

State-Specific Barriers to Methadone for Opioid Use Disorder Treatment

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Abstract: Opioid agonist treatment, including methadone, is the safest and most effective method for treating opioid use disorders and reduces opioid overdose deaths. While access to methadone is highly regulated by federal law, a substantial portion of states impose stricter barriers.

Overdose deaths involving opioids, like heroin, many prescription pain medications, and fentanyl have risen sharply over the past decades.¹ Overdose deaths involving opioids and all drugs during the COVID-19 pandemic have accelerated, with provisional estimates indicating 107,000 deaths occurring in both 2021 and 2022, the most ever reported.² Federal and state policymakers must act now to increase access to lifesaving interventions, including opioid agonist treatment (OAT).

OAT is the safest and most effective method for treating opioid use disorders.³ OAT uses medications to activate the opioid receptors, preventing withdrawal and reduce cravings for opioids like heroin and prescription pain medications. Two opioid agonists are approved by the Food and Drug Administration

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for treating opioid use disorder (OUD) — methadone and buprenorphine.

Over five decades of research has consistently demonstrated that OAT reduces risk of death from all causes, including overdose, by half, as well as reducing use of opioids, injection drug use, risk of HIV and Hepatitis C transmission, and involvement in the criminal legal system.⁴ Given OAT's effectiveness and the need to provide treatment to people with OUDs immediately upon request, OAT should be readily accessible.⁵

However, these medications are underutilized, with research indicating only a small percentage of people with OUDs receive OAT.⁶ Many experts agree that state-level intervention to increase access to OAT would be highly effective in improving patient and population health.⁷ Unfortunately, laws that restrict access, especially for methadone, persist at both federal and state levels.

Federal Laws Restricting OAT Access

OAT is strictly regulated by federal law. Methadone, a schedule II controlled substance, is only available for purposes of treating OUD through Drug Enforcement Administration (DEA)-registered and Substance Abuse and Mental Health Services Administration (SAMHSA)-approved opioid treatment programs (OTPs).⁸ Treatment at OTPs is highly regulated at the federal level, requiring, among other things, that patients demonstrate a minimum of one year of addiction to opioids prior to admission, complete a full medical examination within 14 days of admission, submit to frequent urine toxicology tests, and with limited exceptions, travel daily to receive medication.⁹

During the COVID-19 Public Health Emergency (PHE), SAMHSA issued guidance encouraging states

to request blanket exceptions to the take-home medication limits for methadone.¹⁰ SAMHSA indicated it would approve exceptions to allow “stable” methadone patients to receive up to 28 days of take-home medication and “less stable” patients to receive up to 14 days of take-home medication. Forty-two states requested the blanket exceptions for their OTPs.¹¹

Research has indicated that the temporary flexibilities have significantly increased take-home medication supply, patient engagement, and patient satisfaction without attributable increases in opioid-involved overdose deaths and minimal diversion.¹² Noting these findings, SAMHSA announced that it will extend the methadone take-home flexibilities for one year beyond the eventual expiration of the PHE (May 10, 2024).¹³ Further, SAMHSA has initiated rulemaking to indefinitely change the take-home medication limits to reflect those afforded during the PHE, as well as eliminate the requirement to demonstrate a minimum of one year of OUD prior to admission.¹⁴ Even if the proposed regulations become final, states can still impose their own regulations on OTPs, and individual OTPs can still impose their own rules.¹⁵ For example, methadone patients in Arizona reported that their experience with accessing treatment during the PHE was largely unchanged compared to before the PHE, and that daily clinic visits continued to interrupt their work and home lives.¹⁶

Until January 2023, patients could access buprenorphine, a schedule III controlled substance, through a medical provider who had obtained a special waiver to prescribe buprenorphine outside of an OTP or, like methadone, through an OTP. However, the recently enacted Mainstreaming Addiction Treatment (MAT) Act eliminated these restrictions.¹⁷ Now, all doctors who are otherwise authorized to prescribe controlled substances will be able to prescribe buprenorphine for opioid use disorder.¹⁸ However, there will most likely be a delay between the effective date of this change and changes to insurance and pharmacy policies to allow coverage or dispensing of prescriptions from non-waivered practitioners. Further, state restrictions on buprenorphine may still apply.

Access to OAT differs by race and geography. Black and Latinx people are significantly less likely to have access to buprenorphine than white people,¹⁹ which compared to methadone through an OTP, can be prescribed without requiring patients to submit to such extreme surveillance and restrictions. Conversely, OTPs tend to be concentrated in segregated Black and Latinx communities, suggesting a two-tiered system of access based on race where people of color only

have access to the medication that is subject to much stricter control.²⁰

Federal regulations generally requiring daily travel to an OTP for most patients to receive methadone prevent many in need from receiving treatment due to time, cost, and interference with other obligations, including work and childcare.²¹ This is particularly problematic for those in rural areas where distances to OTPs are farther and many patients may have to cross state lines.²² For example, as of January 2023, there are no OTPs in Wyoming and only one in South Dakota.²³ In Georgia, there are no OTPs accessible within a 15-minute drive time for seven of the nine counties with the highest opioid overdose death rates.²⁴ Similarly, forty percent of U.S. counties, primarily in rural areas, do not have a single provider with approval to prescribe buprenorphine outside an OTP, and two-thirds of counties have low or no provider capacity.²⁵

In June of 2021, the DEA finalized regulations allowing established OTPs to add a mobile component without the need to apply for a separate OTP registration.²⁶ While this may potentially increase access to methadone, especially in rural areas, the regulations still require that an OTP be close enough to allow the mobile component to return to the OTP each day. The utility of the mobile component will also be limited by the restrictions associated with OTPs generally, including the need for most patients to present daily for medication. Research has indicated that access would be vastly improved if methadone was available for dispensing through community pharmacies.²⁷

The concern giving rise to such strict regulation of OAT, and particularly methadone, is to prevent diversion of the medications for non-prescribed use. However, evidence suggests that diversion is more commonly associated with methadone prescribed for pain rather than OUD treatment, and that diversion of methadone prescribed for OUD treatment is associated with lack of access to the medication.²⁸ In other words, diversion commonly involves people giving their methadone to someone who is struggling with OUD and unable to access it through an authorized source.²⁹ People who use diverted methadone often do so because they missed their own medication pickup. Regulations that impose barriers may therefore increase risk of diversion by reducing avenues for authorized access.

Although long-acting injectable naltrexone (i.e., Vivitrol) is often discussed with OAT, it is not an opioid agonist. It is an opioid antagonist, meaning it blocks opioids from producing their effects. Although long-acting injectable naltrexone is not a controlled substance

or subject to additional regulation, it does not have the same robust evidence of effectiveness as OAT.³⁰

State Laws Restricting Methadone Access

Even though federal regulations are already very strict, many states impose additional barriers to access. There has been increased attention on how to reform federal methadone regulations in recent years,³¹ and new rules are currently under consideration.³² However, even if changes were to occur at the federal level, most state requirements would remain the same. Further, restrictions vary by state, potentially attributing to unequal access dependent on geography. Research

(toxicology tests). Thirteen jurisdictions went beyond the federal standard in four or more of the analyzed restrictions. Conversely, thirteen jurisdictions did not impose any restrictions beyond those set at the federal level. Two states, Alaska³⁵ and Idaho,³⁶ explicitly tied their OTP standards to federal regulations. The supplementary spreadsheet details the specifics of each state restrictions and provides a citation to the statute or regulation.

Timeline to Complete a Medical Examination

Federal law requires a physical evaluation at the time of admission to the program and a full medical exami-

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has documented that there is widespread variability in state regulation of OTPs and that a majority of the most common OTP regulations were inconsistent with best practices.³³ Further, states with more OTP regulations had poorer opioid-related outcomes, including increased fatalities and emergency department visits.³⁴

Our research adds to the existing body by providing updated information (some states have amended their laws) and individual citations to state regulations of OTPs. Using Westlaw and LexisNexis, we analyzed statutes and regulations from each state, the District of Columbia, and Puerto Rico to determine if the jurisdictions go beyond the federal standard for methadone access in seven key areas: timeline to complete a medical examination, minimum counseling requirements, required number of random toxicology tests, take-home medication limits, lockbox required for take-home medications, strict OTP approval processes or outright bans, and OTP location limits. We also note particularly stringent regulatory barriers that do not fall into any of these categories.

Table 1 shows each state's restrictions and total number of restrictions by the categories described above. More than one quarter of jurisdictions imposed a stricter barrier than federal law requires in each category, and nearly half of jurisdictions imposed a stricter barrier in two categories (minimum counseling requirements and required number of random

nation of each OTP patient within fourteen days following admission.³⁷ Medical examinations broadly require “the results of serology and other tests,”³⁸ opening the door for testing that patients may view as invasive and acting as an additional barrier to initiation. Fifteen states and Puerto Rico impose stricter regulations, requiring in-person medical examinations in less than fourteen days. Further, half of those states require this examination take place at or before the time of admission into the program.

Minimum Counseling Requirements

Federal regulations require OTPs to provide adequate substance use disorder counseling as clinically necessary but do not impose minimum requirements on counseling frequency or intensity.³⁹ However, nearly half the states (23) impose minimum counseling requirements. For example, Arkansas requires four hours of counseling per week in a patient's first ninety days of treatment, two hours per week in a patient's second ninety days of treatment (in addition to two self-help groups), and one hour per month thereafter.⁴⁰

The federal standard already prevents many people from receiving treatment by requiring daily travel to receive methadone.⁴¹ Imposing minimum counseling requirements not only obliges patients into attending potentially unwanted or clinically unindicated counseling, but also further restricts access for those who do not have the time, financial means, or childcare

Table 1

Analysis of statutes and regulations of OTPs from each state

State/ Jurisdiction	In Person Med. Exam Required within 14 Days of Admission	Minimum Counseling Requirements	More than 8 Toxicology Tests Required First Year	Take-Home Medication Limits Beyond Federal Standard	Lock Box Required for Take-Home Medications	Extremely Strict Approval Process/ Outright Bans on OTPs	Limits on OTP Location	"Yes" Totals by State (out of 7)
Alabama	No	Yes	Yes	Yes	Yes	Yes	Yes	6
Alaska	No	No	No	No	No	No	No	0
Arizona	No	No	No	No	No	No	No	0
Arkansas	Yes	Yes	Yes	No*	No	No	No	3
California	Yes	Yes	Yes	No	No	Yes	No	3
Colorado	No	Yes	Yes	No	Yes	No	No	4
Connecticut	Yes	No	No	No	No	No	No	1
Delaware	No	No	No*	No*	No	No	No	0
D.C.	No	No*	No	No	No	Yes	Yes	0
Florida	Yes	Yes	Yes	No	Yes	Yes	No	4
Georgia	No	No*	Yes	No	Yes	Yes	Yes	3
Hawaii	No	No	No	Yes	No	No	No	1
Idaho	No	No	No	No	No	No	No	0
Illinois	No	No	No	No	No	No	No	0
Indiana	Yes	Yes	No	Yes	No	Yes	Yes	5
Iowa	Yes	No	No	No	No	No	No	1
Kansas	Yes	Yes	Yes	No	No	No	No	3
Kentucky	Yes	Yes	Yes	Yes	No	No	No	3
Louisiana	No	Yes	No*	Yes	No	Yes	Yes	4
Maine	No	Yes	Yes	Yes	No	Yes	Yes	5
Maryland	No	No	Yes	No	Yes	No	No	2
Massachusetts	No	No	Yes	Yes	Yes	No	No	3
Michigan	Yes	No	Yes	Yes	Yes	No	No	4
Minnesota	No	Yes	No	No	No	Yes	No	1
Mississippi	No	Yes	No*	Yes	Yes	Yes	Yes	4

Missouri	No	Yes	No	No	Yes	Yes	Yes	Yes	5
Montana	No	No	No	No	No	No	No	No	0
Nebraska	Yes	No	No	No	No	No	No	No	1
Nevada	No	No	No	No	No	No	No	No	0
New Hampshire	No	Yes	Yes	Yes	No	No	No	No	3
New Jersey	Yes	Yes	Yes	Yes	No	No	Yes	Yes	4
New Mexico	No	No	No*	No	No	No	Yes	No	0
New York	No	No	No	No	No	No	No	No	1
North Carolina	No	No*	Yes	Yes	No	No	No	No	3
North Dakota	No	No	No	No	No	No	Yes	No	1
Ohio	No	Yes	Yes	No	No	No	No	Yes	3
Oklahoma	No	Yes	Yes	Yes	Yes	Yes	Yes	No	4
Oregon	No	No	No	No	No	No	No	Yes	1
Pennsylvania	No	Yes	Yes	Yes	No	No	No	No	2
Puerto Rico	Yes	No*	No	No	No	No	No	No	1
Rhode Island	No	Yes	No	No	No	No	No	No	1
South Carolina	Yes	No	No*	No	No	No	No	No	0
South Dakota	No	No	No	No	No	No	No	No	0
Tennessee	Yes	Yes	Yes	No	No	Yes	Yes	No	4
Texas	Yes	No	Yes	Yes	No	Yes	Yes	No	3
Utah	No	Yes	Yes	Yes	No	No	No	No	2
Vermont	No	No	No	No	No	No	No	No	0
Virginia	No	Yes	No	No	No	No	Yes	Yes	2
Washington	No	No	No	No	No	No	Yes	Yes	2
West Virginia	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	6
Wisconsin	Yes	No*	Yes	Yes	Yes	Yes	No	No	3
Wyoming	No	No	No	No	No	No	No	No	0
"Yes" Totals by Restriction	16	23	23	16	14	19	14	14	
% with Stricter Requirement	31%	44%	44%	31%	27%	37%	27%	27%	

necessary to attend hours of counseling.⁴² Research also indicates that counseling is not necessary for many people and immediate access to medications should be the primary goal.⁴³

Required Number of Random Toxicology Tests

Federal law provides that OTPs must test for “drugs of abuse,” including at least eight random drug tests per year.⁴⁴ Twenty-three states require more than eight of these tests in a patient’s first year of treatment. For instance, Kentucky requires weekly testing for the first ninety days of treatment,⁴⁵ and Massachusetts requires a minimum of 15 tests, nearly double the federal standard.⁴⁶

Many patients view random toxicology testing as invasive and degrading, which may damage therapeutic relationships.⁴⁷ Submitting to toxicology tests also consumes time, potentially putting more stress on patients.⁴⁸

Take-Home Medication Limits

Federal law imposes limitations on unsupervised or “take-home” use of OAT medications by limiting the maximum take-home doses based on length of time in treatment (See Table 2).⁴⁹ Patients have indicated that these limitations negatively impact their ability to satisfy daily responsibilities, are degrading and dehumanizing, and are a reason for discontinuing treatment.⁵⁰ As described above, SAMHSA authorized states to request blanket exceptions to the limitations to allow 28 days of take-home medications to “stable” patients and 14 days of take-home medications to “less stable” patients during the PHE and one year beyond its eventual expiration,⁵¹ and is further considering mechanisms to make it permanent.⁵²

While 42 states have received approval for blanket exceptions under this flexibility, sixteen states’ permanent regulations more strictly regulate permissible take-home doses. For example, while the federal standard allows one take-home dose each week during a patient’s first ninety days of treatment, Mississippi state law prevents any take-home doses during the first ninety days and further requires mandatory urine tests to receive take-home privileges thereafter.⁵³ Further, four states (Kentucky,⁵⁴ Maine,⁵⁵ New Hampshire,⁵⁶ and Pennsylvania⁵⁷) limit the maximum take-home dose to six per week, meaning that long-term patients would still need to visit the OTP on a weekly basis.

Even in states like Arkansas and Delaware where there are technically no limits on take-home medication (other than those set by federal regulations), programs may randomly require patients to travel to the treatment center and show their remaining take-home doses.⁵⁸ There is little evidence that these limita-

Table 2

Federal Standard for OAT Take-Home Doses (as of January 2023)

Time in Treatment	Take-home Doses Allowed under Federal Law
First 90 days	1 per week
Second 90 days	2 per week
Third 90 days	3 per week
Remaining months of the first year	6 per week
1-2 years	2-week supply
2 years or more	1-month supply

Source: 42 C.F.R. § 8.12(i)(3)

tions are necessary for patients or public safety.⁵⁹ This is especially so in light of the relaxed federal standard during the COVID-19 pandemic, which early research indicates may enhance care without negative societal impacts and suggests continuation of this policy beyond the pandemic would be beneficial.⁶⁰ Even if the federal government were to finalize the proposed regulations to expand take-home medication access, nearly all states’ restrictions would be more stringent than the federal standard unless revised, especially upon the eventual expiration of the PHE.

Required Lockbox for Take-Home Medications

Federal law requires patients to assure that take-home medications can be safely stored within their home.⁶¹ OTPs must also ensure take-home medications be stored in child-proof containers.⁶² Fourteen states impose a stricter requirement, mandating that take-home medication be stored in a lockbox or safe, including during transport. This requirement presupposes patients have the means to obtain locked safes, further limiting those who may acquire take-home privileges and avoid the hassle of daily trips for treatment. Requiring lockboxes is also stigmatizing as it serves more to advertise that a patient is carrying medication than to promote safety.⁶³

Strict OTP Approval Processes and Outright Bans

Federal law requires OTPs to receive approval from SAMHSA and register with the DEA.⁶⁴ However, 19 states go further to impose extremely strict approval processes for implementing new OTPs. West Virginia presents the most extreme example: the state cur-

rently has a statewide moratorium on the licensure of new OTPs.⁶⁵

In other states, the strict approval processes lessen the chances that OTPs will be built in areas of need. Louisiana does not accept applications to build an OTP unless the Department of Health issues a statewide announcement specifying that any one area requires OTP services.⁶⁶ Indiana also imposes an extremely strict approval process. The Indiana Department of Family and Social Services cannot grant approval for a new OTP unless it is operated by a hospital, mental health institution, or community mental health center.⁶⁷ Additionally, OTP applicants must show strong community support through letters from interested community members.⁶⁸

Community support is also required in other states like Maine, where public notice and a public forum must be conducted and documented,⁶⁹ and Missouri, where community acceptance must be solicited within a one-mile radius of any proposed site and letters of support from local authorities must be acquired.⁷⁰ The federal approval process for establishing new OTPs already presents challenges to providing necessary access. State laws imposing additional requirements lessens the chances that OTPs will be built in areas of need.

OTP Location Limits

Federal law does not restrict OTP locations, but 14 states do. For example, Alabama⁷¹ and Missouri⁷² prevent new OTP sites from being built within fifty miles of an existing treatment site, and Indiana prohibits new OTPs within 20 miles of an existing OTP.⁷³ Georgia limits the number of OTPs in each region to four.⁷⁴ Mississippi will not approve an OTP if its location is in an area where needs are met by existing services, as determined by the Department of Mental Health.⁷⁵ Louisiana,⁷⁶ New Jersey,⁷⁷ Ohio,⁷⁸ Oregon,⁷⁹ and Virginia⁸⁰ all either prohibit OTPs within certain proximities of schools and other facilities or require additional process for approval. Imposing geographic limits likely lowers daily attendance by increasing the distance patients must travel.⁸¹

Other Restrictions

In addition to the restrictions highlighted above, some states and jurisdictions impose other access barriers. These are noted in the attached spreadsheet. For example, there are no federal limits on how many patients an OTP may treat, yet Washington imposes a patient cap of 350 patients.⁸² Maine similarly restricts OTPs to 500 patients.⁸³

Limitations and Other Considerations

Our review was limited to state statutes and regulations. Thus, we did not review county or local regulations, professional practice board requirements, or individual clinic policies. All of these may affect provision of methadone in a certain jurisdiction. Further, the actual practice of providing methadone may differ than what is enshrined in regulations.

We also limited our review to policies affecting methadone access through OTPs. We did not include states regulations specifically regulating access to buprenorphine. This is an important area for future research, especially with the relaxation of requirements to prescribe buprenorphine for OUD at the federal level. States may need to reform restrictions on buprenorphine access to take full of advantage of the recent federal changes. Even though our analysis was specific to methadone, restrictions on OTPs may also impact access to buprenorphine, especially in places where there are not enough providers willing or able to prescribe buprenorphine outside of an OTP.

Similarly, we did not review regulations that applied to the approval or operation of substance use disorder treatment facilities and programs in general. Some states may impose more stringent requirements than others, which may have impacts on access to methadone because OTPs may be subject to these requirements as well.

Our review did not analyze issues relating to insurance and payment for methadone. Other research has highlighted differences in Medicaid coverage and prior authorization policies and raised concerns of how these requirements may pose as barriers to treatment and exacerbate geographical discrepancies.⁸⁴

Finally, the role of stigma should not be overlooked. Research has documented that stigma is widespread and adversely impacts methadone patients' quality of life and treatment.⁸⁵ While many state restrictions may have grown out of stigma, stigma also exists outside of policy and will remain even if policy is changed. Further efforts are needed to destigmatize methadone treatment.

Conclusion

Federal regulations governing OAT access, particularly for methadone, are already extremely strict. We find that many states go beyond this floor to impose more barriers to access. States should repeal or amend any statutes and regulations that impose more stringent burdens on OAT access than required by federal law. States should tie their OTP standards to federal law, similar to what Alaska⁸⁶ and Idaho⁸⁷ have done. States should further require consistent review to ensure

compliance with changes to federal law. When the federal standard is changed to better facilitate access to these life-saving medications, hopefully sooner rather than later, states that have tied their standards to federal law will be able to quickly follow suit.

Note

Additional data is available for download at drugpolicy.org/JLME-supplement. The authors have no conflicts to disclose.

References

- H. Hedegaard, A. M. Miniño, and M. Warner, "Drug Overdose Deaths in the United States, 1999–2018," National Center for Health Statistics Data Brief, January 2020 [cited 2021 Sept 24] no. 356, available at <<https://www.cdc.gov/nchs/products/databriefs/db356.htm>> (last visited June 1, 2023).
- F. B. Ahmad, J. A. Cisewski, L. M. Rossen, and P. Sutton, "Provisional Drug Overdose Death Counts," National Center for Health Statistics, June 14, 2023 [cited 2023 June 30], available at <<https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm>> (last visited June 30, 2023).
- National Academies of Sciences, Engineering, and Medicine, "Medications for Opioid Use Disorder Save Lives," *The National Academies Press*, 2019 [cited 2021 Sept 24], available at <<https://doi.org/10.17226/25310>> (last visited June 1, 2023).
- Id.*; S. E. Wakeman, M. R. Larochelle, and O. Amel, et al., "Comparative Effectiveness of Different Treatment Pathways for Opioid Use Disorder," *JAMA Network Open* 3, no. 2 (2020): e1920622, doi: 10.1001/jamanetworkopen.2019.20622.
- R. P. Winograd, N. Presnall, and E. Stringfellow et al., "The Case for a Medication First Approach to the Treatment of Opioid Use Disorder," *American Journal of Drug and Alcohol Abuse* 45, no. 3(2019): 333–340, available at <<https://pubmed.ncbi.nlm.nih.gov/31084515/>> doi: 10.1080/00952990.2019.1605372>; A. Sharma, M. K. Sharon, and G. M. Shannon et al., "Update on Barriers to Pharmacotherapy for Opioid Use Disorders," *Current Psychiatry Report* 19, no. 6(2017): 35, available at <<https://pubmed.ncbi.nlm.nih.gov/28526967/>> doi: 10.1007/s11920-017-0783-9> (last visited June 1, 2023).
- N. 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 (2022): 103786, doi: 10.1016/j.drugpo.2022.103786; P. M. Mauro, S. Gutkind, and E. M. Annunziato, et al., "Use of Medication for Opioid Use Disorder Among US Adolescents and Adults with Need for Opioid Treatment," *JAMA Network Open* 5, no. 3 (2019): e223821, doi: 10.1001/jamanetworkopen.2022.3821; A. S. Huhn, et al., "Differences in Availability and Use of Medications for Opioid Use Disorder in Residential Treatment Settings in the United States," *JAMA Network Open* 3, no. 2 (2020): e1920843, doi: 10.1001/jamanetworkopen.2019.20843; S. E. Wakeman, et al., "Comparative Effectiveness of Different Treatment Pathways for Opioid Use Disorder," *JAMA Network Open* 3, no. 2 (2020): e1920622, doi: 10.1001/jamanetworkopen.2019.20622.
- R. Smart, S. Grant, and A. J. Gordon et al., "Expert Panel Consensus on State-Level Policies to Improve Engagement and Retention in Treatment for Opioid Use Disorder," *JAMA Health Forum* 3, no. 9 (2022): e223285, doi: 10.1001/jamahealthforum.2022.3285.
- 21 U.S.C. § 823(g)(1); 42 C.F.R. § 8.11(a).
- 42 C.F.R. § 8.12.
- Substance Abuse and Mental Health Services Administration. Opioid Treatment Program (OTP), available at <<https://www.samhsa.gov/sites/default/files/otp-guidance-20200316.pdf>> (last visited June 1, 2023).
- S. C. Pessar, A. Boustead, and Y. Ge, et al., "Assessment of State and Federal Health Policies for Opioid Use Disorder Treatment During the COVID-19 Pandemic and Beyond," *JAMA Health Forum* 2, no. 11(2021): e213833. doi: 10.1001/jamahealthforum.2021.3833.
- O. Amram et al., "Changes in Methadone Take-Home Dosing Before and After COVID-19," *Journal of Substance Abuse Treatment* 133 (2022): 108552, doi: 10.1016/j.jsat.2021.108552; M. C. Figgatt et al., "Take-Home Dosing Experiences Among Persons Receiving Methadone Maintenance Treatment During COVID-19," *Journal of Substance Abuse Treatment* 123 (2021): 108276, doi: 10.1016/j.jsat.2021.108276; L. W. Suen et al., "The Idea is to Help People Achieve Greater Success and Liberty": A Qualitative Study of Expanded Methadone Take-Home Access in Opioid Use Disorder Treatment," *Substance Abuse* 43, no. 1 (2022): 1143–1150, doi: 10.1080/08897077.2022.2060438; S. M. Walters et al., "Lessons from the First Wave of COVID-19 for Improved Medications for Opioid Use Disorder (MOUD) Treatment: Benefits of Easier Access, Extended Take Homes, and New Delivery Modalities," *Substance Use & Misuse* 57, no. 7 (2022): 1144–1153, doi: 10.1080/10826084.2022.2064509; O. Amram et al., "The Impact of Relaxation of Methadone Take-Home Protocols on Treatment Outcomes In The COVID-19 Era," *American Journal of Drug & Alcohol Abuse* 20 (2021): 1–8, doi: 10.1080/00952990.2021.1979991; S. Brothers, A. Viera, and R. Heimer, "Changes in Methadone Program Practices and Fatal Methadone Overdose Rates in Connecticut During COVID-19," *Journal of Substance Abuse Treatment* 131 (2021): 108449, doi: 10.1016/j.jsat.2021.108449; X. 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, no. 1 (2021): 72, doi: 10.1186/s13722-021-00281-3.
- Substance Abuse and Mental Health Services Administration, *Methadone Take-Home Flexibilities Extension Guidance*, available at <<https://www.samhsa.gov/medication-assisted-treatment/statutes-regulations-guidelines/methadone-guidance>> (last visited June 1, 2023).
- Substance Abuse and Mental Health Services Administration, *SAMHSA Proposes Update to Federal Rules to Expand Access to Opioid Use Disorder Treatment and Help Close Gap in Care*, available at <<https://www.samhsa.gov/newsroom/press-announcements/20221213/update-federal-rules-expand-access-opioid-use-disorder-treatment>> (last visited June 1, 2023).
- X. Levander et al., "COVID-19-Related Policy Changes for Methadone Take-Home Dosing: A Multistate Survey of Opioid Treatment Program Leadership," *Substance Abuse* 43, no. 1(2022): 633–639, doi: 10.1080/08897077.2021.1986768.
- B. E. Meyerson, et al. "Nothing Really Changed: Arizona Patient Experience of Methadone and Buprenorphine Access During COVID," *PLoS One* 17, no. 10(2022): e0274094, doi: 10.1371/journal.pone.0274094.
- S. Doyle and V. Baaklini, "President Signs Bipartisan Measure to Improve Addiction Treatment," *PEW Charitable Trusts*, 2022, available at <<https://www.pewtrusts.org/en/research-and-analysis/articles/2022/12/30/president-signs-bipartisan-measure-to-improve-addiction-treatment>> (last visited June 1, 2023).
- Substance Abuse and Mental Health Services Administration, *Removal of DATA Waiver (X-Waiver) Requirement*, 2023, available at <<https://www.samhsa.gov/medication-assisted-treatment/removal-data-waiver-requirement>> (last visited June 1, 2023).
- M. Hollander et al., "Racial Inequity In Medication Treatment for Opioid Use Disorder: Exploring Potential Facilitators and Barriers to Use," *Drug & Alcohol Dependence* 227 (2021): 108927, doi: 10.1016/j.drugalcdep.2021.108927; W. 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, no. 4 (2020): e203711,

- available at <<https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2764663>> (last visited June 1, 2023); P. A. Lagisetty et al., “Buprenorphine Treatment Divide by Race/Ethnicity and Payment,” *JAMA Psychiatry* 76, no. 9 (2019): 979-981, available at <<https://jamanetwork.com/journals/jamapsychiatry/fullarticle/2732871>> (last visited June 1, 2023).
20. M. Hollander et al., “Racial Inequity in Medication Treatment for Opioid Use Disorder: Exploring Potential Facilitators and Barriers to Use,” *Drug & Alcohol Dependence* 227 (2021): 108927, doi: 10.1016/j.drugalcdep.2021.108927; W. 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, no. 4(2020): e203711, available at <<https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2764663>> (last visited June 1, 2023).
 21. S. Amiri et al., “Increased Distance was Associated with Lower Daily Attendance to an Opioid Treatment Program in Spokane County Washington,” *Journal of Substance Abuse Treatment* 93 (2018): 26-30, available at <<https://pubmed.ncbi.nlm.nih.gov/30126538/>> (last visited June 1, 2023); A. Rosenblum et al., “Distance Traveled and Cross-State Commuting to Opioid Treatment Programs in The United States,” *Journal of Environmental and Public Health* (2011), available at <<https://doi.org/10.1155/2011/948789>> (last visited June 1, 2023).
 22. P. J. Joudrey et al., “Drive Times to Opioid Treatment Programs in Urban and Rural Counties in 5 US States,” *JAMA* 322, no. 13 (2019):1310-1312, available at <<https://pubmed.ncbi.nlm.nih.gov/31573628/>> (last visited June 1, 2023).
 23. Substance Abuse and Mental Health Services Administration, *Opioid Treatment Program Directory* (Rockville MD, 2021), available at <<https://dpt2.samhsa.gov/treatment/directory.aspx>> (last visited June 1, 2023).
 24. T. Anwar, M. Duever, and J. Jayawardhana, “Access to Methadone Clinics and Opioid Overdose Deaths in Georgia: A Geospatial Analysis,” *Drug & Alcohol Dependence* (2022): 238, doi: 10.1016/j.drugalcdep.2022.109565.
 25. C. A. Grimm CA, *Geographic Disparities Affect Access to Buprenorphine Services for Opioid Use Disorder* (Washington DC: U.S. Department of Health and Human Services, Office of Inspector General, 2020), available at <<https://oig.hhs.gov/oei/reports/oei-12-17-00240.pdf>> (last visited June 1, 2023).
 26. Drug Enforcement Administration, *DEA Finalizes Measures to Expand Medication-Assisted Treatment* (2021), available at <<https://www.dea.gov/press-releases/2021/06/28/dea-finalizes-measures-expand-medication-assisted-treatment>> (last visited June 1, 2023).
 27. P. 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 & Alcohol Dependence* 211 (2020): 107968, doi: 10.1016/j.drugalcdep.2020.107968.
 28. C. M. Jones et al., “Trends in Methadone Distribution for Pain Treatment, Methadone Diversion, and Overdose Deaths - United States, 2002-2014,” *Morbidity & Mortality Weekly Report* 65, no. 26 (2016): 667-671, doi: <http://dx.doi.org/10.15585/mmwr.mm6526a2>; P. Duffy and A. J. Mackridge, “Use and Diversion of Illicit Methadone - Under What Circumstances Does it Occur, and Potential Risks Associated with Continued Use of Other Substances,” *Journal of Substance Use* 19, no. 1-2 (2014): 48-55, doi:10.3109/14659891.2012.734539; B. Johnson and T. Richert, “Diversion of Methadone and Buprenorphine from Opioid Substitution Treatment: A Staff Perspective,” *Journal of Psychoactive Drugs* 46, no. 5 (2014): 427-435, doi:10.1080/02791072.2014.960109.
 29. P. Duffy and A.J. Mackridge, “Use and Diversion of Illicit Methadone - Under What Circumstances Does it Occur, and Potential Risks Associated with Continued Use of Other Substances,” *Journal of Substance Use* 19, no. 1-2 (2014): 48-55, doi:10.3109/14659891.2012.734539.
 30. National Academies of Sciences, Engineering, and Medicine, *Medications for Opioid Use Disorder Save Lives: The National Academies Press* (2019), available at <<https://doi.org/10.17226/25310>> (last visited June 1, 2023).
 31. National Academies of Sciences, Engineering, and Medicine, *Methadone Treatment for Opioid Use Disorder: Improving Access through Regulatory and Legal Change: Proceedings of a Workshop* (2022), available at <<https://doi.org/10.17226/26635>> (last visited June 1, 2023); R. Bonnie et al., “An Expedited Regulatory Strategy for Expanding Access to Methadone Treatment for Opioid Use Disorder,” *Health Affairs Forefront* (2022), available at <<https://doi.org/10.1377/forefront.20220524.171269>> (last visited June 1, 2023); P. J. Joudrey et al., “Research Priorities for Expanding Access to Methadone Treatment for Opioid Use Disorder in the United States: A National Institute on Drug Abuse Clinical Trials Network Task Force Report,” *Substance Abuse* 42, no. 3 (2022): 245-254, doi: 10.1080/08897077.2021.1975344.
 32. “Substance Abuse and Mental Health Services Administration (SAMHSA) Proposes Update to Federal Rules to Expand Access to Opioid Use Disorder Treatment and Help Close Gap in Care (2022) available at <<https://www.samhsa.gov/newsroom/press-announcements/20221213/update-federal-rules-expand-access-opioid-use-disorder-treatment>> (last visited June 1, 2023).
 33. S. Doyle, “Overview of Opioid Treatment Program Regulations by State,” Pew Charitable Trusts (2022) available at <<https://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2022/09/overview-of-opioid-treatment-program-regulations-by-state>> (last visited June 1, 2023); J. R. Jackson et al., “Characterizing Variability in State-Level Regulations Governing Opioid Treatment Programs,” *Journal of Substance Abuse Treatment* 115 (2020): 108008, doi: 10.1016/j.jsat.2020.108008.
 34. J. R. Jackson et al., “State-Level Regulations and Opioid-Related Health Outcomes,” *Drug and Alcohol Dependence* 232 (2022): 109294, doi: 10.1016/j.drugalcdep.2022.109294.
 35. Alaska Admin. Code tit. 7, § 70.125(a)(1).
 36. Idaho Admin. Code r. 16.07.17.415(2).
 37. 42 C.F.R. § 8.12(f)(2).
 38. *Id.*
 39. 42 C.F.R. § 8.12(f)(5).
 40. Ark. Code R. § 016.04.2-XII.
 41. S. Amiri et al., “Increased Distance was Associated with Lower Daily Attendance to an Opioid Treatment Program in Spokane County Washington,” *Journal of Substance Abuse Treatment* 93 (2018): 26-30, available at <<https://pubmed.ncbi.nlm.nih.gov/30126538/>> (last visited June 1, 2023), doi: 10.1016/j.jsat.2018.07.006; A. Rosenblum et al., “Distance Traveled and Cross-State Commuting to Opioid Treatment Programs in the United States,” *Journal of Environmental and Public Health* (2011), available at <<https://doi.org/10.1155/2011/948789>> (last visited June 1, 2023).
 42. *Id.*
 43. National Academies of Sciences, Engineering, and Medicine, *Medications for Opioid Use Disorder Save Lives*, The National Academies Press (2019) available at <<https://doi.org/10.17226/25310>> (last visited June 1, 2023).
 44. 42 C.F.R. § 8.12(f)(6).
 45. 908 Ky. Admin. Regs. 1:374, § 7(9)(c); 7(12)(e)(4).
 46. 105 Mass. Code Regs. 164.304(B)(2).
 47. D. 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 (2021): 88, doi: 10.1186/s12954-021-00535-y; C. Strike and C. Rufo, “Embarrassing, Degrading, or Beneficial: Patient and Staff Perspectives on Urine Drug Testing in Methadone Maintenance Treatment,” *Journal of Substance Use* 15, no. 5 (2010): 303-312, available at <<https://www.tandfonline.com/doi/full/10.3109/14659890903431603>> (last visited June 1, 2023), doi.org/10.3109/14659890903431603.
 48. Frank, *id.*
 49. 42 C.F.R. § 8.12(i)(2),(3).
 50. Frank, *supra* note 47.

51. Substance Abuse and Mental Health Services Administration, *Opioid Treatment Program (OTP) Guidance* (Rockville, MD, 2020), available at <<https://www.samhsa.gov/sites/default/files/otp-guidance-20200316.pdf>> (last visited June 1, 2023).
52. Substance Abuse and Mental Health Services Administration (SAMHSA) Extends the Methadone Take-Home Flexibility for One Year While Working Toward a Permanent Solution (2021), available at <<https://www.samhsa.gov/newsroom/press-announcements/202111181000>> (last visited June 1, 2023).
53. Miss. Code R. § 24-3-53.5(L).
54. 908 Ky. Admin. Regs. 1:374(7)(12)(j).
55. 14 118 Me. Code R. 5 § 19.8.10.4.
56. N.H. Code Admin. R. He-A 304.23(o).
57. 28 Pa. Code § 715.16(c)(3).
58. See Ark. Code R. § 016.04.2-XIV(B)(15); 16-6001 Del. Admin. Code § 14.7.
59. C. S. Davis and D. H. Carr, “Legal and Policy Changes Urgently Needed to Increase Access to Opioid Agonist Therapy in the United States,” *International Journal of Drug Policy* 73 (2019): 42-48, available at <<https://pubmed.ncbi.nlm.nih.gov/31336293/>> (last visited June 1, 2023).
60. M. C. Figgatt et al., “Take-Home Dosing Experiences Among Persons Receiving Methadone Maintenance Treatment During COVID-19,” *Journal of Substance Abuse Treatment* 123 (2021): 108276, available at <<https://pubmed.ncbi.nlm.nih.gov/33612201/>> (last visited June 1, 2023); D. Frank, “A Chance to do it Better: Methadone Maintenance Treatment in the Age of COVID-19,” *Journal of Substance Abuse Treatment* 123 (2021): 108246, doi: 10.1016/j.jsat.2020.108246, available at <<https://pubmed.ncbi.nlm.nih.gov/33612189/>> (last visited June 1, 2023).
61. 42 C.F.R. § 8.12(i)(2)(vii).
62. 42 C.F.R. § 8.12(i)(5).
63. Substance Abuse and Mental Health Services Administration, *Federal Guidelines for Opioid Treatment Programs* (Rockville MD, 2015): 79, available at <<https://store.samhsa.gov/sites/default/files/d7/priv/pep15-fedguideotp.pdf>> (last visited June 1, 2023).
64. 21 U.S.C. § 823(g)(1); 42 C.F.R. § 8.11(a).
65. W. Va. Code Ann. § 16-5Y-12.
66. La. Admin. Code tit. 48, § 12907.
67. Ind. Code § 12-23-18-5.5.
68. 440 Ind. Admin. Code 10-2-3(a)(5).
69. 14 118 Me. Code R. 5 § 2.6.1.6.
70. Mo. Code Regs. tit. 9, § 30-3.132(1)(A)(3).
71. Ala. Admin. Code r. 410-2-4.
72. Mo. Code Regs. tit. 9, § 30-3.132(1)(A)(2).
73. 440 Ind. Admin. Code 10-2-3(a)(1).
74. Ga. Code Ann. § 26-5-48.
75. Miss. Code R. § 24-2-2.4(E).
76. La. Admin. Code tit. 48, § 12907(K)(4)(a).
77. N.J. Rev. Stat. § 26:2H-11.1.
78. Ohio Admin. Code 5122-40-04(B).
79. Or. Rev. Stat. § 430.590.
80. Va. Code Ann. § 37.2-406(a), (f).
81. S. Amiri et al., “Increased Distance was Associated with Lower Daily Attendance to an Opioid Treatment Program in Spokane County Washington,” *Journal of Substance Abuse Treatment* 93 (2018): 26-30, available at <<https://pubmed.ncbi.nlm.nih.gov/30126538/>> (last visited June 1, 2023).
82. Wash. Rev. Code § 71.24.590.
83. 14 118 Me. Code R. 5 § 19.8.4.3.
84. A. J. Abraham et al., “Coverage and Prior Authorization Policies for Medications for Opioid Use Disorder in Medicaid Managed Care,” *JAMA Health Forum* 3, no. 11 (2022): e224001, doi: 10.1001/jamahealthforum.2022.4001.
85. J. Woo et al., “Don’t Judge a Book by Its Cover’: A Qualitative Study of Methadone Patients’ Experiences of Stigma,” *Substance Abuse* 11 (2017): 1178221816685087, doi: 10.1177/1178221816685087.
86. Alaska Admin. Code tit. 7, § 70.125(a)(1).
87. Idaho Admin. Code r. 16.07.17.415(2).