

Impact of the Pandemic and the End of the Public Health Emergency on Opioid Use Disorder Treatment

I. Introduction

COVID-19 was accompanied by serious disruptions in care and treatment for persons with opioid use disorder (OUD), as well as isolation, loneliness, grief, job loss, and economic and housing instability. All of this undoubtedly contributed to the overdose death rate increasing by 50 percent in the United States during the pandemic. In 2021 alone, over 107,000 lives were lost to overdoses. While drug overdose death rates increased across all racial and ethnic groups, the increases were larger for people of color than for white people, for the young than for the old, and in sparsely populated and economically disadvantaged areas than in urban areas.

Alongside these bleak trends, there are treatments that work. Research demonstrates that methadone and buprenorphine are highly effective medications for treating OUD (MOUD).⁴ Unfortunately, these drugs are underutilized. They also come under a strong regulatory framework that, while intended to prevent diversion and protect patient safety, has been criticized for being incongruent with evidence and restricting access to lifesaving treatment.^{5,6} As one National Academies of Science report observed, "legal and regulatory barriers prevent broad access to medication-based treatment for OUD within the mainstream of the medical care system."⁷

Box 1. Overdose Trends: Key Data

- By race/ethnicity. In 2021, the <u>highest drug</u>
 overdose death rates were among American
 Indian and Alaska Native people (56.6 per
 100,000) and Black people (44.2 per 100,000).
- By age. The rise in overdoses during the pandemic disproportionately impacted the young: Deaths due to drug overdose among adolescents more than doubled from 2019 (282 deaths) to 2021 (637 deaths).
- **By geography.** Certain states were hit harder than others. The opioid epidemic has historically impacted persons living in <u>rural</u> and frontier communities harder, in part because of lack of access to treatment (fewer providers but also a longer distance to clinics to receive inperson doses of MOUD), as well as socioeconomic stressors and increased <u>stigma</u>.

Recognizing the importance of access to MOUD, many federal COVID-19 pandemic-era flexibilities sought to improve and democratize access, creating the possibility of an even playing field by enacting nationwide telehealth and takehome dose flexibilities for patients who use methadone. These unprecedented flexibilities were coupled with other policy changes seeking to expand access. At the same time, states and providers had autonomy as to how and to what

¹ Panchal, N., Saunders, H., Rodowitz, R., Cox, C. (March 20, 2023). <u>The Implications of COVID-19 for Mental Health and Substance</u> Use. *KFF*.

² National Center for Health Statistics. Provisional Drug Overdose Counts. National Vital Statistics System. CDC.

³ Panchal, N., Saunders, H., Rodowitz, R., Cox, C. (March 20, 2023). <u>The Implications of COVID-19 for Mental Health and Substance</u> Use. *KFF*.

⁴ National Academies of Sciences, Engineering, and Medicine. 2019. <u>Medications for Opioid Use Disorder Save Lives</u>. *The National Academies Press*.

⁵ Davis, C.S., Carr, D.H. (November 2019). <u>Legal and policy changes urgently needed to increase access to opioid agonist therapy in</u> the United States. *Int J Drug Policy*.

⁶ Bonnie, R., Dooling, B.C. (May 27, 2022). <u>An Expedited Regulatory Strategy For Expanding Access To Methadone Treatment For</u> Opioid Use Disorder. Health Affairs.

⁷ National Academies of Sciences, Engineering, and Medicine. 2019. <u>Medications for Opioid Use Disorder Save Lives</u>. *The National Academies Press*.



extent they wanted to take advantage of these flexibilities and other policies, which resulted in a patchy and confusing policy landscape and uneven uptake.

With the COVID-19 public health emergency (PHE)⁸ end on May 11, 2023, many patients, providers, and advocates remain worried about changes to federal flexibilities. There is also confusion as to which policies remain in effect and which expired. Concomitant with the rapid pace of policy change, research is slowly starting to emerge about how federal pandemic-era flexibilities improved access to care and use of services throughout the pandemic, even though they were subject to variable uptake across states and providers.

Emerging changes at the federal level suggest four trends for substance use disorder (SUD) treatment in the post-PHE era:

- A "middle path" for federal limits on access to MOUD.
 Some pre-pandemic policies will return, making it harder for providers to use telehealth and other strategies to ease access to MOUD, but the rules will not fully reinstate all the limitations of the pre-pandemic era.
- Temporary preservation of federal flexibilities. The
 federal government will buy itself time to figure out its
 permanent position on PHE flexibilities. As demonstrated
 with recent federal actions, with a few exceptions, most
 flexibilities remain in place on a temporary basis as the
 federal government settles on which policies should be in
 place and works on issuing those policies as permanent
 regulations.

"In spite of several barriers, the pandemic challenged the notion that there are insurmountable obstacles in addiction medicine and made it clear that where there is a will, there is a way and effective change could occur quickly and efficiently." —Dr. Sarah Wakeman, MD | Medical Director for Substance Use Disorder, Mass General Brigham

- Continued state flexibility, contributing to a patchwork of rules. States will continue to have broad flexibility to
 add their own restrictions on access to MOUD, resulting in variations in what is allowed across the country and
 compounding providers' difficulty in understanding the current "state of play."
- **Flexibilities are necessary but not sufficient.** As seen during the pandemic, the flexibilities afforded at the federal and state levels are essential, but broader and more systemic changes (e.g., around payment and workforce) will also be needed to support equitable access across the continuum of care.

With overdose deaths on the rise—and an ever more potent and dynamic drug supply—clear, cohesive, and equitable policies that increase access to MOUD at the federal and state levels will be critical to stemming the tide of America's current opioid epidemic.

The purpose of this issue brief is to offer providers and policymakers practical information on the current state of play with respect to treatment for OUD and to put the current environment in the context of lessons learned from the pandemic about how to treat OUD. This analysis is based on a comprehensive review of regulations before, during, and after the pandemic, along with closely related changes in federal law and policy regarding OUD that are not directly linked to the PHE, as well as interviews with leading researchers, providers, and advocates, who are acknowledged in the appendix.

II. Regulatory Background

A. Federal Regulations

At the federal level, evidence-based treatment for OUD is controlled by multiple agencies but primarily by the Drug Enforcement Agency (DEA), the Substance Abuse and Mental Health Services Administration (SAMHSA), and the Food and Drug Administration (FDA). See Box 2 for a description of the role of each of these federal agencies.

⁸ In this document, PHE refers to the COVID-19 public health emergency, which ended on May 11, 2023.



Box 2. Key Federal Agencies With Regulatory Authority Over MOUD

- <u>DEA</u>: Enforces the controlled substances laws and regulations, including determining which substances are
 controlled and to what extent, and supports programs to reduce the supply of illicit controlled substances in
 domestic and international markets. The DEA also handles registration of providers who can prescribe
 controlled substances, including MOUD. All prescribers who handle controlled substances must register with
 the DEA for the state in which they are licensed and prescribe such substances.
- <u>SAMHSA</u>: Manages oversight activities to implement federal regulations surrounding drugs used in MOUD by
 practitioners and opioid treatment programs (OTPs), which dispense methadone. SAMHSA also oversees the
 accreditation and certification system for OTPs. Additionally, SAMHSA issues rules and guidance to protect
 patient confidentiality related to disclosure of patient records per 42 CFR Part 2.
- FDA: Ensures and approves the safety, efficacy, and security of human drugs, including medications required for OUD treatment.

The federal regulatory context is detailed and can be confusing. A summary of the current situation as of June 2023 is below and it is followed with a table that gives more context.

Telehealth

PHE-era prescribing flexibilities extend through November 11, 2023. Established practitioner patient telemedicine-only relationships will be permitted through November 11, 2024.



Registration

Providers no longer need an X-waiver but all DEA registrants must take an 8-hour class starting in June. There is no limit or cap on the number of patients a prescriber may treat with buprenorphine.



Take-Home Doses

SAMHSA's proposed rule and guidance issued in April will allow OTPs to provide takehome doses of methadone within specified limits until a permanent rule is filed.



In addition, states can add their own layer of regulation to SUD treatment, as further described below, after the table detailing federal flexibilities.



Table: Federal Pandemic-Era OUD Treatment Policies (as of June 2023)

Agency		Pre-PHE		PHE		Post-PHE	
				Registration of Providers Prescribing MC	UD		
DEA	•	Providers treating patients with controlled substances have to register with the DEA. As of 2000, in accordance with the Drug Addiction Treatment Act (DATA), providers treating patients with buprenorphine for OUD also had to complete an additional registration known as the DATA-waiver or X-waiver, which allowed them to prescribe buprenorphine to up to 30 patients outside the OTP setting. They had to complete an 8-hour training associated with the X-waiver.	•	Not specifically related to the PHE, in April 2021, the Department of Health and Human Services (HHS) issued "Practice Guidelines for the Administration of Buprenorphine for Treating Opioid Use," which exempted eligible physicians and most mid-levels from some requirements related to training and counseling that had been required for obtaining a waiver to treat up to 30 patients with buprenorphine. 10	•	On December 29, 2022, the Consolidated Appropriations Act of 2023 ¹¹ removed the X- waiver requirements. On January 12, 2023, the DEA issued a letter stating that the following changes are in effect in accordance with the act: ¹² A DATA- or X-waiver is no longer required to treat a patient with buprenorphine for OUD. All prescriptions for buprenorphine only require a standard DEA registration number. The previously used DATA-waiver registration numbers are no longer needed for any prescription. There are no longer any limits or caps on the number of patients a registered prescriber may treat for OUD. Effective June 2023, the act requires 8 hours of training on the treatment and management of patients with opioid or other substance use disorders for all DEA registrants (not only MOUD).	
	Telehealth						
DEA	•	The Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (Ryan Haight Act) ¹³ generally required practitioners to see a patient in person before	•	In March 2020, the in-person requirement for prescribing controlled substances was suspended by the DEA	•	On May 10, 2023, DEA issued a temporary rule that would extend all PHE telehealth flexibilities for 6 months (May 11, 2023, to November 11, 2023) and allows providers an additional year (until November 11, 2024) to schedule an in-	

⁹ Pub. L. 106-310. (October 17, 2000). Data Addiction Treatment Act of 2000.

¹⁰ HHS. (April 28, 2021). <u>Practice Guidelines for the Administration of Buprenorphine for Treating Opioid Use</u>.

¹¹ Pub. L. 117-328. (December 29, 2022). Consolidated Appropriations Act, 2023.

¹² DEA. (January 12, 2023). <u>Letter to DEA Registrants</u>.

¹³ Pub. L. 110-425. (October 15, 2008). Ryan Haight Online Pharmacy Consumer Protection Act of 2008.



Agency	Pre-PHE	PHE	Post-PHE
	prescribing controlled substances via telehealth, including MOUD, unless 1 of 7 statutory exceptions is met. Under this law, DEA was given the authority to create a special registration for telemedicine, an authority it has not implemented to date.	 (if certain circumstances are met) in light of the HHS-declared PHE.¹⁴ DEA-registered providers were allowed to prescribe across state lines as long as the laws of both states allowed it.¹⁵ 	person examination for patients with whom the prescribing practitioner has a telemedicine relationship established via PHE telemedicine prescribing flexibilities on or before November 11, 2023. 16 This interim rule was issued to ensure continuity of care while DEA determines next steps and reviews comments on the proposed rule issued on February 24, 2023. See below. • Proposed changes: On February 24, 2023, the DEA published a Notice of Proposed Rulemaking (NPRM) seeking to maintain a subset of the pandemic-era flexibilities for take-home doses and telehealth. The rule would limit telehealth prescribing of buprenorphine to no more than a 30-day supply until a patient is seen in person. It also would require providers to review data in the prescription monitoring program prior to prescribing buprenorphine via telemedicine, and establish additional recordkeeping requirements for audio-only telemedicine. The DEA reported that it had received over 38,000 comments on its proposed rule.
		Take-Home Dosing and Telehealth	
SAMHSA	SAMHSA's regulations for OTPs required in-person visits and only allowed take-home doses of	On March 16, 2020, SAMHSA allowed states to request "blanket exceptions" to allow OTPs to dispense 28-day "takehome," or unsupervised, doses of methadone, where clinically	 SAMHSA updated its Methadone Take-Home Flexibilities Extension Guidance in April 2023, allowing clinicians at OTPs, operating within their judgment, to allow up to 7 unsupervised take- home doses of methadone in the first 2 weeks of

¹⁴ DEA. (March 20, 2020). DEA's response to COVID-19.

¹⁵ DEA. (March 25, 2020). (DEA-DC-018)(DEA067) DEA state reciprocity (final)(Signed).pdf (usdoj.gov).

¹⁶ 88 Fed. Reg. 30037. (May 10, 2023). <u>Temporary Extension of COVID-19 Telemedicine Flexibilities for Prescription of Controlled Medications</u>.

¹⁷ 88 Fed. Reg. 12875. (March 1, 2023). <u>Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person</u> Medical Evaluation.



Agency	Pre-PHE	PHE	Post-PHE
	methadone under certain restrictive circumstances. 18,19	appropriate, which were previously only allowed under rare circumstances. 20 OTPs were also allowed to temporarily waive drug urine-testing requirements. Most states requested and received the exception. 21 To ease concerns about an abrupt ending of these flexibilities, SAMHSA issued guidance in November of 2021 stating that take-home flexibilities will be available for at least a year after the end of the PHE. 22 In OTPs, practitioners were allowed to prescribe buprenorphine via telehealth—including audio-only visits—for new and existing patients; the requirement for an in-person physical evaluation for new patients was waived. Practitioners could continue treating an existing patient of an OTP with methadone via telehealth, including audio-only visits. 23	treatment, up to 14 take-home doses in treatment days 15 to 30, and up to 28 unsupervised take-home doses from 31 days on. 24 This guidance will remain in effect for the period of 1 year from the end of the PHE, or, 'or until such time, if within that 1-year period that HHS publishes final rules, which were proposed on December 13, 2022. See below. • Proposed changes: SAMHSA's NPRM (December 13, 2022) would make permanent pandemic-era flexibilities on take-home doses for methadone and telehealth use for buprenorphine and methadone in OTPs. 25

¹⁸ 42 CFR § 8.12(h)(3)(4). Single take-home doses were available on days the clinic was closed for business or if the medical director of an OTP determined the patient met a number of subjective criteria, which in practice could take months or even years.

¹⁹ Krawczyk, N., Rivera, B.D., Levin, E., Dooling, B.C.E. (March 8, 2023). <u>Synthesizing Evidence on the Impacts of COVID-19 Regulatory Changes on Methadone Treatment for Opioid Use Disorder: Implications for U.S. Federal Policy</u>. *Lancet Public Health*.

²⁰ SAMHSA. (March 16, 2020). Methadone Take-Home Flexibilities Extension Guidance | SAMHSA.

²¹ Pessar, S.C., Boustead, A., Ge, Y., Smart, R., et al. <u>Assessment of State and Federal Health Policies for Opioid Use Disorder Treatment During the COVID-19 Pandemic and Beyond</u>. *JAMA Health Forum*.

²² SAMHSA. (Published April 23, 2023; Updated May 1,2023). Methadone Take-Home Flexibilities Extension Guidance.

²³ SAMHSA. (April 21, 2020). FAQs: Provision of methadone and buprenorphine for the treatment of Opioid Use Disorder in the COVID-19 Emergency.

²⁴ SAMHSA. (Published April 23, 2023; Updated May 1,2023). Methadone Take-Home Flexibilities Extension Guidance.

²⁵ 87 Fed. Reg. 77330. (December 16, 2022). Medications for the Treatment of Opioid Use Disorder.



Agency	Pre-PHE	PHE	Post-PHE				
	Consent						
SAMHSA	 Records from federally assisted SUD treatment programs were provided additional privacy protections under 42 CFR Part 2, which requires that patients provide detailed, specific written consent to disclose their records, including for billing purposes. 	• In accordance with its July 15, 2020 final rule, ²⁶ SAMHSA issued guidance ²⁷ "to ensure that SUD treatment services are uninterrupted" during the PHE. Specifically, the guidance stated that prohibitions on the use and disclosure of patient identifying information under 42 CFR Part 2 without written consent would not apply in these situations to the extent that, as determined by the provider(s), a medical emergency exists.	 Proposed changes: SAMHSA issues on November 28, 2022, an NPRM ²⁸ that would better align 42 CFR Part 2 rules with the privacy standards under the Health Insurance Portability and Accountability Act (HIPAA), decrease the need to segregate 42 CFR Part 2 records, and improve care management and coordination for SUD patients. Until finalization of the November 28th NPRM (described above), the pre-pandemic rules are in place. 				
		Enforcement of Security Provisions Re	Re: Telehealth				
HHS/OCR	Under HIPAA, methods of communicating or disclosing protected health information must meet certain security standards.	HHS released a notice on March 17, 2020, stating that it would not enforce HIPAA rules against clinicians and therapists using private communication services such as FaceTime to provide telehealth services during the PHE. ²⁹	In April 2023, the HHS Office for Civil Rights (OCR) announced that the enforcement discretion in place during the PHE would expire on May 11, 2023. OCR is providing a 90-calendar-day transition period to come into compliance with HIPAA rules related to telehealth, beginning on May 12, 2023, and expiring at 11:59 p.m. on August 9, 2023. During this transition period, OCR will not impose penalties for noncompliance with HIPAA rules that occur in connection with the good-faith provision of telehealth.				

²⁶ 85 Fed. Reg. 42986. (July 15, 2020). <u>Confidentiality of Substance Use Disorder Patient Records</u>.

²⁷ SAMHSA. COVID-19 Public Health Emergency Response and 42 CFR Part 2 Guidance.

²⁸ 87 Fed. Reg. 74216. (Dec. 2, 2022). <u>Confidentiality of Substance Use Disorder (SUD) Patient Records</u>.

²⁹ 85 Fed. Reg. 22024. (Effective March 17, 2020). <u>Notification of Enforcement Discretion for Telehealth Remote Communications During the COVID-19 Nationwide</u>
Public Health Emergency.

³⁰ HHS. (April 11, 2023). HHS Office for Civil Rights Announces the Expiration of COVID-19 Public Health Emergency HIPAA Notifications of Enforcement Discretion.



B. State Regulations

Intersecting this complex federal policy landscape are state policies.³¹ States long have had wide latitude when it comes to regulating care, including but not limited to what is allowed through telehealth; provider licensure, training, and education requirements; and additional state-specific rules governing take-home doses for methadone, licensing of OTP facilities, and confidentiality protections. The overlapping regulation of SUD treatment by multiple federal agencies and states creates a confusing patchwork of requirements.³²

During the pandemic, the federal government eased its restrictions, providing temporary flexibilities in telehealth delivery of OUD care; take-home dosing of methadone; education and registration; patient consent; and other elements linked to the PHE. States, however, varied in the extent to which they embraced federal pandemic-era flexibilities—generating an uneven regulatory landscape that is rapidly evolving.³³

"[During the pandemic], several states had additional preexisting restrictions and regulations in place that imposed barriers to adopting and implementing federal flexibilities and innovative treatment protocols."

—Daliah Heller, PhD, MPH | Vice President, Drug Use Initiatives, Vital Strategies

III. Current State of Play: Q&A

As we emerge from the pandemic, there is confusion when it comes to which pandemic-era policies and flexibilities remain and which revert to pre-pandemic policies, as well as how they interact with a series of changes to OUD policy that unfolded throughout the pandemic but are not linked to the PHE. Below are questions and answers that apply the information in the table above to real-world questions confronting providers, policymakers, advocates, and communities that are navigating this patchwork regulatory framework. In some instances, answers remain unclear.

I'm a primary care doctor who has never prescribed buprenorphine before, but more and more of my patients are struggling with addiction. If I want to be able to prescribe them buprenorphine, what do I need to do?

Answer: You no longer need to obtain an X-waiver from the DEA, but you do need to have a valid DEA registration, and as of June 2023, you must undergo eight hours of training about management of patients with substance use disorder. There is no cap on the number of patients to whom you can prescribe.

I work as a prescriber at the only OTP in a deeply rural state. During the pandemic, I could dispense take-home doses to my patients (28 days for stable patients, 14 days for less stable patients) so they would not have to drive so far each day. Can I still offer take-home doses?

Short Answer: Yes, but you should check with your State Opioid Treatment Authority to see if your state has imposed any additional restrictions that prohibit or limit take-home doses or reversed the flexibility it offered on take-home doses during the pandemic.

³¹ For further information on state pandemic-era MOUD policies, see Pessar, S.C., Boustead, A., Ge, Y., et al. (November 19, 2021). <u>Assessment of State and Federal Health Policies for Opioid Use Disorder Treatment During the COVID-19 Pandemic and Beyond</u>. *JAMA Health Forum*. Baaklini, V., Doyle, S., McGaffey, F. (June 1, 2022). <u>Most States Eased Access to Opioid Use Disorder Treatment During the Pandemic</u>. *Pew Charitable Trusts*.

³² Ibid.

³³ Ibid.



Discussion: Prior to the PHE, the majority of patients using methadone were required to visit a clinic daily, a significant challenge for many patients in light of employment and personal responsibilities, in addition to transportation barriers.³⁴

During the PHE, SAMHSA allowed states to request "blanket exceptions" to allow OTPs to dispense take-home, or unsupervised, doses of methadone, previously only allowed under rare circumstances. OTPs were also allowed to temporarily waive urine drug-testing requirements. Most states requested and received the exception. 36,37,38

In April 2023, SAMHSA extended these flexibilities up until one year after the end of the PHE, giving itself time to make permanent changes to its take-home dosing policy through formal rulemaking. ³⁹ SAMHSA already has indicated that it is likely to make most of the flexibilities permanent; in a proposed rule on methadone issued on December 12, 2022, ⁴⁰ SAMHSA suggested it will allow take-home doses of methadone but would impose certain restrictions on audio-only visits in cases where methadone is being used.

"The current methadone system perpetuates the notion that recovery is a full-time job. Patients are in need of increased social supports and greater access/openness to clinics. Above all, patients are in need of care delivery models that normalize components of MOUD within daily life."

—Beth Meyerson, MDiv., PhD | Professor, Family and Community Medicine, College of Medicine, University of Arizona; Director, Harm Reduction Research Lab, Family and Community Medicine, College of Medicine, University of Arizona

"We need to have methadone in additional settings ... It's frustrating as a physician ... I've lost more patients since 2020 than in the entire time I've been practicing medicine, and these deaths are PREVENTABLE. And it's not because we don't have ... the tools. Methadone is the longest-standing medication with evidence to support decreased mortality when treating an opioid use disorder and we have the data to show its efficacy, yet we continue to limit it."

—Dr. Ayana Jordan, MD, PhD | Barbara Wilson Associate Professor of Psychiatry, Department of Psychiatry, NYU Grossman School of Medicine; Associate Professor, Department of Population Health, NYU Grossman School of Medicine

Preserving take-home flexibilities is supported by research, which strongly suggests that the increase in take-home methadone did not result in an increase in harm, specifically increases in overdoses, or more negative urine drug tests. ⁴¹ The research also reported that patients preferred take-home doses, which allowed them more

³⁴ Levander, X.A., Hoffman, K.A., McIlveen, J.W., et al. (December 11, 2021). <u>Rural Opioid Treatment Program Patient Perspectives on Take-Home Methadone Policy Changes during COVID-19: A Qualitative Thematic Analysis</u>. *Addict Sci Clin Pract*.

³⁵ 87 Fed. Reg. 77330. (Published December 16, 2022). Medications for the Treatment of Opioid Use Disorder.

³⁶ Pessar, S.C., Boustead, A., Ge, Y., et al. (November 19, 2021). <u>Assessment of State and Federal Health Policies for</u> Opioid Use Disorder Treatment During the COVID-19 Pandemic and Beyond. *JAMA Health Forum*.

³⁷ Baaklini, V., Doyle, S., McGaffey, F. (June 1, 2022). <u>Most States Eased Access to Opioid Use Disorder Treatment</u> During the Pandemic. *Pew Charitable Trusts*.

³⁸ Interview on May 8, 2023.

³⁹ SAMHSA. (Published April 23, 2023; Updated May 1, 2023). <u>Methadone Take-Home Flexibilities Extension</u> <u>Guidance</u>.

⁴⁰ 87 Fed. Reg. 77330. (December 16, 2022). Medications for the Treatment of Opioid Use Disorder.

⁴¹ Amram, O., Amiri, S., Panwala, V., et al. (November 2, 2022). <u>The Impact of Relaxation of Methadone Take-Home Protocols on Treatment Outcomes in the COVID-19 Era</u>. *Am J Drug Alcohol Abuse*.



flexibility to meet the demands of work and family. ⁴² This was a finding supported by other studies and especially true of those living in rural communities or very far from their OTP, as they did not have to spend time daily traveling for treatment. ⁴³

I am a physician who treats many patients with OUD. During the pandemic, I used telehealth so that my patients (even those who moved to another state) wouldn't have to see me in person if they needed to start using buprenorphine or required a refill. Can I keep using telehealth in this way after the PHE ends?

Short Answer: It depends. For now, you can unless it's prohibited by your state.

Discussion: The DEA clearly is still debating how best to handle telehealth prescribing of buprenorphine now that the PHE has ended. After its initial proposed rule on the topic that would have limited telehealth flexibilities drew 38,000 comments, the agency opted to extend pandemic-era flexibilities allowing the prescribing of buprenorphine via telehealth. Specifically, on May 10, 2023, the DEA issued a temporary rule that would extend all PHE telehealth flexibilities for six months (May 11, 2023, to

November 11, 2023). In addition, it stated it will extend until November 11, 2024, the ability for providers to continue prescribing buprenorphine via telehealth without inperson visits, but only with respect to patients with whom the prescribing practitioner has a telemedicine relationship established via PHE telemedicine prescribing flexibilities on or before November 11, 2023. It may be months, if not longer, before the "final" DEA policy is settled. State laws may also impose additional restrictions on use of telehealth, including for use across state lines.

The growing body of research supports expanding the use of telehealth to increase access. During the pandemic, receipt of OUD-

"The pandemic precipitated a dramatic change in care delivery. Prior to the pandemic, care was entirely in person and the clinic had difficulty facilitating same-day counseling and medical services. Telehealth substantially improved patient compliance and adherence to plans of care. It also expanded the catchment area of the clinic and allowed providers to see significantly more patients."

—Dr. Sharon Levy, MD, MPH | Director, Adolescent Substance Use and Addiction Program, Boston Children's Hospital; Associate Professor in Pediatrics, Harvard Medical School

related telehealth services was associated with improved MOUD retention and lower odds of medically treated overdose. ⁴⁵ Incorporation of telehealth technology with MOUD was also associated with higher patient satisfaction, comparable rates of retention, an overall reduction in health care costs, an increase in both access to and usage of buprenorphine, and successful patient engagement even for patients with socioeconomic challenges (e.g., persons experiencing homelessness or those with co-occurring

⁴² FORE (2023). How Have COVID-Era Flexibilities Affected OUD Treatment?

⁴³ Levander, X.A., Hoffman, K.A., McIlveen, J.W., et al. (December 11, 2021). <u>Rural Opioid Treatment Program Patient Perspectives on Take-Home Methadone Policy Changes during COVID-19: A Qualitative Thematic Analysis</u>. *Addict Sci Clin Pract*.

⁴⁴ 88 Fed. Reg. 30037. (May 10, 2023). <u>Temporary Extension of COVID-19 Telemedicine Flexibilities for Prescription</u> of Controlled Medications.

⁴⁵ Jones, C., Shoff, C., Hodges, K., et al. (August 31, 2022). <u>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*.</u>



psychiatric needs). 46,47,48,49,50,51 Telehealth is also especially helpful for specific populations of focus, such as adolescents, for whom an in-home MOUD induction, often in their own bedrooms, can be much more comfortable. 52

I am a nurse practitioner (NP). During the pandemic, my state expanded scope of practice laws to allow NPs and physician assistants (PAs) to prescribe buprenorphine. Will I still be able to prescribe buprenorphine after the lifting of the PHE?

Short Answer: It depends. States control this issue, and some opted to provide more flexibility for nonphysician providers to prescribe buprenorphine during the pandemic. You will need to check directly with a trusted source, such as your state's licensing board or current regulations, to figure out where your state has landed now that the PHE has ended.

Discussion: Even before the PHE, the 2016 Comprehensive Addiction and Recovery Act allowed NPs and PAs—in addition to physicians—to obtain buprenorphine-prescribing waivers. The Centers for Medicare & Medicaid Services also waived previous limitations to allow NPs, PAs, and other professionals to provide services to Medicare beneficiaries via telehealth. These federal provisions are subject to state scope of practice laws. Before the pandemic, a minority of states (19 states and Washington, D.C.) gave full practice authority to NPs, and even fewer (five states) waived PA practice agreements, allowing them to initiate as well as manage and prescribe MOUD. ⁵³ During the pandemic, many states, facing workforce shortages, modified their NP and PA licensing requirements and scope of practice laws to meet increased demand. ⁵⁴ Some states have retained these flexibilities, and others have not. ⁵⁵

I am a community-based physician. During the pandemic, my practice was able to take advantage of enhanced telehealth rates for our patients. After the PHE has ended, will these enhanced rates continue?

Short Answer: It depends on which state your community-based practice is located in, but probably not.

Discussion: If your patients use Medicare for insurance, during the PHE, all telehealth claims were paid at the non-facility rate, which is higher than the facility rate, but this ended in CY2023, and all rates will return to being facility- or non-facility-based. So, facility rates will drop.

If your patients use Medicaid, payment parity—paying the same for telehealth and in-person visits—exists in some states but not in others. As of May 2023, 21 states have implemented policies requiring

⁴⁶ FORE. (2023). How have COVID-Era Flexibilities Affected OUD Treatment?

 ⁴⁷ Krawczyk, N., Rivera, B.D., King, C., et al. (March 17, 2023). Pandemic Telehealth Flexibilities for Buprenorphine Treatment: A Synthesis of Evidence and Policy Implications for Expanding Opioid Use Disorder Care in the U.S.
 ⁴⁸ Weintraub, E., Greenblatt, A.D., Chang, J., et al. (December 27, 2018). Expanding Access to Buprenorphine

Treatment in Rural Areas with the Use of Telemedicine. Am J Addict.

⁴⁹ Lockard, R., Priest, K.C., Gregg, J., et al. (2022). <u>A Qualitative Study of Patient Experiences with Telemedicine</u> <u>Opioid Use Disorder Treatment during COVID-19</u>. *Subst Abus*.

⁵⁰ Czeisler, M.É. (2022). <u>A Case for Permanent Adoption of Expanded Telehealth Services and Prescribing</u>
<u>Flexibilities for Opioid Use Disorder: Insights From Pandemic-Prompted Emergency Authorities</u>. *JAMA Psychiatry*.

⁵¹ Interviews on May 8, 2023, and May 9, 2023.

⁵² Interview on May 9, 2023.

⁵³ Pessar, S.C., Boustead, A., Ge, Y., et al. (November 19, 2021). <u>Assessment of State and Federal Health Policies for Opioid Use Disorder Treatment During the COVID-19 Pandemic and Beyond</u>. *JAMA Health Forum*.

⁵⁵ American Association of Nurse Practitioners. (January 18, 2023). <u>COVID-19 State Emergency Response:</u> <u>Temporarily Suspended and Waived Practice Agreement Requirements.</u>



payment parity, seven states have payment parity in place with caveats, and 22 states have no payment parity. 56

My son is struggling with addiction and is not ready for treatment. I want to make sure that he does not overdose while he is using. How can I get access to naloxone, fentanyl testing strips, and other harm reduction supplies?

Short Answer: It depends on which state your son lives in. He should be able to get naloxone without a prescription, but fentanyl strips and harm reduction supplies may be much harder to obtain.

Discussion: Although access to harm reduction services and supplies is governed by state and federal laws, many states' criminal laws, as well as zoning laws and local politics, have curbed access. For example, although SAMHSA removed federal funding restrictions on fentanyl testing strips,⁵⁷ many states continue to have criminal laws on the books that categorize fentanyl strips as drug paraphernalia. And while some states have supported expanding harm reduction access (e.g., launching naloxone and syringe access campaigns, and even, in the case of Rhode Island⁵⁸ and New York City,⁵⁹ opening safe injection sites), other states have grappled with zoning laws and local politics that have prevented

Box 3. Background on Harm Reduction

Harm reduction encompasses evidence-based, practical strategies aimed at reducing the negative consequences associated with drug use and includes education on safe use, syringe access programs, and distribution of naloxone and fentanyl testing strips. A harm reduction perspective sees SUD as a public health issue, and alongside treatment, these strategies are critical to saving lives, especially when individuals are not ready for treatment, by meeting individuals where they are and engaging them in their journeys toward better health. Recognizing the increasing importance of harm reduction strategies—namely naloxone, on March 29, 2023, the FDA approved the first over-the-counter naloxone spray. And prior to that, on April 7, 2021, SAMHSA removed previous restrictions on using federal dollars to pay for fentanyl testing strips.

the expansion of and even shut down syringe access programs. 60

My best friend lives across the country in one of the states that is a known leader in addressing OUD, but she is still struggling to find anyone in her county who will help her with her addiction issues. Is there any hope of access improving where she lives after the pandemic?

Short Answer: It depends. There is significant momentum at the state and federal levels to preserve many of the flexibilities afforded during the pandemic. Even if these flexibilities are preserved, however, it is unclear how it will improve access to care for your friend in the county where she lives. Due to nationwide workforce shortages, even if a state takes full advantage of the federal flexibilities afforded, there still may be provider deserts in that state. If access does not improve, she could potentially rely on telehealth with a provider in another county or another state if state law permits.

⁵⁶ Augenstein, J., Marks Smith, J. (May 5, 2023). <u>Executive Summary: Tracking Telehealth Changes State-by-State in Response to COVID-19</u>. *Manatt Insights*.

⁵⁷ Legislative Analysis and Public Policy Association. (May 2021). Fentanyl Test Strips.

⁵⁸ Warnic, A. (October 2021). <u>Rhode Island Approves Nation's First Site for Safe Drug Injection Use</u>. *The Nation's Health*.

⁵⁹ Mays, J.C., Newman, A. (November 20, 2021). <u>Nation's First Supervised Drug-Injection Sites Open in New York</u>. *New York Times*.

⁶⁰ National Association of Counties. (January 23, 2023). <u>Syringe Service Programs</u>.



Discussion: Both the DEA and SAMHSA have introduced rules to preserve many of the pandemic-era flexibilities, including around telehealth, but none have been finalized. Further, as seen during the pandemic, these federal changes—even if implemented—run the risk of being applied unevenly. As was seen during the pandemic, state laws sometimes limit the flexibilities afforded at the federal level, resulting in disparities and inequities in access and outcomes. Providers also may choose not to take advantage of the flexibilities afforded either at the federal or state level. For example, one study in Arizona found that "nothing really changed" and MOUD patients in Arizona were not offered many of the federally allowed flexibilities for access that were designed to reduce their need to be at the clinic. 61,62

Much of this uneven landscape is due to stigma, a set of negative attitudes and stereotypes, which strongly impacts people who use drugs and who suffer from SUD. When there is allowance for variation in policy application—as has been the case with state flexibilities—it tends to have the effect of reinforcing existing underlying stereotypes, which further compounds disparities and inequities in access and outcomes for people already stigmatized in various ways. This is especially true for persons of color with OUD. For example, one study found that during the pandemic, more white patients than those of color had access to take-home methadone doses. Among the OTPs studied, the researchers could not find evidence that these programs determined who was "clinically stable" based on national protocols, suggesting that "these differences may have been mediated by interpersonal racism, with providers more likely to view white patients as reliable." These observations are supported by a growing body of research highlighting racial and ethnic disparities in the receipt of MOUD, ^{64,65} as well as the pernicious impacts of implicit bias⁶⁶ and research findings that Black patients seeking care for their addiction experience "elevated group-based medical mistrust," which is associated with their receiving worse treatment access and retention outcomes than their white counterparts.^{67,68}

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⁶¹ Meyerson, B., Bentele, K.G., Russell, D.M., et al. (October 25, 2022). <u>Nothing Really Changed: Arizona Patient Experience of Methadone and Buprenorphine Access during COVID</u>. *PLOS ONE*.

⁶² Interview on May 9, 2023.

⁶³ FORE. (2023). How Have COVID-Era Flexibilities Affected OUD Treatment?

⁶⁴ Barnett, M.L., Meara, E., Lewinson, T., et al. (May 11, 2023). <u>Racial Inequality in Receipt of Medications for Opioid Use Disorder</u>. *NEJM*.

⁶⁵ Hansen, H., Siegal, C., Wanderling, J.(July 1, 2016). <u>Buprenorphine and methadone treatment for opioid</u> dependence by income, ethnicity and race of neighborhoods in New York City. *Drug and Alcohol Dependence*.

⁶⁶ Hairston, D.R., Gibbs, T.A., Wong, S.S., et al. (2019). <u>Clinician Bias in Diagnosis and Treatment. In: Medlock, M.,</u> Shtasel, D., Trinh, NH., Williams, D. (eds), Racism and Psychiatry. Current Clinical Psychiatry. *Humana Press, Cham.*

⁶⁷ Hall, O.T., Bhadra-Heintz, N.M., Teater, J., et al. (January 18, 2022). <u>Group-based Medical Mistrust and Care Expectations among Black Patients seeking Addiction Treatment</u>. *Drug Alcohol Depend Rep*.

⁶⁸ Interview on May 16, 2023.



IV. Conclusion

The pandemic brought with it many painful lessons and tremendous loss, but in treatment for OUD, it

also showed us what is possible. Issues that previously seemed intractable or were just accepted as the norm saw rapid advancement and resolution. ⁶⁹ As we emerge from the PHE, we are equipped with a growing body of research supporting enhanced flexibilities, but we are also challenged by the persistent unease about taking advantage of these flexibilities, possibly in part because of the pace of change over the past several years. These dynamics are playing out against an increasingly potent and dynamic drug supply, making it all the more critical to ensure equitable access to effective

"True policy change is always incremental at best, but the pandemic demonstrated that structural, systemic change was possible. There has been tremendous innovation in federal and administrative policy, and hopefully states will begin to move accordingly."

—Beth Meyerson, MDiv., PhD | Professor, Family and Community Medicine, College of Medicine, University of Arizona; Director, Harm Reduction Research Lab, Family and Community Medicine, College of Medicine, University of Arizona

treatment. The opportunities created by the pandemic bring with them several calls to action, as noted in FORE's April 2023 report *How Have Covid-Era Flexibilities Affected OUD Treatment?*⁷⁰ Specifically:

• Democratizing access at the federal level. As underscored by the research, the flexibilities of telehealth and take-home doses—where taken advantage of—helped improve access to care. These flexibilities also afforded providers more discretion to customize treatment protocols based on their patients' needs and preferences and determine what is clinically most appropriate in the face of shifts in the drug supply. For example, as the drug supply has become more contaminated by other novel substances (e.g., xylazine)⁷¹ and fentanyl, a synthetic opioid 50 times stronger than heroin, research is emerging to show that buprenorphine is associated with more precipitated withdrawal symptoms, leading providers to prefer methadone as a more efficacious treatment and in higher doses in certain contexts. ^{72,73,74} Methadone, however, is harder to access than buprenorphine. In fact, a quarter of the U.S. population lives in a county without an OTP, and Wyoming has no OTPs. ⁷⁵ These findings support preserving federal flexibilities when it comes to take-home doses and enhancing responsible access to methadone to meet patients' needs and prescriber and patient preferences.

⁶⁹ Interview on May 4, 2023.

⁷⁰ FORE. (2023). How Have COVID-Era Flexibilities Affected OUD Treatment?

⁷¹ The White House. (April 12, 2023). <u>Biden-Harris Administration Designates Fentanyl Combined with Xylazine as an Emerging Threat to the United States</u>. ONDCP. Briefing Room. Press Release.

⁷² Facher, L. (March 21, 2023) . <u>Methadone doses haven't kept up in the age of fentanyl. A new rule aims to help</u>. *STAT News*.

⁷³American Association for the Treatment of Opioid Dependence in partnership with the National Association of State Alcohol and Drug Abuse Directors. (September 2022). <u>Technical Brief: Census of Opioid Treatment Programs</u>.

⁷⁴ Interviews on April 26, 2023, May 4, 2023, and May 16, 2023.

⁷⁵ Joseph, A. (December 22, 2022). <u>Under new rules, methadone clinics can offer more take-home doses. Will they?</u> *STAT News.*



Both SAMHSA and the DEA have issued proposed rules to make permanent pandemic-era flexibilities on take-home doses and telehealth. SAMHSA's rule draws upon research done during the PHE, including on methadone take-home doses. The unprecedented number of comments on

the DEA's proposed rule on telehealth access to controlled substances suggests that practitioners are ready to move the state of practice forward, given their experience during the PHE.

Ensuring equitable access at the state and local levels. As noted in FORE's April 2023 report, "federal regulatory changes are necessary but not sufficient to expand access to treatment." With the end of the PHE, as federal policies move toward increasingly relaxed regulations, states will maintain their discretion regarding whether and how to support federal regulatory changes. During the PHE, some states invested more resources

"Even if we have a policy that allows people to have easier access to their medication, that does not translate to equitable receipt of care on the ground. [And] mistrust is not the only reason we have inequities in treatment and outcomes. There haven't been enough resources to make sure [there] is access to treatment and harm reduction, which is a real failure of public policy."

—Dr. Ayana Jordan, MD, PhD | Barbara Wilson Associate Professor of Psychiatry, Department of Psychiatry, NYU Grossman School of Medicine; Associate Professor, Department of Population Health, NYU Grossman School of Medicine

into PHE-era changes with enhanced training, technical assistance, detailed guidance, and communication, and others invested less, resulting in providers being less willing to embrace the flexibilities and expand access. According to a recent Pew Charitable Trusts survey, most states

reported that they plan to maintain the flexibilities after the pandemic for as long as the federal government permits.⁷⁷ A few states, however, already have rescinded some of their policies or indicated they had planned to even before the end of the pandemic. 78 Several states also impose stringent regulations on OTPs, impeding access to methadone. Nineteen states and the District of Columbia, according to another 2022 Pew survey, require a certificate of need for a new treatment facility to be opened, and seven states and the District of Columbia enforce zoning regulations that restrict where clinics can operate.⁷⁹ Additionally, several states have restrictive laws on access to harm reduction services (e.g., access to clean syringes⁸⁰ and fentanyl testing strips⁸¹). With the end of the PHE, it is critical

Box 4: State Strategies for Continuity of Coverage

As noted in a State Health & Values Strategies and Manatt Health <u>report</u>, below are critical levers states can use to ensure continuity of Medicaid coverage with the PHE unwinding and the loss of continuous coverage.

- Update member contact information
- Conduct integrated outreach and education campaigns
- Develop unwinding plans and monitoring processes
- Improve redetermination processes
- Engage the community and other key partners
- Leverage health plans and providers
- Address workforce constraints
- Promote seamless coverage transitions

⁷⁶ FORE. (2023). How Have COVID-Era Flexibilities Affected OUD Treatment?

⁷⁷ Baaklini, V., Doyle, S. McGaffey, F. (June 1, 2022). <u>Most States Eased Access to Opioid Use Disorder Treatment During the Pandemic</u>. *Pew Charitable Trusts*.

⁷⁸ Ibid.

⁷⁹ Pew. (September 19, 2022). Overview of Opioid Treatment Program Regulations by State.

⁸⁰ National Association of Counties. (January 23, 2023). Syringe Service Programs.

⁸¹ Legislative Analysis and Public Policy Association. (May 2021). Fentanyl Test Strips.



that states implement supportive policy environments to allow providers to take maximum advantage of whatever federal flexibilities are afforded, which ultimately address disparities and advance health equity. Supportive policy environments mean strengthening the workforce, addressing payment and incentive challenges, and ensuring adequate resources to support a robust continuum of care—from evidence-based prevention activities among our youth to treatment options. ⁸² In addition, as part of ensuring supportive policy environments, it is critical that states mitigate loss of Medicaid coverage during the unwinding of the federal continuous enrollment provision, that prevented them from disenrolling individuals from coverage during the PHE. ^{83,84}

Box 5. A return to normal ignores the important information gleaned during the past three years. During the pandemic, there were several research studies conducted that overall supported preserving PHE MOUD flexibilities. These findings include the following:

- Use of telehealth was associated with improved MOUD retention and lower odds of medically treated overdose, increased access of buprenorphine, increased patient satisfaction, and successful patient engagement. 45,46,47,48,49,50,51,52
- Methadone doses did not result in increased harms (e.g., increased overdoses).⁴¹
- Many patients preferred take-home doses, allowing them to better meet other professional and personal responsibilities.^{42,43}
- Continuing research. As the PHE ends, many policymakers are looking for a "return to normal" as opposed to seeking out the research and acting on lessons learned. A return to normal ignores the important information gleaned during the past three years. We need to develop better measures for quality that hinge on what works, not on what we think we know. Further, as the drug supply continues to change and intensify, it becomes all the more urgent to have actionable and timely data and to continuously research which treatment and harm reduction services are working, as well as information about the most effective ways to increase access.
- Ending stigma. Stigma surrounding people who use drugs is pervasive and creates serious barriers to care. Even with the most data-driven policies in place, there still may be providers reluctant to ease restrictions and expand access, in part because of an implicit bias against drug users in the organization in which they work. During the PHE, this bias—along with risk aversion, financial concerns, and the belief that therapeutic bonds require in-person connection—contributed to some providers being less willing to take advantage of the federal flexibilities. As the PHE ends, however, overdose deaths continue to rise. More than ever before, there is an unprecedented understanding of what it means personally to struggle with addiction. Nearly half of Americans have a family member or friend struggling with addiction.⁸⁵ With this enhanced shared understanding comes an opportunity to address the overdose epidemic with compassion and empathy—potent antidotes to the stigma that has become so deeply entrenched.

⁸² Interviews on April 26, 2023; May 2, 2023; May 4, 2023; May 8, 2023; and May 16, 2023.

⁸³ Gould, G. (December 20, 2021). <u>States Plan for the End of the Medicaid Continuous Coverage Requirement</u>. *National Academy for State Health Policy*.

⁸⁴ Tolbert, J. (April 5, 2020). <u>10 Things to Know About the Unwinding of the Medicaid Continuous Enrollment</u> Provision. *KFF*.

⁸⁵Gramlich, J. (October 26, 2017). <u>Nearly half of Americans have a family member or close friend who's been addicted to drugs</u>. *Pew.*



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