](https://www.jsatjournal.com/article/S0740-5472(21)00240-3/fulltext); Madden et al. <https://linkinghub.elsevier.com/retrieve/pii/S0376871621005950>; Erin F. Madden et al., "Variation in intervention stigma among medications for opioid use disorder," *SSM – Qualitative Research in Health* 2 (December 2022). <https://www.sciencedirect.com/science/article/pii/S2667321522001238?via%3DiHub>; Joudrey et al. <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2782211>.

number of people taking methadone fell.⁷⁰ As another example of a discrepancy, the proportion of Medicare beneficiaries who received MOUD increased after policies were relaxed, but Veterans Health Administration clients were less likely to receive MOUD during the pandemic than before it.⁷¹

Taken together, these numbers indicate that the policies likely buffered COVID-19-related challenges, but on their own may not have been sufficient to truly expand MOUD access during this challenging time and had disparate effects on different groups. Perhaps more telling in regards to MOUD policy and access going forward is the question of whether the changes helped close gaps in access. For example, one study of a large family medicine clinic in Appalachia found that the number of MOUD patients from rural counties increased with the provision of telehealth and that telemedicine visits were used more by patients who lived further from the clinic, suggesting that access to buprenorphine may have been especially useful to people living in rural areas.⁷² Several other studies indicated that, while MOUD-related telehealth expansions benefitted many, disparities in access persisted. In particular, economic, racial and geographic divides in access to connectivity and video-enabled technology persisted, suggesting that we must close these gaps to optimize the potential of telehealth.⁷³

Among the individuals who did receive MOUD treatment after restrictions were relaxed, researchers found a number of promising health and recovery outcomes. Patients with OUD who had increased access to take-home methadone or who attended buprenorphine appointments via telehealth had a dramatically reduced risk for both fatal and nonfatal overdose compared to their counterparts who were not taking MOUD.⁷⁴ In addition, increased take-home methadone access was associated with a reduction in positive urine screenings for illicit opioids, fewer visits to the emergency department, and comparable or improved retention in treatment.⁷⁵ Studies focused on buprenorphine expansion revealed similar patterns. Patients receiving telehealth access to buprenorphine were equally likely to initiate



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70. Substance Abuse and Mental Health Services Administration, "National Survey of Substance Abuse Treatment Services (N-SSATS): 2020. Data on Substance Abuse Treatment Facilities," Department of Health & Human Services, June 2021, p. 49. https://www.samhsa.gov/data/sites/default/files/reports/rpt35313/2020_NSSATS_FINAL.pdf.
71. Nicholas A. Livingston et al., "The impact of COVID-19 and rapid policy exemptions expanding on access to medication for opioid use disorder (MOUD): A nationwide Veterans Health Administration cohort study," *Drug and Alcohol Dependence* 241 (Dec. 1, 2022). <https://www.sciencedirect.com/science/article/pii/S037687162200415X?via%3Dihub>; Judy Ng et al., "Access to Medications for Opioid Use Disorder (MOUD) Among Medicare Fee-for-Service Beneficiaries: Influence of CARES Act Implementation," Centers for Medicare & Medicaid Services, January 2020, pp. 1-22. <https://www.cms.gov/files/document/data-highlight-jan-2022-opiod.pdf>.
72. Phillip M. Hughes et al., "An examination of telehealth policy impacts on initial rural opioid use disorder treatment patterns during the COVID-19 pandemic," *The Journal of Rural Health* 37:3 (Summer 2021), pp. 467-472. <https://onlinelibrary.wiley.com/doi/10.1111/jrh.12570>.
73. Ruth Hailu et al., "Telemedicine Use and Quality of Opioid Use Disorder Treatment in the US During the COVID-19 Pandemic," *JAMA Network Open* 6:1 (Jan. 24, 2023). <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2800718>; Madeline C. Frost et al., "Use of and Retention on Video, Telephone, and In-Person Buprenorphine Treatment for Opioid Use Disorder During the COVID-19 Pandemic," *JAMA Network Open* 5:10 (Oct. 12, 2022). <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2797201>; Tolulope M. Abidogun et al., "Patient experiences of COVID-19-induced changes to methadone treatment in a large community-based opioid program in Baltimore," *Journal of Substance Use and Addiction Treatment* 145 (February 2023). <https://www.sciencedirect.com/science/article/pii/S2949875922000170?via%3Dihub>.
74. Christopher M. Jones et al., "Receipt of Telehealth Services, Receipt and Retention of Medications for Opioid Use Disorder, and Medically Treated Overdose Among Medicare Beneficiaries Before and During the COVID-19 Pandemic," *JAMA Psychiatry* 79:10 (Aug. 31, 2022), pp. 981-992. <https://jamanetwork.com/journals/jamapsychiatry/fullarticle/2795953>; Christopher M. Jones et al., "Association of Receipt of Opioid Use Disorder-Related Telehealth Services and Medications for Opioid Use Disorder With Fatal Drug Overdoses Among Medicare Beneficiaries Before and During the COVID-19 Pandemic," *JAMA Psychiatry*, March 29, 2023. https://jamanetwork.com/journals/jamapsychiatry/fullarticle/2802946?guestAccessKey=c1447a53-113b-46d3-976c-bada3638c308&utm_source=For_The_Media&utm_medium=referral&utm_campaign=ftm_links&utm_content=tfi&utm_term=032923&source=email.
75. Livingston et al. <https://www.sciencedirect.com/science/article/pii/S037687162200415X?via%3Dihub>; Kim A. Hoffman et al., "Treatment retention, return to use, and recovery support following COVID-19 relaxation of methadone take-home dosing in two rural opioid treatment programs: A mixed methods analysis," *Journal of Substance Abuse Treatment* 141 (October 2022). [https://www.jsatjournal.com/article/S0740-5472\(22\)00083-6/fulltext](https://www.jsatjournal.com/article/S0740-5472(22)00083-6/fulltext); Amram et al. <https://www.tandfonline.com/doi/full/10.1080/00952990.2021.1979991>.

MOUD, stay in treatment and use illicit drugs compared to in-person patients both before and after the policy changes.⁷⁶

In addition to the above objective measures, a number of subjective factors shaped patient experiences in meaningful ways. For example, while take-home methadone was lauded across studies for increasing autonomy and improving patients' ability to engage with work and personal responsibilities, some patients struggled to manage the take-home doses or lacked safe storage options.⁷⁷ When regulations were not substantially relaxed, however, patients reported that visiting the clinic daily or almost daily interrupted their work and home lives, making it difficult to stay in treatment.⁷⁸ Findings around telehealth access to counseling appointments and buprenorphine prescribing were similarly mixed. For example, some patients found the approach as appealing or more appealing than in-person visits, whereas others missed the connection they attributed to in-person appointments.⁷⁹ One study found that among MOUD patients who reported struggling to maintain abstinence from illicit substances, many attributed the challenge to factors external to the MOUD treatment protocol, including depression, food insecurity and job or housing loss.⁸⁰ Ultimately, while some providers and patients were initially skeptical of the policy changes, overall, studies found them to be widely supportive after implementation, noting that the new regulations allowed greater flexibility and patient-centered care.⁸¹



Ultimately, while some providers and patients were initially skeptical of the policy changes, overall, studies found them to be widely supportive after implementation, noting that the new regulations allowed greater flexibility and patient-centered care.

Policy Takeaways

The unique circumstances of the COVID-19 pandemic presented an opportunity to assess the effects of relaxing MOUD regulations, and the resulting body of data indicates that more permissive MOUD policy does not increase medication-related harms and gives providers and patients the ability to tailor care to individual needs. These findings provide the following important takeaways for policymakers:

- Fears of diversion and overdose increases should not be used to justify excessive regulation.



Takeaway 1

76. Richard H. Cales et al., "The COVID-19 pandemic and opioid use disorder: Expanding treatment with buprenorphine, and combining safety precautions with telehealth," *Journal of Substance Abuse Treatment* 133 (February 2022). [https://www.jsatjournal.com/article/S0740-5472\(21\)00269-5/fulltext](https://www.jsatjournal.com/article/S0740-5472(21)00269-5/fulltext); Jagdeep Kaur et al., "Impact of Telemedicine on Retention in Medications for Opioid Use Disorder (MOUD) Treatment With Buprenorphine in the Times of COVID-19 Pandemic: A Retrospective Chart Review," *Journal of Rural Mental Health* 46:2 (2022), pp. 75-81. <https://doi.org/10.1037/rmh0000206>; Ruth Hailu et al., "Telemedicine Use and Quality of Opioid Use Disorder Treatment in the US During the COVID-19 Pandemic," *JAMA Network* 6:1 (2023). https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2800718?utm_campaign=articlePDF&utm_medium=articlePDFlink&utm_source=articlePDF&utm_content=jamanetworkopen.2022.52381.
77. Ximena A. Levander et al., "Rural opioid treatment program patient perspectives on take-home methadone policy changes during COVID-19: a qualitative thematic analysis," *Addiction Science & Clinical Practice* 16:72 (Dec. 11, 2021). <https://ascpjournals.biomedcentral.com/articles/10.1186/s13722-021-00281-3>; Megan K. Reed et al., "Sorting through life: evaluating patient-important measures of success in a medication for opioid use disorder (MOUD) treatment program," *Substance Abuse, Treatment, Prevention, and Policy* 18:4 (Jan. 14, 2023). <https://substanceabusepolicy.biomedcentral.com/articles/10.1186/s13011-022-00510-1>; Treitler et al. [https://www.jsatjournal.com/article/S0740-5472\(21\)00240-3/fulltext](https://www.jsatjournal.com/article/S0740-5472(21)00240-3/fulltext).
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- Eliminating excessive regulations would give clinicians more autonomy and flexibility to treat patients according to their individual needs and community contexts.
- States should be encouraged to relax their own guidelines. Currently, most states have at least some additional requirements in place that hinder access to MOUD above and beyond federal regulations.⁸²
- Policies that reduce the regulations on MOUD are necessary but are not sufficient to ensure equity of access. Persistent issues that may stand in the way of equitable access include: disparities in access to digital technology (especially in rural areas and among those with lower incomes); limited access to transportation or child care (a particular problem for those needing daily methadone visits and those with low incomes); provider and pharmacist stigma and misunderstanding (which may prevent adherence to evidence-based guidelines or medication dispensing); and financial barriers (such as inadequate Medicaid access or insurance schemes that disincentivize take-home methadone).⁸³

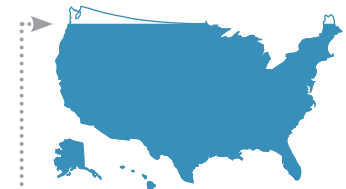


Could Pharmacists Help Close Access Gaps?

Decreasing regulations on methadone and buprenorphine would allow for the development and implementation of innovative, community-based programs that could reduce access barriers while supporting patient safety, autonomy and well-being. For example, pharmacies' ubiquity—more than 89 percent of Americans live within 5 miles of a pharmacy—and typically longer business hours than clinics make them an excellent resource for reducing barriers related to transportation, distance, and work or family obligations.¹

In several countries, including Canada and Australia, pharmacists can dispense methadone—an approach that research suggests would drastically improve methadone access in rural communities in the United States.² Pharmacies may also have a role to play in improving buprenorphine access. A recent trial in Rhode Island found that pharmacy-based buprenorphine initiation resulted in improved retention compared to standard care.³

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Conclusion

As the overdose crisis in the United States persists, MOUD represents an important and underutilized tool to combat these deaths. Indeed, MOUD has been shown to reduce the risk of overdose-related death by as much as 40 to 60 percent.⁸⁴ Nonetheless, the evidence-based medications buprenorphine and methadone remain heavily controlled by state and federal regulatory policy. Rapid emergency provisions during the COVID-19 pandemic provided an opportunity to examine the impact of relaxing some of these policies, expanding telehealth prescribing of buprenorphine and increasing permissible take-home doses of methadone. A growing body of research has demonstrated that such policies did not increase risks associated with the medications, and—for some patients—dramatically improved quality of care and treatment outcomes, increasing retention and reducing use of illicit opioids.

Unfortunately, despite bipartisan pushback, the DEA has expressed plans to revoke pandemic-era telemedicine rules, and a number of states have allowed emergency orders to expire.⁸⁵ However, some steps have already been taken to solidify or expand upon pandemic-era policies. For example, the recently passed Mainstreaming Addiction Treatment Act promises to expand buprenorphine access by eliminating the X-waiver and reducing stigma through MOUD education and awareness.⁸⁶ In addition, SAMHSA has proposed making take-home dose permissions permanent, albeit with more specific definitions of “stable” and “less stable” patients.⁸⁷ Similarly, the recently introduced Modernizing Opioid Treatment Access Act would make methadone available through prescription, thus reducing a number of the barriers highlighted in this study.⁸⁸ Such policies mark an important step toward improving treatment options for people with OUD and would help improve recovery outcomes and reduce overdoses.

Finally, to maximize the benefits of the relaxed regulation of MOUD, we must also ensure equitable access to telehealth services; address stigma and misunderstanding about OUD and MOUD (even among health care professionals); and develop pricing and payment structures that facilitate, rather than discourage, patient-centered care.

KEY TAKEAWAY

A growing body of research has demonstrated that rapid emergency provision policies did not increase risks associated with the medications, and—for some patients—dramatically improved quality of care and treatment outcomes, increasing retention and reducing use of illicit opioids.

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