

MEDICATION-ASSISTED TREATMENT (MAT) For Opioid Use Disorder: Coverage, Access, And Health System Capacity

Executive Summary

Individuals, families and communities are struggling with the opioid crisis and its devastating consequences every day. As local, state and federal policymakers seek to ensure a holistic approach to this public health crisis, addressing coverage and access barriers to various forms of treatment for substance use disorders (SUDs), particularly opioid use disorder (OUD), has become a growing focus. Among patients with an OUD, which involves recurrent use of opioids including prescription opioids and/or illicit drugs such as heroin and synthetic opioids (e.g. fentanyl), less than 20% are receiving treatment.¹

To address this gap and help break the cycle of addiction, policymakers are seeking to expand access to all forms of addiction treatment, including detoxification and medically managed withdrawal, short- and long-term residential treatment, various forms of recovery support—such as individual and group counseling—and medication-assisted treatment (MAT).

MAT is an evidence-based approach that relies on behavioral therapy used alongside medications that block the effects that opioids produce and/or mitigate the symptoms of opioid withdrawal.² Increasing access to and use of MAT has the potential to have a significant and positive impact on the opioid crisis. This recognition has helped fuel increased focus on addressing coverage and access barriers to MAT for OUD.

In this paper, we examine the legal and regulatory landscape governing access to MAT and analyze coverage in the employer-sponsored insurance market, Medicare Part D, Medicaid managed care organizations (MCOs) and the health insurance exchanges. We also discuss the barriers that may impede access to MAT and considerations for policymakers as they seek to address the ongoing crisis. Finally, we highlight several innovative initiatives under way at the state level that may serve as models for other states.

Our analysis of the landscape demonstrates that, while clinical evidence supports the use of MAT for OUD, numerous barriers have limited the uptake and broad utilization of the treatment, including:

- Limited capacity within the health care system to deliver MAT and a shortage of providers who are authorized and willing to prescribe some of the medications used in MAT;
- Lack of access to coverage of all forms of MAT;
- Broad use of utilization management (UM) tools; and
- Lack of enforcement of mental health and addiction treatment coverage parity.

Innovative approaches that states have been piloting with federal support have the potential to reduce the barriers for patients seeking MAT. These approaches include initiatives focused on

improving care coordination, enhancing access to mental health and addiction treatment services and reducing regulatory hurdles to increasing system capacity. As policymakers on both the state and federal levels mobilize a comprehensive response to this public health crisis, robust evaluation and assessment of these initiatives will be critical to ensure best practices can be disseminated and leveraged in communities across the United States.

Overview of Medication Assisted Treatments

OD is a chronic brain disease caused by recurrent use of opioids, including prescription opioids and illicit drugs such as heroin and fentanyl. MAT is an evidence-based approach that has been shown to demonstrate efficacy across a broad range of outcomes for patients with OD (see: *The Value Provided by MATs for the Treatment of OD*). The approach involves a combination of behavioral therapy provided along with medications that block the effects that opioids produce and/or mitigate the symptoms of withdrawal.¹⁰



Medications can be helpful in [the] detoxification stage, easing craving and other physical symptoms that can often trigger a relapse episode. However, this is just the first step in treatment. Medications have also become an essential component of an ongoing treatment plan, enabling opioid-addicted persons to regain control of their health and their lives.”

Dr. Nora Volkow | Director of the National Institute on Drug Abuse¹¹

As with other diseases, individualized treatment plans are developed for OD patients based on the severity of their addiction, co-occurring conditions (e.g., alcoholism, depression), medical histories, preferences and other key factors. Counseling and other forms of support are paired with medications used as part of MAT to minimize the risk of relapse and maximize the effectiveness of treatment. In addition to medications, treatment may include one or more of the following behavioral treatment options:

- Inpatient or residential treatment
- Individual counseling
- Group counseling
- Care management plan, coordinating multiple treatments
- Recovery support services, peer support services
- 12-step programs
- Community-based support programs¹²



The Value Provided by MATs for the Treatment of OUD

A wide body of research supports the use of MAT for the treatment of OUD and the value it provides in reducing the clinical and economic consequences of the disease. Numerous studies demonstrate MAT is associated with a reduction in relapses and overdose deaths—including as much as a 50 percent reduction in risk of relapse and as much as a 59 percent reduction in overdose deaths. MAT also reduces the incidence of infectious disease. For example, among injection drug users, MAT is associated with a 61 percent reduction in hepatitis C infection and a 50 percent reduction in HIV infection. Likewise, MAT has been shown to reduce spending on other costly health care services such as ER visits and hospitalizations, producing tremendous value to patients and society at large. For example, Medicaid enrollees with opioid addiction or dependency who received MAT treatment were found to incur significantly lower annual medical costs, including \$1,625 less per patient in inpatient medical costs, relative to those who were not receiving MAT. Improving use of MAT can also produce significant savings in reducing criminal justice-related costs. In fact, over a six-month period alone, MAT was shown to save \$17,500 in crime-related costs per patient, relative to those not receiving treatment. Ensuring patients can access and sustain treatment with MAT provides a tremendous opportunity to reduce the clinical and economic burden of the disease.^{3,4,5,6,7,8,9}

The medication components of MAT work by reducing or eliminating cravings and withdrawal symptoms. Three medications are currently available in various brand and generic formulations to treat: methadone, buprenorphine and naltrexone. These medications have different mechanisms of action (i.e., they impact the body in different ways), and the prescribing and dispensing practices for each medication vary (see: *Federal Regulations of MATs that are Controlled Substances*).

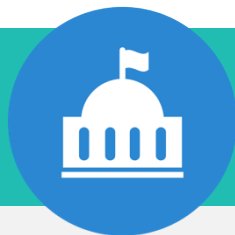
- *Methadone* has been available for use since the mid-1960s and may only be dispensed in federally approved, licensed and accredited opioid treatment programs (OTPs). Methadone is a long-lasting synthetic opioid agonist that works by preventing withdrawal symptoms and relieving drug cravings by acting on opioid receptors in the brain—the same receptors activated by heroin, morphine and other opioids. But methadone activates these receptors more slowly than opioids do, and therefore in an opioid-dependent person, treatment does not produce euphoria. Treatment with methadone is often

referred to as methadone maintenance treatment. As methadone is administered daily at the OTP clinic, it cannot be dispensed from a retail pharmacy. In addition to providing MAT to patients, OTPs provide integrated and comprehensive treatment services (e.g., individual and group psychotherapy and ancillary services such as occupational counseling) and may offer services on an inpatient or outpatient basis. The restrictions related to administration of methadone reflect its scheduling as a Schedule II controlled substance, meaning that it has been determined by the Drug Enforcement Administration (DEA) to have a high potential for abuse. Methadone is available in various once-daily formulations, including tablet, injectable, solution and concentrate forms.¹⁴

- *Buprenorphine* has been available since 2002 for the treatment of OUD and can be prescribed and dispensed in a clinician's office. Buprenorphine is a partial opioid agonist, which means that, like methadone, it binds to opioid receptors in the brain but activates these receptors less strongly. Buprenorphine has pharmacologic properties that produce a "ceiling effect" that help reduce the potential for misuse, diminish the effects of physical dependency to opioids (such as withdrawal symptoms and cravings) and increase safety in cases of overdose.¹⁵ To be eligible to prescribe and dispense buprenorphine medications, clinicians must apply for a waiver from the U.S. Department of Health and Human Services (HHS) and obtain specialized training. While buprenorphine can be prescribed in an OTP, it can also be prescribed by a waived physician and other qualified health practitioners such as physician assistants and nurse practitioners in an office-based setting. Buprenorphine waived prescribers may also be affiliated with substance abuse treatment facilities or programs that may not be an OTP. Buprenorphine is a Schedule III substance, meaning it has been deemed to have a moderate or low potential for physical and psychological abuse. Unlike methadone, this medication can be dispensed from a retail pharmacy. Buprenorphine is available in various formulations, including a sublingual tablet and sublingual film. It is also available in an extended-release formulation dosed once per month and a subdermal implant providing sustained delivery for three months or more.¹⁶
- *Naltrexone* has been available in a once-daily oral formulation since 1984 and in a long-acting once-monthly injectable formulation since 2010. Both formulations are approved to treat OUD as well as alcoholism. Naltrexone is not a controlled substance—meaning there is no abuse or diversion potential. As a result, the medication can be prescribed in a wide range of settings by trained clinicians. Unlike methadone and buprenorphine, which work by activating opioid receptors in the body to suppress cravings, naltrexone acts by blocking the euphoric and sedative effects of opioids. Therefore, if someone relapses, naltrexone prevents the feeling of "getting high."¹⁷

Barriers to Accessing MAT and Successful Delivery of Care

The National Survey on Drug Use and Health (NSDUH) estimates that in 2016, just 10.6 percent of people (2.3 million) with a SUD who needed treatment received it at a specialty facility.¹⁸ Among those with OUD who were 12 years and older, less than 20 percent reported receiving treatment for their disorder (i.e., any form of treatment or counseling for past year opioid or heroin use).¹⁹ Additionally, there are an estimated 8.2 million adults in the United States who have both a SUD and a mental illness.²⁰ Among those with co-occurring disorders, more than half received neither mental health treatment nor substance use treatment in the previous year.²¹ As policymakers seek to develop a comprehensive response to the opioid crisis, understanding the systemic barriers that influence patient access to, and successful delivery of, all forms of addiction and mental health services will be critical.



Federal Regulation of MATs that Are Controlled Substances^{12,13}

The legal and regulatory framework informing the treatment of patients with MAT is extensive and complex. The federal government regulates the prescribing of some forms of MAT via the Controlled Substances Act (CSA). The CSA places all substances into one of five schedules based on an assessment of the substance's medical use, potential for abuse and safety or dependence liability. Schedule V is the least restrictive and Schedule I the most. Methadone and buprenorphine are Schedule II and Schedule III substances, respectively, due to their potential for abuse. In contrast, naltrexone is not regulated under the CSA as it is an opioid antagonist and not itself an opioid.

There are additional requirements for clinicians under the CSA and via the DEA and the Substance Abuse and Mental Health Services Administration (SAMHSA) regulations in order to prescribe methadone and buprenorphine to treat opioid addiction. The Narcotic Addiction Treatment Act of 1974 and the Drug Addiction Treatment Act of 2000 (DATA 2000) amended the CSA regarding the use of controlled substances in MAT. These laws established procedures for the approval and licensing of practitioners involved in treating opioid addiction. Practitioners must apply for approval from the Center for Substance Abuse Treatment (CSAT) within SAMHSA and from the DEA if they wish to administer or dispense Schedule II, III, IV and V controlled substances to treat opioid abuse.

Under these regulations, in order to administer and dispense methadone for maintenance and detoxification treatment, practitioners must also obtain a separate DEA registration as an OTP. In order to prescribe and dispense buprenorphine as part of MAT, prescribers must apply for a waiver from HHS and demonstrate that the provider is "qualified" to prescribe medications for OUD, including

having obtained appropriate licensing and eight hours of training. Though waived practitioners are permitted to treat patients in an outpatient setting with buprenorphine—including in a physician’s office—there are limitations on the number of patients they can treat. There are also additional DEA recordkeeping requirements that apply for opioid dependency treatment with buprenorphine; these are beyond those applying to the prescribing of controlled substances.

This legal and regulatory framework is intended to ensure that addiction treatment providers obtain necessary licensing and complete requisite training while also minimizing the potential for abuse and diversion through tight controls on the prescribing and dispensing of controlled substances in various treatment settings. While these are important goals, these requirements can be onerous and burdensome on prescribers and may ultimately limit the settings in which patients can obtain treatment.

Supply-Side Barriers

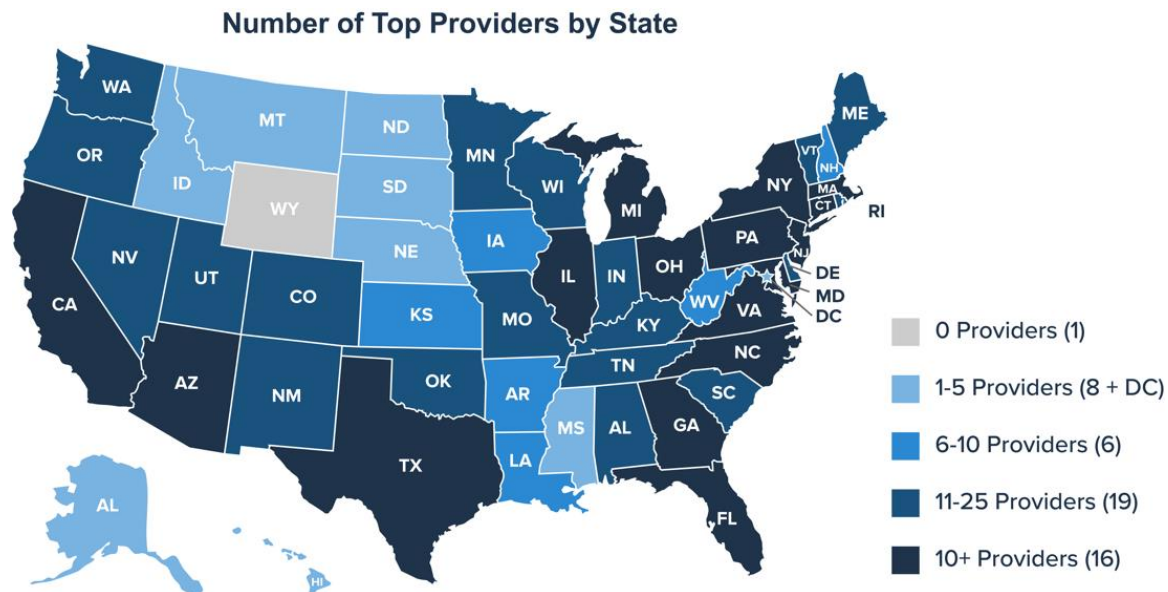
Despite the demonstrated efficacy of MAT in treating OUD, evidence shows that the increase in use of MATs has not kept pace with the growth of the opioid crisis. In fact, OUD diagnosis has increased nearly 500 percent between 2010 and 2016, while MAT use has only increased 65 percent.²² Depending on the particular therapy used and patient needs, MATs can be provided in a variety of settings, including inpatient facilities, residential (non-hospital) treatment centers, outpatient clinics and primary and specialty care settings.^{23,24,25} However, regardless of the specific MAT modality and treatment location, there are numerous reports of supply-side restrictions that impact patient access—particularly for MAT modalities regulated as controlled substances, which must be prescribed and dispensed, as previously noted, in accordance with specific legal and regulatory frameworks.^{26,27,28,29}

Methadone

As noted previously, methadone can only be provided in a certified OTP facility. In 2016, of the 14,399 substance abuse treatment facilities in the United States, only 9 percent (1,308) were certified as an OTP where patients could receive methadone.³⁰ Despite the increasing attention to the opioid crisis, the number of substance abuse facilities certified to provide methadone increased by only 8.7 percent over the past decade.^{31,32}

Patient ability to access an OTP facility, capable of prescribing and dispensing methadone along with counseling and behavioral health services, is also highly dependent on where one lives. In 85 percent of counties in the United States, there is not a single OTP where people with OUDs can access MAT.³³ Additionally, upwards of 90 percent of rural counties do not have an OTP, meaning that patients in these counties may have to travel significant distances to access methadone therapy.³⁴ The geographic distribution of OTP facilities also varies widely. According to the most recent data from SAMHSA, there is not a single certified OTP in the entire state of Wyoming; 14 states and the District of Columbia have 10 or fewer OTP facilities.³⁵ One study found that nearly

10 percent of patients traveled across state lines to obtain treatment in an OTP.³⁶ The overall dearth of OTP facilities as well as their geographic clustering in urban areas significantly impacts patient access to methadone therapy.³⁷



Source: Avalere Analysis of SAMHSA Opioid Treatment Program Directory

Buprenorphine

Relative to methadone, buprenorphine is more widely available, as it can be prescribed in an office-based setting. However, federal regulations still limit buprenorphine prescribing for the treatment of OUD in ways that impact provider treatment capacity. Recent legislative changes and regulatory changes have sought to bolster provider prescribing of buprenorphine to help address the crisis. Originally, only physicians were eligible to receive a DATA 2000 waiver. In July 2016, the Comprehensive Addiction and Recovery Act of 2016 (CARA) amended the CSA to also allow qualifying nurse practitioners and physician assistants to obtain a DATA 2000 waiver.^{a,38} The same year, SAMHSA took steps to increase the statutory limit on the number of patients waived prescribers can treat. In the first year of a provider's DATA 2000 waiver, the provider is permitted to treat 30 patients; after a year, providers can increase the number of patients they treat to 100, and some qualified providers can receive approval to treat up to 275 patients after one year of successfully treating 100 patients.^b The recently passed Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act of 2018 (SUPPORT Act) enabled waived providers to immediately treat 100 patients if they are board certified in addiction medicine or addiction psychiatry.³⁹ The SUPPORT Act also expanded the types of waived health care providers that can seek a waiver to prescribe buprenorphine to clinical nurse specialists, certified nurse midwives, and registered nurse anesthetists. These policy changes

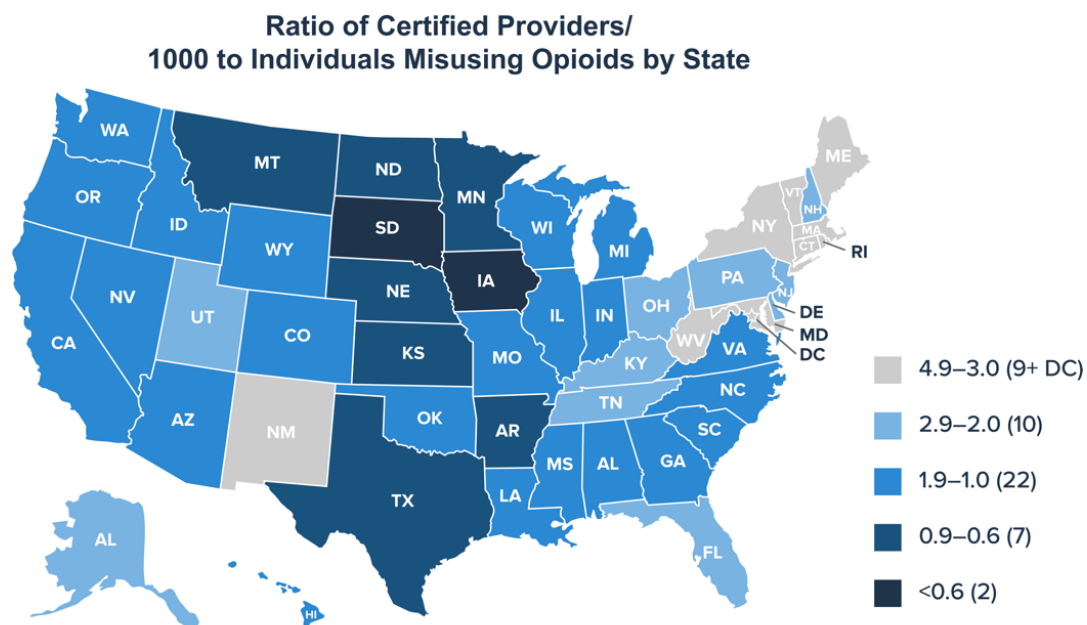
^a Several states have more restrictive laws that limit the scope of practice for nurse practitioners and physician assistants, prohibiting them from prescribing buprenorphine.

^b SAMHSA has authority to change the statutory limits on the number of patients by regulation. 8 U.S.C. § 823(g)(2)(B)(iii). In July 2016, SAMHSA issued a final rule that increased the statutory limit of 100 patients to 275 patients for certain practitioners. 81 Fed. Reg. 44,711 (July 8, 2016).

represent important steps towards addressing supply-side constraints on MAT as there are significant gaps to overcome to ensure patients can appropriately access a waived prescriber. As of 2016, 43 percent of U.S. counties did not have a clinician capable of prescribing buprenorphine as part of MAT.⁴⁰

There is also evidence to suggest significant disparities exist across states. Nationally, 4.5 percent of individuals 12 years or older report misusing prescription painkillers in the past year (ranging from 3.75 percent in New Jersey to 5.44 percent in Oregon).^c However, the number of DATA-waivered clinicians per 1,000 residents varies widely across states, from a low of 0.022 in Iowa to a high of 0.19 in Maine. Analysis of SAMHSA data shows the disparity between the number of waived clinicians and the rate of reported prescription pain reliever misuse by state. Nineteen states and the District of Columbia have proportionately more providers (per 1,000 population) per individual who misuses prescription opioids than average (2.0 providers to 1,000 opioid misusers). Twenty-two states have slightly fewer-than-average qualified providers per capita and 9 states have fewer than half of the national average number of buprenorphine providers per capita.

These challenges are exacerbated in rural areas, as evidence suggests most DATA-waivered clinicians are clustered in urban areas. In fact, just 3 percent of primary care waived-physicians are located in rural areas.⁴¹ Further evidencing the misalignment of available providers and patients in need, a recent survey of rural family physicians found that while 80 percent felt that they “regularly saw patients addicted to opioids,” only 10 percent were waived buprenorphine prescribers.⁴² The overall lack of available providers capable and willing to prescribe MAT is evidence of the significant challenges that patients face in accessing evidence-based treatment—particularly for those struggling with addiction in rural areas.



Source: Avalere Analysis of SAMHSA Opioid Treatment Program Directory

^c As these rates of misuse do not include illicit drug use, rates of opioid abuse are likely much higher – particularly in states where availability of illicit sources such as heroin or fentanyl are more prevalent.

Restrictive Medicare Policies

Federal regulations informing the delivery of methadone can also produce access challenges stemming from coverage of MAT for Medicare patients. As methadone for the treatment of addiction can only be administered within a certified OTP and cannot be dispensed via a prescription from retail pharmacies, Medicare Part D is statutorily prohibited from covering methadone for the treatment of OUD.^d Yet, methadone for the treatment of pain is considered a covered indication in Part D and can be prescribed and dispensed from a retail pharmacy.⁴³

Moreover, until the recent passage of the SUPPORT Act, OTPs were not recognized as Medicare providers.⁴⁴ Due to these limitations, Medicare-eligible patients seeking treatment with methadone had been forced to pay out-of-pocket. The SUPPORT Act made a critical policy change enabling Medicare to pay for outpatient OTPs through bundled payments for comprehensive services, including for necessary medication (e.g., methadone, or any form of MAT) as well as counseling and testing services. Though methadone still cannot be obtained through prescription drug coverage under Medicare Part D for the treatment of OUD, these changes will help better support patient access to methadone as a preferred treatment option alongside necessary outpatient services provided at OTPs when clinically appropriate.



Complexity of OUD Patients and Need for Complex, Coordinated Care ^{45,46,47,48}

While the medications used in MAT are a fundamental cornerstone of OUD therapy, MAT is designed to be a multi-disciplinary approach to treating OUD. Likewise, medications are intended to support or “assist” patients in recovering from opioid dependency alongside a constellation of other interventions. In addition to the necessary counseling and behavioral health services provided with MAT, patients should also receive vocational and educational services. All these services may be delivered by a broad range of providers—including nurses, psychologists, pharmacists, physicians and social workers. In addition to these services, patients suffering from OUD may have other medical conditions requiring additional care coordination and management of co-morbid conditions that may require expertise outside of the primary care or addiction treatment setting.

Unfortunately, the complexity of these patients and the coordination of care required to successfully treat them can challenge the effective delivery of comprehensive addiction treatment. The lack of care coordination across different health care facilities contributes to increased patient morbidity and mortality and reduces the likelihood of treatment success.

^d However, methadone for treatment of pain is considered a covered indication under Part D.

A recent systematic review of effective and innovative models for MAT delivered in primary care settings found that regardless of the model used, close integration and care coordination were essential for the successful delivery of MAT. While many models of care rely on networks of health care professionals to provide comprehensive addiction treatment and counseling services, these care coordination services are not universally available or reimbursed by third-party payers. Likewise, any comprehensive approach to removing barriers to addiction treatment must include a strategy for addressing these care coordination challenges.

Despite the increasing number of patients diagnosed with an OUD and the demonstrated efficacy of MAT, the number of patients obtaining this evidence-based treatment has not kept pace. Patients struggling with addiction are a particularly vulnerable population. While the disease itself is a significant barrier to seeking and sustaining treatment, the legal and regulatory framework within which patients' care is delivered creates additional challenges. Though intended to ensure that addiction providers obtain necessary licensing and appropriate training, while also minimizing the potential for abuse and diversion, tight controls on the prescribing and dispensing of controlled substances can also limit system treatment capacity.

The lack of available providers licensed, certified and waived to treat patients diagnosed with OUD indicates there are inadequate incentives to encourage providers to deliver MAT and limited opportunities for patients to access addiction treatment. The vast majority of U.S. counties do not have an OTP where patients can access MAT and evidence indicates these challenges are exacerbated in rural areas. While buprenorphine offers greater flexibility than methadone, in that it can be prescribed by waived clinicians in office-based settings, 43 percent of US counties do not have a waived clinician capable of prescribing buprenorphine. Additionally, though naltrexone is not a controlled substance, many of the addiction providers and treatment settings where patients may seek out this medication are the same as those where patients may seek out methadone or buprenorphine. Likewise, many of these supply-side restrictions are likely to have spillover effects impacting patient access to naltrexone.

In addition to federal barriers informing the delivery and coverage of methadone, states also vary in the treatment services they provide through Medicaid. A recent survey found that only 32 state Medicaid programs cover inpatient detoxification, 27 cover other inpatient services to treat OUD and 25 cover case management and care coordination services.²⁸ States may also have other policies that can impact access to MAT. Another survey of all 50 states found that some state Medicaid programs:²⁹

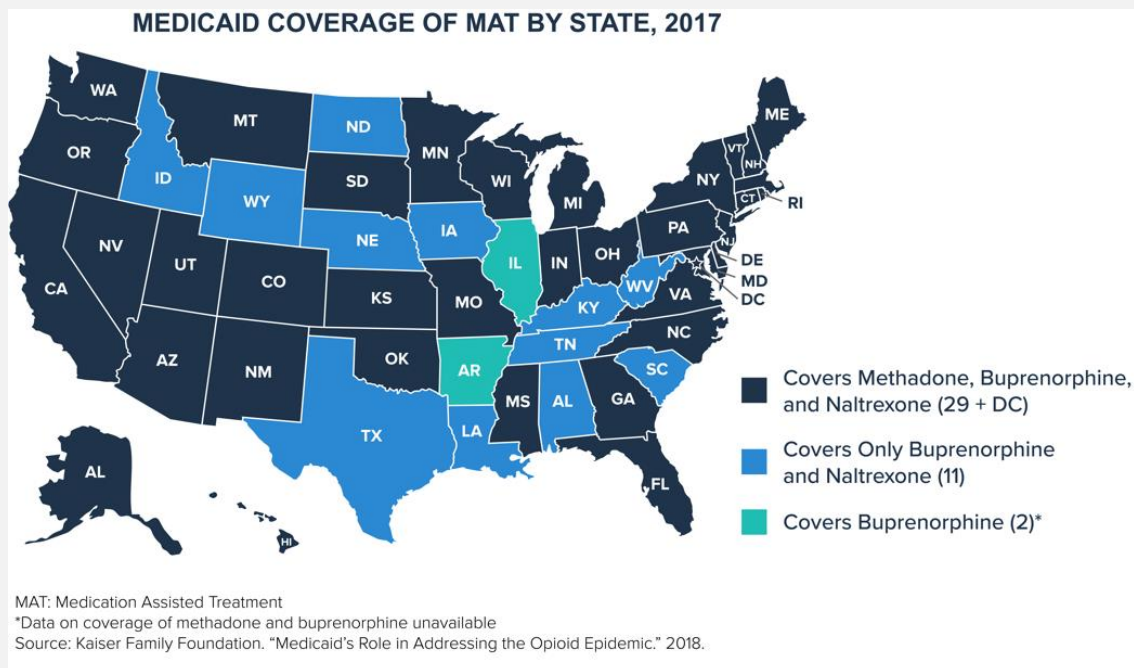
- Place limits on the dosages of MATs that can be prescribed that are not based on clinical recommendations
- Place “lifetime limits” on MAT for methadone and buprenorphine
- Fail to recognize that OUD requires ongoing treatment and instead place limits on prescription refills
- Employ various forms of utilization management tools, including step therapy and prior authorization, before patients can gain access to MAT

Ensuring appropriate training, licensure and safe delivery of care—while also preventing potential abuse and diversion—will continue to be critical goals for policymakers and can be balanced along with efforts to expand access to MAT. However, special consideration needs to be given to the system capacity challenges that limit patients’ ability to access appropriate treatment for OUD—particularly in rural areas. Greater regulatory flexibility and efforts to expand provider treatment capacity to deliver MAT, along with the constellation of counseling, behavioral health and other health care services that are central to successful delivery of care, can help address these challenges.



Spotlight on Medicaid Restrictive Policies ^{49,50}

Individual states may also limit or restrict access to MAT for patients with Medicaid coverage, as states have flexibility to develop regulations and policies regarding MAT. Such policies can challenge a patient’s ability to access and sustain appropriate treatment with MAT. For example, while all 50 states and the District of Columbia covered buprenorphine through Medicaid in 2017, only 38 states covered methadone as a component of MAT.



MAT Coverage Landscape: Pharmacy Benefit Analysis

In addition to the legal and regulatory landscape governing access to MAT, which can limit the settings in which patients can access addiction treatment and the providers capable of treating these patients, patient access challenges are compounded by limitations in insurance coverage. Nearly 15 percent of adults 26 and older who misuse opioids are uninsured. In contrast, only 8.8 percent of all Americans reported lacking health insurance in the past year, meaning that the population who could most benefit from MAT may have the least access to affordable treatment.⁵¹ However, even when patients have insurance, they may have different degrees of access to MAT based on the type of coverage they have and the specific plan they select.

The following analysis provides an assessment of the coverage and cost-sharing landscape for patients in the employer-sponsored insurance market, Medicare Part D, Medicaid MCOs and the health insurance exchanges. Analysis of 2017 formularies^{e,f} found generally high coverage rates of generics across all four markets, though brand coverage rates in Part D and in the exchanges significantly lagged—indicating that some patients may be challenged in their ability to access appropriate treatment options. It is important to note that Medicaid offers the best opportunity to access MAT medications, in large part due to certain statutory requirements regarding the coverage of drugs in Medicaid. These same requirements apply to Medicaid MCOs.⁹ It is also important to note that the Part D analysis reflects the previously outlined restrictions on coverage of methadone in the program.^h

Analysis of utilization management requirements also found these tools were used broadly across all four markets. In fact, even in Medicaid, despite broad formulary access, utilization management was used in almost all cases. These requirements may force many patients to wait for prior authorization from their insurer or undergo step therapy before they are able to access a prescribed treatment regimen. Imposing obstacles for patients at the critical juncture in which they seek out treatment may not only be clinically inappropriate, but it can also be harmful to the patient. Utilization management contributes to sometimes lengthy delays in initiating treatment, which is associated with increased morbidity and mortality, continued illicit drug use, higher rates of infectious disease and reduced likelihood of successful treatment.^{52,53,54,55}

Detailed analysis of pharmacy benefits across these four markets are described below.

^e Avalere Health analysis using PlanScape®, a proprietary database of health plan formularies and benefit designs, December 2017. This analysis is based on data collected by Managed Markets Insight & Technology, LLC.

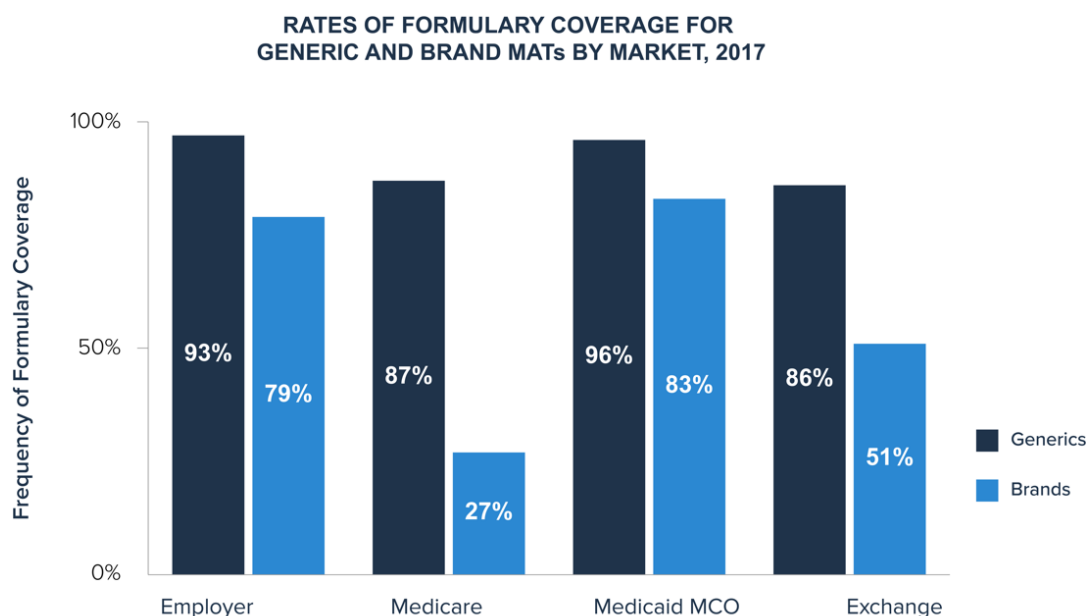
^f Analysis included the range of formulations that are available for methadone, buprenorphine and naltrexone (brand and generic options are available for each). Extended Release Once-Monthly buprenorphine was not included in the formulary analysis as it was approved at the very end of 2017 and does not yet appear in the data.

^g In general, state Medicaid programs must cover all outpatient drugs of a manufacturer that has entered into a rebate agreement with CMS, with limited exceptions specified in the Medicaid rebate statute (42 U.S.C. § 1396r-8). The same drug coverage requirements apply to Medicaid MCOs under current federal regulations. 42 C.F.R. § 438.3(s)(1).

^h Methadone is not covered under Medicare Part D for the treatment of OUD. However, it is covered for the treatment of pain. Interpretation of formulary coverage should take these factors into account.

Formulary Coverage

Analysis of 2017 formularies^{i,j,k} found generally high coverage rates of generics across all four markets. Though brand coverage rates varied by market, with the employer market and Medicaid MCOs having relatively higher coverage rates and Medicare and exchange markets having less generous brand coverage rates.



Source: Avalere Health PlanScape®, a proprietary dataset of health plan formularies and benefit designs, December 2017. This analysis is based on data collected by Managed Markets Insight & Technology, LLC.

On average, plans in the employer market and in Medicaid managed care covered generic MAT medications more than 90 percent of the time, while Medicare and exchange plans had slightly lower generic coverage rates of about 85 percent. Brand-name products were less likely to be covered, with much greater differences by market. Medicaid MCOs had the highest rates of brand coverage (83 percent), followed by employer plans (79 percent).^l Brands were as likely to be covered on exchange formularies (51 percent) as not. Medicare plans had significantly lower coverage rates, with brands covered on formulary only 27 percent of the time.

ⁱ Avalere Health analysis using PlanScape®, a proprietary database of health plan formularies and benefit designs, December 2017. This analysis is based on data collected by Managed Markets Insight & Technology, LLC.

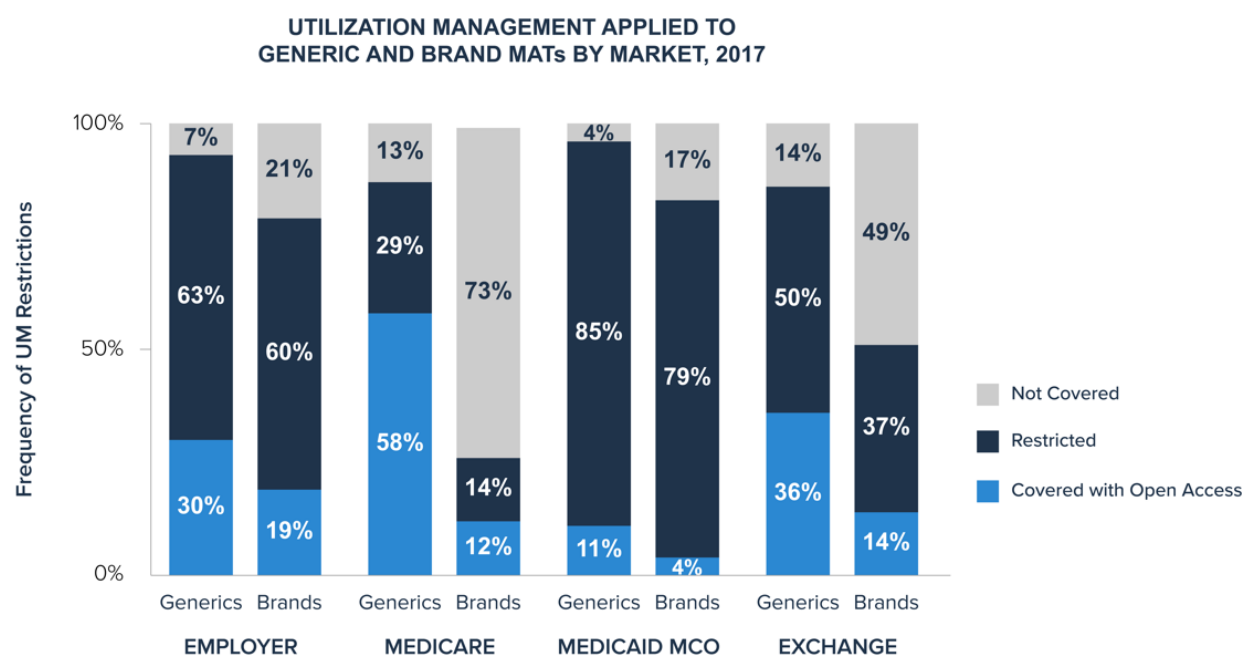
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^k Methadone is not covered under Medicare Part D for the treatment of OUD. However, it is covered for the treatment of pain. Interpretation of formulary coverage should take these factors into account.

^l Though a medicine may not be covered on a Medicaid formulary or “prescription drug list” PDL, patients may seek prior authorization in order to obtain access.

Utilization Management

Plans in most markets applied utilization management restrictions—such as prior authorization and step therapy—liberally to MAT in the analysis. Medicaid MCOs applied utilization management restrictions to brands and generics in almost all cases where MAT was covered. In fact, Medicaid MCOs covered generic MAT medications without restrictions only 11 percent of the time, and brands were unrestricted only 4 percent of the time. Employer plans applied utilization management about 60 percent of the time for both brands and generics, while exchange plans applied the requirements to nearly 40 percent of brands. In Medicare, coverage of generics was much more likely to be unrestricted, with utilization management rates of just 29 percent. Brands, which were rarely covered by Medicare plans, were almost equally restricted and unrestricted (14 percent and 12 percent, respectively).



Source: Avalere Health PlanScape®, a proprietary dataset of health plan formularies and benefit designs, December 2017. This analysis is based on data collected by Managed Markets Insight & Technology, LLC.

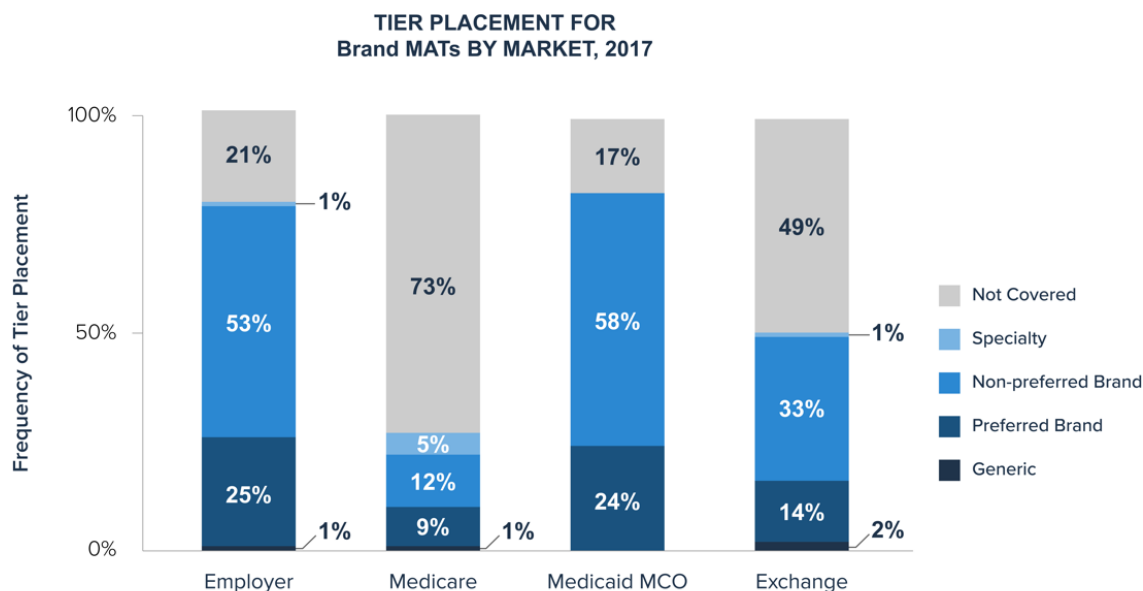
The same utilization management trends applied across markets regardless of whether brand or generic. In most cases across all four markets, plans were twice as likely to restrict access to MAT with these requirements as they were to cover the medicines without restrictions. Utilization management rates were significantly higher in Medicaid MCOs.

Cost Sharing

Although a particular MAT may be covered, high cost sharing can create additional burdens for patients in accessing appropriate treatment for OUD. Tier placement can inform the patient level of cost sharing. Generally, lower cost sharing is associated with generic tiers and incrementally higher cost sharing is associated with preferred, non-preferred and specialty tiers, respectively.

Tier Placement

Analysis of tier placement found generic MATs across markets were largely placed on generic tiers when covered, with some exceptions (not pictured).^m Conversely, brand MATs were primarily placed on non-preferred tiers with relatively higher cost-sharing.



Source: Avalere Health PlanScope®, a proprietary dataset of health plan formularies and benefit designs, December 2017. This analysis is based on data collected by Managed Markets Insight & Technology, LLC. Avalere uses MMIT's universal tier status, rather than raw tier, to facilitate comparisons across plans and markets.

Brand MAT medications were primarily placed on plans' non-preferred tiers. In all markets except Medicare, covered brands were placed on the non-preferred tier more than twice as often as the preferred tier—for example, employer plans put branded MAT medications on the preferred tier 25 percent of the time and on the non-preferred tier 53 percent of the time. In Medicare, where 73 percent of the time brands were not covered at all, tier placement was much more mixed, with brands placed 12 percent of the time on the non-preferred tier, 9 percent on preferred, and 5 percent on specialty tiers.

Use of the specialty tier was infrequent for most products and markets, although brand injectable naltrexone was placed on the specialty tier by almost all Medicare plans covering the drug. Some plans in the employer and exchange markets also placed brand injectable naltrexone on the specialty tier, though much less frequently than Medicare plans did.

^m In Medicaid there are no generic tiers, but rather preferred and non-preferred tiers.

Cost-Sharing Requirementsⁿ

In Medicare, cost sharing for generic MATs was mostly expressed as fixed-dollar copayments, as opposed to coinsurance (a percentage of the drug's cost). In 2017, the average copay for generic MAT medications in Medicare was \$36. For brand medications generally, Medicare plans required copays about as often as coinsurance. For brand MAT medications, the average copay was \$79, while the average coinsurance was 33 percent. Higher copays and use of coinsurance for brand medicines can create affordability challenges for patients.

Analysis of the exchange market found a wide range of cost-sharing requirements. Most of the time, plans required copays for both brand and generic MATs. Some silver plans required zero-dollar cost sharing for both brands and generics after the deductible, though enrollees may have significant out-of-pocket costs for their medicines prior to reaching the plan's deductible. In contrast, copays can reach up to \$595 for the brand-name, once-monthly injectable naltrexone, and \$550 for generic methadone solution. It is important to note that cost-sharing this high likely serves as an obstacle to accessing treatment for many patients for whom these may be the most appropriate and preferred treatment option.



Overview of Mental Health Parity and Addiction Equality Act ^{56,57,58}

The Mental Health Parity and Addiction Equality Act (MHPAEA) of 2008—also known as the Federal Parity Law—requires insurers to apply similar restrictions for treatment and coverage of mental health and SUDs as they do for other medical and surgical benefits. For example, cost-sharing and treatment limits applied to mental health and SUD treatment cannot vary substantially from those applied to other medical and surgical services. The federal parity law applies to most employer-sponsored group health plans, Medicaid managed care organizations, the State Children's Health Insurance Programs, individual health plans sold in the health insurance marketplace and Medicaid plans that were created as part of the Affordable Care Act (ACA). Assessment of parity may be applied to, for example, cost sharing requirements (including deductibles, co-payments or out-of-pocket expenses), limits on services (e.g. the frequency of treatment or days/number of visits), the use of utilization management, out-of-network coverage, and criteria for determining medical necessity. Though MHPAEA provides direction on enforcement of parity activities, states are largely responsible for monitoring compliance.

ⁿ Cost sharing amounts included in this analysis are after-deductible amounts (e.g., if coinsurance is 10 percent after meeting a \$1,000 deductible, the 10 percent coinsurance amount is cited).

The ACA in 2010 expanded parity protections of mental health and SUD benefits by requiring that all health insurance marketplace plans made available as a result of the law cover mental health and SUDs as essential health benefits. Furthermore, the law prohibited denial of coverage for those with a pre-existing mental health or SUD.

It is important to note that the federal parity law does not apply to Medicare, Medicaid fee-for-service, Tricare or individual or group health plans that were “grandfathered” in because they were created prior to March 2010, when the ACA was passed. However, Medicare plans must comply with parity for cost-sharing requirements for outpatient mental health services.

While several studies have found that after passage of MHPAEA, coverage of mental health and SUD treatment did increase, along with decreases in cost sharing requirements, significant gaps remain in enforcement and quality coverage. Enforcement of the law relies on patients to report incidents where mental health and substance abuse treatments are not being equally covered. A recent study from the National Center on Addiction and Substance Abuse found many people likely do not know enough about their rights under MHPAEA to report parity violations. Further, coverage documents provided by plans may not always include enough information for patients to assess relative coverage.

Unfortunately, research shows enforcement of MHPAEA is lacking. A federal-level task force found that a “substantial minority of large employers and health plans still offer benefits that appear to be inconsistent with MHPAEA.” The task force found that insurers frequently required higher cost sharing and had more strict non-quantitative treatment limits (e.g., utilization management tools such as prior authorization, step therapy and other requirements), compared to medical or surgical conditions.

Mental Health and SUD Parity

One common means by which insurers can limit access for patients with OUD is by covering SUD treatment and services with less generosity or with greater restrictions than other medical or surgical treatments and services. In recent years, laws have sought to ensure patients struggling with SUDs and mental health disorders are not disadvantaged in accessing coverage for their conditions relative to patients with other medical conditions (See: *Overview of Mental Health Parity and Addiction Equality Act*). Though the law expanded mental health and SUD treatment, evidence suggests that enforcement of parity is still very much lagging. These laws were critical first steps; however expanded efforts are needed to ensure they are appropriately enforced.

Moreover, MHPAEA exempts a broad range of plans, including Medicare (with the exception of cost-sharing parity requirements) and Medicaid fee for service. Excluding seniors and low-income individuals from many of the protections offered by federal parity law can pose significant challenges—particularly given the growing prevalence of OUD among these populations. For example, Medicare imposes a 190-day lifetime limit on services at an inpatient psychiatric facility.

Importantly, other Medicare specialty inpatient hospital services do not impose this type of arbitrary cap on benefits. Policies such as these effectively limit access to these services with chronic SUD or mental illness, regardless of the appropriateness of receiving lengthier care.⁵⁹

It is important to note parity of coverage of mental health and SUD services is just an initial step towards improving access to addiction treatment for OUD. Ultimately, even a plan which demonstrates good parity may not be one that offers quality coverage; it simply means that benefits are offered at a comparable level. Patients struggling with opioid addiction are often also struggling with other mental health conditions and SUDs as well as other medical conditions that must be treated holistically. Ensuring these patients can access quality medical benefits on the whole—including coverage of mental health and SUD services---should be a central component of strategies to combat the opioid crisis.

* * * *

Despite the demonstrated value of MAT in combination with behavioral health and counseling services as a proven evidence-based treatment for OUD, insurance benefit design does not appear to reflect this value. Among the four markets examined in this analysis, coverage rates for generic MATs appeared relatively high, yet brand MAT coverage rates comparatively lagged—particularly in Medicare Part D plans and exchange plans. In fact, in Medicare, brand MATs were covered just 27 percent of the time and exchange plans covered brands just 51 percent of the time. When brand MATs were covered, they were also primarily placed on non-preferred tiers with relatively higher cost-sharing, suggesting patients may have trouble initiating and remaining adherent to prescribed treatment regimens.

Importantly, although there are a broad range of generic and brand MAT options available to patients to meet a variety of clinical needs, many brand formulations offer properties such as extended release (e.g., once-monthly). Clinical characteristics such as these can be valuable to some patients struggling with addiction, as the difference between a once-daily pill and a once-monthly injection may influence the likelihood of experiencing a relapse. Coverage policies that do not recognize the value that some of these treatment options provide in preventing these outcomes and associated mortality are short-sighted.

Likewise, the broad use of utilization management tools such as prior authorization and step therapy for both brand and generic MATs reflects benefit designs that can create substantial obstacles in accessing appropriate treatment. Requiring patients to fail on a medication prior to accessing an option preferred by the patient and their health care provider may not only be clinically inappropriate but potentially harmful in the context of treating addiction. Ultimately, imposing barriers to MAT for patients at the critical point in which they seek medical care for the treatment of their disease may prove to be the difference between entering treatment or experiencing an overdose or other adverse event.

Though Medicaid has the broadest formulary access to MAT therapies by design, some states may employ policies that place limitations on treatment. As noted earlier, despite generally broad formulary access, several state Medicaid programs also place lifetime or other limits on methadone and buprenorphine for MAT. Additionally, Medicare imposes a 190-day lifetime limit on services provided at an inpatient psychiatric facility. These policies fail to recognize that OUD can be a long-term chronic condition requiring therapy over the course of many years.

As policymakers seek to address the opioid crisis, improved enforcement of parity in health plan benefit design, as well as providing states and insurance regulators with the tools and resources to assess the adequacy of coverage (such as the Parity Compliance Toolkit developed by the Centers for Medicare and Medicaid Services), can ensure that patients with insurance coverage are able to access the care their circumstances require.⁶⁰ These efforts and other strategies aimed to reduce the barriers that patients face in accessing coverage for quality mental health and SUD treatment on the whole will be critical to combatting the opioid crisis.

Innovative State Approaches to Address Barriers to Addiction Treatment

The treatment capacity and coverage barriers to accessing MAT along with the counseling and behavioral health services that patients need to treat their addiction are systemic and widespread. As MAT offers the potential to have a significant impact on stemming the tide of this public health crisis, policymakers are seeking thoughtful approaches to addressing these challenges. Innovative initiatives that states are piloting with federal support—either through regulatory flexibility or grant funding—are promoting access to mental health and addiction services, improving care coordination, reducing regulatory hurdles to increasing system capacity and promoting more access to MAT more broadly. As states face unique challenges in addressing OUDs based on differing populations and specific geographic and socioeconomic characteristics, they provide the ideal empirical framework for understanding which approaches are the most effective and under what circumstances they achieve targeted outcomes. These best practices are serving as models for policymakers as they develop a dynamic and comprehensive response to this public health crisis that can be mobilized in communities across the country.

Improving Care Coordination and System Capacity: The Hub-and-Spoke Model

In 2012, Vermont pioneered the implementation of the hub-and-spoke model, which integrates addiction treatment for Medicaid patients into Vermont's primary care framework. The "hubs" are regional opioid addiction treatment centers, and the "spokes" are general medical and specialist settings, including primary care practices capable of treating OUD with consultation and support from the hubs. Medicaid patients receiving care in the program have a primary care patient-centered medical home and access to Medicaid health home services. The program was negotiated with CMS under Section 2703 of the ACA, which provided the state with flexibility to deliver home health services through a bundled payment rather than a fee-for-service payment.⁶¹

The aim of the hub-and-spoke model is to facilitate communication and diminish "silos" between providers overseeing different aspects of an OUD patient's care. Together, the team of providers oversee the implementation of a treatment plan for each individual, including arranging for community-based support services. The success of the approach also relies on simultaneously seeking to build treatment capacity by encouraging providers in areas without prescribers waived to prescribe MAT in an office-based setting to obtain training and seek a waiver.

Vermont's care coordination system has been well received by both providers and patients and has been associated with a substantial increase in the state's ability to deliver much needed OUD treatment. The adoption of the model has been associated with a 64 percent increase in physicians

Increasing Flexibility to Customize and Expand Delivery of Treatment Services in Medicaid

Under the initiative, state Medicaid programs can apply for waivers seeking reimbursement for substance use treatment delivered in residential facilities previously prohibited from receiving Medicaid funds by the institutions for mental disease (IMD) exclusion. The IMD exclusion prohibits the use of federal Medicaid financing for care provided to adult patients in mental health and residential SUD treatment facilities larger than 16 beds.⁶⁵ Utah and New Jersey were the first states to receive CMS approval for their IMD exclusion waiver programs (see Map: *Medicaid IMD Exclusion Waiver Status, 2018* for the status of Medicaid IMD exclusion waivers).

Legend:

- Waiver Approved (11)
- Waiver Approval Pending* (9)
- No Waiver (30 + DC)

States with approved Section 1115 waivers may also seek assistance from the Medicaid Innovation Accelerator Program (IAP), which provides strategic technical support to states as they design plans for expanding access to SUD and OUD treatment.⁶⁶ The IAP offers rapid response best practices to states requesting robust examples of other state Medicaid SUD activities and facilitates connections with other states to pursue discussions on SUD system delivery reform in areas such as data

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analytics, quality measurement, value-based payment, MAT service and payment design and provider network assessments. In this way, the IAP serves as a broker of best practices between states so they can learn from each other in real-time and hone their demonstration programs accordingly.

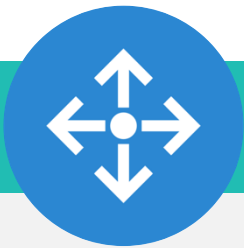
Select examples of innovative demonstration projects that states with approved Section 1115 waivers supported through the Medicaid IAP include:

- Massachusetts' demonstration project, which seeks to strengthen the state's system of recovery-oriented SUD treatments and supports by promoting treatment and recovery through a more comprehensive array of outpatient, residential inpatient and community SUD services.
- West Virginia's demonstration project, which seeks to strengthen the state's system of SUD delivery through expanded coverage of services (including methadone), peer recovery supports, withdrawal management and residential treatment. The demonstration also establishes new care coordination features and introduces new programs to improve the quality of care, including requiring providers to deliver care consistent with national treatment guidelines. Importantly, the effort will involve an extensive quality and performance measurement plan to evaluate and report on the demonstration's impact.

With the recent passage of the SUPPORT Act, the IMD exclusion has now been repealed for Fiscal Years 2019 through 2023. The law will provide state Medicaid programs with the option to cover care in certain IMDs as long as state Medicaid programs meet particular requirements including, for example, covering certain outpatient and inpatient levels of care and maintaining certain spending requirements. The repeal does not prevent a state from conducting or pursuing an already approved Section 1115 waiver. States that served as early adopters through the waiver process will likely be examined for best practices as other states seek to leverage that knowledge to expand SUD services to address the opioid addiction crisis through the authority provided as a result of the repeal.

Federal Grant Programs Provide States with Flexibility to Expand Access to MAT

In addition to expanded regulatory flexibilities provided to state Medicaid programs in the delivery of SUD and OUD treatment, federally funded grant programs have helped to address the crisis (see: *Federal Efforts to Expand Access to MAT*). These efforts are enabling states to employ innovative approaches to deliver targeted responses to curb the opioid crisis. A few of the initiatives funded and evaluated through these grant programs are explored below as they offer potential best practice strategies for building system capacity for the delivery of MAT.



Federal Efforts to Expand Access to MAT

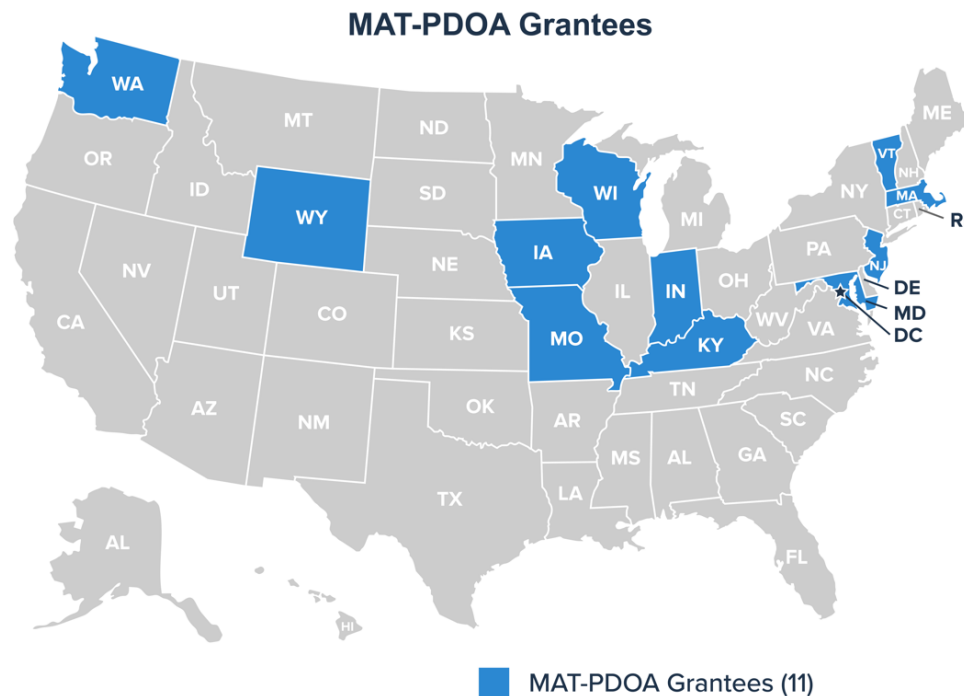
As this public health crisis is diverse and associated with unique characteristics and challenges within each state, the federal response to date has in large part focused on funding various grant programs to help states expand access, capacity and training to deliver addiction treatment and recovery services, while also offering greater flexibility to states to address respective needs. The following are examples of various grant programs that HHS has been mobilizing to address the opioid crisis:⁶⁷

- *State Targeted Response (STR) to the Opioid Crisis Grants.* The STR grant program is administered by SAMHSA and provides funding to states and others to increase access to SUD treatment services, including evidence-based practices such as MAT, and reduce opioid-related overdose deaths. In 2017, SAMHSA awarded two-year grants to 50 states, the District of Columbia, four US territories and the free-associated states of Micronesia and Palau.
- *Substance Abuse Service Expansion to Health Centers.* Administered by the Health Resources and Services Administration (HRSA), this program funds existing health centers to improve and expand delivery of SUD services. Recipients are expected to increase the number of patients with health center funded access to MAT by adding available SUD providers or enhancing SUD services—particularly for patients with OUDs in underserved communities. HRSA has awarded two-year grants to 271 health centers nationwide.
- *MAT-Prescription Drug and Opioid Addiction Grant Program (MAT-PDOA).* Administered by SAMHSA, the MAT-PDOA grant program provides funding to states to increase their capacity to provide treatment and recovery support services. Grant recipients are expected to target high risk communities within the state and partner with local government and/or community organizations to improve access to MAT. Twenty-two, three-year grants have been awarded since 2015, with total funding expected to be up to \$66 million.
- *Increasing Access to MAT in Rural Primary Care Practices.* The Agency for Healthcare Research and Quality (AHRQ) administers this program, which funds demonstration research projects seeking to expand access to MAT for OUD in rural primary care practices. Funding is expected to allow for the recruitment and training of primary care providers and their practices. The program is also aimed towards identifying and testing strategies for overcoming the challenges associated with MAT in primary care settings. The recipients of these AHRQ grants are teams of state health departments, academic health centers, local community organizations, physicians, and others. Three, two-year grants have been awarded to four recipients with total possible funding of \$12 million.

The recently passed SUPPORT Act also reauthorized many of these grant programs while also increasing authorization amounts to further help states expand the delivery of MAT and OUD services in the years ahead. Moving forward, evaluation of these efforts will be critical to developing and disseminating information on best practices that can serve as models for effectively expanding access to MAT and building addiction treatment capacity.

MAT-PDOA Grant Program⁶⁸

States receiving MAT-PDOA grants are providing community-based care with an emphasis on the social and cultural characteristics of the target population.



Indiana is using its grant to target people who are living below the poverty line and/or at risk of infectious disease related to intravenous drug use (e.g., hepatitis C and HIV) in certain rural areas in the state. In particular, the facilities receiving grant funding are implementing a treatment team approach to provide MAT and wrap-around services to the target population. Both Kentucky's and Massachusetts's grant programs are expanding MAT use among pregnant and post-partum women with OUDs.

Wisconsin will use its grant funding to increase access to specific types of MAT for certain target populations (e.g., pregnant women, those with hepatitis C, those living below the poverty line and those who are incarcerated and within four months of release). Washington state's program focuses specifically on expanding access to buprenorphine using an office-based opioid treatment program with the aim of replicating the approach statewide. Under this model, people with OUDs may receive buprenorphine either at an OTP or at their primary care doctor's office. In addition, the program includes telehealth services to facilitate more frequent contact with patients.

Continued evaluation of the success of these state programs at reaching the goals established by SAMHSA will be critical—particularly as others seek to replicate these approaches to target specific populations in other states.

Increasing Access to MAT in Rural Primary Care Practices Grant Program⁶⁹

AHRQ is investing in a series of grants to increase access to MAT for OUD in rural primary care practices that is building on the success of a telehealth program started with AHRQ support in New Mexico, called Project ECHO. The program is a widely successful and innovative approach that links specialists located at an academic hub to primary care providers in rural communities to help overcome the barriers involved in accessing MAT by enhancing provider training and building treatment capacity. Four grants have been awarded in the following states and collectively, they will provide access to MAT to over 20,000 individuals with opioid addiction using innovative technology and telehealth strategies:

- In Oklahoma, where the majority of OUD treatment is occurring in urban areas, the state is partnering with the American Institutes of Research, Project ECHO from New Mexico and experts from the American Society of Addiction Medicine to expand treatment services to thousands of people living in 28 rural counties. The initiative is focused on engaging hundreds of physicians to provide customized and ongoing training for physicians and members of their teams to support them in providing MAT to patients in need. The project will also involve a robust evaluation and development of training materials on expanding access to MAT to assist other rural communities and primary care practices across the state.
- A Colorado initiative is focused on expanding access to MAT in 24 counties across the state. The program will provide comprehensive training, coaching and support for delivery of MAT to rural primary care practices using the telehealth training model pioneered by Project ECHO. This approach will also partner with community members to create locally relevant messages and materials to build community awareness. The initiative will include robust evaluation and the development of educational resources for use by other states and primary care providers to expand access to OUD treatment.
- In Pennsylvania, a partnership between the state's Department of Human Services and Mental Health and the Office of Mental Health and Substance Abuse Services, along with the University of Pittsburgh, is piloting a project to double the number of primary care physicians delivering MAT in 23 rural counties. The initiative will connect primary care practices with SUD focused medical homes in rural communities and blend onsite physician support on MAT with ongoing expert teleconsultation services and telepsychiatry services for OUD patients. Similar to the other grant programs, this initiative will include a comprehensive evaluation and dissemination plan.
- The University of North Carolina (UNC) is leading a demonstration project called the UNC ECHO for MAT that aims to broaden understanding of and evaluate strategies for overcoming barriers to implementing and expanding MAT in primary care. The demonstration also seeks to achieve this goal while expanding access to MAT in 22 counties through a multi-layered provider and practice engagement approach that aims to reduce the risk of overdose deaths. Additionally, the program will use an innovative approach, called Reach, Effectiveness, Adoption, Implementation, Maintenance (RE-AIM) Framework, as well as telehealth strategies, to gather and evaluate participation and quality data.

AHRQ will use each of the comprehensive evaluation protocols employed in these grant programs to build a blueprint for how other communities and primary care teams can overcome the access barriers of providing MAT across America's rural communities. Efforts to expand MAT and build

system capacity in rural areas where an OTP or waived provider may be limited holds tremendous opportunity for addressing the opioid crisis and in mobilizing a community-based response. Robust evaluation of these efforts, as well as the other state-based approaches to expand access to MAT described here, will be critical to assessing these efforts and mobilizing successful models for future action by all interested stakeholders.

Conclusion

Medication-assisted treatment, along with the constellation of counseling and behavioral health services that are critical to successful delivery of treatment for OUD, is widely recognized as a valuable tool in combatting the opioid crisis. Yet despite the wealth of evidence supporting the use of MAT, less than 20 percent of patients diagnosed with OUDs are receiving treatment. As policymakers seek to mobilize a holistic response to combatting this public health crisis, a comprehensive understanding of the challenges patients face in obtaining appropriate evidence-based treatment is imperative. The evidence provided here demonstrates that there are widespread and systemic barriers to accessing MAT, both in terms of system capacity and coverage limitations.

The legal and regulatory framework informing the delivery of MAT significantly limits patients' ability to access treatment and discourages the expansion in provider capacity needed to stem the tide of addiction. The vast majority (85 percent) of counties in the United States do not have an available OTP, and 43 percent of counties still do not have a waived clinician capable of prescribing office-based MAT. These challenges are particularly compounded for those struggling with addiction in rural areas where accessing an OTP or waived clinician are further limited.

In addition to challenges in accessing a treatment provider and facility, patients may also face coverage limitations, which can impede successful delivery of MAT. Though coverage rates of generic MATs in the employer-sponsored insurance market, Medicare Part D, Medicaid MCOs and the health insurance exchanges appear relatively high, brand coverage is comparatively lagging—particularly in Medicare Part D and exchange plans. When brand MATs were covered, they were primarily placed on higher cost-sharing tiers, suggesting some patients may face affordability challenges in initiating treatment and remaining adherent to prescribed treatment regimens over the longer-term.

Evidence also suggests that utilization management requirements imposed by payers create hurdles to accessing appropriate treatment for addiction. Tools such as prior authorization and step therapy were broadly used across all four markets, including Medicaid, which offers the most generous formulary access. Obstacles such as these are clinically inappropriate in the context of addiction and can result in serious adverse events for patients who may already be struggling to initiate treatment for OUD. Additionally, policies such as lifetime limits on MAT in Medicaid and on inpatient psychiatric services in Medicare, as well as unequal enforcement of mental health and SUD parity laws, reflect the stigma patients continue to face and a lack of recognition of OUD as a debilitating chronic condition.

Despite the widespread barriers to accessing MAT, federal and state policymakers are seeking to overcome some of these obstacles as they pursue a comprehensive and strategic response to combat the opioid crisis. Recent federal efforts to expand access to addiction treatment through greater regulatory flexibility and grant programs is beginning to take hold and allowing states to pilot innovative approaches focused on enhancing access to office-based and residential addiction treatment services, improving coordination of care and expanding MAT by bolstering treatment

capacity and provider training. As states test these promising initiatives in communities across the country, robust evaluation and assessment will be imperative to mobilize best practices and effective resources in areas of need. Fortunately, the recently passed SUPPORT Act includes a broad range of directives for various federal agencies to develop and disseminate best practices based on many of the innovative activities explored in the states. These efforts offer promise in collectively leveraging our nation's state and local expertise to meaningfully combat this devastating public health crisis.

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