A. Introduction

Substance use disorders (SUDs), particularly opioid use disorders (OUDs) and opioid-related overdoses, continue to cause immense harm in the United States. The CDC recently released data showing that drug overdose deaths in the U.S. surpassed 100,000 annually for the first time during the twelve-month period ending in April 2021, represent a 28.5% increase from the year prior.1 Over 75,000 of the deaths were opioid-related overdose deaths.2

The COVID-19 pandemic has exacerbated the underlying crisis, and recent data has highlighted racial health disparities in overdose rates; from 2016 to 2020, the share of overdose deaths among White people fell by nine percentage points, whereas the share of overdose deaths among Black and Hispanic people rose by six and four percentage points, respectively.3

2 Id.
While many reasons help explain the uncontrolled rise in OUD-associated deaths, one specific problem stands out: the persistent lack of access to medication-assisted treatment (MAT), which combines the use of medications for opioid use disorders (MOUDs) with counseling and behavioral services. MAT, particularly with the MOUDs methadone and buprenorphine, is highly effective in reducing the risk of relapse, reducing the rate of engaging in risky activities, and reducing costs of SUD treatment.\(^4\) It is also highly effective in increasing the likelihood that a person will remain in treatment, thus reducing overdose deaths.\(^5\)

Despite its effectiveness, however, only a small minority of individuals with OUD are currently accessing these medications. Moreover, significant disparities exist regarding access to MAT, with Black and Hispanic people having more access to methadone (which has historically been subject to widespread discrimination and bias) and less access to the more socially accepted buprenorphine than their white counterparts.\(^6\)

Because Medicaid is the single largest payer of OUD treatment (covering 38 percent of all nonelderly adults with OUD in the U.S.), efforts to improve access to MAT and MOUDs should start with an evaluation of coverage levels and the elimination of potential barriers to accessing OUD care for Medicaid beneficiaries.\(^7\) The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (“SUPPORT Act”), federal legislation enacted in 2018, served as an important step in improving access to OUD treatment by requiring state Medicaid programs to cover MAT. However, coverage is only the first step; beneficiaries with OUD continue to face barriers to accessing this treatment, such as prior authorization requirements, step therapy protocols, quantity limits, provider limitations, and more.

This paper will provide an overview of the federal requirements for state Medicaid programs to cover MAT and evaluate state compliance with coverage requirements. In addition, it will


\(^5\) SAMHSA, Medication-Assisted Treatment (MAT) (Nov. 29, 2021), [https://www.samhsa.gov/medication-assisted-treatment](https://www.samhsa.gov/medication-assisted-treatment).

\(^6\) KFF, Panchal et al., supra note 3.

identify persisting barriers in to treatment in Medicaid policy and make recommendations to improve access to this life-saving treatment for beneficiaries.

**B. The SUPPORT Act and MAT Coverage**

The SUPPORT Act was enacted in October 2018 and its requirements went into effect on October 1, 2020. It requires all state Medicaid programs to cover medication-assisted treatment (MAT), including all medications approved by the FDA for MAT (MOUDs), from October 2020 to September 2025. The SUPPORT Act defines MAT treatment to include related counseling and behavioral therapy services, although it stops short of making coverage contingent on access to either service.⑧ That is, states can and should make MOUDs available regardless of whether the beneficiary is also accessing behavioral therapy. The law allows a state to obtain an exemption from the requirement by the Secretary only if it satisfactorily demonstrates that implementation would not be feasible due to a shortage of qualified providers.⑨

CMS has issued guidance interpreting the SUPPORT Act’s requirements as they relate to Medicaid coverage of MAT. The agency interpreted the Act to require all states to include as part of the new MAT mandatory benefit all forms of drugs and biologicals that the FDA has approved for MAT to treat OUD.⑩ CMS guidance identifies three medications approved by the FDA to treat OUD: methadone, buprenorphine, and naltrexone, and noted that buprenorphine is available in several dosage forms.⑪ While CMS leaves up to states which counseling services and behavioral therapy they will include under the new mandatory benefit, it notes that states that already cover MAT successfully often cover a range of effective behavioral health services, including individual and group therapy, peer support services, and crisis intervention services.⑫ CMS also notes in their guidance that they expect states to conduct provider outreach and enrollment in Medicaid in order to meet these requirements, including enrolling

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⑧ *Id.* at § 1006(b)(3) (codified at 42 U.S.C. § 1396d(ee)(1)(B)).
⑫ SHO 20-005, at 4.
opioid treatment programs (OTPs) as Medicaid providers if the state does not yet do so, particularly if a State is seeking a waiver of the MAT coverage requirement.\footnote{SHO 20-005, at 8.}

Importantly, the SUPPORT Act requirements do not override states’ long-standing requirement to cover prescription drugs used for outpatient OUD treatment pursuant to 42 U.S.C. § 1396r-8. Under 1396r-8, states were already required to cover all FDA-approved medications for OUD when the medications are used on an outpatient basis. In practice, this means that states were required to cover buprenorphine and naltrexone when prescribed as take-home medications. However, because of the federal requirement that methadone for OUD must always be administered in an OTP, the coverage requirement of 1396r-8 does not extend to methadone maintenance treatment or to buprenorphine when administered in a clinical setting. The SUPPORT Act’s requirement fixed that gap temporarily and also puts additional pressure on states that were out-of-compliance with 1396r-8 requirements regarding MAT coverage.

C. State Coverage of MOUDs and Formularies

Prior to the SUPPORT Act, some but not all state Medicaid programs covered all MOUDs approved for MAT treatment. In 2018, before the SUPPORT Act went into effect, the Substance Abuse and Mental Health Services Administration (SAMHSA) released a report documenting each state’s Medicaid policies regarding coverage of different drugs and formularies used for SUD treatment.\footnote{SAMHSA, Medicaid Coverage of Medication-Assisted Treatment for Alcohol and Opioid Use Disorders and of Medication for the Reversal of Opioid Overdose (Nov. 2018), \url{https://store.samhsa.gov/product/Medicaid-Coverage-of-Medication-Assisted-Treatment-for-Alcohol-and-Opioid-Use-Disorders-and-of-Medication-for-the-Reversal-of-Opioid-Overdose/SMA18-5093} [hereinafter “SAMHSA Report”].} All states covered at least some MOUDs, but the report identified nine state Medicaid programs which did not cover all three medications (methadone, buprenorphine, and naltrexone) as is now required by the legislation.\footnote{Specifically, the report found that Medicaid programs in Arkansas, Idaho, Kentucky, Louisiana, Nebraska, North Dakota, South Carolina, and Tennessee did not cover methadone for MAT treatment. \textit{Id.} at 50, 105-106.} Since the SAMHSA report was published, each of these states has submitted Medicaid State Plan Amendments to
add coverage for these medications to their programs. Thus, all states and Washington D.C. now cover all three medications approved by the FDA for MAT.

However, not all states cover “all forms” of MOUDs, as CMS has indicated to be required by the SUPPORT Act. As of December 2020, CMS reported that all state Medicaid programs cover some form of buprenorphine, but the 2018 SAMHSA report identified that Medicaid programs in fourteen states do not cover implantable buprenorphine and eighteen do not cover extended-release injectable buprenorphine. Those eighteen states are not yet in compliance with the SUPPORT Act.

In addition to violating the law, failure to provide all different forms of MOUDs will likely hinder states efforts to effectively and comprehensively treat OUD. Which MOUD is most beneficial depends on the patient; different forms pose benefits and risks depending on the individual. For example, oral formats of buprenorphine are more commonly used for beneficiaries in the early stages of treatment, while injectable and implantable formats are more often used for individuals already stable on a low or moderate oral dose. Injectable and implantable formats minimize risk of inappropriate use and increase compliance with treatment, given that the medication is administered by a provider. Extended-release buprenorphine has also been

18 SHO 20-005 at 5.
19 SAMHSA Report, at 95-99 (Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Iowa, Nebraska, Nevada, South Dakota, Tennessee, Wisconsin, and Wyoming are the states that do not cover implantable buprenorphine; and Alaska, Arizona, Connecticut, Florida, Georgia, Hawaii, Iowa, Kansas, Louisiana, Montana, Nebraska, Nevada, Oklahoma, Oregon, South Dakota, Tennessee, Texas, and Wyoming are the states that do not cover extended-release injectable buprenorphine).
20 See U.S. GOV’T ACCT. OFFICE, Opioid Use Disorder: Barriers to Medicaid Beneficiaries’ Access to Treatment Medications (Jan. 2020), at 16, https://www.gao.gov/assets/gao-20-233.pdf [hereinafter “GAO Report”] (“According to CMS officials, all the manufacturers of MAT medications in our review participate in the Medicaid Drug Rebate Program, and as a result, state Medicaid programs are required to cover these medications in all of their formats.”).
21 GAO Report at 5.
22 Id. at 5-6.
shown to improve program adherence, in contrast to medications which require administration daily.

**D. Barriers to Treatment – State and Medicaid Policies**

Coverage of MOUDs is not the only barrier Medicaid beneficiaries face in accessing MAT treatment. In addition, common Medicaid benefit design elements, limitations on providers, and societal factors make accessing treatment difficult. These persisting barriers and their prevalence in state Medicaid plans are described in this section.

**Preferred Drug Lists and Prior Authorization**: State preferred drug lists (PDLs) are lists of drugs that Medicaid will cover without the need to seek prior authorization from the state Medicaid agency; drugs not on the list are subject to prior approval requirements. The SAMHSA report from 2018 found that buprenorphine is a preferred drug in only 29 states, with preferred status in those states typically limited to certain populations, such as pregnant people. Oral naltrexone has preferred status in 44 states and extended-release naltrexone is preferred in just 34 states. Similarly, prior authorization for buprenorphine is required by 40 state Medicaid programs, while 8 states require it for oral naltrexone and 19 states require it for injectable naltrexone. A recent report found that Medicaid programs are more likely to require prior authorization for medications than for counseling for people with SUD. While preferred status for methadone as a form of MAT is not possible given OTP requirements, a few states have required prior authorization for methadone maintenance.

PDLs and prior authorization requirements are often put in place to reduce costs and unnecessary use of medications, but they may also cause life-threatening delays for beneficiaries in need of MAT. In a report mandated by the SUPPORT Act, the Government

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24 SAMHSA at 34.

25 *Id.* at 34.

26 *Id.* at 35-36.


28 *Id.* at 39. The states are Connecticut, Maine, and North Carolina.
Accountability Office (GAO) found that prior authorization requirements can “prevent[] timely access to MAT” and that “these delays could be life-threatening, because patients may return to drug use and possibly overdose before receiving their medication.” Additionally, the report found that use of PDLs can cause confusion for providers that ultimately results in “reduced beneficiary access to MAT medications.” Similarly, SAMHSA reports that prior authorization restrictions may delay access to treatment, add to provider burden, and “[t]he end result is often that the patient does not receive any medication.” Studies have also found that prior authorization policies lead to higher rates of treatment discontinuation and hospitalization, while removing prior authorization policies was associated with increased use of medications and improved outcomes.

**Step Therapy:** Step therapy is a drug utilization management strategy that requires patients to first try a more cost-effective medication before they can receive a more expensive alternative. In order for the “next step up” to be authorized, the first-line treatment must have been ineffective or not tolerated by the patient. For example, a step therapy requirement could mandate that a patient try naltrexone before receiving disulfiram for treatment of an alcohol use disorder, or to first use oral naltrexone before receiving extended-release injectable naltrexone.

Step therapy is required in nine states for buprenorphine, including nine for implantable buprenorphine and three for extended-released injectable buprenorphine. Most of these states require a showing of serious documented adverse reaction to naloxone before a patient can step up to buprenorphine. In addition, step therapy is required in 4 states for injectable naltrexone and 1 state for oral naltrexone.

29 GAO Report at 17.
30 *Id.* at 20.
31 SAMHSA at 48.
32 *Id.*
34 SAMHSA at 33.
35 *Id.* at 39.
36 *Id.*
37 *Id.*
Research suggests that step therapy requirements may result in delayed treatment and are counterproductive to the patient’s course of treatment. This is because MAT, at one level or another, is recommended for all patients with OUD, which means the most effective strategy to treat the condition is to initiate MOUD treatment as soon as possible. Conditioning MAT initiation upon failing other non-medication-based therapy only perpetuates the stigma associated with MOUDs while delaying access to evidence-based treatment.

**Quantity Limits**: State Medicaid programs may use quantity limits, which define the maximum quantity of medication that is covered for one prescription or copayment. While current quantity limits mostly restrict the amount of medication a beneficiary can receive at one time, historically some states have imposed lifetime treatment limits on MAT medications. While lifetime limits are “disappearing, consistent with clinical evidence and best practices, given that addiction is a chronic disease,” dosing limits are still very common: forty-five state Medicaid programs imposed quantity limits for buprenorphine and forty-six states apply them to buprenorphine-naloxone.

Quantity limits can ensure patient safety and quality of care when appropriately tied to patient needs. However, such policies can also reduce access to MAT. MACPAC recommends that any quantity limits be flexible enough to allow for a patient’s specific needs and phase of treatment.

**Scope of Practice Limitations**: While federal law allows for certain non-physician professionals, such as nurse practitioners and physician assistants, to obtain waivers to prescribe buprenorphine for MAT, some states still have laws prohibiting non-physicians to

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39 SAMHSA at 4; see MACPAC, at 25 (“In 2018, only 2 states (Maine and New York) had lifetime limits for buprenorphine-naloxone, down from 11 states in 2011-2013”).

40 SAMHSA at 37.

41 MACPAC at 24 (citing Hoover 2019).

42 Rinaldo & Rinaldo, *supra* note 38.

43 Id. at 24.
provide this treatment.44 Others require non-physician providers to be supervised by a physician in order to provide the treatment.45 These state level requirements can limit patients’ access to MAT by restricting providers who could safely provide these treatments from doing so. Research has identified restrictions on the ability of nurse practitioners and physician assistants to prescribe buprenorphine as a barrier to developing and expanding the opioid treatment workforce.46

**E. Public Health Emergency Flexibilities**

In response to the COVID-19 pandemic, many states as well as the federal government temporarily loosened or suspended policies which restrict access to prescription medications, including MAT medications.47 State Medicaid programs amended their state plans to increase quantity limits, allow for early refills, suspend prior authorization requirements, and allow exceptions to preferred drug lists.48 The Center on Budget and Policy Priorities reports that 26 states made changes to their preferred drug lists and 30 waived or suspended drug prior authorizations during the pandemic.49 In addition, 35 states expanded the scope of practice laws for both physician assistants and nurse practitioners during COVID-19.50

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45 Id.
49 Schubel, supra note 47.
these policies during the public health emergency demonstrates that they can and should be safely implemented on a permanent basis to improve access to MAT treatment.

**F. Additional Barriers to Treatment**

While the barriers identified below are not Medicaid-specific policies, they continue to limit access to MAT treatment. In addition, recent flexibilities permitted during the COVID-19 public health emergency have led to renewed conversations about eliminating these barriers permanently.

**The Buprenorphine X-Waiver**: Providers seeking to prescribe buprenorphine are limited by the requirement that they seek either DEA registration or a waiver (the “X-waiver”), which necessitates certain licensing, training, or experience requirements. The SUPPORT Act loosened requirements on buprenorphine prescribing, including allowing advanced practice providers to prescribe and increasing the number of patients a provider may treat under an X-waiver. However, the waiver requirement remains a barrier to effective treatment.

Researchers and experts have argued that the X-waiver requirement is not necessary for safe treatment and noted that the requirement inaccurately sends the message that prescribing buprenorphine for MAT is dangerous. In addition to posing logistical and licensing barriers, the waiver requirements place limits on the number of patients that the provider may treat with MAT medications, thus limiting the number of people who can access this treatment. Eliminating the X waiver altogether is essential in order to improve buprenorphine access.

**In-Person Dispensing and OTP Requirements**: Current federal law requires providers to conduct in-person visits with patients before prescribing buprenorphine. Methadone requirements are even more stringent; methadone for treatment of OUD may only be administered in-person in a licensed OTP, which must be certified by SAMHSA, accredited by a

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53 See GAO Report at 22-23.
54 GAO Report at 23.
specific body, and licensed with the DEA.\textsuperscript{57} While the in-person dispensing requirement for buprenorphine was waived during the public health emergency, methadone treatment still cannot be initiated via telehealth, although SAMHSA has allowed states to apply to allow stable patients to take home MOUDs.\textsuperscript{58}

Nearly two years into providing this flexibility, SAMHSA has shared initial reports that these flexibilities have increased treatment engagement, improved patient satisfaction with care, and that there were few cases in which the take-home medication was misused or diverted.\textsuperscript{59} In-person requirements should be removed and the use of telehealth should be increased in order to improve accessibility to MAT treatment.

**Stigma:** Stigma against people who use drugs and have SUDs is widespread and negatively effects treatment, outcomes, policies, and quality of care provided.\textsuperscript{60} Experiencing stigma has been shown to prevent individuals from seeking out and completing SUD treatment, while simultaneously creating social exclusion that can increase the need for treatment.\textsuperscript{61} However, studies have shown that many health care providers hold negative or stereotyped views

\textsuperscript{57} See 42 C.F.R. § 8 (2019); SAMHSA, *Certification of Opioid Treatment Programs (OTPs)* (Nov. 4, 2021, https://www.samhsa.gov/medication-assisted-treatment/become-accredited-opioid-treatment-program.)


towards individuals with SUD, and that these attitudes caused patients to have diminished feelings of empowerment and poor healthcare treatment.62 MAT medications specifically face stigma and misunderstanding, such as the belief that MAT is simply “swapping one drug for another.” These incorrect beliefs contribute to physicians being less willing to prescribe MAT, thus undercutting evidence-based treatment options for patients.63

Further, societal stigma against drug use and SUD has a negative effect on policies and programs intended to treat SUD, such as reductions in access to care, inadequate or ineffectual policies, or poor attention from policymakers overall.64 Research demonstrates that stigmatization of drug use contributes to public acceptance of discriminatory measures against people with OUD as well as more punitive and less evidence-based policies for addressing opioid misuse and overdose.65

Reducing and fighting stigma against people who use drugs is essential to promoting access to SUD treatment and ensuring Medicaid and other policies aimed at treating SUD are supportive and effective. Educating the public, stakeholders, and policymakers on the facts of drug use and correcting inaccurate stereotypes, as well as using non-stigmatizing language can help fight stigma.66 In addition, doctors suggest that integration of SUD treatment with other health services and addressing the physical and mental health conditions of patients with SUDs can improve access to care.67

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65 NAT’L ACADEMIES OF SCIENCES, ENGINEERING, AND MEDICINE, supra note 63.
67 Dannatt et al., supra note 22.
G. Recommendations

**Full Compliance with the SUPPORT Act:** State Medicaid programs that do not cover all formularies of MAT medications should do so. According to the GAO’s report required under the SUPPORT Act, “CMS has not taken steps to determine whether state Medicaid programs do cover all of these MAT medications and their formats, as required [by the SUPPORT Act].”\(^68\) CMS should do so in order to ensure that all states are complying with the SUPPORT Act.

**Remove Identified Medicaid and State Policy Barriers:** State Medicaid programs should stop subjecting MAT drugs to prior authorization, step therapy requirements, and quantity limits. States should not use preferred drug lists for MAT medications or all MAT medications and formularies should be included on such lists. Medicare can serve as a model for removing prior authorization requirements, which it has done for buprenorphine.\(^69\) Additionally, state should permit advanced practice providers to administer MAT drugs.

**Making Public Health Emergency Flexibilities Permanent:** In addition prior authorization preferred drugs lists, and provider scope of practice requirements, COVID-19 flexibilities have shown that many federal policy barriers can safely be removed to improve access to MOUDs. Policies should permanently allow for take-home methadone and reassess need for methadone to be exclusively administered through OTPs.\(^70\) Other countries, such as Australia, Great Britain, and Canada allow for methadone to be prescribed in office-based settings and filled in pharmacies, and pilot programs in the U.S. have demonstrated that administering methadone in a primary care setting is safe and effective.\(^71\)

**Repeal the X-Waiver Requirement:** The federal government should permanently get rid of the requirement that providers must seek a waiver in order to treat MAT patients (or increase

\(^68\) GAO at 29.
the number of patients they are allowed to see). Federal legislation has been introduced to repeal the waiver.\footnote{Mainstreaming Addiction Treatment Act of 2021, S. 445, 117th Cong. (2021), \url{https://www.congress.gov/bill/117th-congress/senate-bill/445}.}

**Continue and Expand Use of Telehealth:** Telehealth should be expanded and policies should allow for prescribing and administering MOUDs without an in-person visit, including methadone. Federal legislation has been introduced to improve access to MAT treatment, including repealing a requirement that individuals be dependent on opioids for one year before being admitted to certain treatment programs; allowing providers to prescribe MAT via telehealth; creating grant programs for harm reduction activities; and expanding access to naloxone.\footnote{STOP Fentanyl Act of 2021, H.R. 2366, 117th Cong. (2021), \url{https://www.congress.gov/bill/117th-congress/house-bill/2366}.}

**Fight Stigma through Education:** Finally, all federal, state, and local policies related to substance use, opioids, and overdose should be free of stigma and affirmatively work to counter societal stigma towards drug users that serves as a barrier to treatment. The federal government and state Medicaid programs should invest in public and medical education and training to debunk myths about MAT and reduce stigma which limits access to this treatment.