

Buprenorphine Prescribing Requirements and Limitations

February 2024

Cydney M. Murray, JD
Adam Herpolsheimer, JD
Alexander Frazer, JD

Introduction

In the United States, 6.1 million people over the age of 12 had an opioid use disorder (OUD) in 2022,¹ and 80,411 opioid-related overdose deaths were recorded in 2021 alone.² In addition to harming an individual's physical health (e.g., elevated risk of bloodborne infectious diseases, weakened immune system), OUD can severely disrupt a person's ability to engage with their family, work, and community.³ The cause of the overdose crisis is multifaceted, with contributing factors including poor regulation, dishonest practices within the pharmaceutical industry, and the rise of synthetic opioids such as fentanyl.⁴ Federal and state law play critical roles in both exacerbating and ameliorating the crisis. The legal classification of opioids, punitive drug criminalization, restrictions on prescribing opioids for pain management, and the implementation of various mitigation strategies all have unique impacts on the ebb and flow of the overdose crisis.

Expanding the use of medications for opioid use disorder (MOUD), specifically agonist medications buprenorphine and methadone, is a successful mitigation strategy to reduce opioid overdose deaths. MOUD is a treatment approach using medications approved by the Food and Drug Administration (FDA) to treat OUD.⁵ The FDA has approved three medications for the treatment of OUD — methadone, buprenorphine, and naltrexone⁶ — but methadone and buprenorphine are the only two proven to save lives.^{3,7} As a partial opioid agonist, buprenorphine reduces opioid withdrawal symptoms and cravings⁸ to support an individual's recovery. Although buprenorphine is classified as a Schedule III controlled substance and has been subject to heightened regulation since its approval for the treatment of OUD in 2002, the medication can be prescribed outside of specialized treatment settings, including in primary care settings, commonly referred to as “office-based opioid treatment” or “OBOT.”⁹ This contrasts sharply with methadone, which must be dispensed through a federally certified opioid treatment program (OTP).

This policy brief provides an overview of the legal landscape of buprenorphine prescribing requirements and limitations in non-OTP practice settings as of March 1, 2023, summarizes key findings of evidence evaluating their impact on treatment access and quality, and provides policy and research recommendations moving forward. The research protocol accompanying the legal dataset created by the Center for Public Health Law Research at Temple University Beasley School of Law with the Vital Strategies Overdose Prevention Program includes additional information on the scope of state laws captured by the dataset and this policy brief.¹⁰

Current Legal Landscape

Because of its federal classification as a Schedule III controlled substance, buprenorphine is governed by the Controlled Substances Act (CSA). Federal regulation of buprenorphine for OUD has evolved over time, trending toward fewer restrictions to expand access to treatment.¹¹ Federal law generally requires a separate DEA registration to use narcotic drugs in the treatment of OUD,¹² but the Drug Addiction Treatment Act of 2000 (DATA 2000) created an exception commonly referred to as the X-Waiver.⁹

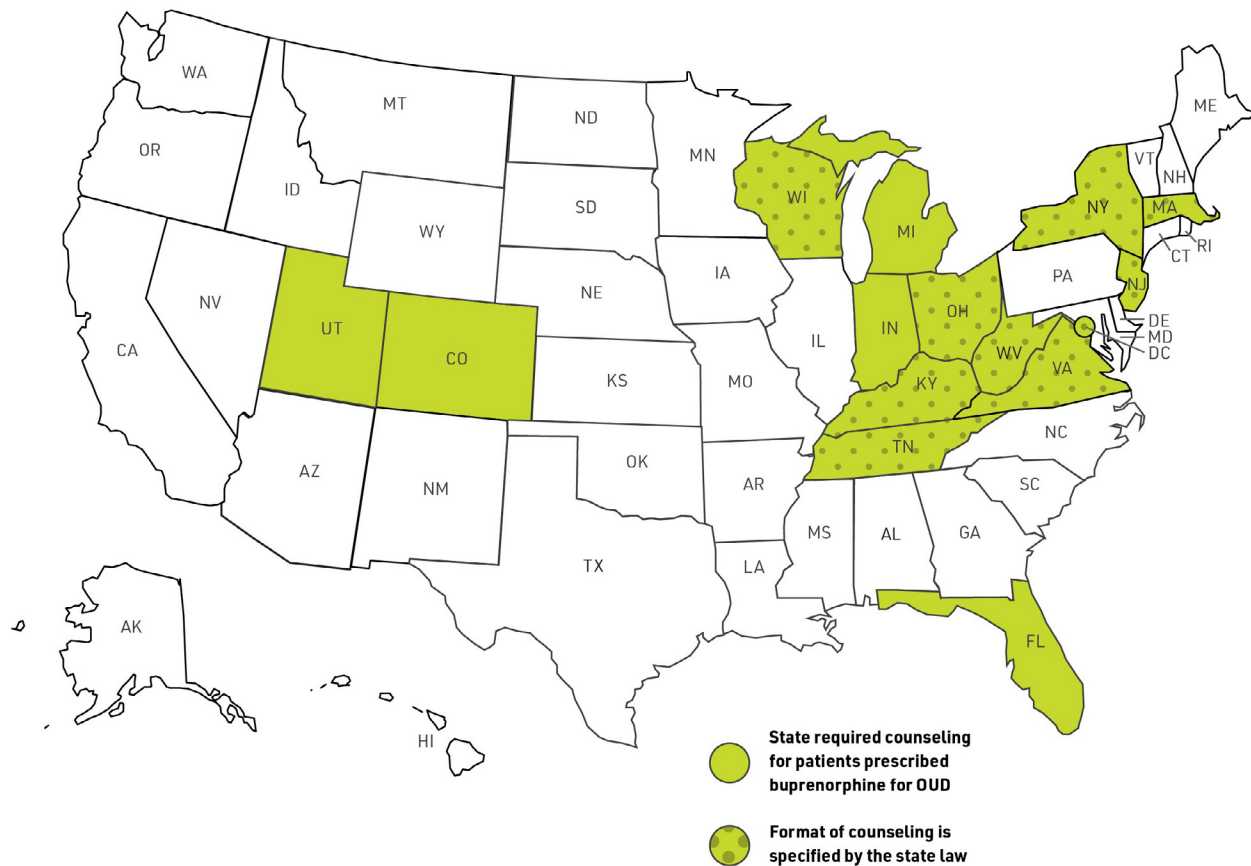


Figure 1. As of March 1, 2023, 19 states and the District of Columbia explicitly regulated buprenorphine prescribing for OUD.

The X-Waiver was a federal requirement that demanded providers undergo additional training and enrollment processes to prescribe controlled substances classified as Schedule III through V, like buprenorphine for the treatment of OUD outside of an OTP setting. This meant that prescribers were tasked with fulfilling cumbersome requirements such as administrative filings, certifications, and patient caps.⁹ In 2016, the Comprehensive Addiction and Recovery Act (CARA) expanded access, extending X-Waiver eligibility to nurse practitioners and physician assistants.^{13, 14, 15} Then, in 2018, the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) further extended X-Waiver eligibility to clinical nurse specialists, certified nurse midwives, and certified registered nurse anesthetists through October 2023.^{14, 16}

Regulatory hurdles to buprenorphine prescribing for OUD remained despite this expanded provider eligibility. On December 29, 2022, the CSA was again amended to entirely remove the requirement that practitioners obtain an X-Waiver to prescribe buprenorphine for OUD.¹⁷ Any practitioner with a DEA registration that includes Schedule III prescriptive authority may now prescribe buprenorphine to treat OUD.¹⁸ However, while federal law has gradually moved toward more permissive regulation of buprenorphine prescribing, practitioners must still adhere to any applicable state laws on the issue.¹⁸

State buprenorphine prescribing requirements and limitations vary, with some state laws maintaining restrictive barriers to buprenorphine access, while some states implement protective provisions for patients in treatment. As of March 1, 2023, 19 states and the District of Columbia had statutes and/or regulations that explicitly governed buprenorphine prescribing for OUD in non-OTP settings.¹⁰ These state laws are equally varied; decriminalization of buprenorphine possession, regulations surrounding initial evaluations, counseling and drug testing requirements, regulation of perceived patient “non-compliance,” tapering requirements, and dosage restrictions all differ across jurisdictions.¹⁰

Notably, as of March 1, 2023,

- Fifteen states explicitly incorporated federal law provisions related to the X-Waiver, which is no longer consistent with federal law.¹⁰
- Fourteen states and the District of Columbia required counseling for patients prescribed buprenorphine for OUD, with four states establishing a minimum frequency of counseling.¹⁰
- Seventeen states and the District of Columbia required drug testing when prescribing buprenorphine for OUD, with eight of these states specifying the frequency of required testing.¹⁰
- Six states regulated buprenorphine initiation dosages and seven states regulated buprenorphine maintenance dosages.¹⁰
- Fourteen states regulated how a practitioner responds to patient “non-compliance.”¹⁰

As implicitly reflected by the movement toward deregulation by federal lawmakers and explicitly reflected in recent federal guidance,¹⁹ restrictive regulations of buprenorphine prescribing for OUD create barriers to access for this lifesaving treatment. These barriers may exacerbate existing disparities in treatment outcomes among traditionally marginalized populations such as Black and Hispanic patients,²⁰ and research suggests their removal may have outsized benefits for certain racial or ethnic minorities.²¹ The recent repeal of the X-Waiver and associated requirements provide state policymakers with an opportunity to revisit any existing laws on the issue, and to strongly consider applying a low-barrier (also referred to as low-threshold) buprenorphine treatment framework to their policy decision-making. For example, policymakers could follow the lead of four states (IN, NY, OH, WI) that codified requirements regarding the provision of or prescription for opioid overdose reversal drugs (e.g., naloxone), or the three states (MA, NY, VT) that prohibit involuntary discharge from treatment in response to one or more types of patient non-compliance.¹⁰ Within a low-barrier buprenorphine treatment framework, policymakers can prioritize same-day treatment entry, a harm reduction approach, flexibility, and availability of treatment in non-traditional settings.^{19, 22}

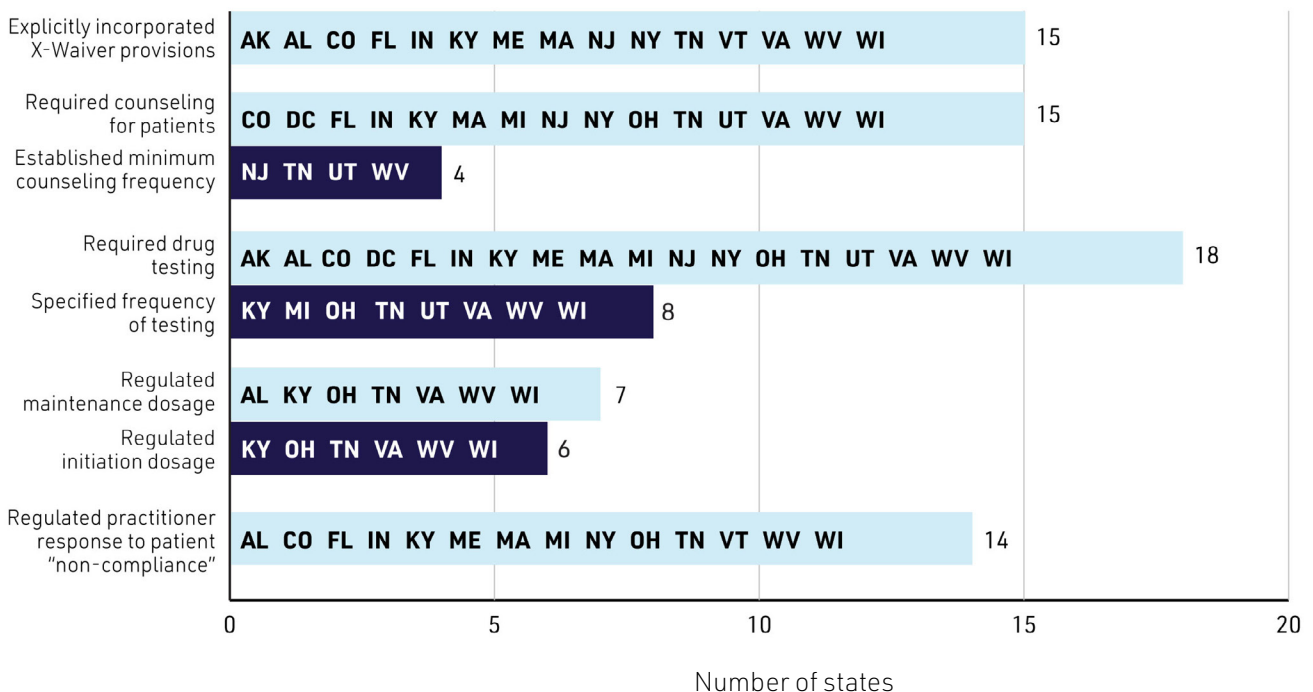


Figure 2. Notable buprenorphine provisions as of March 1, 2023

Evidence

There is strong evidentiary support for the implementation of a low-barrier buprenorphine treatment framework in policymaking.^{19, 21, 23-27} The federal government itself has acknowledged its support for lower barrier access. For example, the Substance Abuse and Mental Health Services Administration (SAMHSA) has clearly expressed that an inability to provide counseling services or referrals should not disqualify potential buprenorphine prescribers from providing treatment,¹⁸ the provision of buprenorphine should not be contingent upon a patient's participation in counseling or other ancillary services,²⁸ and medication misuse or diversion does not automatically disqualify patients from treatment.²⁹ SAMHSA also explicitly acknowledged the removal of patient caps (via the elimination of the X-Waiver) as a means to quickly provide treatment to more patients.¹⁸ A recent advisory from SAMHSA goes further, broadly embracing the importance of low barrier models of care and the need for “[p]olicymakers and stakeholders [...] to identify and address any inhibitors to low barrier care, including [...] regulatory policies.”¹⁹

Research has shown that low-barrier buprenorphine treatment not only expands access to more patients, but does so equitably.²³ Specifically, quicker initiation of treatment, elimination of dosage limits, removal of mandatory counseling requirements, and safeguards against involuntary discharge for return to use may improve treatment retention for more patients while narrowing treatment gaps between different socio-economic groups.^{19, 23, 25-27} Studies conducted around the COVID-19 pandemic, when a myriad of healthcare regulations were relaxed in response to the emergency, support this contention. Improved treatment retention during that period was associated with extended prescription lengths,³⁰ reduced drug testing,³⁰ and generally less restrictive guidelines, such as expanded telemedicine use.²⁴ Research outside of the pandemic has also found no loss in treatment effectiveness²¹ or long-term treatment retention²⁵ among studied populations receiving treatment within a low-barrier framework.

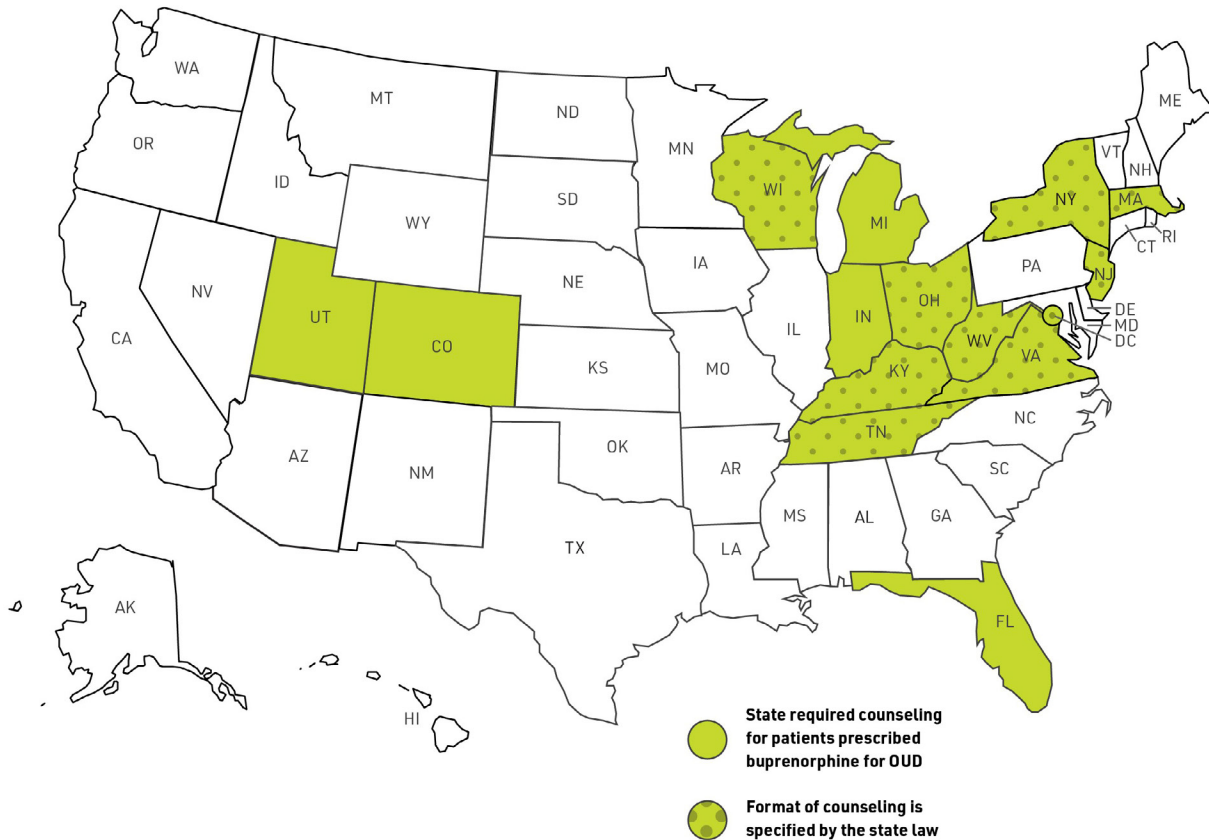


Figure 3. As of March 1, 2023, 14 states and the District of Columbia required mandatory counseling for patients prescribed buprenorphine. Nine of those states and the District of Columbia allowed the state law to decide the required format of counseling.

Policy Recommendations

Considering the federal deregulation of buprenorphine prescribing for OUD in non-OTP settings and the research demonstrating the positive outcomes of low-barrier treatment, state policymakers should strongly consider applying a low-barrier buprenorphine treatment framework to any laws they may have on the issue. In doing so, state policymakers should:

1. Remove outdated references to the X-Waiver. Policymakers in the 15 states that explicitly incorporated federal provisions related to the X-Waiver as of March 1, 2023, should consider amendment or repeal.¹⁰ Doing so would bring state law into congruity with federal law¹⁷ and better align with federal guidance and policies aimed at ensuring expanded access to buprenorphine treatment.^{11, 19, 28}
2. Align state law with evidence-based best practices. Research supports the contention that low-barrier buprenorphine treatment for OUD expands access and improves retention and outcomes in a more equitable manner.^{19, 23, 26} Among other policy changes, state policymakers should strongly consider removing overly burdensome regulations, such as mandatory counseling, tapering, and frequent visit requirements. Instead, policymakers should consider expediting the process for initiating treatment and safeguarding against involuntary treatment termination.
3. Coordinate consistent policymaking across all levels of government. As exemplified by the preservation of X-Waiver provisions in some state laws despite federal repeal, the regulation of buprenorphine prescribing can become inconsistent across different levels of government. Aligning law with evidence-based best practices should go beyond the state level, and policymakers should instead adopt a “Whole-of-Government approach” by prioritizing comprehensive, coordinated action across all levels of government to ensure effective policymaking.³¹ Increasing access to buprenorphine, for example, takes coordination vertically between federal, state, and local governments and at the same time, horizontally among different agencies and actors at one level of government. For example, state and local governments, in coordination with individual correctional facilities, can review and revise policies that hinder access to buprenorphine for OUD while incarcerated.^{31, 32}
4. Center and involve impacted communities in policymaking. Research has associated better treatment retention and engagement with patient trust and prioritizing patient safety over provider concerns about diversion and misuse.^{30, 33, 34} Therefore, policymaking should intentionally include the input and participation of those directly impacted by the overdose crisis, including those living with OUD.

Research Agenda

The Buprenorphine Prescribing Requirements and Limitations dataset on PDAPS.org provides an overview of key features of state laws regulating buprenorphine prescribing for OUD in non-OTP practice settings.¹⁰ While this dataset captures the law as it existed across the country on March 1, 2023, an update would be useful for examining changes in the law, especially as state policymakers react to the federal repeal of the X-Waiver. Additionally, further evaluation of low-barrier buprenorphine treatment, as compared to outcomes under more restrictive approaches, would provide an even stronger evidentiary foundation upon which to base effective, accessible, and equitable laws and policies. Laws and policies regarding buprenorphine prescribing that fell outside of this project’s scope (e.g., Medicaid policy) are also opportunities for further research. Finally, as states trend toward decriminalizing buprenorphine possession (OR and VT having done so by 2021, with RI joining by 2022), research into the impact of decriminalization becomes even more warranted.

Conclusion

With the recent removal of the X-Waiver and associated federal regulations, attention has shifted even more closely to state regulation of buprenorphine treatment. Close monitoring and effective advocacy for evidence-based policymaking is needed since, with federal deregulation, the role of state law has become even more important. With thousands of lives interrupted and ended because of the overdose crisis each year, ensuring equitable, low-barrier access to life-saving treatment must be a priority for researchers, advocates, and policymakers.

Acknowledgements

Support for the creation of this policy brief and the associated Buprenorphine Prescribing Requirements and Limitations dataset was provided by the Vital Strategies Overdose Prevention Program. The authors gratefully acknowledge Derek Carr, JD, and Kate Boulton, JD, MPH, from the Vital Strategies Overdose Prevention Program, as well as Bethany R. Saxon, MS; Hope M. Holroyd, MA; Elizabeth Platt, JD, MA; and Jonathan Larsen, JD, MPP, from the Center for Public Health Law Research at the Temple University Beasley School of Law for their contributions to this dataset and report.

References

- 1 Substance Abuse and Mental Health Services Administration. (2023). *Key Substance Use and Mental Health Indicators in the United States: Results from the 2022 National Survey on Drug Use and Health*, (p. 36) <https://www.samhsa.gov/data/sites/default/files/reports/rpt42731/2022-nsduh-nnr.pdf>
- 2 National Institute on Drug Abuse. (2023, June 30). *Drug Overdose Death Rates*. <https://nida.nih.gov/research-topics/trends-statistics/overdose-death-rates>
- 3 National Academies of Sciences, Engineering, and Medicine. (2019). *Medications for Opioid Use Disorder Save Lives*. Washington, DC: The National Academies Press. <https://doi.org/10.17226/25310>
- 4 The Lancet Regional Health – Americas. (2023). Opioid crisis: addiction, overprescription, and insufficient primary prevention. *The Lancet Regional Health – Americas*, 23, 100557. <https://doi.org/10.1016/j.lana.2023.100557>
- 5 Substance Abuse and Mental Health Services Administration. (2021). *Medications for Opioid Use Disorder: Treatment Improvement Protocol 63*. <https://store.samhsa.gov/sites/default/files/pep21-02-01-002.pdf>
- 6 Substance Abuse and Mental Health Services Administration. (2023, October 3). *Medications for Substance Use Disorders*. <https://www.samhsa.gov/medications-substance-use-disorders>
- 7 Dasgupta, N., Ajazi, E. M., Schwartz, T. A., & Marshall, S. W. (2023). Misclassification of overdose events in the X:BOT study. *The Lancet*, 402(10401), 526–527. [https://doi.org/10.1016/s0140-6736\(23\)00113-7](https://doi.org/10.1016/s0140-6736(23)00113-7)
- 8 Substance Abuse and Mental Health Services Administration. (2023, September 18). *Buprenorphine*. <https://www.samhsa.gov/medications-substance-use-disorders/medications-counseling-related-conditions/buprenorphine>
- 9 Davis, C. (2023, February 27). *Removal of the “X-Waiver” Requirement*. The Network for Public Health Law. <https://www.networkforphl.org/resources/removal-of-the-x-waiver-requirement/>
- 10 Center for Public Health Law Research & Vital Strategies. (2023). *Buprenorphine Prescribing Requirements and Limitations* [Data set]. Prescription Drug Abuse Policy System. <https://pdaps.org/datasets/buprenorphine-prescribing-requirements-and-limitations>
- 11 Milgram, A. (2023). *Dear Registrant Letter*. U.S. Dep't of Justice Drug Enforcement Admin. <https://www.deadiversion.usdoj.gov/pubs/docs/A-23-0020-Dear-Registrant-Letter-Signed.pdf>
- 12 21 U.S.C. § 823(h).
- 13 Medicaid and CHIP Payment and Access Commission. (2019, November). *Buprenorphine Prescribing by Nurse Practitioners, Physician Assistants, and Physicians after CARA 2016*. <https://www.macpac.gov/publication/buprenorphine-prescribing-by-nurse-practitioners-physician-assistants-and-physicians-after-cara-2016>
- 14 American Psychiatric Nurses Association. (2020, June 10). *APNA Position: APRNs Prescribing Buprenorphine & Buprenorphine/Naloxone & the Continuing Opioid Crisis*. <https://www.apna.org/news/aprns-prescribing-buprenorphine-buprenorphine-naloxone-the-continuing-opioid-crisis/>
- 15 Comprehensive Addiction and Recovery Act of 2016, Pub. L. No. 114-198, 130 Stat. 695 (2016).
- 16 Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act of 2018, Pub. L. No. 115-271, 132 Stat. 3894 (2018).
- 17 Consolidated Appropriations Act, 2023, Pub. L. No. 117-328, § 1262, 136 Stat. 4459 (2022).
- 18 Substance Abuse and Mental Health Services Administration. (2023, October 10). *Waiver Elimination (MAT Act)*. <https://www.samhsa.gov/medications-substance-use-disorders/removal-data-waiver-requirement>
- 19 Substance Abuse and Mental Health Services Administration. (2023). *Advisory: Low Barrier Models of Care for Substance Use Disorders*. <https://store.samhsa.gov/sites/default/files/advisory-low-barrier-models-of-care-for-substance-use-disorders-pep23-02-00-005.pdf>
- 20 Weinstein, Z.M., Kim, H.W., Cheng, D.M., Quinn, E., Hui, D., Labelle, C.T., Drainoni, M., Bachman, S.S., & Samet, J.H. (2016). Long-term retention in Office Based Opioid Treatment with buprenorphine. *Journal of Substance Use and Addiction Treatment*, 74, 65-70. <https://doi.org/10.1016/j.jsat.2016.12.010>
- 21 Lee, C.S., Rosales, R., Stein, M.D., Nicholls, M., O'Connor, B.M., Ryan V.L., & Davis E.A. (2019). Brief Report: Low-Barrier Buprenorphine Initiation Predicts Treatment Retention Among Latinx and Non-Latinx Primary Care Patients. *Am J Addict*, 28(5), 409-412. Doi: 10.1111/ajad.12925.
- 22 Jakubowski, A., & Fox, A. (2020). Defining low-threshold buprenorphine treatment. *J Addict Med*, 14(2), 95-98. doi: 10.1097/ADM.0000000000000555.
- 23 The Pew Charitable Trusts. (2021, May 24). *Policies Should Promote Access to Buprenorphine for Opioid Use Disorder*. <https://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2021/05/policies-should-promote-access-to-buprenorphine-for-opioid-use-disorder>
- 24 Ward, K.M., Scheim, A., Wang, J., Cocchiario, B., Singley, K., & Roth, A.M. (2022). Impact of reduced restrictions on buprenorphine prescribing during COVID-19 among patients in a community-based treatment program. *Drug Alcohol Depend Rep*, 3, 100055. <https://doi.org/10.1016/j.dadr.2022.100055>
- 25 Bhatraju, E. P., Grossman, E., Tofighi, B., McNeely, J., DiRocco, D., Flannery, M., Garment, A., Goldfeld, K., Gourevitch, M. N., & Lee, J. D. (2017). Public sector low threshold office-based buprenorphine treatment: outcomes at year 7. *Addiction Science & Clinical Practice*, 12(7). <https://doi.org/10.1186/s13722-017-0072-2>
- 26 Lyle, V., Harris, S., Heidari, O., Boulton, K., Hulsey, E., Saloner, B., & Gibbons, J. (2024). Association between high-threshold practices and buprenorphine treatment termination. *International Journal of Drug Policy*, 124, 104318. <https://doi.org/10.1016/j.drugpo.2024.104318>

- 27 Gertner, A. K., Clare, H. M., Powell, B. J., Gilbert, A. R., Jones, H. E., Silberman, P., Shea, C. M., & Domino, M. E. (2022). A mixed methods study of provider factors in buprenorphine treatment retention. *International Journal of Drug Policy*, 105, 103715. <https://doi.org/10.1016/j.drugpo.2022.103715>
- 28 Delphin-Rittmon, M.E., & Cavazzoni, P. (2023). *Dear Colleague Letter*. U.S. Dep't of Health and Human Services. <https://www.samhsa.gov/sites/default/files/dear-colleague-letter-fda-samhsa.pdf>
- 29 Substance Abuse and Mental Health Services Administration. (n.d.). *Buprenorphine Quick Start Guide*. <https://www.samhsa.gov/sites/default/files/quick-start-guide.pdf>
- 30 Caton, L., Cheng, H., Garneau, H. C., Fisher, T., Harris-Mills, B., Hurley, B., Newman, S., & McGovern, M. P. (2021). COVID-19 Adaptations in the Care of Patients with Opioid Use Disorder: a Survey of California Primary Care Clinics. *Journal of General Internal Medicine*, 36, 998-1005. <https://doi.org/10.1007/s11606-020-06436-3>
- 31 Terry, N.P., Burris, S., Johnson, S., Larsen, J., & Platt, E. (2023). *The Legal Path to a Whole of Government Opioids Response*. Center for Public Health Law Research. <https://phlr.org/product/legal-path-whole-government-opioids-response>
- 32 Scott, C.K., Dennis, M.L., Grella, C.E., Mischel, A.F., & Carnevale, J. (2021). The impacts of the opioid crisis on U.S. state prison systems. *Health Justice*, 9(1):17. doi: 10.1186/s40352-021-00143-9.
- 33 Substance Abuse and Mental Health Services Administration. (2023, June 5). Participation Guidelines for Individuals with Lived Experience and Family. <https://www.samhsa.gov/grants/how-to-apply/forms-and-resources/guidelines-lived-experience>
- 34 Substance Abuse and Mental Health Services Administration. (2023). Strategic Plan: Fiscal Year 2023-2026. Publication No. PEP23-06-00-002. <https://www.samhsa.gov/sites/default/files/samhsa-strategic-plan.pdf>