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Whole of Government and Opioid Use Disorder Health Care

THE LEGAL PATH TO A WHOLE OF GOVERNMENT OPIOIDS RESPONSE: PART 4

November 2023

Nicolas Terry, LLM
Scott Burris, JD

Executive Summary

The treatment gap between people who need opioid use (OUD) treatment and those who receive it continues to grow — about two million people of the 20 million people diagnosed with substance use disorder in the United States. The barriers responsible for that gap are structural, policy, or legal misalignments that pervade all US health care, not just behavioral health. Deficiencies in health equity, bias, cost, access, and quality are not unique to those needing OUD treatment; it just so happens that the OUD cohort is particularly disadvantaged because of income and employment status. Fragmentation and lack of care coordination have a particular impact on chronic diseases that need constant care and management in and beyond the examination room. This paper uses a whole-of-government (W-G) approach to review the current landscape of opioid use disorder health care and outlines a series of evidence-based recommendations to improve access and remove barriers to essential care.

Among the top-level recommendations, we suggest that the US Department of Health and Human Services (HHS) (with a congressional assist) can and should improve health care access and service delivery and, as a result, greatly improve OUD treatment. However, by itself, that will be insufficient. Congress also must finish the work it has started in redesigning health care to elevate behavioral health away from its stigma-driven historical antecedents and finally build an integrated care model. Congress should strengthen parity laws and provide the Department of Labor with enforcement powers. Meanwhile the Centers for Medicare and Medicaid Services (CMS) must strengthen the regulation of health insurers to increase in-network coverage for behavioral care.

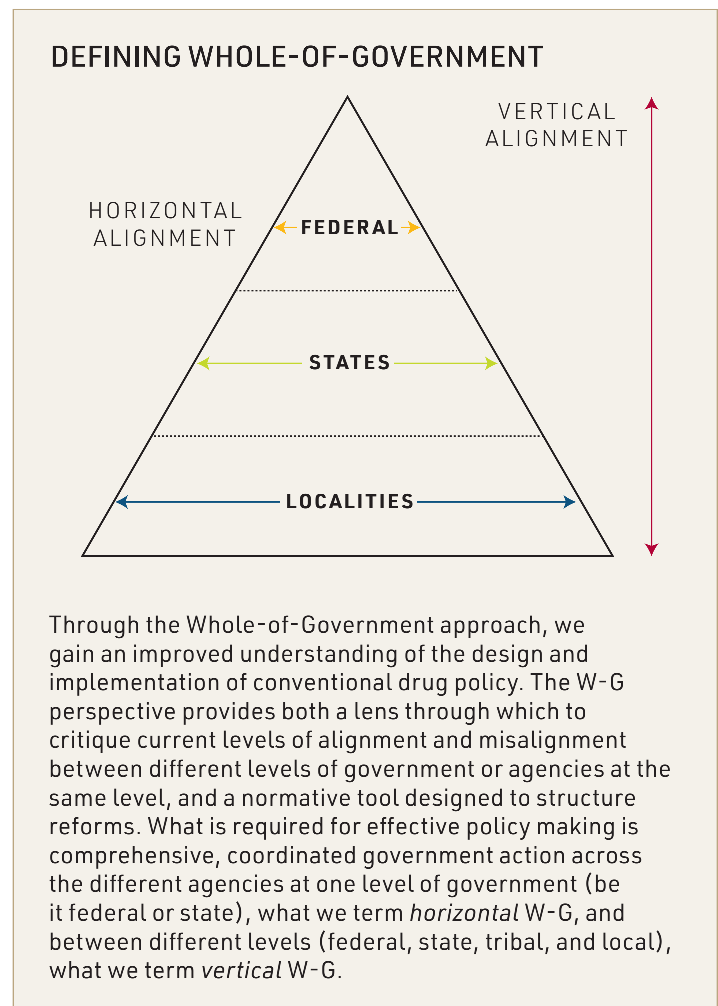
A major horizontal whole-of-government (W-G) approach by the federal government will be required to put the pharmacological treatment of opioid use disorder back on track. This must emphasize reducing regulatory burdens to opioid agonist treatment (OAT) and educating clinicians to reject stigma. A priority must be to safely increase the availability of methadone treatment. The Department of Justice must also keep up the pressure on health care entities, jails, and prisons with Americans with Disabilities Act enforcement that recognizes OUD as a protected disability. Congressional help will be needed to continue some of the mandates, such as Medicaid coverage for medication assisted treatment (MAT) and institutions for mental disease (IMDs) introduced by the SUPPORT Act of 2018. The federal government must work in a coordinated manner to improve the treatment continuum (prevention, treatment, and recovery) reversing the decades of policy that forced health care to follow the criminal justice playbook, and doing away with the final “war on drugs” regulatory impediments to treatment.

Making the health care system work better for people with and at risk of OUD will require federal and state horizontal W-G commitments to improving access to equitable care and reducing barriers to prevention, treatment, and recovery. In the absence of major health care reform, Medicaid is the key to increasing more and better prevention and treatment. Indeed, Medicaid is key, the largest payer of behavioral health services and with the largest percentage of those with substance use disorder (SUD) among all insures (Saunders, 2023). Medicaid expansion by holdout states and resisting political pressures to introduce work requirements are obvious. But states can do more such as submitting Section 1115 waivers for, care coordination, peer support services, improved integration of behavioral health services, pre-release services for the incarcerated, and supportive housing services. States also should encourage the shift to telehealth and invest in multi-disciplinary mobile teams that respond to crisis calls. Overall, health care must work better for people who use drugs.

Introduction

There are two million people who fall within a treatment gap of those who need SUD treatment but do not receive

it (Substance Abuse and Mental health Administration, 2021). The United States spends considerably more per capita on health care than any other developed country (Kaiser Family Foundation, 2022). The relative lack of preventive mental health care and treatment for people who use drugs is a glaring failure. Many of our peer countries reach 50 percent or more of the high-risk opioid users with medications like methadone, while only 11 percent of Americans with opioid use disorder (OUD) report receiving those treatments (Baumgartner et al., 2022). There is no shortage of research pointing to dramatic improvements that are both necessary and possible. Many system enhancements have repeatedly been endorsed by federal and state commissions, reports, and strategies, including the 2016 Surgeon General's report (Office of the Surgeon General, 2016) and the 2022 Biden administration's National Drug Control Strategy (The White House Executive Office of the President, 2022). Yet, for all those exhortations, some sincere efforts, and growing expenditures, our health care system (from prevention through treatment to recovery) continues to fail people with opioid and other substance use disorders (OUD/SUD).



Whole-of-Government and Health Care

The whole-of-government (W-G) perspective provides both a lens with which to critique current levels of alignment between different levels of government or agencies at the same level, and a normative tool to drive reforms. Elsewhere we have applied a W-G lens to drug policing and harm reduction. The former highlights the "war on drugs," a failed 50-year program to eradicate drugs through criminalization, policing, and incarceration, the latter a public health initiative to provide coordinated services that "[e]nsure and improve the health and wellness of people who use opioids and other drugs" (Washington State Health Care Authority). The health care opioids W-G story itself is complex, First, health care continues to struggle with its own W-G demons, some of which overlap with its substance use fails. Second, historically health care was not designed or funded to deal with substance use, with behavioral health segregated away. Third, the "war on drugs" has severely hampered the pharmacological treatment of opioid use disorder, either directly through regulatory burdens or indirectly by stigmatizing those in need of treatment.

Health Care's Whole-of-Government Issues

The health care sector in the United States consists of an array of clinicians, hospitals and other health care facilities, insurance plans, and purchasers of health care services, all operating in various configurations of groups, networks, and independent practices. Some are based in the public sector; others operate in the private sector as either for-profit or not-for-profit entities. The health care sector also includes regulators, some voluntary and others governmental. Although these various individuals and organizations are generally referred to collectively as "the health care delivery system," the phrase suggests an order, integration, and accountability that do not exist. Communication, collaboration, or systems planning among these various entities is limited and is almost incidental to their operations (Institute of Medicine (US) Committee on Assuring the Health of the Public in the 21st Century, 2002).

Health care itself is riddled with horizontal and vertical W-G failures. Many of those failures are rooted in the absence of any national health policy, a critical disconnect between health care finance and delivery, and the over-reliance on profit-driven private actors (Ameringer, 2018; Terry, 2020). The list of symptoms is long and includes access problems (particularly for the poor and the marginalized), high and increasing costs (including

insurance costs, prescription drug costs, and cost-shifting), substandard care coordination, a frequently incoherent health care delivery model involving multiple types of entities and financing or reimbursement models, and severe deficiencies in data management and sharing.

For almost a quarter of a century, reformist policymakers have highlighted health care system flaws (Institute of Medicine Committee on Quality of Health Care in, 2000), specifically system underperformance because of the disaggregated nature of health care individuals and entities, and their misaligned incentives. As a result, proposed reforms have focused on transforming health care from an underperforming aggregation of independent entities into a high performance "system" in which the participants recognize their dependence and influence on every other component of the system (National Academy of Engineering and Institute of Medicine, 2005). These reforms emphasize replacing individual with collective responsibility, aligning payment with quality or value (Porter, 2010), promoting evidence-based practice (Sackett & Rosenberg, 1995), strengthening clinical information systems (Institute of Medicine Committee on Quality of Health Care in, 2001), and improving system "learning" through evidence-generation and utilization (Institute of Medicine Roundtable on Evidence-Based, 2007).

Defects (many of the W-G type) in the US health care system are not solely responsible for the quantitative and qualitative treatment gap. But they are partly responsible. The makeup of the OUD cohort (frequently lower-income people, people of color) already places it in the vanguard for experiencing the failures of our health care system. Their stories are as familiar as they are unheeded. Ten states stubbornly refuse to adopt Medicaid expansion (Kaiser Family Foundation, 2018) notwithstanding the clear evidence that expansion dramatically increases the level of OUD treatment (Broaddus et al., 2018; Maclean & Saloner, 2019). These patients suffer from familiar obstacles, such as limited access, fragmentation, and health disparities (Buntin, 2021; Garson Jr, 2000; Stange, 2009; Terry, 2020). The increasing political polarization of the last few decades and, in particular, during the pandemic (Findling et al., 2022; Hegland et al., 2022), is making things worse. For example, Texas has the highest percentage of uninsured people in the nation and two-thirds of its population favor expansion; yet, reportedly the state's executive leadership had maintained its hostile partisan position to all aspects of the Affordable Care Act (Krisberg & Leffler, 2022).

Other health care system defects deserve highlighting because of their serious impact on the behavioral health population. Fragmentation and lack of care coordination have a particular impact on chronic diseases that need constant care and coordination inside and outside of the health care system (Chang et al., 2018; Frandsen et al., 2015). Care coordination is of particular importance for patients with more complex medical needs, like people with OUD, who interact with multiple health care providers (Pew Charitable Trusts, 2020). Many of these health care defects are products of path dependency, policy or structural choices, such as reliance on employer-provided health insurance, that prove inadequate today. It has been posited that universal health care, that favors treatment for painful conditions rather than management with opioids, and superior care coordination account for the reduced impact of OUD in Europe (Kalkman et al., 2022). In the United States, health care segregation (by income and insurance type) has been enshrined in policies and laws that continue to act as barriers to effective care and treatment, such as the previously mentioned overregulation of drugs used to treat OUD and the over-reliance on distinct opioid treatment providers. Still other barriers have become apparent as stakeholders have confronted the opioid overdose crisis as a "wicked problem" (Lee, 2018), one that is constructed out of numerous strands of law and policy, some intentional, some unanticipated, but all adversely affecting care, treatment, and recovery.

Law and policy changes made during the COVID-19 public health emergency (PHE) decisively rebut the notion that we are incapable of addressing some of the flaws in our health care or OUD treatment systems. Various COVID aid statutes enacted in 2020, including The Families First Coronavirus Response Act (FFCRA) (Families First Coronavirus Response Act, 2020) and the Coronavirus Aid, Relief, and Economic Security Act (CARES) (Coronavirus Aid, Relief, and Economic Security Act, 2020) essentially extended COVID diagnosis, treatment, and vaccination to the uninsured, including the undocumented. For example, the FFCRA included a 6.2 percentage point increase in the federal share of certain Medicaid spending (Consolidated Appropriations Act, 2023) (§6008(a)) conditioned on ensuring continuous coverage for current enrollees, known

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as Maintenance of Enrollment (MOE) (Dolan et al., 2020). MOE was responsible, at least in part, for increasing Medicaid enrollment by approximately 20 million people (Tolbert & Ammula, 2023).

Those statutes, together with The American Rescue Plan Act of 2021 (ARPA) (American Rescue Plan Act, 2021), dramatically decreased the number of uninsured people by increasing spending on Medicaid and individual marketplace subsidies (Levitt, 2022). Furthermore, powers triggered by the PHE relaxed or waived many of the barriers to OAT (Amram et al., 2021; Davis, 2021). Many of these temporary reforms were unwound when the PHE expired in early 2023, (Cubanski et al., 2023; Executive Office of the President, 2023) although some improved access to health care through individual marketplace subsidies has been preserved (although again only temporarily) by The Inflation Reduction Act of 2022 (Gustafsson & Collins, 2022). Indeed, the unwinding of Medicaid itself is demonstrating a misalignment between federal and state governments. The Consolidated Appropriations Act of 2023 (Consolidated Appropriations Act, 2023) created a 12-month unwinding period so states could develop alternate financing or mechanisms for re-enrollment. However, some conservative-led states are executing an accelerated glide path that may leave millions of people without health insurance (Messerly, 2023).

There is conceptual overlap between urgently needed W-G approaches to OUD treatment and arguments for health care systems reform and. A key W-G OUD reform proposal is improved coordination across levels of government (horizontal) and among levels of government (vertical). Similarly, health care systems reform is dependent on an "integrator" responsible for redesign, management, and, of course, system integration (Berwick et al., 2008). However, most of the flaws identified by W-G run deeper and wider, frequently with exogenous factors, non-health care actors, policies, and practices, that promote friction or, worse, create barriers. Just as we need to broaden our analysis of the role of social determinants to include structural and other determinants (Galea, 2022), when it comes to treatment for OUD, key players are neither working together nor pursing the same ultimate goals.

The Behavioral Health Divide

Fixing some of health care's systemic defects would reduce the behavioral health treatment gap, but by not nearly enough. Improved access achieved by increasing Medicaid penetration and lowering costs of private insurance will only go so far to remedying a divide derived from deep structural impediments in our legacy health care system. As highlighted in the Surgeon General's Report in 2016,

> Despite the compelling national need for treatment, the existing health care system was neither trained to care for, nor especially eager to accept, patients with substance use disorders… [W]ith the exception of withdrawal management in hospitals (detoxification), virtually all substance use disorder treatment was delivered by programs that were geographically, financially, culturally, and organizationally separate from mainstream health care (Office of the Surgeon General, 2016, p. 6-5).

Restructuring and fixing previously detailed challenges facing health care must occur in parallel. It won't be enough to repair public and private health insurance to improve access or to reduce care/recovery fragmentation with improved coordination of care. We must encourage the further cooperation of harm reduction and treatment services. For example, emergency department interventions must be reevaluated as being more than lifesaving, but as harm reduction opportunities to move patients toward treatment with, for example, early initiation of buprenorphine. Increasingly, health care providers must resemble harm reduction services, meeting those who need treatment outside of traditional health care facilities through the use of community mobile crisis intervention or rapid response teams. This transformation also requires that we recognize that drug use, even illegal drug use, is not inherently dangerous or harmful, and so does not present a major threat to users or society. Some people who use drugs will not or are not yet ready to stop using. Our public aim should be to reduce the prevalence of harmful drug use through mechanisms that do not themselves produce harm.

A coordinated W-G approach will require explicit and enthusiastic affirmation across government and the health care system that behavioral health is as important as any other kind of health care, and that we have major work to do over the next decade to build up human and institutional resources to provide the integrated care we so badly need. Tinkering at the margins is a sure path to circling back to where we are right now.

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Individual health insurance policies sold on the marketplace are narrower for behavioral health care than for primary care (Zhu et al., 2017) while private health insurance coverage generally is deficient in providing coverage for drug use treatment (Mojtabai et al., 2020). The contemporary legal responses to these deficiencies have been twofold: parity laws and narrow network laws. They have been unsuccessful because they lack adequate enforcement mechanisms and because they encourage a separate but equal mindset. Treating those with behavioral health issues differently from those with other medical needs itself is inequitable (Wong, 2022). Further, the burdens of mental health and substance use fall inequitably on the disabled (Thomas et al., 2023), the poor and people of color (Allen et al., 2022; Panchal et al., 2022; Satcher Health Leadership Institute, 2022). Race and poverty are also important structural determinants when it comes to prevention, treatment, and recovery. Take just one example, buprenorphine, itself a case study in over-regulation because of horizontal W-G failures stemming from the war on drugs. White people and those who self-pay or have private health insurance are far more likely to receive buprenorphine treatment (Lagisetty et al., 2019). Black patients are less likely to receive buprenorphine in emergency departments (Dong et al., 2023), while hospitals in areas with a high percentage of Black or Hispanic residents were significantly less likely to offer OUD services (Chang et al., 2022). Even when Black and Hispanic patients are started on buprenorphine their typical treatment regimen typically will be shorter than for white patients (Dong et al., 2023).

Structural determinants such as racial or economic inequities or the stigma attached to addiction also shape the distribution of social determinants (Crear-Perry et al., 2021), such as lack of transportation or a paucity of physicians or other resources, leading to OUD treatment disparities. During the period in which the X-waiver was required for buprenorphine prescribing there were considerable geographic disparities in access; in 2018, 40 percent of counties lacked any waivered providers (Health & Services, 2020). It is also unclear whether recent deregulation by itself will reduce disparities because of, for example, provider shortages, lack of training, inadequate reimbursement, and stigma (Stringfellow et al., 2021).

A series of federal parity laws beginning with the Mental Health Parity and Addiction Equity Act of 2008 (Mental Health Parity Act, 1996) have failed to deliver the levelling up they promised in large part because of provider shortages, a deficient regulatory scheme, and insurer business practices (Shana, 2020). There is evidence strong state parity laws are positively correlated with increases in SUD treatment rates (Wen et al., 2013). However, even effective state laws will be preempted by federal law in the case of self-insured employer provided insurance (known as ERISA plans). A 2022 Department of Labor report urged Congress to provide it with the authority to impose civil monetary penalties on non-compliant health plans and amend ERISA to provide the agency with authority to enforce parity laws against insurers providing Administrative Services Only (ASO) services to ERISA plans (Department of Labor, 2022).

Even when policies cover substance use, there are access problems. In 2022, the Government Accountability Office (GAO) reported that consumers faced serious challenges in finding in-network care, with providers not accepting new patients, long wait times, restrictive health plan approval processes, and coverage limitations (General Accounting Office, 2022). CMS should adopt the three most common metrics for network adequacy — geographical distance, appointment wait time, and provider-enrollee ratios — and states should align themselves with those standards (Weber, 2020).

Regulatory Burdens on Treatment

Federal drug policies on pharmacological treatments for substance use have dramatically lagged the evidence-base, depriving those with OUD of treatment and creating a generation of clinicians wary of treating those people. The Drug Enforcement Administration (DEA) and the Substance Abuse and Mental Health Services Administration (SAMHSA) moved too slowly in allowing mainstream prescribing of buprenorphine and methadone, creating unnecessary barriers for emergency room and general practitioners. DEA has done little to reduce the appearance of agency capture by the Opioid Treatment Program (OTP) industry, while FDA was years behind the evidence in approving over-the-counter naloxone (Davis & Carr, 2020). These and other impediments are remnants of "war on drugs" and are both the product of and the nourishment for moral defect judgments that perpetuate stigma against people with OUD (Adams & Volkow, 2020; Kelly et al., 2015; Madden, 2019). Such moral judgments also have permeated other institutions such as residential facilities, specialty courts, prisons, and jails promoting abstinence over opioid agonist treatment.

The fundamental W-G failure for opioid use disorder has not been one of emphasis or miscalibration, but of misalignment. Governments at all levels have continued to fund both supply-side (e.g., criminal justice) and demand-side (e.g., harm reduction and treatment) policies. This

is a characteristic of a public health paradox (Fleming et al., 2021), as criminalization actively frustrates treatment and harm reduction. Progress depends on recognizing that criminal justice, harm reduction, and treatment do not exist in a relatively benign triad. Criminal justice interventions do little to slow drug use and they worsen health outcomes (Jurecka & Barocas, 2023). Unless and until the United States pivots away from the criminalization of addiction, harm reduction will be slowed and the failure to get people into treatment and recovery will continue.

The criminal justice system erects both direct and indirect pervasive barriers to treatment. Direct barriers can be casual, such as the law enforcement officer hanging around outside a syringe service, or far more structural. After the declaration of the "war on drugs" in the 1970s, DEA used its powers under the Controlled Substances Act to establish multiple barriers to the medicinal uses of scheduled drugs to treat OUD, such as the partial agonist buprenorphine and the agonist methadone (Drug Abuse Prevention And Control, 2014). Because of "drug war logic" (Cohen et al., 2022) opioid agonist treatment has faced federal restrictions absent from prescription drug treatment of other chronic diseases.

The primary federal restriction on the normalizing of buprenorphine treatment was the requirement of the so-called "X-waiver" that required specialized training for clinicians before they could prescribe the drug. In April 2021, the Biden administration replaced the waiver with a simpler "notice of intent" to prescribe for clinicians treating up to 30 patients. The Consolidated Appropriations Act of 2023 removed even this requirement (Consolidated Appropriations Act, 2023) meaning that all DEA registered clinicians with Schedule III authority may now prescribe buprenorphine (Substance Abuse and Mental health Administration, 2023b). However, rigorous DEA scrutiny of "suspicious" prescribing activity (Drug Enforcement Agency), the continuing stigma associated with treating people who use drugs (Mendiola et al., 2018), a lack of training or information reaching physicians (Wakeman et al., 2016), and remaining DEA registration and reporting requirements (Dooling & Stanley, 2022, p. 31-34)) create serious doubts whether initial steps toward deregulation of OAT will be sufficient (Mahr K, 2023; Welland, 2023).

There are further barriers at the state level. For example, some states outright prohibit buprenorphine prescribing by nurse practitioners or limit it to nurse practitioners who have collaborative agreements with physicians, a significant barrier in states with few physicians willing to work with scheduled drugs (Vestal, 2017) or in rural areas that face a shortage of qualified prescribers (Andrilla et al., 2017). There is also evidence that patients face considerable difficulty in having their buprenorphine prescriptions filled at pharmacies (Weiner et al., 2023).

Methadone, a Schedule II drug, is even more highly regulated. A patient must receive the medication under the supervision of a practitioner along with counseling, tying methadone access to accredited and certified Opioid Treatment Programs (OTPs) (Federal opioid treatment standards, 2001). "At home" doses are permitted only after a period of stability, placing "liquid handcuffs" on the patient (Frank et al., 2021). The apparently successful liberalization of telemedicine access, take-home methadone doses (Amram et al., 2021), and other innovations, such as home delivery (Harocopos et al., 2021) and video observation of take-home doses (Hallgren et al., 2022) during the COVID-19 pandemic (Davis & Samuels, 2020), led to calls for broader deregulation (American Telemedicine Association, 2022). Even factoring in recent deregulation, such as the liberalization of take-home criteria (Substance Abuse and Mental health Administration, 2023a), new guidance on split doses, and improved access through telemedicine (Centers for Medicare & Medicaid Services, 2022a; Janos, 2023), there are remaining state barriers that frustrate the W-G model. For example, some states layer additional requirements on top of the already stringent federal rules such as certificate of need, specialist licensure, or zoning limitations (Okla. Admin. Code § 450:70, 2021; Pew Charitable Trusts, 2022), while states have quite notably heterogeneous telemedicine laws and policies (Center for Connected Heath Policy / Public Health Institute, 2022). Further, it is arguable that the proposed deregulation goes far enough. Even with the recent liberalization OTPs retain a monopoly on distribution (Substance Abuse and Mental Health Services Administration, 2023), raising questions of agency capture by a predominantly for-profit industry (Redmond, 2022). Indeed, Nora Volkow, the director of the National Institute on Drug Abuse, has called for the broad deregulation of methadone to allow it to be prescribed by physicians and, in some situations, even pharmacists (Facher, 2022).

The failed "war on drugs" not only criminalized addiction but also erected significant barriers to treatment for people involved in the justice system, particularly the continuation or initiation of opioid agonist therapy (Fiscella et al., 2018; Grella et al., 2020). Drug courts and prisons maintain negative policies to evidence-based agonist treatments notwithstanding that drugs and alcohol are the third leading cause of death in US jails (Fiscella et al., 2020). Fewer than 5 percent of justice-referred clients receive agonist treatment, with courts and diversionary programs least likely to refer people to such treatment (Krawczyk et al., 2017). Some drug courts have policies against agonist use (Matusow et al., 2013) while many law enforcement officers, prosecutors, and court staff hold negative attitudes toward agonist treatments, particularly methadone (Andraka-Christou et al., 2019). Recently, the Department of Justice has published guidance (Department of Justice,

2022) pointing out that the failure to offer such services can run afoul of the Americans with Disabilities Act (ADA) because, while ADA does not protect those illegally using drugs, it does extend to "the use of a drug taken under supervision by a licensed health care professional" (42 U.S.C. §12210(d), 2008) and successfully settled a case it brought against the Massachusetts drug courts (US Attorney's Office, 2022).

OUD screening and access to treatment have been severely limited in US corrections facilities (Csete, 2019). Notwithstanding the evidence-base that clearly establishes benefits of carceral and post-carceral access to agonist treatment (National Commission on Correctional Health Care, 2021; Wakeman, 2017) only a minority of states have explicit MOUD treatment policies (Prescription Drug Abuse Policy System, 2022). Recent case law (*Pesce v. Coppinger*, 355 F. Supp. 3d 35 (D. Mass. 2018); *Smith v. Aroostook* Cnty., 376 F. Supp. 3d 146, 150 (D. Me.), aff'd, 922 F.3d 41 (1st Cir. 2019), 2019) and settlements (*Kortlever et al. v. Whatcom County Settlement Agreement*, 2022; *Sclafani v. Mici, Settlement Agreement*, 2020) based on constitutional claims and the ADA make it clear that jails and prisons refusing OAT are increasingly in legal peril (Macomber, 2020).

We must continue to take a long hard look at exactly what forces operating at a horizontal level and what vertical misalignments lead to our regulatory dysfunction. Federal and state policymakers, including those who recognize the W-G approach, have approached the opioid overdose and other substance use disorder crises as requiring adjustments in approach, recalibrating the criminal justice-harm reduction-treatment triad. However, recalibration is insufficient. The criminal justice system is responsible for too many barriers to treatment, direct and indirect, that the W-G imperative must be to get criminal justice and its detritus out of the way of treatment. First principles as voiced by Justice Douglas need to be restated, "We would forget the teachings of the Eighth Amendment if we allowed sickness to be made a crime and permitted sick people to be punished for being sick. This age of enlightenment cannot tolerate such barbarous action" (Robinson v. California, 82 S.Ct. 1417, 1426 (1962)).

Making Health Care Work for People with OUD

There are significant areas of the country, primarily in the west, that are effectively OTP deserts with no opioid treatment programs (OTP) that accept Medicare within a 60-minute driving time (Cantor et al., 2022). Indeed, large numbers of OTPs accept no insurance and are cash-only (Patrick et al., 2019; Van Zee & Fiellin, 2019) rendering them inaccessible for the majority of those suffering from OUD. Tying methadone distribution to OTPs (21 C.F.R.§1306.07(a), 2020) creates a barrier in that patients (absent take-home doses) are forced to travel daily to clinics for their doses, a constraint that may explain why many people are not in treatment (Amiri et al., 2018; Dooling & Stanley, 2022, p. 16). The COVID-19 pandemic provided an opportunity for some experimental deregulation (Davis & Samuels, 2020). However, in some states OTPs seemed to continue to operate as they always have and failed to offer their patients the flexibilities available during the PHE (Meyerson et al., 2022), raising questions about W-G vertical alignment after federal deregulation.

Historically, policymakers and lawmakers made the decision to allocate fewer resources to behavioral health, to allow toxic policing and penal policies to stigmatize those with OUD and hinder the availability of OAT. Those policies have combined with classism and racism to further disadvantage cohorts which overlap with those with OUD. As we discuss elsewhere, making health care work for people with OUD means reducing these inequities and barriers by rebuilding the behavioral health system, merging health care and social services, and addressing racism and bias in the system.

There are good emerging models for meeting those with OUD literally where they live. For example, in July 2021, DEA implemented a new regulation increasing the number of mobile methadone treatment facilities in an effort to expand access to treatment in remote and underserved communities (Whelan & Hazelton, 2023). ARPA (American Rescue Plan Act, 2021) provided for additional Medicaid reimbursement although only 20 states have applied for the funding (Centers for Medicare & Medicaid Services, 2022b). More fundamentally, the OTP monopoly needs to be rethought and consideration given to providing access to OAT treatments through rural safety net providers such as Federally Qualified Health Centers (FQHCs) or even chain retail pharmacies (Brooner et al., 2022; Iloglu et al., 2021; Wu et al., 2021).

If we truly can move on from the "war on drugs" then there are also opportunities for rethinking the roles of law enforcement and prisons. For example, mobile agonist treatment models can also be integrated into other first responder initiatives such as paramedicine and joint law enforcement-behavioral health teams (Firesheets et al., 2022; Traube et al., 2021). Many localities have created deflection programs, non-arrest pathways for people to access treatment and recovery services that reduce stigma and improve better services for people with OUD (Legislative Analysis and Public Policy Association, 2021b). Some type of deflection program exists in about half the states but differ as to definitions, funding sources, and liability protections (Legislative Analysis and Public Policy Association, 2021a). The Model Law Enforcement and Other First Responder Deflection Act (The Model Law

Enforcement and Other First Responder Deflection Act, 2022) is a well-constructed model for defining the purpose and reach of such programs, creating a funding model, training, and requiring including interagency agreements delineating the roles and responsibilities of the various organizations that need to partner on such initiatives. Here, SAMHSA and DOJ funding "nudges" should be employed.

Finally, if as discussed above, we can reform jails and prisons from places of withdrawal and abstinence to treatment and recovery, we need to better connect their populations with the outside world. Death from overdoses is the leading cause of death in the immediate post-release period (Binswanger et al., 2013; Waddell et al., 2020). Connecting people released from prisons and jails with health care (Guyer et al., 2019; Jannetta et al., 2017) and other social supports such as safe housing and employment (Hunter et al., 2023) is a priority. One promising initiative is to restart Medicaid for incarcerated individuals prior to their expected date of release as in California's Sec. 1115 waiver request recently approved by CMS; the agency making it clear that it will be encouraging other states to implement similar strategies (Centers for Medicare & Medicaid Services, 2023).

Structural determinants such as race and poverty impact many of the social determinants of health, key determinants include income and economic stability, education access and quality, and the social and community context (including family support and safety) (US Department of Health and Human Services). Indeed, "high opioid utilization and overdose are symptoms of structural dysfunction in American society" (Beletsky, 2019, p. 849). Health care itself is seldom a lever for changing these deep drivers, but the health care system can do a much better job of acknowledging and acting on the things in patients' lives that make it harder for them to access or maintain care. Sometimes negative determinants such as poverty, lack of community, or housing insecurity can become inseparable from someone's clinical diagnosis. Frequently, they will be part of the SUD diagnosis when persons in overdose present in emergency rooms or family members dial state hot lines seeking recovery services.

Medicalizing the social risk factors can encourage a more integrated approach to improving health care services (Webb & Matthew, 2018) and leverage continuing sources of funding. In this regard using Medicaid funds to address social determinants can be attractive to states

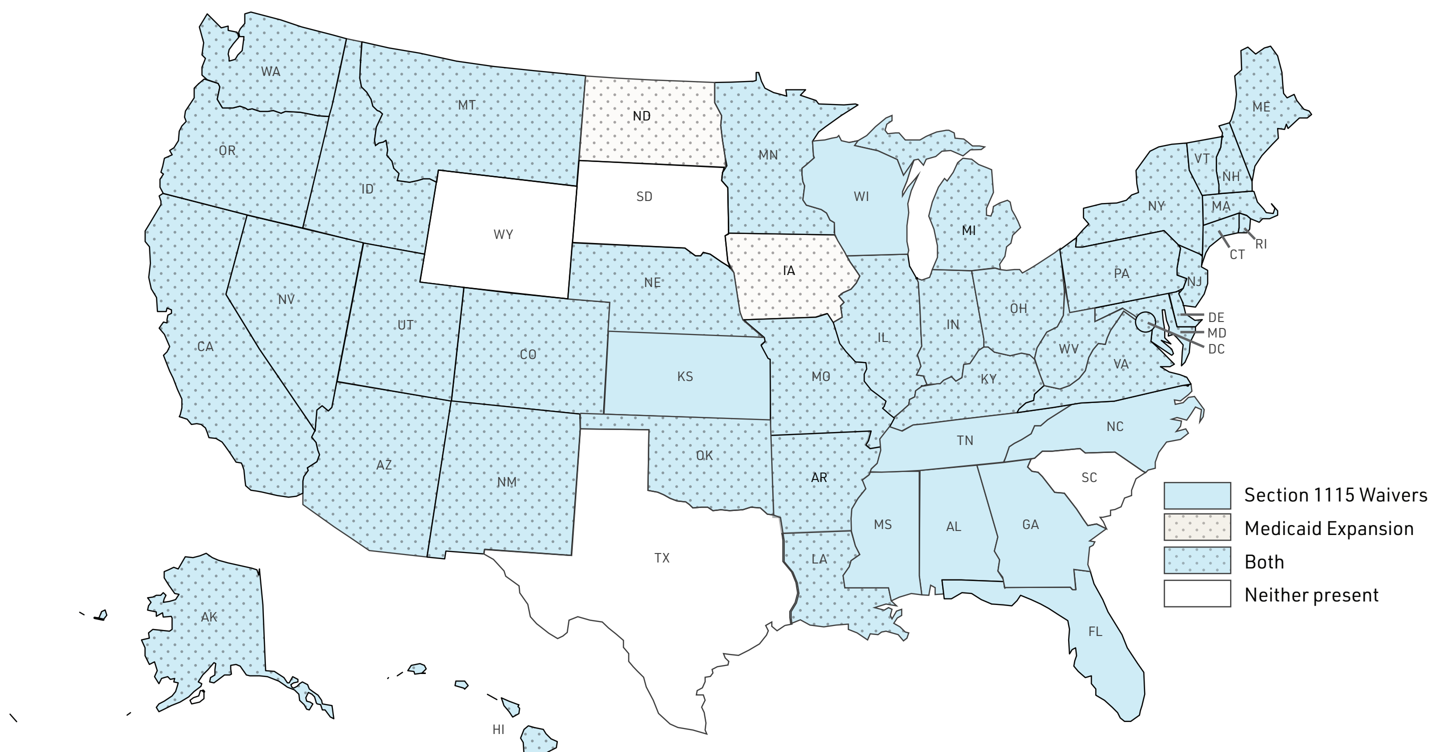

Figure 1: As of April 20, 2023, 45 jurisdictions received an approved Section 1115 Waiver. 39 jurisdictions adopted the Affordable Care Act Medicaid Expansion. 37 jurisdictions had both. (PDAPS, 2023).

(Daniel-Robinson & Moore, 2019; Kushner & McConnell, 2019). Examples include North Carolina's Healthy Opportunities Pilots program that uses Medicaid funding to address social risk factors such as food, housing, transportation, and interpersonal violence/toxic stress (Rapfogel & Rosenthal, 2022). California is fundamentally restructuring its Medicaid program through its "California Advancing and Innovating Medi-Cal" (CalAIM) project aiming to integrate health care with and providing reimbursement for a range of social services such as housing supports, medically tailored meals, and peer supports (Kelly, 2022). A major goal of CalAIM is to reduce fragmentation and promote integration for behavioral health services (Enos, 2022). Both of these programs involve Section 1115 Medicaid waivers (Kaiser Family Foundation, 2023) that, themselves are one of the best examples of effective vertical W-G policymaking.

Conclusion

How we treat those with OUD has clearly evolved over the past two decades. There are clinical as well as W-G opportunities to improve paths to treatment, access to and availability of care, and an extended continuum of care that stretches from prevention to recovery. The W-G agenda must be to make criminal justice read from the health care playbook, not vice versa.

Success in the effort to reduce OUD and the harm it causes will require dramatic change built on a commitment across government, between layers of government, and the health care system to address OUD through prevention, treatment, and harm reduction. We have identified some key priorities for federal and state policymakers that go beyond fixing health care's own collection of problems: first, recognize that substance use is a health care issue that requires something more than the recalibration of "health care as usual," but the re-architecting of health care to elevate behavioral health away from its stigma-driven historical antecedents; second, remove the final "war on drugs" regulatory impediments (and their incidental stigmatization) from the treatment, care, and recovery domain; third, make the health care system work better for people with and at risk of OUD by improving access to equitable care and reducing impediments to prevention, treatment, and recovery, thereby making health care work better for the "Whole of Society" and for the "Whole of Person." ◆

ACKNOWLEDGEMENTS

The authors thank their colleagues Sterling Johnson, Jonathan Larsen, Elizabeth Platt, Bethany Saxon, and Hope Holroyd for their substantial contributions to this project.

We also recognize the contributions of the Expert Advisory Committee (EAC), who provided valuable feedback while developing the white paper series over the course of this project. The EAC includes Daniel Blaney-Koen, American Medical Association; Fred Wells Brason, Project Lazarus; Jessica Breslin, ChangeLab Solutions; Nabarun Dasgupta, University of North Carolina at Chapel Hill Injury Prevention Research Center; Corey Davis, Network for Public Health Law; Jeremy Douglas, Housing Works; Taleed El-Sabawi, Florida International University; Tracie Gardner, Legal Action Center; Daliah Heller, Vital Strategies; Kelli Komro, Emory University; Matthew Lawrence, Emory University; Dave Lucas, Center for Court Innovation; Emma (Beth) McGinty, Weill Cornell Medicine; Keli McLoyd, City of Philadelphia; Jennifer Karas Montez, Syracuse University; Kate Nicholson, National Pain Advocacy Center; Anand K. Parekh, Bipartisan Policy Center; and Louise Vincent, Urban Survivors Union.

This work was funded by the Foundation for Opioid Response Efforts (FORE). The views and conclusions contained in this document are those of the authors and should not be interpreted as representing the official policies or stance, either expressed or implied, of FORE. FORE is authorized to reproduce and distribute reprints for Foundation purposes notwithstanding any copyright notation hereon.

ABOUT THE AUTHORS

Nicolas Terry, LLM is the Hall Render Professor of Law at the Indiana University Robert H. McKinney School of Law and executive director of the Hall Center for Law and Health.

Scott Burris, JD is a professor at the Temple University Beasley School of Law and College of Public Health and director of the Center for Public Health Law Research.

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