



Commentary

Legal and policy changes urgently needed to increase access to opioid agonist therapy in the United States

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ABSTRACT

The United States continues to face a public health crisis of opioid-related harm, the effects of which could be dramatically reduced through increased access to opioid agonist therapy with the medications methadone and buprenorphine. Despite overwhelming evidence of their efficacy, unduly restrictive federal, state, and local regulation significantly impedes access to these life-saving medications. We outline immediate, concrete steps that federal, state, and local governments can take to change law from barrier to facilitator of evidence-based treatment for opioid use disorder. These include removing onerous restrictions on the prescription and dispensing of buprenorphine and methadone for opioid agonist therapy, requiring insurance coverage of these medications, and mandating that they be provided in correctional settings and promoted by drug courts. Finally, we argue that jurisdictions should proactively offer opioid agonist therapy to individuals at high risk of overdose, remove barriers to establishing methadone treatment facilities, and address underlying social determinants and barriers to treatment. These changes have the ability to save thousands of lives annually.

Background

The overdose crisis, which claimed the lives of nearly 72,000 Americans in 2017, continues to worsen (National Center for Health Statistics, 2018). Opioids and opioids in combination with other drugs were responsible for nearly 49,000 of these deaths—a six-fold increase over the past two decades (National Center for Health Statistics, 2018). The number of Americans who use heroin more than doubled from 2002 to 2016 (Substance Abuse & Mental Health Services Administration, 2017), and emergency department visits for suspected opioid overdose have surged (Vivolo-Kantor et al., 2018). In 2016, an estimated 2.1 million Americans met the criteria for opioid use disorder (OUD) (Substance Abuse & Mental Health Services Administration, 2017).

Law and policy can facilitate reductions in OUD-related harm, as in the proliferation of state laws increasing access to the overdose reversal medication naloxone, laws providing limited immunity to individuals who summon emergency responders in the event of an overdose, and the reversal of the longstanding federal ban on funding for syringe access programs (Davis & Carr, 2015; Green, Martin, Bowman, Mann, & Beletsky, 2012; McClellan et al., 2018). However, they can also act as a significant barrier to promising and proven prevention and treatment interventions.

The regulation of opioid agonist therapy (OAT) with the medications methadone and buprenorphine provides a particularly cogent example of unnecessary and counterproductive legal barriers to evidence-based OUD treatment. Both medications significantly reduce many negative consequences associated with OUD, and their use is considered the “gold standard” for OUD treatment (Connery, 2015; Lawrinson et al., 2008). Indeed, as the Secretary of Health and Human Services recently noted, treating OUD without OAT is “like trying to treat an infection without antibiotics” (Rouben, 2018). However, unduly restrictive federal, state, and local laws and policies, combined with structural and systemic factors such as stigma, misinformation, and insufficient funding, significantly impede access to OAT. Meaningfully reducing opioid-related harm in the United States requires removing these barriers. Although addressing stigma, underlying inequities, and barriers to care generally are vital medium to long-term goals, this Commentary focuses on legal and regulatory changes with the potential to quickly and decisively increase access to evidence-based care.

Legal and regulatory barriers to opioid agonist therapy

Methadone and buprenorphine adhere to the brain receptors to which opioids such as heroin and prescription opioid analgesics attach,

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fully or partially blocking their effects (Connery, 2015). Methadone, approved by the Food and Drug Administration (FDA) for treating opioid addiction in 1972, is a long-acting full mu opioid agonist, whereas buprenorphine, approved for OUD in 2002, is a partial mu agonist (Connery, 2015).

Both medications reduce the painful and sometimes debilitating withdrawal and craving that often accompanies cessation of long-term opioid use, conveying substantial individual and societal benefits (Connery, 2015). Most importantly, numerous studies demonstrate that OAT dramatically reduces mortality risk for persons with OUD (Larochelle et al., 2018; Lawrinson et al., 2008), with one recent systematic review finding that both methadone and buprenorphine treatment often reduce overdose-related and all-cause mortality risk in opioid-dependent individuals by 50% or more (Sordo et al., 2017).

OAT also reduces the risk of relapse, increases treatment retention, reduces problematic opioid use, and decreases HIV and Hepatitis C risk (Connock et al., 2007; Wilson, Schwartz, O'Grady, & Jaffe, 2010). Indeed, as the National Academies of Sciences, Engineering, and Medicine declared in an exhaustive 2019 report, "Withholding or failing to have available all classes of FDA-approved medication for the treatment of opioid use disorder in any care or criminal justice setting is denying appropriate medical treatment" (Leshner & Dzau, 2019). Despite the overwhelming evidence base for OAT, however, numerous laws and policies—many of which pre-date the current crisis—strictly limit access to both methadone and buprenorphine.

The modern regulatory system for OAT in the United States originated with the 1914 Harrison Narcotics Tax Act. The Act and court cases interpreting it, which occurred amidst a backdrop of racism and nativism, effectively outlawed the then-common practice of prescribing opioids to opioid-dependent individuals (Williams, 1914). This remained the status quo for roughly half a century.

In 1965, however, an influential study highlighted methadone's efficacy in treating heroin addiction, and methadone maintenance treatment (MMT) expanded rapidly under a series of FDA Investigational New Drug applications (Dole & Nyswander, 1965). Within a decade, Congress created exceptions to the Act's categorical ban on OAT, but federal law still imposes greater restrictions on the prescribing (and, in the case of methadone, dispensing) of OAT medications than apply to any other prescription medication—including the *exact same* medications when prescribed to treat pain (United States Code, 2019a).

With limited exceptions, only federally certified opioid treatment programs (OTP) may dispense methadone for MMT, and practitioners providing MMT must obtain an annual registration from the federal Drug Enforcement Agency (DEA) (United States Code, 2019a, 2019d). Federal law requires that most MMT patients have been addicted to an opioid for at least one year, with limited exceptions for pregnant patients, patients released from incarceration within the preceding six months, and patients who received MMT within the preceding two years (United States Code, 2019e). All MMT patients are also required to complete a full medical evaluation prior to receiving treatment and to attend comprehensive counseling sessions (United States Code, 2019h).

Moreover, federal law strictly regulates the provision of the medication itself. OTPs may provide methadone only in oral form, patients generally must ingest it under supervision (take-home doses are permitted under limited circumstances), and initial dosages must not exceed specified limits (United States Code, 2019f, 2019g). Little evidence suggests that these restrictions are necessary for patient or public safety. To the contrary, patients are at increased risk during methadone treatment initiation, in part due to insufficient dosages for those using high-dose illicit opioids (Kimber, Larney, Hickman, Randall, & Degenhardt, 2015). Patients also cite the required daily or near daily travel to a specialized clinic to obtain methadone as a significant barrier to accessing MMT (Amiri et al., 2018; Rosenblum et al., 2011).

Several states impose additional requirements and restrictions on

MMT providers, and current and historical local land use regulations have complicated efforts to expand access to MMT (Weber, 2005). These restrictions include caps on the number of MMT facilities and burdensome approval processes. For example, Georgia allows no more than four licensed MMT programs within each region of the state, and Indiana requires that proposed OTPs demonstrate strong community support for the program through letters from interested community members (Georgia statutes; Indiana Administrative Code). West Virginia, which has the highest drug overdose death rate in the country, has a blanket moratorium preventing the establishment of any new OTPs (W. Va. Code Ann. § 16-5Y-12). Moreover, although multiple federal appellate courts have invalidated laws that prohibit the siting of MMT facilities as violating the Americans with Disabilities Act (ADA) (Sixth Circuit, 2002; Third Circuit, 2007), numerous states still require MMT facilities to obtain local zoning or other approval, and localities continue to seek to block the establishment of such facilities (Washington statutes).

Federal restrictions on the use of buprenorphine for OUD, although less cumbersome than those applicable to MMT, also create significant barriers to access (Davis & Carr, 2017). Unlike MMT, most pharmacies may dispense buprenorphine prescribed for OUD, and numerous formulations of the medication are available. However, only physicians and certain other health professionals who have received regulatory approval from the federal government are permitted to prescribe buprenorphine for OUD (United States Code, 2019a).

To obtain this approval (typically referred to as a "waiver" because it waives the annual registration requirement and the requirement to practice in an OTP), physicians must either hold a certification in addiction medicine or complete specified training requirements, typically including an eight-hour series of instruction (United States Code, 2019c). Physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives must complete a 24-hour training (United States Code, 2019c). The authority for clinical nurse specialists, certified registered nurse anesthetists, or certified nurse midwives to obtain a waiver will expire in October 2023 (United States Code, 2019a).

Federal law also limits the number of patients a waived provider may treat at a time to 30 patients in the first year after receiving a waiver and 100 patients thereafter (United States Code, 2019b). Providers with specialized credentials or offering treatment in certain qualified practice settings may treat up to 100 patients immediately upon receiving a waiver, and physicians may treat up to 275 patients at a time upon meeting additional criteria (United States Code, 2019b). Although most providers do not prescribe at the upper limit, the cap remains a barrier for some prescribers, particularly addiction medicine specialists (Stein et al., 2016).

Insurance restrictions remain widespread in both private insurance and state Medicaid programs (Creedon & Cook, 2016). These restrictions include "fail first" requirements that force providers to prescribe less costly drugs or non-medication treatment before an insurer will cover a particular medication and onerous prior authorization requirements whereby patients and providers must go through an approval process for the insurer to cover a particular service or medication. Nearly every state Medicaid program, for example, requires prior authorization for at least one OAT medication (Miller, 2018). Moreover, despite the absence of evidence that counseling improves outcomes for individuals receiving buprenorphine, many state Medicaid programs require such counseling as a condition of covering the medication in some or all situations (Amato, Minozzi, Davoli, & Vecchi, 2011; Miller, 2018).

In part because of these legal and policy barriers, only approximately four percent of American physicians were waived to prescribe buprenorphine in 2016, leaving nearly half of America's 3100 counties, including over 60 percent of rural counties, without a single physician authorized to prescribe the medication (Andrilla, Coulthard, & Larson, 2017). Moreover, not all waived practitioners prescribe

buprenorphine for OUD and those who do often treat far fewer patients than allowed under existing regulations (Huhn & Dunn, 2017; Jones, Campopiano, Baldwin, & McCance-Katz, 2015). This dearth of practitioners willing and able to prescribe OAT is a significant contributing factor to the roughly 80 percent of Americans with OUD who did not receive any treatment in the previous year (Saloner & Karthikeyan, 2015).

Actionable strategies to reduce legal and policy barriers to OAT

Opioid agonist therapy improves outcomes and saves lives. More than a decade into a crisis in which more Americans die every year than were lost at the height of the HIV/AIDS crisis, laws and policies continue to make it difficult or impossible for many people with OUD to access evidence-based treatments that would likely improve—and might save—their lives. These restrictions are largely rooted in stigma and overblown fears, not scientific evidence and sound medical practice.

Although the opioid overdose and addiction crisis demands a comprehensive approach focused on prevention, treatment, and addressing the many underlying determinants that increase individuals' susceptibility to developing OUD, targeted legal and policy changes have the ability to quickly and dramatically increase access to OAT and reduce opioid-related harm (Dasgupta, Beletsky, & Ciccarone, 2017). Immediate opportunities to improve access to evidence-based care exist at the federal, state, and local levels.

Federal level

Several recently enacted federal laws aim to improve access to care and treatment for people with OUD, but much more remains to be done. The 2018 SUPPORT for Patients and Communities Act (SUPPORT Act), for example, takes several important steps to increase access to OAT. These include requiring that the Children's Health Insurance Program provide mental health and substance use disorder (SUD) benefits on parity with physical health conditions and mandating Medicare coverage of OTP services including OAT. It also makes permanent a change initially contained in the 2016 Comprehensive Addiction and Recovery Act that temporarily permitted some nurse practitioners and physician assistants to prescribe buprenorphine for OUD, and liberalizes the patient cap (Davis, 2019). These changes will likely reduce opioid-related morbidity and mortality, but, as noted in a letter sent to the Secretary of Health and Human Services by top state and territorial health officials, "more aggressive and comprehensive reforms are urgently needed to stem the overwhelming tide of this epidemic" (Twenty-two State Health Directors, 2019).

To further increase access to OAT, Congress should remove the outdated, ineffective, and stigmatizing requirement that restricts buprenorphine prescribing to waived practitioners and remove the cap on the number of patients a practitioner can treat at any given time—barriers that exist for no other medications (Fiscella, Wakeman, & Beletsky, 2019; Haffajee, Bohnert, & Lagisetty, 2018). Increasing the numbers and improving the distribution of physicians waived to prescribe buprenorphine dramatically reduces the percentage of the US population living in counties with OUD treatment shortages, increasing access to evidence-based OUD treatment (Dick et al., 2015).

Congress should also remove limitations on the types of professionals who can prescribe buprenorphine. The SUPPORT Act temporarily expanded the list of professionals who can obtain a waiver to include clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives. There is no reason, however, for buprenorphine prescribing for OUD to be more restrictive than buprenorphine prescribing for pain (Fiscella et al., 2019). Proposed federal legislation, the Mainstreaming Addiction Treatment Act, would eliminate the waiver requirement and federal limitations on the types of practitioners authorized to prescribe buprenorphine, as well as require

an educational campaign to encourage providers to integrate SUD treatment into their practices (H.R. 2482 (116th Congress)).

Likewise, cumbersome restrictions on MMT should be modified to improve access to methadone treatment. Many existing MMT programs operate at or near capacity, and both insufficient funding and stigma associated with MMT often impedes efforts to establish new or expand existing clinics (Jones et al., 2015). The federal government can help address these issues by authorizing practitioners to prescribe and pharmacists to dispense methadone for OUD in office- and community-based settings (Samet, Botticelli, & Bharel, 2018). The DEA should also reverse its current prohibition on licensing new mobile methadone clinics (Vestal, 2018).

Authorizing the provision of MMT outside of OTPs will require substantial changes to federal law, and sustained funding will be necessary to support clinics, education programs, and increased reimbursement rates. However, while increased funding would be extremely helpful, legal changes to expand access to MMT are long overdue, with the regulations governing MMT and OTPs having remained largely consistent with those first issued nearly a half-century ago (Davis & Carr, 2017). In the absence of broader liberalization of MMT regulations, the Department of Justice should ensure that state and local governments do not unduly impede access to MMT by taking swift enforcement action against jurisdictions that illegally discriminate against MMT facilities.

Leveraging its "power of the purse," Congress should condition federal funding for state diversion programs, drug courts, and similar initiatives on states screening individuals for OUD upon entering correctional settings, offering OAT to all for whom it is indicated, and ensuring OAT remains accessible to individuals following release from incarceration—actions proven to dramatically reduce opioid overdose deaths (Green et al., 2018). The Attorney General should also take enforcement action against jails and prisons that refuse to continue OAT, actions that federal courts have recently found likely violate both the ADA and the Eighth Amendment (Casper, 2018).

Additionally, the federal government can promote workforce development, reduce stigma, and improve care by conditioning federal funding for medical residency programs on trainees receiving education on the causes and treatment of SUD and obtaining a federal waiver to prescribe buprenorphine unless and until that requirement is removed (Davis & Carr, 2016). Such a requirement would build on the temporary financial incentives authorized by the SUPPORT Act for health professionals working with individuals with SUD in underserved or high-need areas. It should also require that state Medicaid programs cover OAT medications without prior authorization or other barriers such as mandatory counseling, and vigorously enforce the Mental Health Parity and Addiction Equity Act.

State and local level

There are also many promising opportunities at the state and local level. As an initial step, states should require that public and private insurance plans cover all OUD medications without cost sharing, prior authorization, or other barriers such as step therapy. They should also set Medicaid reimbursement rates at a level sufficient to ensure an adequate supply of professionals providing OAT. Early evaluations of a Virginia initiative which increased Medicaid reimbursement rates, for example, found substantial increases in the number of providers prescribing and beneficiaries receiving OAT (Virginia Commonwealth University, 2018).

States can further improve access by ensuring state practice laws authorize the provision of OAT via telehealth and provide Medicaid reimbursement for such services, consistent with recent memos issued by DEA and HHS clarifying that federal law permits such practices (Drug Enforcement Administration, 2018; Egan et al., 2010; U.S. Department of Health & Human Services, 2018; Yang, Weintraub, & Haffajee, 2018). Moreover, although federal law does not permit

pharmacists to prescribe buprenorphine, opportunities exist to engage pharmacists within integrated care regimes, which can save both time and money (DiPaula & Menachery, 2015). Many other countries have integrated methadone into pharmacy practice with positive results (Calcaterra et al., 2019).

From a workforce perspective, states should require that all medical practitioners licensed in the state receive training in evidence-based pain and addiction treatment, and mandate that such courses be taken by students in state-supported medical, dental, and nursing schools. States can also enact legislation or leverage Medicaid managed care contracts to ensure that health care facilities employ or contract with practitioners authorized to prescribe OAT and ensure patient access to these practitioners. Finally, they can amend state practice laws to encourage prescribers to treat patients with OAT. This includes allowing all federally qualified non-physician practitioners to prescribe OAT without unnecessary barriers such as physician supervision, repealing state laws that impose more onerous restrictions on OTPs and MMT than are required by federal law, and encouraging initiation of buprenorphine treatment in emergency departments (D'Onofrio, McCormack, & Hawk, 2018).

Most people convicted of crimes or awaiting trial are housed in state or county facilities, and individuals leaving these facilities are at extremely elevated risk of overdose (Bohnert et al., 2014; Ranapurwala et al., 2018). Ensuring that individuals who are receiving OAT when they enter jails or prisons are maintained on those medications and that those who are not are screened and offered OAT as indicated can dramatically reduce subsequent overdose rates. Rhode Island, for example, has modified state policy so that all individuals receiving MAT when they are incarcerated are maintained on such treatment, and to initiate MAT for incarcerated individuals if they are interested and medically indicated for receiving medication treatment. The program has achieved extraordinary successes, including a 61% reduction in past 12 month incarceration-associated overdose deaths within 6 months of full-scale implementation and an 12% overall reduction in overdose mortality across the state (Green et al., 2018). In addition to mandating that OAT be provided in all correctional facilities, state and local governments should ensure OAT remains accessible upon release from such settings, including by facilitating Medicaid enrollment (MACPAC, 2018).

States should also require that drug courts and other diversion programs permit and encourage OAT and eliminate penalties for individuals who relapse. Since 2015, the federal government has required that drug courts receiving federal funding allow individuals to initiate or continue on OAT and prohibits drug courts from denying access to individuals based on the use of prescribed OAT (Bureau of Justice Assistance, 2018; Nadelmann & LaSalle, 2017). Nevertheless, studies find that drug courts and other diversion programs are still less likely to refer individuals for OAT. State-level policies can address these gaps by extending the federal requirements to drug courts and diversion programs that do not receive federal funding.

State and local governments should act to limit collateral consequences from the criminalization of OUD, including prohibiting the use of drug-related convictions in employment decisions and occupational licensing and redoubling efforts to eliminate racial inequities in the enforcement of drug laws (National Employment Law Project, 2018). They should also robustly enforce anti-discrimination protections for persons with OUD and enact stronger protections where gaps remain, including prohibiting recovery homes from refusing to serve individuals on OAT, as Philadelphia has done with halfway houses (City of Philadelphia, 2017). Finally, agencies should take steps to address real and perceived barriers to persons seeking treatment such as concerns that revealing their drug use may result in child custody issues or the loss of government benefits.

Localities also have many opportunities to increase access to OAT. Some local governmental units have initiated programs by which people who have experienced non-fatal overdose are visited by peer

coaches or other trained individuals shortly after the overdose and offered services including access to OAT (Formica et al., 2018). Although initial programs foreground law enforcement and other uniformed officials, future efforts should ensure that local public health and community-based organizations are funded and empowered to lead these activities.

Additionally, local governments should promote low-barrier access OAT in a variety of clinical and community-based settings, including among individuals without permanent housing. San Francisco's Low Barrier to Medications for Addiction Treatment Program, for example, employs waived practitioners who proactively visit locations where people use drugs to offer buprenorphine prescriptions, and offers on-demand treatment services in city-operated health facilities and syringe access sites (Carter, Zevin, & Lum, 2019; Farrell, 2018). State and local jurisdictions can also implement a "medication-first" model, such as the one adopted by Missouri's Opioid State Targeted Response and State Opioid Response projects, that prioritizes OAT initiation without pre-conditions such as mandatory counseling (Winograd et al., 2019). Local law enforcement agencies should not make arrests, and prosecuting attorneys should decline to prosecute, individuals who possess or use illicitly-obtained OAT medications in an attempt to treat OUD. State and local governments should also enact laws codifying such non-enforcement policies or decriminalizing the possession of illicitly-obtained OAT medications entirely.

Both state and local governments should also focus on interventions that address broader social determinants and barriers to effective OUD treatment. Transportation, for example, is a well-established barrier to health care access, including access to treatment for SUD (Syed, Gerber, & Sharp, 2013). Individuals receiving OAT report substantial travel times and costs, as well as employment challenges resulting from such travel (Sigmon, 2014). Obligations such as childcare can also pose significant barriers (Chatterjee, Yu, & Tishberg, 2018). Policies requiring paid employment leave, expanding public transportation, and establishing universal early childhood education programs can not only address many barriers to OUD treatment, but support community health and OUD prevention more broadly. Finally, comprehensive public education campaigns should focus on reducing stigma associated with OUD and OAT (Corrigan & Nieweglowski, 2018; Olsen & Sharfstein, 2014).

Non-regulatory barriers to opioid agonist therapy

Although the identified strategies focus on reducing federal, state, and local regulatory barriers to OAT, achieving the rapid and dramatic expansion of methadone and buprenorphine access necessary to meaningfully reduce OUD-related harm also requires addressing non-regulatory barriers. Many physicians remain uncomfortable prescribing OAT, citing factors such as time constraints, potential diversion, and low reimbursement rates. Others continue to question the use of OAT in spite of conclusive evidence demonstrating its efficacy (Huhn & Dunn, 2017). Concerted efforts are needed to educate practitioners about the benefits of OAT and misconceptions related to the efficacy of detoxification and abstinence-based treatment. Government officials and existing OAT providers should also engage the broader medical community to dispel myths preventing the widespread integration of OAT into primary care and related settings. For example, waived practitioners have reported that "buprenorphine treatment ... is no more burdensome than treating other chronic illnesses" (Wakeman & Barnett, 2018). Finally, OAT providers—particularly MMT facilities—should promote low-barrier access by reevaluating internal regulatory structures and organizational practices that may discourage treatment participation and retention such as abstinence-only models.

Conclusion

Laws and policies can serve as both barriers to and facilitators of

Goal	Policy Action		Potential Pathways
Reduce Regulatory Barriers to OAT Prescription and Dispensing	Federal	Eliminate the waiver requirement for prescribing buprenorphine for OUD	L
		Eliminate the patient cap for practitioners prescribing buprenorphine for OUD	L
		Repeal limitations on the types of practitioners who can prescribe buprenorphine for OUD	L
		Facilitate office- and community-based MMT	L, R
	State	Ensure state law is no more restrictive of OAT provision than federal law	L, R
		Forbid municipalities from using zoning and other laws to limit OTPs	L
Federal & State	Take enforcement action against jurisdictions that discriminate against OTPs	E	
Enhance the Availability and Affordability of OAT	State	Establish Medicaid reimbursement rates that ensure sufficient availability of OAT providers	L, R, SR
		Authorize provision of OAT via telehealth and ensure Medicaid reimbursement for services	L, R, SR
		Ensure health care facilities employ or contract with providers authorized to prescribe OAT	L, R, SR
		Require emergency departments to initiate buprenorphine treatment where appropriate	L, R
	Federal & State	Enforce the Mental Health Parity and Addiction Equity Act and equivalent state laws	E
		Require insurers to cover OAT without cost sharing, prior authorization, or other barriers	L, R
State & Local	Implement programs offering low-barrier access to buprenorphine in community settings	F	
Expand the OUD Treatment Workforce	Federal	Condition federal funding for medical residency programs on trainees: <ul style="list-style-type: none"> Receiving training on causes and treatment of SUD and evidence-based pain treatment Obtaining a federal waiver to prescribe buprenorphine 	L, R
	State	Mandate training in evidence-based pain and addiction treatment: <ul style="list-style-type: none"> For all medical practitioners licensed in the state In state-sponsored medical, dental, and nursing schools 	L, R, SR
Improve Outcomes for Justice-Involved Individuals	Federal	Condition federal funding for state justice initiatives on states: <ul style="list-style-type: none"> Screening individuals for OUD upon entering criminal justice settings Offering OAT to all for whom it is indicated Ensuring continued access to OAT upon individuals' release 	L, R, SR
		Require drug courts and diversion programs to permit OAT as a condition of federal funding	L, R, SR
		Mandate OUD screening and provision of OAT in criminal justice settings	L, R
	State & Local	Upon release from criminal justice settings: <ul style="list-style-type: none"> Ensure OAT is accessible Automatically enroll eligible individuals in Medicaid 	L, R
		Require drug courts and other diversion programs to: <ul style="list-style-type: none"> Permit and encourage OAT Eliminate penalties for individuals who relapse 	L, R
	All	Take enforcement action against jails and prisons that refuse to initiate or continue OAT	E
Remove Other Barriers to Evidence-based Treatment	State & Local	Prohibit the use of drug-related convictions in employment and occupational licensing	L, R
		Eliminate racial disparities in enforcement of drug laws	L, R, E
		Enforce and expand anti-discrimination protections for persons receiving OAT	L, R, E, F
		Remove treatment barriers such as concerns related to child custody and loss of benefits	L, R, SR, E
		Implement policies addressing social determinants that impede access to treatment	L, R
Foreground public health and community-based organizations in non-fatal overdose response	L, R		
Conduct comprehensive public education campaigns to reduce stigma	F		

E = Enforcement of existing laws; F = Funding; L = Legislation; R = Regulation; SR = Sub-regulatory actions

Fig. 1. Policy Actions to Increase Access to Opioid Agonist Therapy.

evidence-based care for people with OUD. The current regulatory regime for OAT unduly restricts access to OAT and reflects policymaking based on stigma, not science. In the midst of such overwhelming and largely preventable loss of life, medications effective in treating OUD should not be more difficult to access than those that often cause the condition. It is time to replace stigma with science and indifference with compassion. We must shift the paradigm from one preventing

access to care to one encouraging it, by making legal and policy changes at all levels of government (Fig. 1).

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The authors have no conflicts to declare.

References

- Amato, L., Minozzi, S., Davoli, M., & Vecchi, S. (2011). Psychosocial combined with agonist maintenance treatments versus agonist maintenance treatments alone for treatment of opioid dependence. *The Cochrane Database of Systematic Reviews*, (10), CD004147.
- Amiri, S., Lutz, R., Socias, M. E., McDonell, M. G., Roll, J. M., & Amram, O. (2018). Increased distance was associated with lower daily attendance to an opioid treatment program in Spokane County Washington. *Journal of Substance Abuse Treatment*, 93, 26–30.
- Andrilla, C. H. A., Coulthard, C., & Larson, E. H. (2017). *Changes in the supply of physicians with a DEA DATA waiver to prescribe buprenorphine for opioid use disorder, Data Brief #162*. University of Washington.
- Bohnert, A. S., Ilgen, M. A., Trafton, J. A., Kerns, R. D., Eisenberg, A., Ganoczy, D., et al. (2014). Trends and regional variation in opioid overdose mortality among Veterans Health Administration patients, fiscal year 2001–2009. *The Clinical Journal of Pain*, 30, 605–612.
- Bureau of Justice Assistance (2018). *Medication-assisted treatment*.
- Calcaterra, S. L., Bach, P., Chadi, A., Chadi, N., Kimmel, S. D., Morford, K. L., et al. (2019). Methadone matters: What the United States can learn from the global effort to treat opioid addiction. *Journal of General Internal Medicine*, 34(6), 1039–1042.
- Carter, J., Zevin, B., & Lum, P. J. (2019). Low barrier buprenorphine treatment for persons experiencing homelessness and injecting heroin in San Francisco. *Addiction Science & Clinical Practice*, 14, 20.
- Casper, J. (2018). *Memorandum and order, civil action No. 18-11972-DJC*.
- Chatterjee, A., Yu, E. J., & Tishberg, L. (2018). Exploring opioid use disorder, its impact, and treatment among individuals experiencing homelessness as part of a family. *Drug and Alcohol Dependence*, 188, 161–168.
- City of Philadelphia (2017). *The Mayor's task force to combat the opioid epidemic in Philadelphia: Final report and recommendations*.
- Connery, H. S. (2015). Medication-assisted treatment of opioid use disorder: Review of the evidence and future directions. *Harvard Review of Psychiatry*, 23, 63–75.
- Connock, M., Juarez-Garcia, A., Jowett, S., Frew, E., Liu, Z., Taylor, R. J., et al. (2007). Methadone and buprenorphine for the management of opioid dependence: A systematic review and economic evaluation. *Health Technology Assessment*, 11, 1–171 iii–iv.
- Corrigan, P. W., & Niewegowski, K. (2018). Stigma and the public health agenda for the opioid crisis in America. *The International Journal of Drug Policy*, 59, 44–49.
- Creedon, T. B., & Cook, B. L. (2016). Access to mental health care increased but not for substance use, while disparities remain. *Health Affairs (Millwood)*, 35, 1017–1021.
- D'Onofrio, G., McCormack, R. P., & Hawk, K. (2018). Emergency departments – A 24/7/365 option for combating the opioid crisis. *The New England Journal of Medicine*, 379, 2487–2490.
- Dasgupta, N., Beletsky, L., & Ciccarone, D. (2017). Opioid crisis: No easy fix to its social and economic determinants. *American Journal of Public Health*, 108, 182–186.
- Davis, C. S. (2019). The SUPPORT for Patients and Communities Act – What will it mean for the opioid-overdose crisis? *The New England Journal of Medicine*, 380(1), 3–5.
- Davis, C. S., & Carr, D. (2015). Legal changes to increase access to naloxone for opioid overdose reversal in the United States. *Drug and Alcohol Dependence*, 157, 112–120.
- Davis, C. S., & Carr, D. (2016). Physician continuing education to reduce opioid misuse, abuse, and overdose: Many opportunities, few requirements. *Drug and Alcohol Dependence*, 163, 100–107.
- Davis, C. S., & Carr, D. (2017). The law and policy of opioids for pain management, addiction treatment, and overdose reversal. *Indiana Health Law Review*, 14.
- Dick, A. W., Pacula, R. L., Gordon, A. J., Sorbero, M., Burns, R. M., Leslie, D., et al. (2015). Growth in buprenorphine waivers for physicians increased potential access to opioid agonist treatment, 2002–11. *Health Affairs (Millwood)*, 34, 1028–1034.
- DiPaula, B. A., & Menachery, E. (2015). Physician-pharmacist collaborative care model for buprenorphine-maintained opioid-dependent patients. *Journal of the American Pharmacists Association: JAPhA* (2003), 55, 187–192.
- Dole, V. P., & Nyswander, M. (1965). A medical treatment for diacetylmorphine (Heroin) addiction. A clinical trial with methadone hydrochloride. *JAMA*, 193, 646–650.
- Drug Enforcement Administration (2018). *Use of telemedicine while providing medication assisted treatment (MAT)*.
- Egan, J. E., Casadonte, P., Gartenmann, T., Martin, J., McCance-Katz, E. F., Netherland, J., et al. (2010). The Physician Clinical Support System-Buprenorphine (PCSS-B): A novel project to expand/improve buprenorphine treatment. *Journal of General Internal Medicine*, 25, 936–941.
- Farrell, M. (2018). *Mayor Mark Farrell announces innovative program to fight opioid crisis on San Francisco Streets*.
- Fiscella, K., Wakeman, S. E., & Beletsky, L. (2019). Buprenorphine deregulation and mainstreaming treatment for opioid use disorder: X the X waiver. *JAMA Psychiatry*, 76(3), 229–230.
- Formica, S. W., Apsler, R., Wilkins, L., Ruiz, S., Reilly, B., & Walley, A. Y. (2018). Post opioid overdose outreach by public health and public safety agencies: Exploration of emerging programs in Massachusetts. *The International Journal of Drug Policy*, 54, 43–50.
- Ga. Stat. § 26-5-48(b).
- Green, T. C., Clarke, J., Brinkley-Rubinstein, L., Marshall, B. D. L., Alexander-Scott, N., Boss, R., et al. (2018). Postincarceration fatal overdoses after implementing medications for addiction treatment in a statewide correctional system. *JAMA Psychiatry*, 75, 405–407.
- Green, T. C., Martin, E. G., Bowman, S. E., Mann, M. R., & Beletsky, L. (2012). Life after the ban: An assessment of US syringe exchange programs' attitudes about and early experiences with federal funding. *American Journal of Public Health*, 102, e9–16.
- H.R. 2482 (116th Congress): *Mainstreaming Addiction Treatment Act of 2019*.
- Haffajee, R. L., Bohnert, A. S. B., & Lagisetty, P. A. (2018). Policy pathways to address provider workforce barriers to buprenorphine treatment. *American Journal of Preventive Medicine*, 54, S230–S242.
- Huhn, A. S., & Dunn, K. E. (2017). Why aren't physicians prescribing more buprenorphine? *Journal of Substance Abuse Treatment*, 78, 1–7.
- 440 Ind. Admin. Code 10-2-3(a)(5).
- Jones, C. M., Campopiano, M., Baldwin, G., & McCance-Katz, E. (2015). National and state treatment need and capacity for opioid agonist medication-assisted treatment. *American Journal of Public Health*, e1–e9.
- Kimber, J., Larney, S., Hickman, M., Randall, D., & Degenhardt, L. (2015). Mortality risk of opioid substitution therapy with methadone versus buprenorphine: A retrospective cohort study. *The Lancet Psychiatry*, 2, 901–908.
- Larochelle, M. R., Bernson, D., Land, T., Stopka, T. J., Wang, N., Xuan, Z., et al. (2018). Medication for opioid use disorder after nonfatal opioid overdose and association with mortality: A cohort study. *Annals of Internal Medicine*, 169(3), 137–145.
- Lawrinson, P., Ali, R., Buavirat, A., Chiamwongpaet, S., Dvoryak, S., Habrat, B., et al. (2008). Key findings from the WHO collaborative study on substitution therapy for opioid dependence and HIV/AIDS. *Addiction*, 103, 1484–1492.
- Leshner, A. I., & Dzau, V. J. (2019). Medication-based treatment to address opioid use disorder. *JAMA*, 321(21), 2071–2072.
- MACPAC (2018). *Medicaid and the criminal justice system*.
- McClellan, C., Lambdin, B. H., Ali, M. M., Mutter, R., Davis, C. S., Wheeler, E., et al. (2018). Opioid-overdose laws association with opioid use and overdose mortality. *Addictive Behaviors*, 86, 90–95.
- Miller, N. (2018). *Comprehensive update on state Medicaid coverage of Medication Assisted treatments and substance use disorder services*. Advocates for Human Potential.
- Nadelmann, E., & LaSalle, L. (2017). Two steps forward, one step back: Current harm reduction policy and politics in the United States. *Harm Reduction Journal*, 14, 37.
- National Center for Health Statistics. *Vital Statistics Rapid Release: Provisional Drug Overdose Death Counts*. Retrieved September 1, 2018 from <https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm>.
- National Employment Law Project (2018). *Fair chance licensing reform: Opening pathways for people with records to join licensed professions*.
- Olsen, Y., & Sharfstein, J. M. (2014). Confronting the stigma of opioid use disorder—and its treatment. *JAMA*, 311, 1393–1394.
- Ranapurwala, S. I., Shanahan, M. E., Alexandridis, A. A., Proescholdbell, S. K., Naumann, R. B., Edwards, D., Jr., et al. (2018). Opioid overdose mortality among former North Carolina inmates: 2000–2015. *American Journal of Public Health*, 108, 1207–1213.
- Rosenblum, A., Cleland, C. M., Fong, C., Kayman, D. J., Tempalski, B., & Parrino, M. (2011). Distance traveled and cross-state commuting to opioid treatment programs in the United States. *Journal of Environmental and Public Health*, 2011, 948789.
- Roubein, R. (2018). *HHS chief pitches new measures to expand opioid addiction treatment. The Hill*. Washington, D.C: Capitol Hill Publishing Corp.
- Saloner, B., & Karthikeyan, S. (2015). Changes in substance abuse treatment use among individuals with opioid use disorders in the United States, 2004–2013. *JAMA*, 314, 1515–1517.
- Samet, J. H., Botticelli, M., & Bharel, M. (2018). Methadone in primary care - one small step for congress, one giant leap for addiction treatment. *The New England Journal of Medicine*, 379, 7–8.
- Sigmon, S. C. (2014). Access to treatment for opioid dependence in rural America: Challenges and future directions. *JAMA Psychiatry*, 71, 359–360.
- MX Group, Inc. v. City of Covington, 293 F.3d 326 (6th Cir. 2002).
- Sordo, L., Barrio, G., Bravo, M. J., Indave, B. I., Degenhardt, L., Wiessing, L., et al. (2017). Mortality risk during and after opioid substitution treatment: Systematic review and meta-analysis of cohort studies. *BMJ*, 357, j1550.
- Stein, B. D., Sorbero, M., Dick, A. W., Pacula, R. L., Burns, R. M., & Gordon, A. J. (2016). Physician capacity to treat opioid use disorder with buprenorphine-assisted treatment. *JAMA*, 316, 1211–1212.
- Substance Abuse and Mental Health Services Administration (2017). *Key substance use and mental health indicators in the United States: Results from the 2016 national survey on drug use and health*. Rockville, MD.
- Syed, S. T., Gerber, B. S., & Sharp, L. K. (2013). Traveling towards disease: Transportation barriers to health care access. *Journal of Community Health*, 38, 976–993.
- Third Circuit (2007). *New directions treatment servs. v. City of reading*, 490 F.3D 293.
- Twenty-two State Health Directors (2019). *Letter to Alex Azar*.
- U.S. Department of Health and Human Services (2018). *Telemedicine and prescribing buprenorphine for the treatment of opioid use disorder*.
- United States Code (2019a). 21 U.S.C. § 823(g).
- United States Code (2019b). 21 U.S.C. § 823(g)(2)(B).
- United States Code (2019c). 21 U.S.C. § 823(g)(2)(G).
- United States Code (2019d). 42 C.F.R. § 8.11(a).
- United States Code (2019e). 42 C.F.R. § 8.12(e).
- United States Code (2019f). 42 C.F.R. § 8.12(h)(3).
- United States Code (2019g). 42 C.F.R. § 8.12(i).
- United States Code (2019h). 42 C.F.R. §§ 8.12(f).
- Vestal, C. (2018). *Federal ban on methadone vans seen as barrier to treatment*. Washington, D.C: Stateline.
- Virginia Commonwealth University (2018). *An evaluation report prepared for the Virginia department of medical assistance services addiction and recovery treatment services: Access and utilization during the first year (April 2017–March 2018)*.

- Vivolo-Kantor, A. M., Seth, P., Gladden, R. M., Mattson, C. L., Baldwin, G. T., Kite-Powell, A., et al. (2018). Vital signs: Trends in emergency department visits for suspected opioid overdoses - United States, July 2016–September 2017. *MMWR Morbidity and Mortality Weekly Report*, *67*, 279–285.
- W. Va. Code Ann. § 16-5Y-12.
- Wakeman, S. E., & Barnett, M. L. (2018). Primary care and the opioid-overdose crisis - buprenorphine myths and realities. *The New England Journal of Medicine*, *379*, 1–4.
- Wash. Rev. Code Ann. § 71.24.590(1)(b).
- Weber, E. (2005). Bridging the barriers: Public health strategies for expanding drug treatment in communities. *Rutgers Law Review*, *57*.
- Williams, E. (1914). *Negro cocaine "Fiends" are a new southern menace*. New York, NY: New York Times.
- Wilson, M. E., Schwartz, R. P., O'Grady, K. E., & Jaffe, J. H. (2010). Impact of interim methadone maintenance on HIV risk behaviors. *Journal of Urban Health*, *87*, 586–591.
- Winograd, R. P., Presnall, N., Stringfellow, E., Wood, C., Horn, P., Duello, A., et al. (2019). The case for a medication first approach to the treatment of opioid use disorder. *The American Journal of Drug and Alcohol Abuse*, 1–8.
- Yang, Y. T., Weintraub, E., & Haffajee, R. L. (2018). Telemedicine's role in addressing the opioid epidemic. *Mayo clinic proceedings. Mayo Clinic*, *93*, 1177–1180.