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Expand Access to Methadone Treatment

Remove Barriers to Primary Care Practitioners Prescribing Methadone

By Jeffrey A. Singer and Sofia Hamilton

EXECUTIVE SUMMARY

A catastrophic drug overdose crisis is afflicting the United States. The National Center for Health Statistics reported that more than 107,000 people died from drug overdoses in 2021. More than three-quarters of overdose deaths involved opioids. The growing number of people in the United States with opioid use disorder (OUD) helps drive the mounting number of overdose deaths.

For decades, clinicians have successfully treated OUD with the synthetic opioid methadone. In the United Kingdom, Canada, and Australia, clinicians have been using methadone to treat OUD in primary care settings and have prescribed take-home methadone since the late 1960s. However, in the United States, federal and state laws segregate people with OUD who seek treatment with methadone, requiring them to travel to government-approved opioid treatment programs, where staff must directly observe them ingesting the methadone and where the government imposes strict limits on when and how much methadone patients can take home.

These federal and state regulations discriminate against, stigmatize, and dehumanize opioid users. They also limit access to methadone treatment for many people who need and can benefit from such treatment. U.S. lawmakers should learn from the experiences of Australia, Canada, and the United Kingdom and allow primary care clinicians to treat OUD with methadone in primary care settings.


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INTRODUCTION

Research shows the drug overdose problem in the United States has been "inexorably tracking along an exponential growth curve since at least 1979."[1] The National Center for Health Statistics reported more than 107,000 people died from drug overdoses in 2021, of which around 80,000 were opioid-related.[2] Roughly 90 percent of opioid-related overdose deaths in 2022 involved illicit fentanyl. The National Institute on Drug Abuse has estimated that approximately three million people aged 12 and over suffer from OUD.[3] However, research published in 2022 concluded that OUD prevalence are "biased and undercount the number of people with OUD," placing the number of adults living with OUD from 6.7 million to 7.6 million.[4] These estimates suggest that one to two of every 100 U.S. residents has OUD. Increasing access to OUD treatment would reduce the number of people who seek drugs in the dangerous black market and, in turn, reduce the risk and incidence of overdose deaths.

Opioid addiction and opioid dependency are two distinct subsets of OUD. Dependency refers to the physiologic adaptation to the drug such that abrupt cessation can cause a physical withdrawal reaction. Addiction is a behavioral disorder characterized by compulsive use despite negative consequences. People with addiction still feel compelled to use opioids even when they are no longer physically dependent.[5]

Much evidence confirms that long-term treatment with the opioid agonists methadone and buprenorphine is the most effective treatment for OUD.[6] These medications work to stabilize the lives of people with OUD. They do this by eliminating the fear of painful withdrawal symptoms *without* impairing cognitive faculties. This reduces the need for OUD patients to raise funds to purchase illicit drugs on the black market, thus providing them time to resume employment, conventional relationships, and connection with others. These forces combine to facilitate recovery.

In the United States before 1972, primary care physicians would prescribe methadone to people with OUD.[7] Since 1972, however, only government-approved opioid treatment programs (OTPs) have been able to dispense methadone to treat OUD. The Comprehensive Drug Abuse Prevention and Control Act of 1970 required the secretary of the Department of Health and Human Services to "determine the appropriate methods of professional practice in the medical treatment of the narcotic addiction of various classes of narcotics addicts."[8] As a result, the Substance Abuse and Mental Health Services Administration (SAMHSA) places regulations and restrictions on organizations that seek to operate OTPs. OTPs must obtain certification from the Drug Enforcement Administration (DEA) to operate a narcotics treatment program. States must also license OTPs, imposing additional regulations and restrictions. The various layers of regulations obstruct the proliferation of OTPs.

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These regulations impede access to methadone treatment by placing burdensome requirements on patients who seek it. For example, patients must wait one year from their diagnosis of OUD before they can begin receiving methadone, submit to drug testing, and take the methadone in the presence of clinic staff each day. These and other government obstacles explain why only about 400,000 people with OUD received methadone in 2019, though 1.6 million U.S. residents reported that they developed OUD that year.[9]

The Drug Addiction Treatment Act of 2000 placed numerous restrictions on clinicians wishing to prescribe buprenorphine for OUD, initially allowing only physicians to prescribe the drug and limiting the number of patients that clinicians may treat.[10] In December 2022, Congress passed legislation removing many of the more onerous restrictions and permitting some nonphysician clinicians (e.g., nurse practitioners) to prescribe buprenorphine for OUD in primary care settings. Prescribers must still follow DEA and SAMHSA regulations.[11] Table 1 compares opioid overdose deaths, instances of OUD, and the number of OTPs in the 50 states and the District of Columbia.

MEDICATIONS FOR OUD

Methadone and buprenorphine are common medications for opioid use disorder (MOUDs). They are a form of opioid-replacement therapy that involves replacing a usually illegal opioid, such as heroin (diacetylmorphine or diamorphine) or illicit fentanyl, with a legal one that is less sedative and euphoric.[12] The purpose of opioid-replacement therapy is to help avoid withdrawal, reduce drug cravings, and eliminate the euphoria associated with nonmedical drug use. Clinicians who treat addiction aim to facilitate a resumption of stability in the user's life, end the spread of disease through needle sharing, reduce the risk of overdose, and over time wean the user off the replacement drug. Some people with OUD stay on an MOUD indefinitely.

Clinicians have used methadone as an MOUD for years in the United States and many other developed countries. It has roughly the same potency as heroin, which is 2.5 times the strength of morphine. Buprenorphine is another drug clinicians use to treat OUD. Patients usually take buprenorphine and methadone orally. Buprenorphine is a partial opioid agonist, meaning it partially activates opioid receptors. It can sometimes precipitate withdrawal in patients with opioid dependency. Therefore, to avoid precipitating withdrawal, practitioners usually prescribe buprenorphine to patients after an opioid-free interval.[13] Methadone is a full agonist, meaning it fully activates receptor sites. Because patients can take the drug in amounts that occupy all the opioid receptors, it is more effective in treating patients who have grown dependent on high doses of opioids. Because buprenorphine is only a partial agonist, it causes less respiratory depression than methadone and thus has less overdose potential.

A systematic review and meta-analysis of cohort studies in the *BMJ* in March 2017 found that methadone treatment for OUD correlated with a 69 percent reduction in all-cause mortality and that buprenorphine treatment correlated with a 55 percent reduction in all-cause mortality.[14]

Clinicians treating addiction have used methadone for a long time, but they have used buprenorphine for a shorter period, so few good studies compare the two to determine the better treatment. A 2003 Cochrane Review found buprenorphine considerably less successful than methadone in retaining patients in treatment.[15] A 2012 review found methadone slightly more successful and less expensive than buprenorphine as an opioid replacement.[16] However, a 2015 study by Adam Peddicord and others concluded: "The research does not indicate that one medication is a better option than the other. This decision must be made individually after reviewing important patient factors such as health status and access to the medication."[17] A May 2023 systematic review by Australian researchers found no statistically significant differences in mortality between methadone and sublingual buprenorphine, even though more patients dropped out of the buprenorphine arm.[18]

"Clinicians who treat addiction aim to facilitate a resumption of stability in the user's life, end the spread of disease through needle sharing, reduce the risk of overdose, and over time wean the user off the replacement drug."

A different approach to medication-assisted therapy uses naltrexone (Vivitrol). Naltrexone is a long-acting opioid antagonist that blocks the opioid receptors, similar to the overdose antidote naloxone. Thus, it may precipitate withdrawal symptoms in patients physically dependent on opioids. It can be taken orally, with the effects lasting 24 to 48 hours, or injected intramuscularly in an extended-release form every month. For it to be effective, treatment should start only after the patient has detoxified. A 2011 analysis showed that oral naltrexone therapy had high dropout rates because of its short duration of action and was no better than a placebo, with or without adjuvant psychotherapy.[19]

In 2020, Sarah Wakeman and others published comparative effectiveness research on over 40,000 adults with OUD using six different therapeutic pathways: inpatient detoxification or residential services, intensive behavioral health, nonintensive behavioral health, buprenorphine or methadone, naltrexone, or no treatment. The study found that compared to the other treatments, methadone and buprenorphine were the only treatments associated with "reductions in overdose and serious opioid-related acute care use."[20]

Heroin maintenance treatment began in Switzerland in 1994 for people with OUD who failed methadone

Table 1

Estimates of active opioid treatment programs (OTPs) per number of patients with opioid use disorder (OUD) throughout the United States, 2021

State	Rank of people with OUD per OTP	Number of people with OUD per OTP	Opioid overdose deaths	Number of people with OUD	Number of OTPs
Delaware	1	810	450	17,000	21
Massachusetts	2	873	2,267	96,000	110
Rhode Island	3	909	385	20,000	22
Connecticut	4	980	1,393	50,000	51
Maryland	5	1,030	2,460	102,000	99
New Hampshire	6	1,455	382	16,000	11
New Jersey	7	1,594	2,672	102,000	64
District of Columbia	8	1,667	348	10,000	6
Alaska	9	1,714	201	12,000	7
Vermont	10	1,714	218	12,000	7
Arizona	11	1,836	2,000	123,000	67
Ohio	12	1,966	4,456	232,000	118
New York	13	2,036	4,946	285,000	140
Maine	14	2,083	547	25,000	12
Colorado	15	2,143	1,289	75,000	35
Georgia	16	2,165	1,799	171,000	79
New Mexico	17	2,319	750	51,000	22
Utah	18	2,333	446	42,000	18
Illinois	19	2,483	3,050	221,000	89
North Dakota	20	2,500	74	10,000	4
Pennsylvania	21	2,548	4,081	265,000	104
North Carolina	22	2,558	3,339	220,000	86
Virginia	23	2,702	2,230	127,000	47
Oregon	24	2,800	779	70,000	25
California	25	3,083	7,181	521,000	169
Florida	26	3,216	5,940	357,000	111
Hawaii	27	3,250	91	13,000	4
Nevada	28	3,313	605	53,000	16
Michigan	29	3,346	2,536	174,000	52
South Carolina	30	3,393	1,712	95,000	28
Washington	31	3,410	1,623	133,000	39
Minnesota	32	4,000	978	72,000	18
Kentucky	33	4,129	1,897	128,000	31
Indiana	34	4,320	2,206	108,000	25
Wisconsin	35	4,375	1,437	105,000	24
Oklahoma	36	4,455	468	98,000	22
Idaho	37	4,833	236	29,000	6

Table 1 (continued)

Estimates of active opioid treatment programs (OTPs) per number of patients with opioid use disorder (OUD) throughout the United States, 2021

State	Rank of people with OUD per OTP	Number of people with OUD per OTP	Opioid overdose deaths	Number of people with OUD	Number of OTPs
Texas	38	4,853	2,770	461,000	95
Montana	39	5,000	114	20,000	4
West Virginia	40	5,444	1,253	49,000	9
Missouri	41	5,722	1,582	103,000	18
Alabama	42	5,913	981	136,000	23
Kansas	43	6,000	435	54,000	9
Tennessee	44	6,130	3,038	141,000	23
Iowa	45	6,375	259	51,000	8
Arkansas	46	10,167	386	61,000	6
Nebraska	47	10,667	113	32,000	3
Louisiana	48	11,400	1,335	114,000	10
South Dakota	49	15,000	46	15,000	1
Mississippi	50	18,250	556	73,000	4
Wyoming	51	–	71	8,000	0
U.S. total			**80,411**	**5,559,000**	**2,002**

Sources: "Opioid Overdose Deaths and Opioid Overdose Deaths as a Percent of All Drug Overdose Deaths," State Health Facts, Kaiser Family Foundation, 2023; "2021 National Survey on Drug Use and Health (NSDUH) Releases," Substance Abuse and Mental Health Services Administration (SAMHSA), U.S. Department of Health and Human Services; and "Opioid Treatment Program Directory," SAMHSA, U.S. Department of Health and Human Services.

treatment. Since then, programs have started in the United Kingdom, Germany, the Netherlands, Spain, and Canada. A 2011 analysis comparing heroin maintenance treatment to other MOUDs concluded it is an effective adjunct in treating OUD, particularly in patients for whom methadone was unsuccessful.[21]

The governments of the United States, Australia, Canada, and the United Kingdom each schedule drugs according to their respective controlled substances laws.[22] These schedules sort substances by their intended uses, the potential for patients to abuse them, pharmaceutical purpose, and potential danger. The DEA classifies heroin as a Schedule I drug. That description means that—in the DEA's judgment—a drug has no medical use and a high potential for abuse. By making that judgment and listing heroin as a Schedule I drug, the DEA prohibits heroin maintenance treatment in the United States.

The DEA categorizes methadone as a Schedule II drug: "dangerous with a high potential for abuse and dependence."[23] Australia categorizes methadone as a "controlled drug" with strict legislative prescription controls.[24] In Canada, patients must obtain a valid methadone prescription, and a pharmacist must dispense the drug.[25] The United Kingdom classifies methadone among the most dangerous drugs that may be legally prescribed.[26]

The DEA classifies buprenorphine as a Schedule III drug: "less potential for abuse and may lead to moderate or low physical or psychological dependence."[27]

INTERNATIONAL APPROACHES TO METHADONE TREATMENT

The government health services of Canada, the United Kingdom, and Australia do not strictly dictate OUD treatment plans as federal and state governments do in the United States. Instead, they provide guidelines to practitioners and leave exact treatment details (e.g., allowing take-home doses) to the discretion of health care professionals. Furthermore, these countries allow a broader spectrum of practitioners to provide methadone treatment to patients. This makes recovery more accessible to those suffering from

OUD. Patients' ability to choose between treatment facilities or community pharmacies further expands access.

German scientists discovered methadone in 1938. Harris Isbell, an American pharmacologist, found it effective for treating OUD in 1947. Studies from as early as the 1940s have shown that methadone effectively treats heroin withdrawal symptoms. The Narcotics Addiction Foundation established the world's first methadone treatment program in the late 1960s in Vancouver, Canada.[28] Methadone treatment has since become an established therapeutic approach for OUD and is used extensively and liberally in developed countries such as Australia, Canada, and the United Kingdom.

Canadian clinicians have been using methadone to treat OUD since 1964.[29] In Canada, the Controlled Drugs and Substances Act and the Narcotic Control Regulations regulate methadone treatment. In 2018, the Canadian government loosened its regulations on methadone by removing the requirement that practitioners obtain exemptions from Health Canada to prescribe it. Pharmacists no longer need to confirm with Health Canada that prescribers have valid exemptions.[30] Exact guidelines on methadone treatment vary in each province, but throughout the country, primary care practitioners prescribe methadone.[31] In British Columbia, for example, clinicians treating patients with methadone must register the patients with the Methadone Maintenance Program, which the College of Physicians and Surgeons of British Columbia runs.[32] Pharmacists must supervise registered patients who must take their initial methadone treatments in a pharmacy. As patients' treatment progresses, physicians may, at their discretion, approve patients for take-home doses.[33] Ontario has similar requirements for methadone treatment programs. Pharmacists must notify the Ontario College of Pharmacists within seven days of administering methadone to patients. The College sets guidelines for practitioners and pharmacists under their jurisdiction.[34]

The United Kingdom established drug dependency units in 1968 to administer methadone for OUD.[35] The United Kingdom permits consultant psychiatrists, nurses, pharmacists, and general practitioners to prescribe methadone for OUD.[36] Practitioners must regularly perform drug tests on patients receiving methadone to ensure they are not misusing other drugs. Patients must go into the pharmacy daily to take their methadone under a pharmacist's supervision until their practitioners deem that they are stable on the medication. Then, usually after three months of methadone treatment, practitioners may prescribe take-home doses if their patients qualify.[37] Pharmacists are responsible for dispensing the methadone, supervising the patients to ensure they take the methadone correctly, and communicating with the drug treatment team and the patient to help coordinate recovery care planning.[38]

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Clinicians have used methadone for OUD treatment in Australia since 1970.[39] To prescribe methadone for OUD, Australian clinicians must get permission from the national secretary of health to become approved methadone prescribers.[40] Prescribers must also obtain permits from their state's Department of Health and Human Services. General practitioners, nurse practitioners, or specialist treatment services (facilities that treat OUD) may administer methadone.[41]

OUD methadone treatment usually begins with patients attending a community pharmacy or a treatment service location daily to take their dose of methadone in the presence of a pharmacist or treatment service provider. Then, depending on the provider's clinical judgment, patients may get take-home dose privileges once they reach a stable dose—usually after about three months.[42]

Of the three countries, Australia's government provides the most complete data on methadone treatment for OUD, allowing for a direct comparison to the United States (see Table 2). Australia has a ratio of about 13 patients to 1 clinician; the United States has a ratio of 190 patients to 1 treatment location.

FEDERAL AND STATE OTP REGULATIONS AND REQUIREMENTS

In the United States, the DEA, SAMHSA, and state governments all oversee OTPs. OTPs must get accredited and certified by SAMHSA, licensed by their state, and registered with the DEA.[43]

Some federal OTP requirements are not evidence-based. For example, in December 2022, SAMHSA recognized that its requirement that patients be addicted to opioids for at least one year prior to admission to OTPs was not evidence-based and proposed ending the prerequisite.[44] As of August 2023, that proposed rule change was still pending.

Additionally, SAMHSA requires OTPs to offer counseling services for substance abuse, HIV/AIDS prevention, and rehabilitation.[45] While these services can be helpful to some patients, staffing these services diverts resources that could otherwise support urgently needed methadone treatment.

Regulators do not prohibit OTPs from administering buprenorphine in addition to methadone.[46] However, because patients can receive buprenorphine treatment from primary care clinicians, OTPs don't often prescribe buprenorphine.

Regulators also limit how OTPs provide take-home doses to patients, regardless of how stable their medication dosage is and how responsible and compliant patients have been in their treatment program. Within the first 90 days of treatment, patients cannot have more than one take-home dose a week. In the following 90 days of treatment, patients may only receive two weekly take-home doses. Patients can gradually work toward larger take-home quantities (e.g., after two years of successful treatment, patients may have up to one month's supply of methadone) but must always return to the OTP on at least a monthly basis.[47]

Complicating things further, states vary in regulating OTPs. Differing state regulations cause patient access to OTPs to vary widely across the country (see Figure 1). For example, states differ in how they regulate take-home doses of methadone. Some states add their own benchmarks to federal criteria that determine if patients are stable enough for take-home privileges (see Figure 2). The federal government alone imposes eight "stability" criteria for patients to be eligible for take-home methadone, including not having any recent criminal activity and not using any other drugs or alcohol.[48]

States also impose differing barriers to opening a new OTP (see Figure 3). Nineteen states require OTPs to obtain a "certificate of need" from the state declaring that a new OTP is necessary. In 2016, the West Virginia legislature placed a moratorium on new OTPs. The law prohibits new OTPs from

(Text continues on page 10)

Table 2

Methadone treatment for opioid use disorder (OUD) in the United States and Australia

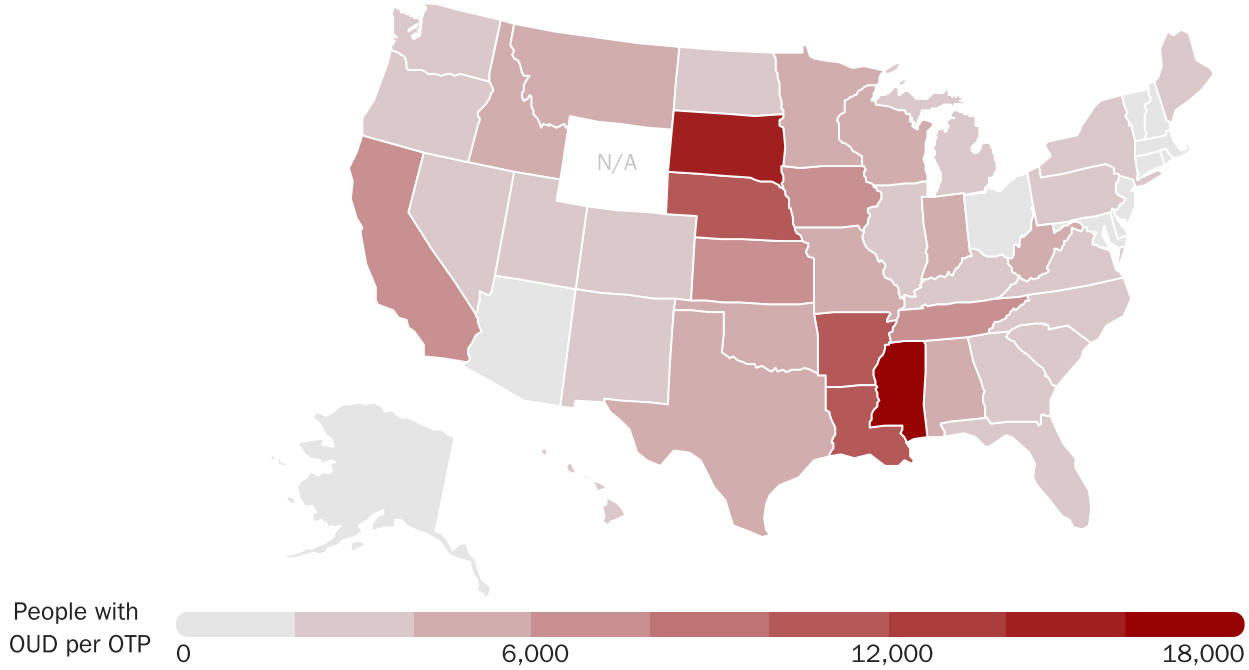
	United States	Australia
Clinicians prescribing methadone for OUD	1,641* (2020)	2,166** (2022)
Patients receiving methadone for OUD	311,531 (2020)	27,999 (2022)
Percentage of people with OUD receiving methadone treatment	5.60%	9.89%
Percentage of population receiving methadone for OUD	0.09%	0.11%
Number of patients per prescribing clinician	190	13
Opioid-related death rate (per 100,000 population, age standardized)	25 (2021)	4 (2021)
Methadone-related death rate (per 100,000 population, age standardized)	1 (2021)	1 (2021)

*In the United States, methadone for OUD can only be legally prescribed in an opioid treatment program (OTP). Clinicians may not prescribe methadone for OUD outside of OTPs. This number represents the treatment locations that prescribe methadone.
**In Australia, prescribers include general practitioners, nurse practitioners, and specialized treatment services.

Sources: "National Opioid Pharmacotherapy Statistics Annual Data Collection," Australian Institute of Health and Welfare, last updated April 20, 2023; "Alcohol, Tobacco & Other Drugs in Australia," Australian Institute of Health and Welfare, last updated June 30, 2023; "Drug Overdose Death Rates," National Institute on Drug Abuse, National Institutes of Health, June 30, 2023; Merianne Rose Spencer, Arialdi M. Miniño, and Margaret Warner, "Drug Overdose Deaths in the United States, 2001–2021," National Center for Health Statistics Data Brief no. 457, December 2022; "Opioid Treatment Program Directory," Substance Abuse and Mental Health Services Administration (SAMHSA), U.S. Department of Health and Human Services; and "National Survey of Substance Abuse Treatment Services (N-SSATS): 2020, Data on Substance Abuse Treatment Facilities," SAMHSA, U.S. Department of Health and Human Services, July 14, 2021.

Figure 1

The ratio of people with an opioid use disorder (OUD) per active opioid treatment programs (OTP) in each state, 2023



State	Number of people with OUD per OTP	Number of OTPs
Mississippi	18,250	4
South Dakota	15,000	1
Louisiana	11,400	10
Nebraska	10,667	3
Arkansas	10,167	6
California	7,551	169
Iowa	6,375	8
Tennessee	6,130	23
Kansas	6,000	9
Alabama	5,913	23
West Virginia	5,444	9
Missouri	5,421	19
Montana	5,000	4
Idaho	4,833	6
Texas	4,753	97
Oklahoma	4,455	22
Wisconsin	4,375	24
Indiana	4,320	25

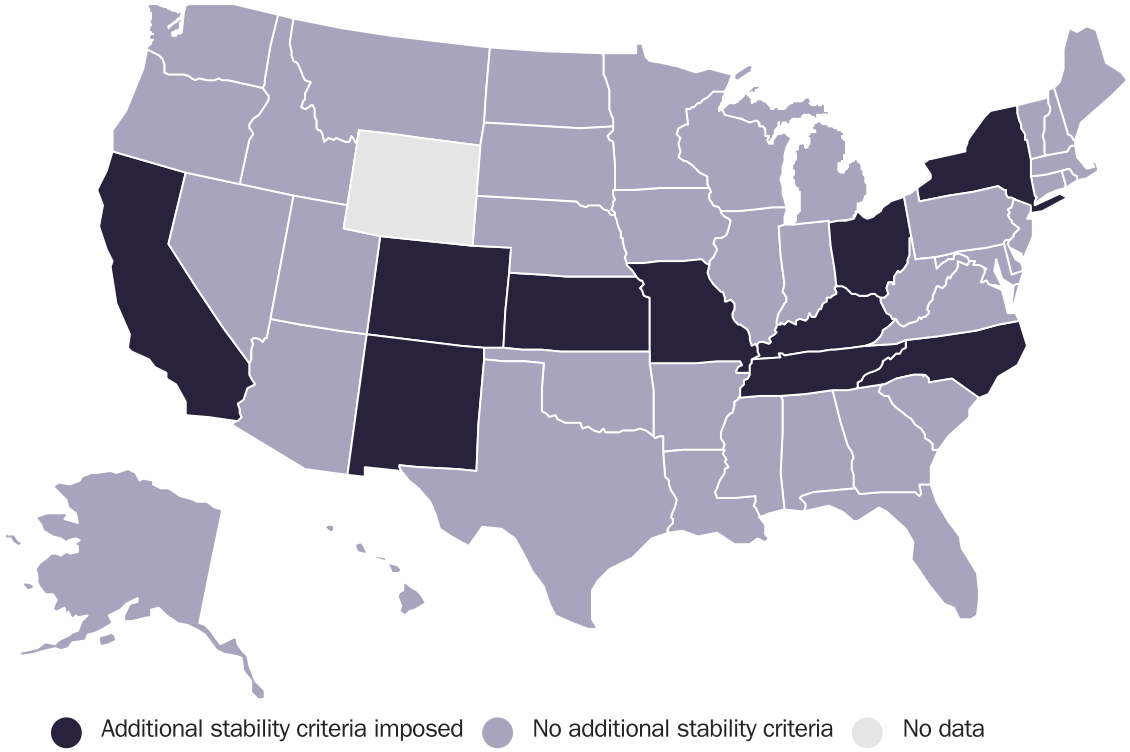
State	Number of people with OUD per OTP	Number of OTPs
Minnesota	4,000	18
Kentucky	3,879	33
Michigan	3,412	51
Washington	3,410	39
South Carolina	3,393	28
Nevada	3,313	16
Hawaii	3,250	4
Florida	3,245	110
Oregon	2,800	25
Virginia	2,702	47
Pennsylvania	2,548	104
North Carolina	2,529	87
North Dakota	2,500	4
Illinois	2,483	89
Utah	2,333	18
New Mexico	2,318	22
Georgia	2,165	79

State	Number of people with OUD per OTP	Number of OTPs
Colorado	2,143	35
Maine	2,083	12
New York	2,050	139
Ohio	1,966	118
Arizona	1,836	67
Alaska	1,714	7
Vermont	1,714	7
District of Columbia	1,667	6
New Jersey	1,569	65
New Hampshire	1,455	11
Maryland	1,030	99
Connecticut	980	51
Rhode Island	909	22
Massachusetts	873	110
Delaware	810	21
Wyoming	N/A	0

Sources: "Opioid Treatment Program Directory," Substance Abuse and Mental Health Services Administration (SAMHSA), U.S. Department of Health and Human Services; and "2021 National Survey on Drug Use and Health (NSDUH) Releases," SAMHSA, U.S. Department of Health and Human Services.
Note: OUD = opioid use disorder.

Figure 2

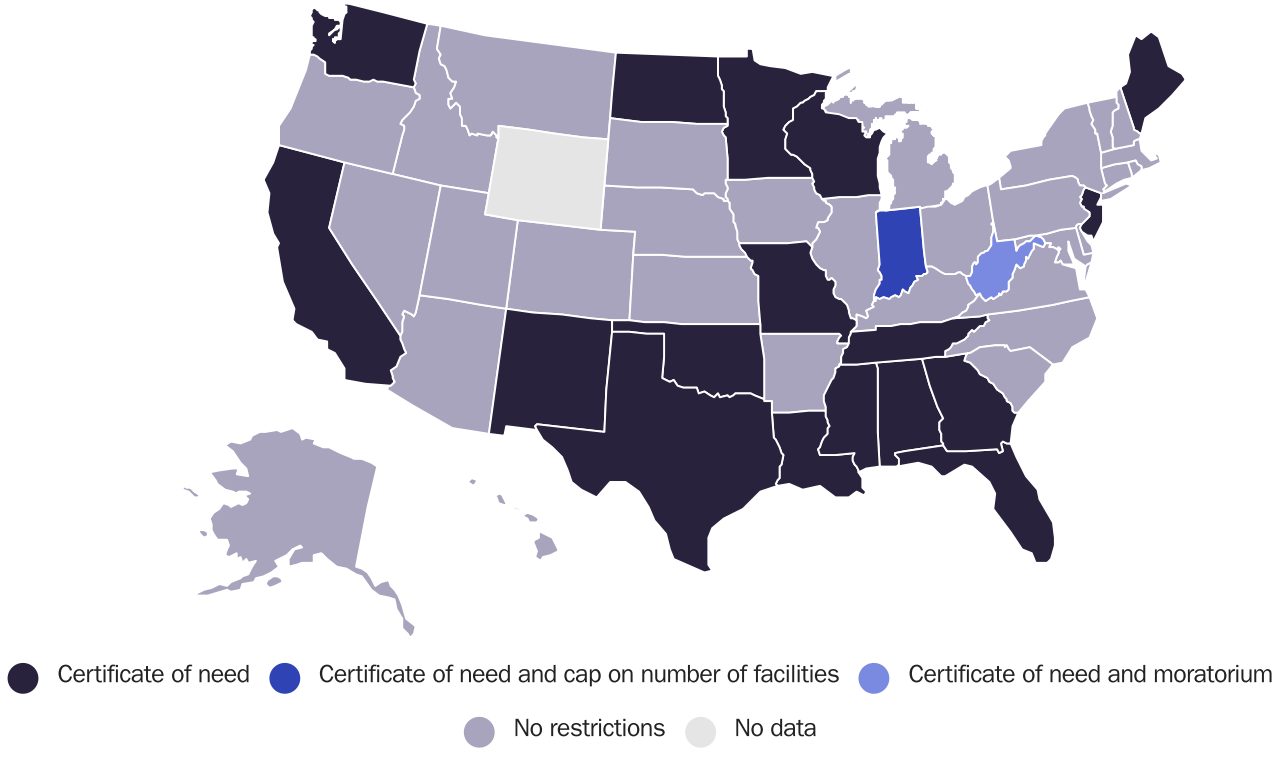
Take-home methadone restrictions vary by state



Source: Sheri Doyle et al., "Overview of Opioid Treatment Program Regulations by State," Pew Charitable Trusts, September 19, 2022.

Figure 3

Some states create roadblocks to opening opioid treatment programs



Source: Sheri Doyle et al., "Overview of Opioid Treatment Program Regulations by State," Pew Charitable Trusts, September 19, 2022.

opening in the state if they had not obtained a certificate of need by the time the legislature enacted the moratorium.[49]

There are currently only nine OTPs in West Virginia, despite an estimated 49,000 individuals struggling with OUD for a ratio of almost 5,500 patients to each treatment center.[50] Wyoming currently has no OTPs and has not promulgated state-specific OTP regulations.[51]

Residents often oppose and protest the opening of OTPs in their neighborhoods. This "not in my backyard" (NIMBY) stance can affect the timing and number of OTP openings on both the state and local levels.[52] Interest groups lobby local governments to impose zoning restrictions that prohibit building OTPs within cities. NIMBY activists argue that OTPs would bring crime to their neighborhoods, a concern that seems reasonable on its face. But a 2015 study focusing on drug treatment programs in Baltimore concluded, "Violent crime associated with drug treatment centers is similar to that associated with liquor stores and is less frequent than that associated with convenience stores and corner stores."[53]

A 2018 study found a decrease in total crime and property crime within a 200-meter radius of OTPs in Philadelphia.[54] Allowing clinicians to prescribe methadone and other MOUDs in primary care settings is a way to circumvent NIMBYism.

ONE WAY TO EXPAND AMERICANS' ACCESS TO METHADONE TREATMENT: ENABLE PRIMARY CARE CLINICIANS TO PRESCRIBE

Clinicians who hold a license to practice from a state and a narcotics prescription license from the DEA may legally prescribe methadone—but only to treat pain.[55] Federal and state laws prohibit clinicians from prescribing methadone to treat OUD. Patients with OUD may only obtain methadone treatment from government-approved OTPs. Enabling other clinicians, including neighborhood primary care clinicians, to prescribe methadone treatment to patients in their clinics would significantly increase access to this effective treatment. It would also avoid attracting attention and resistance from residents who don't want an OTP in their "backyard."

Clinicians could thus treat patients in a more private, discreet setting, where they share waiting rooms with patients with other mental and physical health disorders. This would spare patients the stigma associated with queuing outside designated OTPs. Destigmatizing people with OUD facilitates their access to care and improves the likelihood of recovery.[56] This necessitates policymakers removing regulations and restrictions that require clinicians to treat people with OUD differently than they treat other people with behavioral and mental health problems.

Public health and addiction medicine specialists have been calling for several years for policymakers to allow primary care clinicians to treat OUD with methadone. Writing in the *New England Journal of Medicine* in 2018, Jeffrey Samet and others stated:

> Methadone prescribing in primary care is standard practice and not controversial in these places [countries that allow MOUD in primary care settings] because it benefits the patient, the care team, and the community and is viewed as a way of expanding the delivery of an effective medication to an at-risk population.[57]

A Health and Medicine Division panel of the National Academies of Sciences, Engineering, and Medicine released its report *Opportunities to Improve Opioid Use Disorder and Infectious Disease Services* in January 2020. The panel comprised academics, medical professionals, epidemiologists, nurses, and health policy specialists. Among the panel's recommendations was to allow clinicians to prescribe methadone treatment in primary care settings.[58] Zoe Adams and others called on Congress to "expand methadone prescribing beyond addiction care providers," stating that "take-home methadone dosing should be decided by science, clinicians, and patients."[59]

PILOT PROGRAMS IN THE UNITED STATES

Federally approved pilot studies repeatedly show that enabling primary care clinicians to prescribe methadone for OUD can work as well in the United States as in Australia, Canada, and the United Kingdom.

In 2001, Yale University School of Medicine researchers studied 47 patients with OUD who were receiving methadone in an OTP and then randomly assigned to six primary

care providers' offices for methadone treatment for six months. The researchers concluded, "Our results support the feasibility and efficacy of transferring stable opioid-dependent patients receiving methadone maintenance to primary care physicians' offices for continuing treatment."[60]

Researchers at the University of Washington conducted a one-year federally approved pilot program treating 28 patients with methadone in a primary care setting. They concluded that the approach was feasible and "can result in good clinical outcomes."[61]

Dennis McCarty and others conducted a "scoping review" that broadly surveyed all of the outcomes evidence when treating patients with methadone in primary care office-based settings.[62] Reporting in the *American Journal of Psychiatry* in July 2021, their findings suggested that "office-based methadone treatment and pharmacy dispensing could enhance access to methadone treatment for patients with opioid use disorder without adversely affecting patient outcomes and, potentially, inform modifications to federal regulations."[63]

TAKE-HOME METHADONE DURING THE COVID-19 PUBLIC HEALTH EMERGENCY

The recent COVID-19 public health emergency provided another opportunity to study the safety and efficacy of prescribing take-home methadone. Because lockdowns and social distancing requirements during the pandemic impeded OTP operation and access, in March 2020, SAMHSA permitted methadone clinics to dispense up to 28 days' worth of take-home methadone to clinic participants as an emergency measure. Thus ensued an emergency-induced pilot study. In March 2022, citing "sufficient evidence to conclude that this exemption has enhanced and encouraged use of OTP services," SAMHSA extended the take-home rule and stated that it is "considering mechanisms to make this flexibility permanent."[64] Researchers at the Centers for Disease Control and Prevention reported in the July 13, 2022, issue of *JAMA Psychiatry* that the percentage of overdose deaths involving methadone declined between January 2019 and August 2021. They found that the emergency take-home methadone program "was not associated with harms" but rather "add[ed] evidence to support take-home treatment for opioid use disorder."[65]

THE MODERNIZING OPIOID TREATMENT ACCESS ACT

On March 2, 2023, Senators Edward J. Markey (D-MA) and Rand Paul (R-KY) introduced the Modernizing Opioid Treatment Access Act in the U.S. Senate.[66] Representatives Donald Norcross (D-NJ) and Don Bacon (R-NE) introduced the same bill in the House of Representatives.[67] The Senate and House bills have several bipartisan cosponsors.

The bills would allow patients to receive OUD treatment in doctors' offices and clinics in the community. However, the proposed legislation only permits methadone prescriptions from addiction medicine physicians or addiction psychiatrists who hold specialty or subspecialty board certification in addiction medicine from one of four certifying organizations: the American Board of Preventive Medicine, the American Board of Addiction Medicine, the American Board of Psychiatry and Neurology, and the American Osteopathic Association.[68]

Unfortunately, not nearly enough doctors in the United States meet those requirements to increase access to the degree the bill's sponsors envision. Table 3 lists the number of physicians registered in each specialist category by state as of March 6, 2023.

Even if all these physicians were accepting new patients, it would not be enough. There must be more of them to serve the millions of Americans with OUD who are not currently getting treated. Some states have very few qualifying physicians. Wyoming has only five. Another shortcoming is that the bill limits the amount that doctors could prescribe to their patients to a supply of "not more than 30 days."

Despite its shortcomings, the Modernizing Opioid Treatment Access Act is the first serious attempt in many years to remove unnecessary government barriers to methadone treatment. The bill also helps to destigmatize people with OUD by treating them as suffering from a medical condition.

POLICY RECOMMENDATIONS

Lawmakers should not tie clinicians' hands. Doctors treating substance use disorder best know how, when, and how much MOUD to prescribe, especially to long-term patients.[69] Clinicians in the United Kingdom, Canada, and Australia exercise their medical judgment in deciding the timing and

Table 3
Certified addiction specialists/subspecialists, United States

State	American Board of Addiction Medicine (Addiction Medicine)	American Board of Preventive Medicine (Addiction Medicine)	American Board of Psychiatry and Neurology (Addiction Psychiatry)	American Osteopathic Association (Addiction Medicine)	Total specialists	Number of people with OUD per total number of specialists
Alabama	7	26	8	0	41	3,317
Alaska	1	10	2	0	13	923
Arizona	19	61	20	3	103	1,194
Arkansas	2	10	5	1	18	3,389
California	147	423	157	2	729	715
Colorado	25	46	37	0	108	694
Connecticut	21	63	58	1	143	350
Delaware	4	7	4	0	15	1,133
District of Colombia	4	14	5	0	23	435
Florida	94	139	72	3	308	1,159
Georgia	28	59	42	0	129	1,326
Hawaii	7	13	10	1	31	419
Idaho	6	11	0	0	17	1,706
Illinois	36	82	44	0	162	1,364
Indiana	13	44	14	3	74	1,459
Iowa	3	9	4	0	16	3,188
Kansas	5	12	10	0	27	2,000
Kentucky	14	87	11	0	112	1,143
Louisiana	19	43	13	0	75	1,520
Maine	10	24	6	2	42	595
Maryland	44	74	52	0	170	600
Massachusetts	30	144	80	0	254	378
Michigan	41	63	32	0	136	1,279
Minnesota	8	61	29	0	98	735
Mississippi	6	15	6	0	27	2,704
Missouri	9	45	7	0	61	1,589
Montana	2	10	3	0	15	1,333
Nebraska	1	6	5	0	12	2,667
Nevada	8	22	4	0	34	1,559
New Hampshire	4	15	9	1	29	552
New Jersey	52	90	40	0	182	560
New Mexico	6	31	10	0	47	1,085
New York	76	224	198	1	499	571
North Carolina	30	72	23	0	125	1,760
North Dakota	0	6	1	0	7	1,429
Ohio	45	142	40	5	232	1,000

Table 3 (continued)

Certified addiction specialists/subspecialists, United States

State	American Board of Addiction Medicine (Addiction Medicine)	American Board of Preventive Medicine (Addiction Medicine)	American Board of Psychiatry and Neurology (Addiction Psychiatry)	American Osteopathic Association (Addiction Medicine)	Total specialists	Number of people with OUD per total number of specialists
Oklahoma	9	23	5	1	38	2,579
Oregon	13	57	14	1	85	824
Pennsylvania	42	153	56	7	258	1,027
Rhode Island	9	13	5	0	27	741
South Carolina	17	22	26	1	66	1,439
South Dakota	1	5	3	0	9	1,667
Tennessee	34	117	19	0	170	829
Texas	47	114	83	0	244	1,889
Utah	10	38	11	0	59	712
Vermont	4	7	5	0	16	750
Virginia	25	77	26	0	128	992
Washington	14	86	39	1	140	950
West Virginia	5	25	11	0	41	1,195
Wisconsin	17	81	19	0	117	897
Wyoming	2	3	0	0	5	1,600
U.S. total	**1,076**	**3,024**	**1,383**	**34**	**5,517**	**1,008**

Sources: "Find a Physician," American College of Academic Addiction Medicine; "ABMS Board Certification Report," American Board of Medical Specialties; "Addiction Medicine—207RA0401X," NPIdb; and "2021 National Survey on Drug Use and Health (NSDUH) Releases," Substance Abuse and Mental Health Services Administration, U.S. Department of Health and Human Services.
Note: OUD = opioid use disorder.

amount of take-home methadone. Clinicians and patients in the United States deserve the same freedom.

Ideally, lawmakers should end drug prohibition. As a result of the war on drugs, federal bureaucrats, police, SAMHSA, and the DEA regulate how clinicians practice medicine.[70] Drug prohibition lets lawmakers, policymakers, and law enforcement agents intrude into clinical decisionmaking and the patient–doctor relationship.[71] Furthermore, treating people with OUD differently than people with other substance use and behavioral or physical health problems stigmatizes these patients, creating further obstacles to treatment.

A second-best solution would be for lawmakers to enable patients with OUD to receive methadone treatment from sources other than government-approved OTPs. Providers should include office-based addiction specialists, primary care physicians, nurse practitioners, and physician assistants. These treatment options can coexist with more traditional inpatient or outpatient treatment programs.

Treating substance use disorder is complicated. Practitioners must commit to developing close relationships with their patients, taking the time for deep discussions, and monitoring them closely. Not every primary care practitioner will feel competent to treat patients with OUD. They will refer such patients to appropriate practitioners. However, allowing all primary care providers to provide methadone treatment would significantly expand treatment options and access to care.

If enabling people with OUD to access methadone treatment through primary care clinicians is not politically feasible, then a third-best solution would be to allow patients to obtain methadone treatment from addiction medicine specialists in an office setting. Lawmakers should

avoid enacting timelines, dosages, and amounts of take-home methadone that clinicians may prescribe. They should defer to clinicians' expertise and judgment.

CONCLUSION

Amid a worsening opioid-driven overdose crisis that mostly involves illicit fentanyl, it is crucial to increase access to methadone treatment for people with OUD. With as many as 7.6 million people with OUD in the United States, only about 400,000 have access to this effective treatment modality.

Lawmakers should remove the cumbersome regulations that govern methadone treatment programs and allow people with OUD to access methadone treatment from clinicians in primary care settings.

NOTES

1. Hawre Jalal et al., "Changing Dynamics of the Drug Overdose Epidemic in the United States from 1979 through 2016," *Science* 361, no. 6408 (September 21, 2018). A 2019 study by the Joint Economic Committee of Congress found that drug overdose deaths began rising in 1959. "Long-Term Trends in Deaths of Despair," Social Capital Project Report no. 4-19, Joint Economic Committee—Republicans, September 2019.

2. "Provisional Drug Overdose Death Counts," National Vital Statistics System, National Center for Health Statistics, Centers for Disease Control and Prevention, last reviewed June 14, 2023.

3. "Medications to Treat Opioid Use Disorder Research Report," National Institute on Drug Abuse, National Institutes of Health, revised December 2021.

4. Katherine M. Keyes et al., "What Is the Prevalence of and Trend in Opioid Use Disorder in the United States from 2010 to 2019? Using Multiplier Approaches to Estimate Prevalence for an Unknown Population Size," *Drug and Alcohol Dependence Reports* 3 (June 2022).

5. Nora D. Volkow and A. Thomas McLellan, "Opioid Abuse in Chronic Pain—Misconceptions and Mitigation Strategies," *New England Journal of Medicine* 374 (March 31, 2016): 1253–63; Gavan P. McNally et al., "Pathways to the Persistence of Drug Use Despite Its Adverse Consequences," *Molecular Psychiatry* (2023); and Jeffrey A. Singer, "The March toward a Pre-modern Approach to the Treatment of Pain Continues, Undeterred by Science," *Cato at Liberty* (blog), Cato Institute, August 12, 2019.

6. An agonist is "a chemical capable of combining with a specific receptor on a cell and initiating the same reaction or activity typically produced by the binding endogenous substance." *Merriam-Webster*, s.v. "agonist (*n*)"; and John Strang et al., "Opioid Use Disorder," *Nature Reviews Disease Primers* 6, no. 3 (2020).

7. Richard A. Rettig and Adam Yarmolinsky, eds., *Federal Regulation of Methadone Treatment* (Washington: National Academy Press, 1995), Google Books edition, chap. 5, pp. 120–44.

8. Richard A. Rettig and Adam Yarmolinsky, eds., *Federal Regulation of Methadone Treatment* (Washington: National Academy Press, 1995), Google Books edition, chap. 1, p. 2.

9. Sheri Doyle, "Federal Agencies Have Substantial Authority to Boost Methadone Access," Pew Charitable Trusts, August 11, 2022.

10. Drug Addiction Treatment Act of 2000, H. R. 2634, 106th Cong. (2000); Jeffrey A. Singer, "Will Congress Finally X-Out the 'X' Waiver," *Cato at Liberty* (blog), Cato Institute, July 16, 2019; and Joyce Frieden, "HHS Loosens Rules for Prescribing Buprenorphine," *Medpage Today*, April 27, 2021.

11. Noah Weiland, "More Doctors Can Now Prescribe a Key Opioid Treatment. Will It Help?," *New York Times*, March 3, 2023; "Buprenorphine," Substance Abuse and Mental Health Services Administration, U.S. Department of Health and Human Services, updated June 20, 2023; Jeffrey A. Singer, "Congress Made It Easier to Treat Addiction but Harder to Treat Pain," *Cato at Liberty* (blog), Cato Institute, December 23, 2022; and Jeffrey A. Singer, "DEA Pumps the Breaks on Congress' Move to Increase Access to Addiction Treatment," *Cato at Liberty* (blog), Cato Institute, March 15, 2023.

12. "Medications for Opioid Use Disorder Study (MOUD Study)," Centers for Disease Control and Prevention, last reviewed January 24, 2022.

13. K. K. Adams, M. Machnicz, and D. M. Sobieraj, "Initiating Buprenorphine to Treat Opioid Use Disorder without Prerequisite Withdrawal: A Systematic Review," *Addiction Science and Clinical Practice* 16, no. 36 (2021).

14. Luis Sordo et al., "Mortality Risk during and after Opioid Substitution Treatment: Systematic Review and Meta-Analysis of Cohort Studies," *BMJ* 357 (April 26, 2017).

15. Richard P. Mattick et al., "Buprenorphine Maintenance versus Placebo or Methadone Maintenance for Opioid Dependence," *Cochrane Database of Systematic Reviews* no. 2 (February 6, 2014).

16. Paul J. Whelan and Kimberly Remski, "Buprenorphine vs Methadone Treatment: A Review of Evidence in Both Developed and Developing Worlds," *Journal of Neurosciences in Rural Practice* 3, no. 1 (2012): 45–50.

17. Adam N. Peddicord, Chris Bush, and Crystal Cruze, "A Comparison of Suboxone and Methadone in the Treatment of Opiate Addiction," *Journal of Addiction Research and Therapy* 6 (November 27, 2015): 248.

18. Louisa Degenhardt et al., "Buprenorphine versus Methadone for the Treatment of Opioid Dependence: A Systematic Review and Meta-Analysis of Randomised and Observational Studies," *Lancet Psychiatry* 10, no. 6 (June 2023): 386–402.

19. Silvia Minozzi et al., "Oral Naltrexone Maintenance Treatment for Opioid Dependence," *Cochrane Database of Systematic Reviews* no. 4 (April 13, 2011).

20. Sarah E. Wakeman et al., "Comparative Effectiveness of Different Treatment Pathways for Opioid Use Disorder," *JAMA Network Open* 3, no. 2 (February 5, 2020).

21. Marica Ferri, Marina Davoli, and Carlo A. Perucci, "Heroin Maintenance for Chronic Heroin-Dependent Individuals," *Cochrane Database of Systematic Reviews* (December 7, 2011).

22. The Controlled Substances Act regulates drug scheduling in the United States. U.S. Drug Enforcement Administration, "The Controlled Substances Act," U.S. Department of Justice; Controlled Substances Act of 1971, 21 U.S.C. § 801 (1971). The Standard for the Uniform Scheduling of Medicines and Poisons regulates drug scheduling in Australia. Therapeutic Goods Administration, "The Poisons Standards (the SUSMP)," Department of Health and Aged Care, updated July 3, 2023; and Therapeutic Goods Administration, "Scheduling Basics of Medicines and Chemicals in Australia," Department of Health and Aged Care. The Controlled Drugs and Substances Act regulates drug scheduling in Canada. Controlled Drugs and Substances Act, S.C. 1996, c.19 (1996). The Misuse of Drugs Act 1971 and the Misuse of Drugs Regulations 2001 regulate drug scheduling in the United Kingdom. "Guidance: List of Most Commonly Encountered Drugs Currently Controlled under the Misuse of Drugs Legislation," United Kingdom Government, updated August 8, 2022; Misuse of Drugs Act 1971, c. 38 (1971); and The Misuse of Drugs Regulations 2001, no. 3998 (2001).

23. U.S. Drug Enforcement Administration, "Controlled Substances," U.S. Department of Justice, July 7, 2023; and "Drug Scheduling," U.S. Drug Enforcement Administration, U.S. Department of Justice.

24. "Methadone," Alcohol and Drug Foundation, November 30, 2022; and Sara Bird, "Prescribing Schedule 8 Drugs," *Australian Family Physician* 35, no. 1/2 (January/February 2006): 59–60.

25. Controlled Drugs and Substances Act, S.C. 1996, c.19 (1996).

26. "Guidance: List of Most Commonly Encountered Drugs Currently Controlled under the Misuse of Drugs Legislation," United Kingdom Government, updated August 8, 2022; "FAQs on Controlled Drugs," Chartered Society of Physiotherapy, November 2018; and "Schedules," Release.

27. U.S. Drug Enforcement Administration, "Controlled Substances," U.S. Department of Justice, July 7, 2023; and "Drug Scheduling," U.S. Drug Enforcement Administration, U.S. Department of Justice.

28. "Methadone Maintenance Program: Clinical Practice Guideline," College of Physicians and Surgeons of British Columbia, updated September 2015.

29. Joseph K. Eibl et al., "The State of Opioid Agonist Therapy in Canada 20 Years after Federal Oversight," *Canadian Journal of Psychiatry* 62, no. 7 (July 2014): 444–50.

30. "Methadone Program," Government of Canada, modified April 27, 2017.

31. "Methadone Maintenance Treatment Policies," Canadian Addiction Treatment Centres.

32. "Methadone Maintenance Program: Clinical Practice Guideline," College of Physicians and Surgeons of British Columbia, updated September 2015. Provincial law allows the College of Physicians and Surgeons of British Columbia to regulate the practice of medicine throughout British Columbia. All doctors are required to be registered with the College to lawfully practice medicine. "Regulating the Practice of Medicine in British Columbia," About the College, College of Physicians and Surgeons of British Columbia.

33. "Methadone Maintenance Program: Clinical Practice

Guideline," College of Physicians and Surgeons of British Columbia, updated September 2015.

34. "Key Requirements for Methadone Maintenance Treatment (MMT)," Ontario College of Pharmacists, updated March 2021; and "Methadone Maintenance Treatment Policies," Canadian Addiction Treatment Centres.

35. Nicola J. Kalk et al., "Treatment and Intervention for Opiate Dependence in the United Kingdom: Lessons from Triumph and Failure," *European Journal on Criminal Policy and Research* 24 (2018): 183–200.

36. "Guidance: Part 1: Introducing Opioid Substitution Treatment (OST)," Public Health England, United Kingdom Government, July 21, 2021.

37. "Methadone," National Health Service, updated March 24, 2021.

38. "Guidance: Part 1: Introducing Opioid Substitution Treatment (OST)," Public Health England, United Kingdom Government, July 21, 2021.

39. Morag Mcarthur, "A History of Methadone Treatment in Australia: The Influence of Social Control Arguments in Its Development," Australian Catholic University, January 2001.

40. "Methadone," New South Wales Health, New South Wales Government, updated December 16, 2015.

41. Department of Health and Human Services Victoria, *Methadone Treatment in Victoria: User Information Booklet* (Victoria, Australia: Victoria State Government, 2016). Canberra Health Services' Opioid Treatment Service is an example of a specialist treatment service. The health service has two locations that are each staffed with specially trained doctors, nurses, and counselors. Patients receive opioid maintenance treatment and can be referred to other medical services by the practitioners if the need arises. "Opioid Treatment Service," Canberra Health Services, Australian Capital Territory Government.

42. Department of Health and Human Services Victoria, Methadone Treatment in Victoria: User Information Booklet (Victoria, Australia: Victoria State Government, 2016).

43. "Certification of Opioid Treatment Programs (OTPs)," Substance Abuse and Mental Health Services Administration, U.S. Department of Health and Human Services, updated March 22, 2023.

44. Medications for the Treatment of Opioid Use Disorder, 87 Fed. Reg. 77330 (December 16, 2022) (to be codified at 42 C.F.R. pt. 8); and Substance Abuse and Mental Health Services Administration, *Federal Guidelines for Opioid Treatment Programs* (Rockville, Maryland: U.S. Department of Health and Human Services, January 2015. Jeffrey A. Singer, one of the authors of this policy analysis, submitted a public comment on the proposed rule change in January 2023. Jeffrey A. Singer, "Public Comment on Notice of Proposed Rulemaking on Medications for the Treatment of Opioid Use Disorder," Cato Institute, January 2, 2023.

45. Federal Opioid Treatment Standards, 42 C.F.R. § 8.12 (2002).

46. Federal Opioid Treatment Standards, 42 C.F.R. § 8.12 (2002).

47. Federal Opioid Treatment Standards, 42 C.F.R. § 8.12 (2002).

48. Federal Opioid Treatment Standards, 42 C.F.R. § 8.12 (2002).

49. Moratorium; Certificate of Need, W.V.C. § 16-5Y-12 (2016).

50. "2021 NSDUH: Model-Based Estimated Totals for States (In Thousands)," Substance Abuse and Mental Health Services Administration, U.S. Department of Health and Human Services, March 8, 2023.

51. Sheri Doyle et al., "Overview of Opioid Treatment Program Regulations by State," Pew Charitable Trusts, September 19, 2022; and "Summary of the Revisions to the Wyoming Pharmacy Act and Wyoming Controlled Substances Act Rules and Regulations," *Wyoming State Board of Pharmacy Newsletter to Promote Pharmacy and Drug Law Compliance* 30, no. 4 (December 2021): 3. There are, however, several treatment programs in Wyoming that prescribe buprenorphine.

52. C. Debra M. Furr-Holden et al., "Not in My Back Yard: A Comparative Analysis of Crime around Publicly Funded Drug Treatment Centers, Liquor Stores, Convenience Stores, and Corner Stores in One Mid-Atlantic City," *Journal of Studies on Alcohol and Drugs* 77, no. 1 (2016): 17–24; and Kathryn M. Stadeli, "Opioid Deaths Are Preventable—Don't NIMBY Treatment Centers," *Seattle Times*, January 9, 2019.

53. C. Debra M. Furr-Holden et al., "Not in My Back Yard: A Comparative Analysis of Crime around Publicly Funded Drug Treatment Centers, Liquor Stores, Convenience Stores, and Corner Stores in One Mid-Atlantic City," *Journal of Studies on Alcohol and Drugs* 77, no. 1 (2016): 17–24.

54. Ruth A. Moyer and Greg Ridgeway, "The Effect of

Outpatient Methadone Maintenance Treatment Facilities on Place-Based Crime," *Journal of Experimental Criminology* 16 (2020): 227–45. The researchers noted an increase in drug and violent crime but pointed out that some of the increase may be due to an increase in reporting by staff at the facilities. "Methadone Clinics: How Do They Affect Crime Rates?," American Society of Evidence-Based Policing.

55. "Dolophine Hydrochloride CII," Roxane Laboratories Inc., 2006; and Jeffrey A. Singer, "Methadone and Mixed Messages," *Cato at Liberty* (blog), Cato Institute, July 13, 2018.

56. Zara Greenbaum, "The Stigma That Undermines Care," *American Psychological Association* 50, no. 6 (June 2019): 46.

57. Jeffrey H. Samet, Michael Botticelli, and Monica Bharel, "Methadone in Primary Care—One Small Step for Congress, One Giant Leap for Addiction Treatment," *New England Journal of Medicine* 379 (July 5, 2018): 7–8.

58. "Recommendations: Opportunities to Improve Opioid Use Disorder and Infectious Disease Services: Integrating Responses to a Dual Epidemic," National Academies of Sciences, Engineering, and Medicine, January 2020, Recommendation 3-9.

59. Zoe Adams et al., "To Save Live from Opioid Overdose Deaths, Bring Methadone into Mainstream Medicine," *Health Affairs*, May 27, 2022.

60. D. A. Fiellin et al., "Methadone Maintenance in Primary Care: A Randomized Controlled Trial," *JAMA* 286, no. 14 (October 10, 2001): 1724–31.

61. Joseph O. Merrill et al., "Methadone Medical Maintenance in Primary Care. An Implementational Evaluation," *Journal of General Internal Medicine* 20, no. 4 (April 2005): 344–49.

62. A scoping review broadly surveys the evidence without formally rating study quality.

63. Dennis McCarty et al., "Office-Based Methadone Treatment for Opioid Use Disorder and Pharmacy Dispensing: A Scoping Review," *American Journal of Psychiatry* 178, no. 9 (September 1, 2001): 804–17.

64. "Methadone Take-Home Flexibilities Extension Guidance," Substance Abuse and Mental Health Services Administration, U.S. Department of Health and Human Services, updated May 1, 2023.

65. Christopher M. Jones et al., "Methadone-Involved Overdose Deaths in the US before and after Federal Policy Changes Expanding Take-Home Methadone Doses from Opioid Treatment Programs," *JAMA Psychiatry* 79, no. 9 (September 2022): 932–34.

66. Modernizing Opioid Treatment Access Act, S. 644, 118th Cong. (2023).

67. Ed Markey, "Sens. Markey, Paul and Reps. Norcross, Bacon Introduce Modernizing Opioid Treatment Access Act to Reach More Americans Suffering from Opioid Use Disorder as Annual Overdoses Surpass 100,000 across U.S.," press release, March 6, 2023.

68. Zoe Adams et al., "To Save Live from Opioid Overdose Deaths, Bring Methadone into Mainstream Medicine," *Health Affairs*, May 27, 2022; and Jeffrey A. Singer, "The Modernizing Opioid Treatment Access Act Is a Good Step in the Right Direction, but It Should Go Further," *Cato at Liberty* (blog), Cato Institute, March 20, 2023.

69. Jeffrey A. Singer and Trevor Burrus, "Cops Practicing Medicine: The Parallel Histories of Drug War I and Drug War II," Cato Institute White Paper, November 29, 2022.

70. "The Controlled Substances Act," U.S. Drug Enforcement Administration, U.S. Department of Justice; and The Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, 84 Stat. (1970).

71. Jeffrey A. Singer and Trevor Burrus, "Cops Practicing Medicine: The Parallel Histories of Drug War I and Drug War II," Cato Institute White Paper, November 29, 2022.

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