



# OPIOID USE DISORDER

## Barriers to Medicaid Beneficiaries' Access to Treatment Medications

Accessible Version

January 2020

## Why GAO Did This Study

Almost 70,000 people died from drug overdoses in 2018, an estimated 69 percent of which involved opioids. Medicaid, a joint federal-state health care program for low-income and medically needy individuals, is one of the largest sources of coverage for individuals undergoing treatment for opioid use disorder.

Congress included a provision in statute for GAO to review access barriers to MAT medications, including the distribution methods. This report describes policies that can restrict Medicaid beneficiaries' access to MAT medications, including any related to the distribution methods.

To do this work, GAO reviewed relevant laws, policies, and documents, as well as studies describing access barriers and the benefits and challenges of the distribution methods. GAO also interviewed federal officials; stakeholders representing state Medicaid directors, health care providers, patients, and pharmacies; and state officials and health care providers from Minnesota, North Carolina, and Ohio, as well as the District of Columbia. GAO selected these three states and the District of Columbia based on their Medicaid programs' coverage of the MAT medications, their programs' spending for the treatment of opioid use disorder, and other criteria.

## What GAO Recommends

GAO recommends that CMS determine the extent to which states are in compliance with federal requirements to cover MAT medications, and take action as appropriate. HHS concurred with this recommendation.

View [GAO-20-233](#). For more information, contact Mary Denigan-Macauley at (202) 512-7114 or [deniganmacauleym@gao.gov](mailto:deniganmacauleym@gao.gov).

# OPIOID USE DISORDER

## Barriers to Medicaid Beneficiaries' Access to Treatment Medications

### What GAO Found

Medication-assisted treatment (MAT)—which combines behavioral therapy and the use of certain medications, such as buprenorphine—has been shown to be effective at reducing the misuse of or addiction to opioids and increasing treatment retention. The federal government has identified expanding access to MAT as important for reducing opioid use disorders and overdoses, and has taken action to increase access. However, GAO found that some state and federal policies can restrict Medicaid beneficiaries' access to MAT medications. Some of these policies, and three selected states' and the District of Columbia's efforts to address potential access barriers, include the following:

**MAT medication coverage.** A 2018 study found that about 40 percent of states may not provide Medicaid coverage for some formats of MAT medications, such as injectable and implantable formats, as required by federal law; however, the Centers for Medicare & Medicaid Services (CMS), which oversees Medicaid, has not determined the extent to which states are in compliance with the federal requirements to cover MAT medications.

**Prior authorization requirements.** Some MAT medications and formats are subject to prior authorization, which requires these medications to be pre-approved before being covered by Medicaid. While these requirements are generally used to reduce expenditures, unnecessary utilization, and improper payments, stakeholders told GAO the requirements may cause life-threatening delays in the case of MAT medications. Some states, including three states and the District of Columbia that GAO reviewed, have taken steps to remove prior authorization requirements for MAT medications.

**Distribution methods.** States may mandate the ways MAT medications can be distributed. For example, Minnesota's fee-for-service plan requires the use of the buy-and-bill distribution method for all injectable and implantable medications. This method requires providers, such as physicians, to purchase and store these medications until administered to the patient, allowing immediate access to the MAT medication for Medicaid beneficiaries. However, for expensive injectable medications, which can cost \$1,200 per treatment, this method places providers at financial risk if the medication is not used or the reimbursement is less than the providers' costs, requiring resources some providers may lack, according to providers in the selected states and District of Columbia. As a result, some states have removed such restrictions to maximize beneficiary access.

**Federal waiver for prescribing buprenorphine.** According to stakeholders GAO interviewed, some providers are unwilling to obtain the federal waiver necessary to prescribe or administer buprenorphine for opioid use disorder—due to reasons such as the hours of training associated with the waiver—which can restrict beneficiary access to this MAT medication. In addition, while nurse practitioners and physician assistants are eligible for these waivers, some state laws require them to be supervised by a physician. Stakeholders told GAO that some nurse practitioners may find it difficult to identify a qualified physician, which may affect patient access to MAT.

---

# Contents

---

Letter		1
	Background	4
	State and Federal Policies, Including Some Related to Distribution Methods, Can Restrict Medicaid Beneficiaries' Access to MAT Medications	11
	Conclusions	25
	Recommendations for Executive Action	26
	Agency Comments	26

---

Appendix I: Comments from the Department of Health and Human Services		27
---	--	----

Appendix II: GAO Contact and Staff Acknowledgments		31
--	--	----

Appendix III: Accessible Data		32
	Agency Comment Letter	32

---

Table		
	Table 1: Key Characteristics Related to Distribution Methods of Medications Used in Medication-Assisted Treatment	9

---

Figure		
	Figure 1: Distribution Methods for MAT Medications for Beneficiaries	8

---

## Abbreviations

CMS	Centers for Medicare & Medicaid Services
CSA	Controlled Substances Act
DATA 2000	Drug Addiction Treatment Act of 2000
DEA	Drug Enforcement Administration
FDA	Food and Drug Administration
HHS	Department of Health and Human Services
MACPAC	Medicaid and CHIP Payment and Access Commission
MAT	medication-assisted treatment

---

---

MCO	managed care organization
OD	opioid use disorder
PDL	preferred drug list
SAMHSA	Substance Abuse and Mental Health Services Administration
SUPPORT Act	Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act

This is a work of the U.S. government and is not subject to copyright protection in the United States. The published product may be reproduced and distributed in its entirety without further permission from GAO. However, because this work may contain copyrighted images or other material, permission from the copyright holder may be necessary if you wish to reproduce this material separately.



January 24, 2020

The Honorable Charles E. Grassley  
Chairman  
The Honorable Ron Wyden  
Ranking Member  
Committee on Finance  
United States Senate

The Honorable Frank Pallone, Jr.  
Chairman  
The Honorable Greg Walden  
Republican Leader  
Committee on Energy and Commerce  
House of Representatives

The misuse of and addiction to prescription opioid pain relievers (such as oxycodone) and illicit opioids (such as heroin) has become a significant public health problem in the United States. In 2018, an estimated 2 million Americans age 12 or older had an opioid use disorder (OUD)—the misuse of or addiction to opioids—according to the Substance Abuse and Mental Health Services Administration (SAMHSA).<sup>1</sup> According to the latest, preliminary data from the Centers for Disease Control and Prevention, in 2018, almost 70,000 Americans died of a drug overdose, with an estimated 69 percent of those deaths involving an opioid.<sup>2</sup> For those with OUD, research shows that medication-assisted treatment (MAT), which combines behavioral therapy and the use of certain medications, can be effective at reducing opioid use and increasing treatment retention, in comparison to other treatments. However, we have previously reported on barriers—such as federal laws, provider

---

<sup>1</sup>SAMHSA, *Key Substance Use and Mental Health Indicators in the United States: Results from the 2018 National Survey on Drug Use and Health*, PEP19-5068, NSDUH Series H-54 (Rockville, Md.: 2019).

<sup>2</sup>According to the Centers for Disease Control and Prevention, preliminary or “provisional” drug overdose death data may underestimate actual numbers, as they can be incomplete and subject to random variation. The final 2018 data are to be available in 2020, according to the agency.

availability, perception, and cost—that can restrict patient access to the medications used in MAT.<sup>3</sup>

The Department of Health and Human Services (HHS) has identified expanding access to MAT as an important strategy for reducing opioid use disorders and opioid overdoses.<sup>4</sup> HHS’s Medicaid program—which provided health coverage to an estimated 75 million low-income and medically needy individuals in fiscal year 2018—is one of the largest sources of federal funding of health care services for individuals with OUD, including MAT. According to an analysis of SAMHSA’s National Survey on Drug Use and Health by the Kaiser Family Foundation, Medicaid provided health care coverage in 2017 to 38 percent of nonelderly adults with OUD.<sup>5</sup> States’ Medicaid programs have flexibility in how they design their programs and can therefore vary in how MAT medications are covered and distributed, such as through retail pharmacies. However, little information exists on how different distribution methods may affect beneficiaries’ access to the medications.

The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) included a provision for GAO to study the effect of states’ Medicaid programs and policies related to the distribution methods of MAT medications in terms of beneficiary access, cost, and provider willingness to provide these medications.<sup>6</sup> In this report, we describe policies that may restrict such access to MAT medications for Medicaid beneficiaries, including any related to the distribution methods.

---

<sup>3</sup>See GAO, *Opioid Addiction: Laws, Regulations, and other Factors Can Assist Medication-Assisted Treatment Access*, [GAO-16-833](#) (Washington, D.C.: Sept. 27, 2016).

<sup>4</sup>We previously reported on initiatives, such as grants and regulatory changes by HHS, to expand access to OUD treatments. See GAO, *Opioid Use Disorders: HHS Needs Measures to Assess the Effectiveness of Efforts to Expand Access to Medication-Assisted Treatment*, [GAO-18-44](#) (Washington, D.C.: Oct. 31, 2017).

<sup>5</sup>Kaiser Family Foundation, Kendal Orgera and Jennifer Tolbert, “The Opioid Epidemic and Medicaid’s Role in Facilitating Access to Treatment,” accessed October 4, 2019, <http://files.kff.org/attachment/Issue-Brief-The-Opioid-Epidemic-and-Medicoids-Role-in-Facilitating-Access-to-Treatment>. The report defined non-elderly adults as those aged 18-64.

<sup>6</sup>Pub. L. No. 115-271, § 1011, 132 Stat. 3894, 3919 (Oct. 24, 2018).

For our report, we focused our work on three of the medications used for MAT: buprenorphine, buprenorphine-naloxone, and naltrexone.<sup>7</sup> We reviewed scientific studies and literature describing policies that could create potential access barriers, as well as the benefits and challenges of the distribution methods, identified through searching bibliographic databases, including Medline and Scopus, for articles published from 2009 to 2019. We also reviewed relevant laws and regulations related to MAT medications. We also interviewed federal officials and officials from 14 stakeholder organizations representing state Medicaid directors, general health care providers, providers that specialize in treating OUD, patients with OUD, and pharmacies, distributors, certain manufacturers of MAT medications, as well as a policy research organization.<sup>8</sup> We identified these organizations through our background research on the topic and through our interviews.

In addition, we selected three states—Minnesota, North Carolina, and Ohio—and the District of Columbia, based on their Medicaid programs' coverage of all of the MAT medications, as well as variation in terms of program spending on MAT medications; expansion of Medicaid to uninsured, low-income adults; the number of opioid overdose deaths per state; and the number of MAT prescriptions for Medicaid beneficiaries.<sup>9</sup> We also used information gathered from our stakeholders pertaining to access barriers to MAT medications or initiatives by the states to expand

---

<sup>7</sup>The SUPPORT Act listed three specific medications to be included in the study: buprenorphine, buprenorphine-naloxone, and naltrexone. Methadone is also used in MAT, but was excluded from our review because, when used for that purpose, it can only be administered and dispensed in opioid treatment programs and therefore does not use the distribution methods reviewed for this report. An opioid treatment program refers both to a program or a practitioner engaged in opioid treatment of individuals. See 42 C.F.R. § 8.2 (2019). Opioid treatment programs are also called narcotic treatment programs or, often, methadone clinics. They may offer opioid medications, counseling, and other services for individuals addicted to heroin or other opioids. Opioid treatment programs are certified by SAMHSA and registered by the Drug Enforcement Administration.

<sup>8</sup>Federal agencies that we interviewed were HHS, the Centers for Medicare & Medicaid Services (CMS), SAMHSA, Agency for Healthcare Research and Quality, Office of the Assistant Secretary for Planning and Evaluation, Medicaid and CHIP Payment and Access Commission, and the HHS Office of Inspector General. Stakeholder organizations we interviewed were the National Association of Medicaid Directors, American Association of Nurse Practitioners, American Academy of Physician Assistants, American Academy of Addiction Psychiatry, American Society of Addiction Medicine, American Association of the Treatment of Opioid Dependence, American Pharmacists Association, National Association of Specialty Pharmacy, National Association of Chain Drug Stores, Healthcare Distribution Alliance, The Urban Institute, Center on Addiction, Indivior, and Alkermes.

<sup>9</sup>For the purposes of this report, we consider the District of Columbia a state.

access to MAT medications. In these states, we reviewed relevant state documents and policies, and interviewed state Medicaid officials, officials from the managed care organizations (MCO)—private organizations that contract with the state to provide health care services to Medicaid beneficiaries—that served the largest number of Medicaid beneficiaries in those states, and providers who specialize in addiction medicine identified by the state chapters of the American Society of Addiction Medicine. Of our four selected states, North Carolina was the only state that did not contract with MCOs at the time of our review.

We conducted this performance audit from February 2019 to January 2020 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that that evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

---

## Background

Medicaid is a joint federal-state health care program that provides health care coverage to low-income and medically needy individuals. At the federal level, the Centers for Medicare & Medicaid Services (CMS), within HHS, is responsible for overseeing Medicaid, while states administer their respective Medicaid programs' day-to-day operations. Each state's Medicaid program, by law, must cover certain categories of individuals and provide a broad array of benefits. Within these requirements, however, states have significant flexibility to design and implement their programs, resulting in more than 50 distinct state-based programs. The federal government requires coverage for certain mandatory services under Medicaid, but states may decide to include other optional services as well. Some of the largest and most commonly included services include prescription drugs, nursing facilities, home and community-based care, and hospital inpatient care.

---

## Medicaid and Prescription Drugs

Although pharmacy coverage is an optional service under Medicaid, all 50 states and the District of Columbia provide coverage for prescription drugs. State Medicaid programs that opt to cover prescription drugs are generally required to cover all of the outpatient drugs of any drug manufacturer participating in the Medicaid Drug Rebate Program,

including all of the drugs' formats.<sup>10</sup> State Medicaid programs do not directly purchase prescription drugs, but instead reimburse pharmacies for covered prescription drugs dispensed to Medicaid beneficiaries. Providers (including physicians, nurse practitioners, and physician assistants) and pharmacies provide health care services, seek payment, and are reimbursed for services by state Medicaid agencies. States may directly pay health care providers for services rendered using a fee-for-service system or may delegate these responsibilities to MCOs.<sup>11</sup> Under managed care, the state contracts with MCOs to provide comprehensive health care services through its network of providers.

---

## MAT Medications

Buprenorphine, buprenorphine-naloxone, and naltrexone may be prescribed, administered, or dispensed for use in MAT. These medications come in a variety of formats, including oral, implantable, and injectable.

**Buprenorphine.** Buprenorphine is a partial opioid agonist, meaning it binds to opioid receptors and activates them. It reduces or eliminates opioid withdrawal symptoms, including drug cravings, and blunts the euphoria or dangerous side effects of other opioids, such as heroin. It can be used for detoxification treatment and maintenance therapy. Buprenorphine is available as a MAT medication in two oral formats—(1) tablets for sublingual (under the tongue) administration, and (2) film for sublingual or buccal (inside the cheek) administration; as a subdermal (under the skin) implant; and in an injectable format. Oral formats are often used for beneficiaries that are in the beginning stages of treatment. The implantable format is generally used for beneficiaries who are already stable on a low or moderate dosage of oral buprenorphine. The oral formats are taken daily, while the injectable format is administered monthly, and the implantable format is administered every 6 months. The medication carries a risk of abuse, particularly in oral formats where it can be used inappropriately or illegally re-sold. The injectable and implantable

---

<sup>10</sup>Drug manufacturers participating in the Medicaid Drug Rebate Program provide discounts to state Medicaid programs in the form of rebates for certain outpatient prescription drugs. States that elect to cover outpatient drugs in their Medicaid program must cover all Food and Drug Administration (FDA)-approved drugs made by a manufacturer that has entered into a rebate agreement, outside of certain permitted exclusions or restrictions that are outlined in the law. See 42 U.S.C. §1396r-8(d).

<sup>11</sup>In fee-for-service, states make payments directly to providers for services provided.

---

formats of buprenorphine are intended to minimize this risk and to increase beneficiary compliance, because the medication is administered by a provider.

**Buprenorphine-naloxone.** Naloxone is a medication added to some oral formats of buprenorphine to reduce the chances of misuse or abuse. Buprenorphine-naloxone is available in an oral format as either a film or a tablet. It discourages people from inappropriately injecting a crushed and dissolved tablet of buprenorphine by inducing symptoms of opioid withdrawal when injected by individuals physically dependent on opioids.

**Naltrexone.** Naltrexone is an opioid antagonist, meaning it binds to opioid receptors, but does not activate them, thereby blocking the euphoria the user would normally feel from opioids. It also may result in withdrawal symptoms if recent opioid use has occurred. Therefore, it is used for relapse prevention following complete detoxification from opioids. It can be taken daily in an oral format or as a once-monthly injection; though due to low patient compliance, SAMHSA does not recommend using oral naltrexone for OUD treatment. Naltrexone carries no known risk of abuse. For the injectable format of naltrexone, beneficiaries have to be free from opioids for at least a week before they can begin the medication.

---

## Prior Authorization and Preferred Drug Lists

Subject to certain requirements, state Medicaid agencies may use different strategies, such as prior authorization and preferred drug lists (PDL), to manage the cost of prescription medications and ensure that patients are taking medications that are clinically appropriate. Prior authorization requires that certain conditions are met before services can be provided to patients, in part, to control utilization and prevent improper payments. PDLs reflect state Medicaid agencies' determinations on whether medications, including those used for MAT, will be covered and whether these medications will be categorized as preferred or non-preferred. A PDL indicates the first-choice or preferred medication for a beneficiary's particular medical condition.<sup>12</sup> PDLs are utilized by state Medicaid agencies to incentivize providers to prescribe certain types of medications. In addition, the preferred or non-preferred categorization of medication can vary between fee-for-service and managed care plans

---

<sup>12</sup>PDLs are not used in all state Medicaid programs. According to CMS officials, four states—Hawaii, New Jersey, New Mexico, and South Dakota—do not have PDLs.

---

within a state. If a medication is not listed on a PDL, prior authorization may be required. However, medications listed on a PDL may still have prior authorization requirements, such as requirements to ensure patient safety.

---

## Distribution Methods

There are three distribution methods by which beneficiaries can obtain MAT medications. (See fig. 1.)

1. **Retail pharmacy.** After receiving a prescription from a health care provider, pharmacists at a retail pharmacy, such as CVS or Walgreens, prepare and dispense (or deliver) the medication directly to a beneficiary. The pharmacist is reimbursed for the cost of the medication by a payer, such as Medicaid or private insurance, and by any co-payment from the beneficiary.
2. **External delivery from a specialty pharmacy.** After receiving a prescription from a physician or other health care provider, a specialty pharmacy delivers the medication directly to the provider so the medication can be administered (injected or implanted by the provider) to the beneficiary for whom it was prescribed. The specialty pharmacy ensures that any specific requirements for a medication are maintained; for example, injectable naltrexone requires the use of refrigerated warehouses, insulated shipping containers, and temperature monitoring equipment. The specialty pharmacy is reimbursed by Medicaid or another payer.
3. **Buy-and-bill.** A health care provider purchases the medication from a manufacturer or distributor and stores the medication until it is dispensed or administered to the appropriate patient. After the medication is dispensed or administered, the provider bills Medicaid or another payer for the cost of the medication.

Figure 1: Distribution Methods for MAT Medications for Beneficiaries

Retail pharmacy



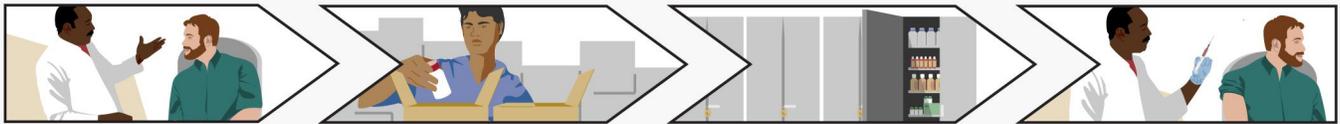
Provider prescribes medication-assisted treatment (MAT) for opioid use disorder (OUD) for a specific beneficiary.

Pharmacy fills the prescription.

Beneficiary picks up the prescription and takes medication.

↑  
Payer, such as Medicaid, reimburses the pharmacy for the cost of the prescription.

External delivery by specialty pharmacy



Provider prescribes MAT for OUD for a specific beneficiary.

Specialty pharmacy fills the prescription and sends it to the provider.

Provider stores medication until administered to specific beneficiary.

Beneficiary goes to provider to receive medication.

↑  
Payer, such as Medicaid, reimburses the pharmacy for the cost of the prescription.

Buy-and-bill



Provider orders MAT to treat OUD.

Distributor fulfills the provider's order.

Provider stores medication until administered to any beneficiary deemed appropriate for treatment.

Beneficiary goes to provider to receive medication.

↓  
Provider pays distributor for medication.

↑  
Payer, such as Medicaid, reimburses the provider for the cost of the medication after it is administered to the beneficiary.

Source: GAO. | GAO-20-233

Note: These three distribution methods are available for buprenorphine, buprenorphine-naloxone, and naltrexone. Methadone is also used in MAT, but when used for that purpose, it can only be administered or dispensed in opioid treatment programs.

Each of the distribution methods used for MAT medications has characteristics with implications for beneficiaries, providers, pharmacies, and payers. (See table 1.)

**Table 1: Key Characteristics Related to Distribution Methods of Medications Used in Medication-Assisted Treatment**

Distribution method	Characteristics
Retail pharmacy	<ul style="list-style-type: none"> <li>• <b>Beneficiaries</b> are generally familiar with using a retail pharmacy.</li> <li>• <b>Beneficiaries</b> are generally able to easily pick up a prescribed medication.</li> <li>• <b>Retail</b> pharmacies deal with insurance requirements and storage of the medications.</li> <li>• <b>Retail</b> pharmacies may not carry these types of medications.</li> <li>• <b>Retail</b> pharmacies generally cannot distribute or administer injectable medications to beneficiaries.</li> <li>• <b>Payers</b> have no financial risk since reimbursement is not made until administered or distributed to a patient.</li> </ul>
External delivery from a specialty pharmacy	<ul style="list-style-type: none"> <li>• <b>Beneficiaries</b> may not have immediate access to the medications, because the provider has to order them from the specialty pharmacy.</li> <li>• <b>Providers</b> are responsible for the logistics in receiving the medication.</li> <li>• <b>Specialty pharmacies</b> deal with insurance requirements and storage of the medication before it is delivered to the provider.</li> <li>• <b>Payers</b> bear the financial risk of unused medications.</li> </ul>
Buy-and-bill	<ul style="list-style-type: none"> <li>• <b>Beneficiaries</b> have immediate access to the medication through their provider.</li> <li>• <b>Beneficiaries</b> do not have to go to the pharmacy to get their medication.</li> <li>• <b>Providers</b> bear the financial risk for unused medication.</li> <li>• <b>Providers</b> are responsible for the logistics in receiving the medication.</li> <li>• <b>Providers</b> are responsible for ordering, storing, and billing for medication.</li> <li>• <b>Payers</b> have no financial risk, because reimbursement is not made until administered or distributed to a patient.</li> </ul>

Source: GAO analysis of interviews and literature. | GAO-20-233

## Laws and Regulations for Prescribing Buprenorphine and Buprenorphine-Naloxone

Medications containing buprenorphine, including buprenorphine-naloxone, are considered controlled substances, which are governed at the federal level by the Controlled Substances Act (CSA), and may be subject to state laws as well.<sup>13</sup> The CSA assigns controlled substances—including narcotics, stimulants, depressants, hallucinogens, and anabolic

<sup>13</sup>The CSA and its implementing regulations establish a framework through which the federal government regulates the use of these substances for legitimate medical, scientific, research, and industrial purposes, while preventing them from being diverted for illegal purposes.

steroids—to one of five schedules based on the substance’s medical use, potential for abuse, and risk of dependence.<sup>14</sup>

In addition to the laws and regulations that apply to controlled substances generally, buprenorphine—when used in the treatment of OUD—is subject to additional requirements under the CSA and implementing regulations issued by the Drug Enforcement Administration (DEA) and SAMHSA. Buprenorphine can be administered or dispensed in a SAMHSA-certified and DEA-registered opioid treatment program when used for OUD treatment. In addition, eligible providers may obtain a Drug Addiction Treatment Act of 2000 (DATA 2000) waiver from SAMHSA in order to dispense or prescribe buprenorphine, including buprenorphine-naloxone, to a limited number of patients for OUD treatment in an office-based setting, such as a doctor’s office.<sup>15</sup> Until 2016, only physicians were eligible to receive a DATA 2000 waiver. However, the Comprehensive Addiction and Recovery Act of 2016 amended the CSA to allow nurse practitioners and physician assistants to receive a DATA 2000 waiver through October 1, 2021.<sup>16</sup> In 2018, the SUPPORT Act eliminated the time limit, thereby permanently allowing nurse practitioners and physician assistants to obtain DATA 2000 waivers.<sup>17</sup>

To qualify for a waiver, providers must be appropriately licensed under state law and meet applicable certification, training, or experience requirements. Providers who prescribe, dispense, or administer buprenorphine under a DATA 2000 waiver are also subject to the CSA’s

---

<sup>14</sup>Buprenorphine is a Schedule III substance, meaning that it has less potential for abuse than Schedule I and II substances, has recognized medical uses, and that abuse of the drug may lead to moderate or low physical dependence or high psychological dependence. Naltrexone is not a controlled substance and is therefore not subject to the CSA.

<sup>15</sup>Specifically, DATA 2000 amended the CSA to authorize SAMHSA to grant qualifying practitioners a waiver of the separate registration requirement applicable to opioid treatment programs, for the purpose of treating opioid addiction with FDA-approved Schedule III, IV, or V opioid medications. Currently, the only Schedule III, IV, or V medication approved by FDA to treat opioid addiction is buprenorphine. Although DATA 2000 authorized qualifying practitioners to receive a waiver of the separate registration requirement for opioid treatment programs, they must still have a valid DEA registration, as applicable to anyone who administers, dispenses, or prescribes controlled substances.

<sup>16</sup>Pub. L. No. 114-198, § 303(a)(1), 130 Stat. 695, 720 (July 22, 2016).

<sup>17</sup>Pub. L. No. 115-271, § 3201(b), 132 Stat. 3894, 3943 (Oct. 24, 2018). The SUPPORT Act also authorizes certified registered nurse anesthetists, certified nurse midwives, and clinical nurse specialists to obtain DATA 2000 waivers until October 1, 2023.

---

inventory and recordkeeping requirement.<sup>18</sup> The waiver requirements include the following:

- Physicians must complete an 8-hour training course or have certain certifications or experiences, while nurse practitioners and physician assistants must complete a 24-hour training course.
- Physicians that receive a DATA 2000 waiver can generally treat 30 patients in their first year and may apply to increase to 100 patients after a year.
- Physicians that meet certain criteria can treat 100 patients in the first year and up to 275 patients after one year of prescribing at the 100-patient limit.
- Nurse practitioners and physician assistants may treat 30 patients in their first year with the waiver and 100 patients thereafter.

---

## State and Federal Policies, Including Some Related to Distribution Methods, Can Restrict Medicaid Beneficiaries' Access to MAT Medications

State Medicaid programs have policies related to the coverage and distribution of prescription drugs that can restrict beneficiary access to MAT medications. CMS has undertaken various coordination efforts aimed generally at addressing OUD. Federal requirements and state laws can also restrict beneficiaries' access to the treatment medications.

---

### State Medicaid Policies on Coverage for MAT Medications, Prior Authorization Requirements, Preferred Drug Lists, and Distribution Methods May Restrict Beneficiary Access

Our review of research and interviews with stakeholders found that several state Medicaid program policies related to prescription drug

---

<sup>18</sup>The CSA requires certain practitioners to maintain inventories and records of controlled substances and to make those inventories and records available for inspection for at least 2 years. See 21 U.S.C. § 827; 21 C.F.R. pt. 1304.

coverage and distribution can restrict beneficiaries' access to MAT medications. These are policies governing coverage of MAT medications, prior authorization requirements, preferred drug lists, and limits placed on distribution methods. While some of these policies are generally used to manage utilization and costs related to a wide range of medications, the research we reviewed and stakeholders we interviewed said that these policies can also restrict beneficiaries' access to the medications used in MAT. In what follows, we describe these policies, including selected states' and CMS efforts to address the potential access barriers related to these policies.

### Coverage of MAT Medications

Recent research suggests that several state Medicaid programs may not cover all MAT medications in all formats. Specifically, in 2018, SAMHSA reported that while all 50 states' and the District of Columbia's Medicaid programs covered oral formats of MAT medications and extended-release injectable naltrexone, it found no indication that 21 states (41 percent) covered either implantable buprenorphine, extended-release injectable buprenorphine, or both.<sup>19</sup> CMS officials said that evidence of coverage may be difficult to find if the medications are billed as part of a medical procedure rather than separately as a medication. However, according to the study's methodology, SAMHSA took steps to check whether the MAT medications were covered as a medical procedure, and did not find any evidence of such coverage. 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 and all their formats. CMS officials stated that the agency generally investigates complaints about lack of drug coverage, but had not received any complaints regarding MAT medications. In addition, the officials said they were unaware of the SAMHSA report and had not taken action based on the report's findings. Therefore, CMS lacks the information to confirm whether or to what extent gaps may exist in state Medicaid programs' coverage of MAT medications in all formats, as SAMHSA's report indicates. As such,

---

<sup>19</sup>SAMHSA, *Medicaid Coverage of Medication-Assisted Treatment for Alcohol and Opioid Use Disorders and of Medication for the Reversal of Opioid Overdose*, HHS Publication No. SMA-18-5093 (Rockville, Md.: November 2018). The Medicaid and CHIP Payment and Access Commission (MACPAC) recently reiterated SAMHSA's findings and also studied coverage in a sample of eight states. See MACPAC Report to Congress: *Utilization Management of Medication-Assisted Treatment in Medicaid*. (Washington, D.C.: October 2019).

Medicaid beneficiaries undergoing medication-assisted treatment may not have access to the medications they need for treatment and that are required by law to be covered.

In addition, the SUPPORT Act includes a new requirement for state Medicaid programs to cover medication-assisted treatment, including all Food and Drug Administration-approved MAT medications, from October 2020 through September 2025.<sup>20</sup> CMS officials stated that the agency is drafting guidance related to this requirement and plans to communicate the guidance to state Medicaid programs through a State Medicaid Director Letter prior to October 2020. The officials told us that they have not determined when the guidance will be issued.

### Prior Authorization Requirements

When state Medicaid agencies cover a MAT medication, they may impose certain constraints, including requiring prior authorization from the MCO or the state Medicaid agency, before a beneficiary can receive the medication.<sup>21</sup> However, these requirements can have unintended consequences, such as preventing timely access to MAT. According to SAMHSA's 2018 report, several states use prior authorizations to ensure that patients receive behavioral therapy in addition to their MAT medications or to ensure that patients have abstained from opioids for a certain period of time, which is necessary before receiving a naltrexone injection.<sup>22</sup> Further, when a patient switches from one medication to another (or another format of the same medication), prior authorization may be required for a variety of reasons, such as to ensure patient safety.

Officials from a stakeholder organization representing providers and officials from a manufacturer said that prior authorization for injectable buprenorphine was particularly burdensome and that decisions on whether the state Medicaid agency will allow a prescription to be dispensed can take up to 14 days. Providers in our selected states and

---

<sup>20</sup>Pub. L. No. 115-271, § 1006(b), 132 Stat. 3894, 3914 (Oct. 24, 2018). States may obtain an exception to this requirement if it would not be feasible because of a shortage of qualified providers or facilities offering MAT.

<sup>21</sup>Prior authorization processes must meet certain federal requirements. For example, a 72-hour supply of any medication in the Medicaid Drug Rebate Program must be made available in emergency situations, regardless of prior authorization processes. See 42 U.S.C. § 1396r-8(d)(5).

<sup>22</sup>SAMHSA, *Medicaid Coverage*.

literature we reviewed noted that these delays could be life threatening, because patients may return to drug use and possibly overdose before receiving their medication. We were also told by officials from one manufacturer that small providers may not have the office staff to promptly process the prior authorization paperwork, creating additional delays.

**Potential Consequences of OUD Patients Missing Treatment**

A health care provider told us that patients receiving treatment for opioid use disorder (OUD) need consistent access to medication-assisted treatment (MAT) medications, just as diabetic patients need consistent access to insulin. According to a survey of providers, patients with OUD who experience delays in their MAT medications could lose motivation for their treatment, which could be life threatening.<sup>a</sup>

Source: GAO. | GAO-20-233.

<sup>a</sup>B. Andraka-Christou and M. J. Capone, "A Qualitative Study Comparing Physician-Reported Barriers to Treating Addiction Using Buprenorphine and Extended-Release Naltrexone in U.S. Office-Based Practices," *International Journal of Drug Policy*, vol. 54 (2018).

Literature we reviewed and stakeholders we interviewed described other ways that prior authorization requirements can delay access to MAT medications for Medicaid beneficiaries and other patients. The examples described include the following:

**Talking to patients before authorizing medications.** According to literature we reviewed and officials we spoke with from a manufacturer and an organization representing providers, some insurance companies require that their staff or the pharmacist talk to the patient before approving a MAT medication when using external delivery from a specialty pharmacy. This is to affirm that the patient wants the medication and agrees that the pharmacy can bill the state Medicaid program. However, speaking directly to patients can be particularly challenging for this population. Officials representing a manufacturer of a MAT medication and officials representing a health care provider organization noted that patients undergoing residential treatment may not have access to a phone, and patients in outpatient treatment are often encouraged to change their phone numbers to reduce contact with people involved in their past drug use. Also, patients may not answer phone calls from unrecognized numbers.

- **Medication reauthorization.** Providers from the District of Columbia told us that they need to reauthorize MAT medication prescriptions every 6 months, but patients may not realize the authorization is about to expire so they run out of the medication, causing them to wait hours or days to get the new prescription filled.
- **Transportation.** Prior authorization requirements for MAT medications can result in multiple trips to the pharmacy, which is problematic for patients and beneficiaries without adequate transportation. Providers from the District of Columbia noted that sometimes prescriptions for MAT medications are not ready for patients when they arrive at the pharmacy, and repeated trips to the pharmacy can be problematic for those who lack adequate transportation. Nevertheless, the patient may need

multiple trips to go back to the provider and then the pharmacy again, which can be especially challenging.<sup>23</sup>

- **Fail-first requirements.** Literature we reviewed, officials we interviewed representing a provider organization, and state Medicaid officials and providers noted that some prior authorizations require that a provider cannot begin treatment with certain MAT medications until treatment with other MAT medications has failed. This literature indicated that this treatment failure can increase the risk of drug use, overdose, and death.

Some states have taken steps to reduce these access barriers by removing prior authorizations through changes in state policies or laws. Officials from a nonprofit organization specializing in addressing addiction told us that, as of September 1, 2019, at least 12 states had laws that prohibited prior authorizations for substance use disorder medications, including MAT medications. States may also address prior authorizations through other means, such as policies or guidance. Among our selected states, all four have taken steps to remove prior authorization requirements.

- **The District of Columbia** began to generally allow providers to prescribe and dispense MAT medications without prior authorization in April 2019.<sup>24</sup>
- **Minnesota** Medicaid officials told us that in August 2018 they removed prior authorization requirements for all MAT medications on their PDL.
- **North Carolina** Medicaid officials told us that in November 2017 they eliminated their prior authorization requirement for providers to submit a treatment plan before treating patients with any MAT medication. After the requirement was removed, the officials observed an increase in beneficiaries receiving MAT medications and an increase in the number of providers writing prescriptions for buprenorphine. The officials said North Carolina has never required prior authorization for injectable buprenorphine, but that the state does have some prior authorization requirements for certain forms of oral buprenorphine or buprenorphine-naloxone. Specifically, in order to prescribe an alternative oral

---

<sup>23</sup>We also reported on how transportation can be an access barrier to OUD treatment for veterans in rural areas. See GAO, *Veterans Health Care: Services for Substance Use Disorders, and Efforts to Address Access Issues in Rural Areas*, [GAO-20-35](#) (Washington, D.C.: Dec. 2, 2019).

<sup>24</sup>The District of Columbia allows providers to prescribe without prior authorization up to the FDA approved maximum daily dose, which varies for each of the medications.

---

medication, the provider needs to demonstrate the patient tried and failed with or is medically unable to use the buprenorphine-naloxone film.

- **Ohio** Medicaid officials told us they have no prior authorization requirements for injectable naltrexone, and they removed prior authorization requirements for oral buprenorphine in January 2019. According to the officials, the state has prior authorization requirements for implantable and injectable buprenorphine to ensure patients are initially stable on oral buprenorphine before beginning these other formats.

### Preferred Drug Lists

According to stakeholders we interviewed, having multiple PDLs within a state or changing PDLs can create confusion for health care providers, because they need to keep track of and follow different requirements for the same MAT medication. Such confusion can result in reduced beneficiary access to MAT medications. For example, in the District of Columbia, four MCOs and the fee-for-service program have separate PDLs. Health care providers in the District of Columbia told us that the four MCOs have different dosage restrictions for the same MAT medications. A stakeholder group representing pharmacies told us that having a uniform PDL for the state makes it easier for pharmacists to comply with the relevant restrictions and minimize delays in accessing MAT medications. In addition, a PDL may change multiple times within a short time frame, which can create further problems for patients who had become comfortable with the medication they had been taking, according to officials from a provider organization.

To address any possible confusion due to the use of multiple PDLs, some states have a uniform PDL for their Medicaid programs, which means that all PDLs used in the state cover the same MAT medications in the same way. Uniform PDLs can simplify the process for prescribers and eliminate some confusion for beneficiaries when they switch health plans.<sup>25</sup> For example, Minnesota implemented a uniform PDL in July 2019 to ensure more consistent access for Medicaid beneficiaries and minimize disruptions if a beneficiary changes health plans. In addition, North

---

<sup>25</sup>In 2019, 13 of the 30 states with Medicaid managed care use a uniform PDL, according to Open Minds. See A. Mandros, "What is a Uniform PDL & Why Does It Matter?" *Executive Briefing for Open Minds*, October 24, 2019, accessed October 28, 2019, <https://www.openminds.com/market-intelligence/executive-briefings/what-is-a-uniform-pdl-why-does-it-matter/>.

Carolina plans to institute a uniform PDL when its Medicaid program moves to a managed care model in November 2019. Ohio also plans to institute a uniform PDL across the state in January 2020. Ohio Medicaid officials told us the uniform PDL will have both brand name and generic oral buprenorphine as preferred medications.

### States' Distribution Method Policies for MAT Medications

According to stakeholders we interviewed, the characteristics of each distribution method, as well as states' policies on distribution methods, have implications for beneficiary access to MAT medications. The following describe the different ways in which the distribution methods may restrict beneficiaries' access to MAT medications.

- **Retail pharmacies** generally offer access to oral formulations of medications. However, retail pharmacies do not typically administer injectable or implantable buprenorphine, and some retail pharmacies may choose not to offer any MAT medications. One survey of physicians found that some pharmacies may either treat individuals prescribed buprenorphine poorly or refuse to carry the MAT medications.<sup>26</sup>
- **External delivery from specialty pharmacies** is often used by providers for the injectable or implantable MAT medications, because the specialty pharmacy deals with the administrative responsibilities of the prescription; however, processing delays can impede access to MAT medications through this method, according to literature we reviewed and stakeholders we interviewed. These specialty pharmacies handle the administrative responsibilities of acquiring the medication, including purchasing the medication and sending it to the provider for administration, and receiving reimbursement from the payer, such as Medicaid. Health care providers who administer these medications may still encounter logistical challenges in their acquisition and storage. Other challenges identified by literature and stakeholders include the following:
  - The patient must return to the provider for a follow-up appointment to receive the medication, because the medication is delivered to the provider. However, if the patient does not return, stakeholders—including those representing specialty

---

<sup>26</sup>C. H. A. Andrilla, T. E. Moore, and D. G. Patterson, "Overcoming Barriers to Prescribing Buprenorphine for the Treatment of Opioid Use Disorder: Recommendations from Rural Providers," *The Journal of Rural Health*, vol. 35 (2019).

pharmacies—told us that the unused medication must be disposed of.

- Providers may face challenges ensuring staff are available to receive medication deliveries—particularly in rural locations or in small practices with multiple office locations that are not always staffed, according to stakeholders representing specialty pharmacies and providers.
- Prescriptions are not always filled by the specialty pharmacy until they have confirmed that they will be reimbursed by the payer, according to officials from one manufacturer we interviewed. The officials stated that when the claim is processed manually, it can take over 20 days to fill the prescription. In contrast, the officials said that if a claim can be processed electronically, payment and delivery of the medication can be almost immediate.
- **Buy-and-bill distribution** allows patients to have immediate access to MAT medications, because their provider has the medications in stock; however, some providers prefer not to use this method, because it places them at financial risk. In particular, smaller health care practices may not have the infrastructure or resources to deal with the administrative responsibilities associated with buy-and-bill, and they may not have the financial ability to pay for medications up front and then wait for reimbursement, according to stakeholders we interviewed. For example, one stakeholder we interviewed said that the cost for just 2 to 3 doses of injectable medication obtained through buy-and-bill could take up a significant portion of the profit margin for a smaller medical practice.

Furthermore, if patients do not use these medications before they expire or if the reimbursement from the payer does not equal the cost of the medication, the provider may face a financial loss. According to providers we interviewed in our four selected states, the high cost of some medications—as much as \$1,200 per dose for injectable medications—makes the financial risk of buy-and-bill too high. Providers also told us that some providers choose not to store buprenorphine, because they are concerned that they could be subject to a DEA inspection. Surveys of health care providers have found provider concerns related to these inspections.<sup>27</sup> And as with

---

<sup>27</sup>See Andrilla, Moore, and Patterson, “Overcoming Barriers”; B. Andraka-Christou and M. J. Capone, “A Qualitative Study Comparing Physician-Reported Barriers to Treating Addiction Using Buprenorphine and Extended-Release Naltrexone in U.S. Office-Based Practices,” *International Journal of Drug Policy*, vol. 54 (2018); and C. H. A. Andrilla, C. Coultbard, and E. H. Larson, “Barriers Rural Physicians Face Prescribing Buprenorphine for Opioid Use Disorder,” *Annals of Family Medicine*, vol. 15, no. 4 (2017).

---

specialty pharmacies, the provider must have someone available to receive deliveries, which can be difficult for smaller practices, according to providers in our selected states.

**How Access Barriers Can Affect Opioid Use Disorder Treatment**

A health care provider we interviewed described how access barriers affected a Medicaid beneficiary's opioid use disorder treatment. This beneficiary was initially prescribed oral buprenorphine, but the medication was repeatedly stolen by the patient's partner. The provider and beneficiary agreed that injectable buprenorphine would allow treatment to continue without the risk of theft. Initially, the provider was not able to find a specialty pharmacy with an electronic prescription system compatible with the provider's system, which was necessary to receive the prescriptions. The provider told us that after a compatible specialty pharmacy was identified and the order was completed, the delivery was further delayed, because two staff members—as required—were not available to sign for the delivery when it arrived. Three months after the decision was made to switch medications, the delivery was completed and the provider administered the medication.

Source: GAO. | GAO-20-233.

Furthermore, state Medicaid policies that require or prevent the use of certain distribution methods for MAT medications can restrict providers from using methods that may be best suited for their patients or practice, which may in turn affect beneficiaries' access to the medications, according to stakeholders. Medicaid officials and providers we interviewed told us that some states require the use of certain distribution methods when a provider prescribes a MAT medication. For example, Minnesota's fee-for-service plan (which covers about 25 percent of the state's Medicaid population) requires that health care providers use buy-and-bill for all physician administered medications, including those that are injected or implanted.<sup>28</sup> Minnesota providers we interviewed told us that they are reluctant to prescribe either the injectable or implantable versions of MAT medications, due to payment delays or other problems they experienced when they attempted to use buy-and-bill.

Stakeholders told us that access to MAT medications would be maximized if providers and beneficiaries are not restricted when choosing among the three distribution methods—and some states have removed such restrictions. Officials from one manufacturer told us that since 2016, nine states that required use of buy-and-bill for their medication have eliminated those requirements. Medicaid officials in North Carolina told us that because smaller medical practices do not want the inventory costs associated with buy-and-bill, the state has moved to allow providers to obtain the injectable buprenorphine through either buy-and-bill or a specialty pharmacy. According to the officials, this has resulted in the increased use of the medication. Similarly, Medicaid officials in the District of Columbia told us that prior to 2017, injectable MAT medications were only available through buy-and-bill—despite Medicaid reimbursements being lower than providers' costs. In 2017, these medications became available from specialty pharmacies.

---

<sup>28</sup>According to Minnesota Medicaid officials, this requirement is based on a payment-related state law that applies to all outpatient physician-administered medications, and is not specific to MAT medications. See Minnesota Statutes 2018, section 256B.0625, subdivision 13e(e).

---

---

## CMS Has Undertaken Opioid Coordination Efforts

CMS has undertaken various coordination efforts aimed generally at addressing OUD. These efforts include the following:

- **Opioid Steering Committee**—composed of CMS senior leadership and staff, according to agency officials—helps coordinate opioid policy across the agency. CMS officials told us that the bi-weekly committee meetings have included discussions about reducing barriers related to prior authorization, other utilization management practices, and implementation of the SUPPORT Act, among other opioid related topics.
- **Action Plan to Prevent Opioid Addiction and Enhance Access to MAT**—an effort by an interagency task force—is intended to address OUD barriers in Medicaid, among other things, as required by the SUPPORT Act.<sup>29</sup> In September 2019, CMS held a public meeting and requested public input to develop this action plan, which it plans to issue by January 2020, as mandated by the act.
- **State Opioid Workshop**, organized by CMS, brought together state officials to share innovative practices and discuss efforts to decrease barriers to accessing treatment for OUD, according to CMS officials. The second of such workshops was held in September 2018, and CMS documentation shows that the workshop included sessions focused on MAT, including a session on states' approaches to improving the availability and use of MAT through benefit, payment, and system design.
- **Informational bulletins** have been used by CMS to communicate information states need to manage their Medicaid programs, including recommended actions. For example, in July 2014, CMS issued a bulletin to states providing background information on MAT, examples of state-based initiatives to increase access to MAT, and resources to help ensure proper delivery of MAT services. In January 2016, CMS issued another bulletin that focused on best practices for addressing prescription opioid overdoses, misuse, and addiction, and urged states to take action to reduce the potentially dangerous usage of opioids used for pain. While this bulletin was not focused on MAT, it suggested generally that states consider reviewing benefits coverage and service utilization to ensure beneficiaries have sufficient access to MAT services, and indicated that

---

<sup>29</sup>The SUPPORT Act requires the Secretary of HHS, in collaboration with the HHS Pain Management Best Practices-Inter-Agency Task Force, to develop an action plan to prevent opioid addictions and enhance access to MAT. Pub. L. No. 115-271, § 6032, 132 Stat. 3894, 3978 (Oct. 24, 2018).

some benefit requirements, such as prior authorizations, can reduce the use of and access to MAT.

- **Drug Utilization Review Survey**, conducted annually by CMS, contains information that the agency publishes on states' activities related to all prescription drugs in the Medicaid program, including some limited information about MAT medications.
- **Other CMS efforts** also addressed Medicaid beneficiaries' access to MAT. In November 2017, CMS announced a new policy to increase flexibility for states seeking a section 1115 demonstration to improve access to and quality of OUD treatment for Medicaid beneficiaries.<sup>30</sup> CMS has approved section 1115 demonstrations that included OUD-related provisions for 26 states and the District of Columbia between August 2015 and November 2019. States implementing these demonstrations are expected to take action to ensure access to MAT for Medicaid beneficiaries, including by establishing a requirement that inpatient and residential settings provide access to MAT. CMS has also examined access to OUD treatment through its Innovation Accelerator Program, which provides resources to states to introduce delivery system and payment reforms in a variety of areas, including OUD.

---

## Requirements for Federal Waivers and State Laws Limit Who Can Administer the Medications

Our review of literature and interviews with stakeholders show that in addition to Medicaid policies, other federal and state policies can limit Medicaid beneficiaries' access to MAT medications.

### Waiver Requirements for Buprenorphine

According to stakeholders we interviewed and literature we reviewed, requirements associated with DATA 2000 waivers may limit the number of providers willing to prescribe or administer buprenorphine for MAT. Stakeholders and the literature note that providers may be reluctant to obtain the DATA 2000 waiver, due to the hours of training associated with

---

<sup>30</sup>Under section 1115 of the Social Security Act, the Secretary of HHS may waive certain federal Medicaid requirements and approve new types of expenditures that would not otherwise be eligible for federal Medicaid matching funds for experimental, pilot, or demonstration projects that, in the Secretary's judgment, are likely to promote Medicaid objectives.

the waiver and the cost of registering with the DEA after obtaining the waiver, among other things.

- According to officials from a stakeholder organization representing providers and providers in one of our selected states, the requirements to obtain a DATA 2000 waiver, including the associated hours of required training—ranging from 8 hours for physicians to 24 hours for nurse practitioners and physician assistants—contributes to perceptions that prescribing buprenorphine for the treatment of OUD is dangerous, particularly since waivers are not required to prescribe buprenorphine for pain management. A 2019 National Academy of Sciences report also notes that treatment with buprenorphine is less risky than many other OUD treatments that do not require special training.<sup>31</sup> Another study suggested that other opioids not used in the treatment of OUD—and not requiring special training—are more commonly misused, diverted, or responsible for overdoses, compared with buprenorphine.<sup>32</sup>
- All providers who prescribe controlled substances are required to register with DEA. For providers with a DATA waiver who wish to administer injectable or implantable buprenorphine in multiple office locations, the requirement that each office location be registered with DEA may be an additional burden, as these fees are \$731 for 3 years, according to DEA. DEA requires that the provider pay the registration fee for each location where controlled substances are stored, administered, or dispensed, which might not be recouped if only a small number of patients are treated at the various locations.<sup>33</sup>
- Stakeholders we interviewed and literature we reviewed also noted a concern among some health care providers that having a waiver would subject them to increased oversight from DEA and other law enforcement agencies. Specifically, officials from an organization representing addiction providers and providers in our selected states told us that the possibility of interaction with law enforcement can intimidate some providers and can be anxiety-provoking and disruptive. Literature we reviewed reported that this can lead to providers not pursuing a waiver or

---

<sup>31</sup>National Academy of Sciences, Engineering, and Medicine, *Medications for Opioid Use Disorder Save Lives* (Washington, D.C: 2019).

<sup>32</sup>R. L. Haffajee, A. S. B. Bohnert, and P. A. Lagisetty, "Policy Pathways to Address Provider Workforce Barriers to Buprenorphine Treatment," *American Journal of Preventive Medicine*, vol. 54 no. 6S3 (2018).

<sup>33</sup>Providers do not need to pay multiple registration fees to prescribe oral buprenorphine from different office locations within the same state.

ceasing to prescribe buprenorphine.<sup>34</sup> Surveys of health care providers have found similar concerns.<sup>35</sup>

These factors can create a potential treatment barrier for patients and beneficiaries by limiting the number of available providers, according to officials from an organization representing addiction providers we interviewed and literature we reviewed. The waivers also limit how many patients, including Medicaid beneficiaries, providers may treat with MAT medications. These limits may create an additional barrier to OUD treatment, particularly for providers who specialize in addiction medicine. Studies have consistently found that providers who have waivers treat fewer OUD patients than their waiver allows—and some may not accept new patients. For example:

- A 2016 study of rural physicians found that more than half of providers with waivers were not accepting new patients; those with a 30-patient waiver limit were treating an average of fewer than nine patients; and more than half of the providers with waivers were not treating any patients. Providers with a 100-patient waiver limit treated an average of 57 patients, although more than one-quarter were at or approaching their patient limit.<sup>36</sup>
- A survey of physicians, nurse practitioners, and physician assistants who obtained a waiver or increased their patient waiver limit in 2017 found that these providers were treating about one-third of their patient limit.<sup>37</sup>

Literature we reviewed noted that providers might not treat the maximum number of patients allowed by their waiver limit, because they are not specialists in addiction medicine, or they do not want to treat a larger number of patients with OUD. These providers may have obtained a

---

<sup>34</sup>See, for example, A. E. Woodruff, et al., “Dismantling Buprenorphine Policy Can Provide More Comprehensive Addiction Treatment,” *NAM Perspectives*, Commentary, National Academy of Medicine (Washington, D.C.: 2019).

<sup>35</sup>See Andrilla, Moore, and Patterson, “Overcoming Barriers”; Andraka-Christou and Capone, “A Qualitative Study”; Andrilla, Coulthard, and Larson, “Barriers Rural Physicians Face.”

<sup>36</sup>C. H. A. Andrilla, C. Coulthard, and D. G. Patterson, “Prescribing Practices of Rural Physicians Waivered to Prescribe Buprenorphine,” *American Journal of Preventive Medicine*, vol. 54, no. 6S3 (2018).

<sup>37</sup>C. M. Jones and E. F. McCance-Katz, “Characteristics and Prescribing Practices of Clinicians Recently Waivered to Prescribe Buprenorphine For the Treatment of Opioid Use Disorder,” *Addiction*, vol. 114 (2018).

waiver to respond to the needs of their existing patients who have OUD, rather than to add new patients.<sup>38</sup> In contrast, one of these studies and officials from one organization representing health care providers in addiction medicine we interviewed noted that there are providers who are addiction medicine specialists that cannot work a full-time schedule if they are only allowed to treat 275 patients, which is the maximum allowed under the waiver rules. The study projected that a capacity range of 378 to 524 patients would be necessary for providers to practice addiction medicine full time.<sup>39</sup>

CMS officials told us they have taken some steps to increase the number of providers with DATA 2000 waivers through funding new planning grants in 15 states, as authorized by the SUPPORT Act. According to CMS officials, the grants cover training expenses to help providers obtain the waiver, among other things.

### State Laws That Prevent Certain Providers from Prescribing MAT Medications

Federal laws allow certain non-physicians—such as nurse practitioners and physician assistants—to obtain a DATA 2000 waiver to prescribe and administer buprenorphine to treat OUD; however, some states' laws may restrict their ability to do so. These laws determine the type of health care services that can be provided by different types of providers. According to literature we reviewed and stakeholders we interviewed representing physician assistants and nurse practitioners, some state laws do not allow non-physicians to write prescriptions for any controlled substances and some specifically limit their ability to write prescriptions for buprenorphine for the treatment of OUD, while others may impose no restrictions for non-physicians beyond the federal training and patient limit requirement associated with the DATA 2000 waiver. For example, officials from an organization representing providers reported that physician assistants in some states, such as Kentucky and Tennessee, cannot prescribe buprenorphine for the treatment of OUD.<sup>40</sup> Further, according to officials

---

<sup>38</sup>See B. Albright, "How to Add Medication-Assisted Treatment Services," *Behavioral Healthcare*, vol. 36, no. 4 (2016); and A. G. Barthwell, et al., "What's In a Number? Recommending Practicality in the DATA 2000 Patient Limits," *Journal of Opioid Management*, vol. 12 no. 4 (2016).

<sup>39</sup>A. G. Barthwell, et al., "What's In a Number?"

<sup>40</sup>In Kentucky, physician assistants cannot prescribe controlled substances at all.

from another organization representing providers, most states require nurse practitioners to be supervised by or have a collaborative agreement with a physician. Thus, to prescribe buprenorphine for MAT, the nurse practitioners in these states must obtain a DATA 2000 waiver and have supervision from or a collaborative agreement with a physician. North Carolina Medicaid officials told us that physician assistants and nurse practitioners in the state that have a DATA 2000 waiver must consult with a physician, but do not need to have direct affiliation with a supervising physician.

The supervision requirements can affect patients' access to MAT, including for Medicaid beneficiaries, according to stakeholders. For example, officials from an organization representing providers told us that some nurse practitioners may find it difficult to identify a qualified physician with whom they can have a collaborative agreement. In the states where nurse practitioners are not required to collaborate with a physician, these officials also told us that they see higher percentages of nurse practitioners prescribing MAT medications.

---

## Conclusions

HHS has identified expanding access to medication-assisted treatment as a key component of its efforts to reduce opioid use disorder and opioid overdoses. Through our work, we identified state Medicaid policies and federal and state laws that may create barriers to treatment for Medicaid beneficiaries and other patients with OUD by restricting access to MAT medications. We also identified efforts by states and CMS to address these barriers. Under federal law, state Medicaid programs are required to cover all formats of MAT medications reviewed in our study, because all manufacturers of those medications participate in the Medicaid Drug Rebate Program. In addition, the SUPPORT Act will mandate broader coverage of MAT beginning in October 2020. However, a study by SAMHSA found that nearly half of all state Medicaid programs do not cover all formats of MAT medications in our review. Yet, CMS has not taken steps to determine whether state Medicaid programs do cover all of these MAT medications and their formats, as required. Until CMS determines the extent to which state Medicaid programs cover all MAT medications, as required—and address coverage gaps when found—Medicaid beneficiaries may not be able to obtain the most effective medications to treat their opioid use disorder.

---

## Recommendations for Executive Action

We are making the following recommendation to CMS:

The Administrator of CMS should determine the extent to which state Medicaid programs are in compliance with federal requirements to cover MAT medications in all formats and take actions to ensure compliance, as appropriate. (Recommendation 1)

---

## Agency Comments

We provided a draft of this report to HHS for review. HHS provided written comments which are reprinted in appendix I. HHS also provided technical comments, which we incorporated as appropriate. In its written comments, HHS concurred with our recommendation. Specifically, HHS stated that it will examine the extent to which state Medicaid programs are in compliance with the requirements of the Medicaid Drug Rebate Program as it relates to the coverage of MAT medications and take actions to ensure compliance, as appropriate. HHS also reiterated its plans to develop guidance for states on the SUPPORT Act's new requirement for states to cover MAT medications.

We are sending copies of this report to the appropriate congressional committees, the Secretary of the Health and Human Services, and other interested parties. In addition, the report is available at no charge on the GAO website at <http://www.gao.gov>.

If you or your staff have any questions about this report, please contact me at (202) 512-7114 or [DeniganMacauleyM@gao.gov](mailto:DeniganMacauleyM@gao.gov). Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix II.



Mary Denigan-Macauley  
Director, Health Care

---

# Appendix I: Comments from the Department of Health and Human Services

**Appendix I: Comments from the Department of Health and Human Services**



DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation  
Washington, DC 20201

Mary Denigan-Macauley  
Director, Health Care  
U.S. Government Accountability Office  
441 G Street NW  
Washington, DC 20548

JAN 08 2020

Dear Ms. Denigan-Macauley:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, "*OPIOID USE DISORDER: Barriers to Medicaid Beneficiaries' Access to Treatment Medications*" (GAO-20-233).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

A handwritten signature in blue ink, appearing to read "Sarah Arbes".

Sarah Arbes  
Acting Assistant Secretary for Legislation

Attachment

**GENERAL COMMENTS FROM THE DEPARTMENT OF HEALTH & HUMAN SERVICES ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED – OPIOID USE DISORDER: BARRIERS TO MEDICAID BENEFICIARIES' ACCESS TO TREATMENT MEDICATIONS (GAO-20-233)**

The U.S. Department of Health & Human Services (HHS) appreciates the opportunity from the Government Accountability Office (GAO) to review and comment on this draft report examining opioid use disorder and barriers to Medicaid beneficiaries' access to Medication-Assisted Treatment (MAT). HHS is committed to combatting the opioid epidemic and ensuring that Medicaid beneficiaries have access to the addiction treatment medications they need.

Substance Use Disorders (SUD) impact the lives of millions of Americans in the general population, including individuals that are enrolled in the Medicaid program. Nearly 12 percent of Medicaid beneficiaries over 18 have a SUD, and HHS is committed to helping states effectively serve Medicaid beneficiaries with SUDs. Additionally, the recently-enacted Substance Use-Disorder Prevention that Promotes Recovery and Treatment for Patients and Communities Act (SUPPORT for Patients and Communities Act) (Public Law 115-271) includes several measures to combat the opioid crisis by advancing treatment and recovery initiatives, improving prevention, protecting communities, and bolstering efforts to fight deadly illicit synthetic drugs.

As the GAO notes in its report, HHS has created a comprehensive approach to combat the opioid crisis that focuses on prevention, treatment, and data. One initiative that HHS has already implemented as part of this comprehensive approach is the approval of section 1115 demonstrations designed to improve access to SUD treatment, including new flexibility to cover inpatient and residential treatment, for Medicaid beneficiaries. These demonstrations require that states take action to improve access to Medication Assisted Treatment (MAT) in those settings as well as throughout their states. HHS has also recently awarded planning grants to 15 states intended to increase the capacity of Medicaid providers to deliver SUD treatment or recovery services, including MAT, consistent with section 1003 of the SUPPORT Act. In addition, HHS is developing guidance for states on section 1006(b) of the SUPPORT for Patients and Communities Act, which establishes a new mandatory Medicaid benefit requiring states to cover all FDA-approved drugs to treat opioid use disorder for categorically needy beneficiaries, as well as related counseling and behavioral therapy, from October 1, 2020 to September 30, 2025, with a narrow exception for states that certify statewide access is not feasible. Through technical assistance and support programs such as the State Opioid Workshop, which has provided state officials with the opportunity to share innovative practices designed to improve access to SUD treatment, HHS can help states to effectively design, deliver and pay for services to treat SUD for Medicaid beneficiaries.

There is strong evidence that MAT provides substantial cost savings and leads to improved quality of life and health outcomes for individuals with SUDs. As noted in the GAO's report, many state Medicaid programs have implemented policies, such as prior authorization requirements, to help manage the prescribing and distribution of addiction medications and delivery of evidence-based behavioral therapies. HHS is committed to working with states to determine if MAT coverage policies are aligned with statutory requirements so that policies do not significantly impact beneficiary access while also effectively reinforcing program integrity.

The Medicaid Drug Rebate program requires that state Medicaid programs cover all of a participating manufacturer's Covered Outpatient Drugs when prescribed for a medically accepted indication. As a result, states must cover all formats of MAT medications that are Covered Outpatient Drugs produced by participating manufacturers when prescribed for a

**GENERAL COMMENTS FROM THE DEPARTMENT OF HEALTH & HUMAN SERVICES ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED – OPIOID USE DISORDER: BARRIERS TO MEDICAID BENEFICIARIES' ACCESS TO TREATMENT MEDICATIONS (GAO-20-233)**

medically accepted indication. HHS will work to ensure that state Medicaid agencies are complying with these requirements so that beneficiaries are able to access effective MAT medications.

The GAO's recommendation and HHS' response is below.

**GAO Recommendation**

The Administrator of CMS should determine the extent to which state Medicaid programs are in compliance with federal requirements to cover MAT medications in all formats and take actions to ensure compliance, as appropriate.

**HHS Response**

HHS concurs with the GAO's recommendation. HHS will examine the extent to which state Medicaid programs are in compliance with the requirements of the Medicaid Drug Rebate program as it relates to coverage of MAT medications. HHS will take actions to ensure compliance, as appropriate, within our authority.

---

# Appendix II: GAO Contact and Staff Acknowledgments

---

## GAO Contact

Mary Denigan-Macauley, (202) 512-7114 or  
[DeniganMacauleyM@gao.gov](mailto:DeniganMacauleyM@gao.gov)

---

## Staff Acknowledgments

In addition to the contact named above, Will Simerl (Assistant Director), Carolyn Feis Korman (Analyst-in-Charge), Rebecca Hendrickson, Shirin Hormozi, Virginia Lefever, Drew Long, Leslie McNamara, and Carla Miller made key contributions to this report. Also contributing were Leia Dickerson, Carolyn Garvey, Ethiene Salgado-Rodriguez, and Emily Wilson Schwark.

---

# Appendix III: Accessible Data

---

## Agency Comment Letter

---

Accessible Text for Appendix I Comments from the  
Department of Health and Human Services

Page 1

Mary Denigan-Macauley Director, Health Care

U.S. Government Accountability Office

441 G Street NW

Washington, DC 20548

JAN 8 2020

Dear Ms. Denigan-Macauley:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, "OPIOID USE DISORDER: Barriers to Medicaid Beneficiaries' Access to Treatment Medications" (GAO-20-233).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

Sarah Arbes

Acting Assistant Secretary for Legislation

Attachment

Page 2

The U.S. Department of Health & Human Services (HHS) appreciates the opportunity from the Government Accountability Office (GAO) to review

and comment on this draft report examining opioid use disorder and barriers to Medicaid beneficiaries' access to Medication-Assisted Treatment (MAT). HHS is committed to combatting the opioid epidemic and ensuring that Medicaid beneficiaries have access to the addiction treatment medications they need.

Substance Use Disorders (SUD) impact the lives of millions of Americans in the general population, including individuals that are enrolled in the Medicaid program. Nearly 12 percent of Medicaid beneficiaries over 18 have a SUD, and HHS is committed to helping states effectively serve Medicaid beneficiaries with SUDs. Additionally, the recently-enacted Substance Use- Disorder Prevention that Promotes Recovery and Treatment for Patients and Communities Act (SUPPORT for Patients and Communities Act) (Public Law 115-271) includes several measures to combat the opioid crisis by advancing treatment and recovery initiatives, improving prevention, protecting communities, and bolstering efforts to fight deadly illicit synthetic drugs.

As the GAO notes in its report, HHS has created a comprehensive approach to combat the opioid crisis that focuses on prevention, treatment, and data. One initiative that HHS has already implemented as part of this comprehensive approach is the approval of section 1115 demonstrations designed to improve access to SUD treatment, including new flexibility to cover inpatient and residential treatment, for Medicaid beneficiaries. These demonstrations require that states take action to improve access to Medication Assisted Treatment (MAT) in those settings as well as throughout their states. HHS has also recently awarded planning grants to 15 states intended to increase the capacity of Medicaid providers to deliver SUD treatment or recovery services, including MAT, consistent with section 1003 of the SUPPORT Act. In addition, HHS is developing guidance for states on section 1006(b) of the SUPPORT for Patients and Communities Act, which establishes a new mandatory Medicaid benefit requiring states to cover all FDA-approved drugs to treat opioid use disorder for categorically needy beneficiaries, as well as related counseling and behavioral therapy, from October 1, 2020 to September 30, 2025, with a narrow exception for states that certify statewide access is not feasible. Through technical assistance and support programs such as the State Opioid Workshop, which has provided state officials with the opportunity to share innovative practices designed to improve access to SUD treatment, HHS can help states to effectively design, deliver and pay for services to treat SUD for Medicaid beneficiaries.

There is strong evidence that MAT provides substantial cost savings and leads to improved quality of life and health outcomes for individuals with SUDs. As noted in the GAO's report, many state Medicaid programs have implemented policies, such as prior authorization requirements, to help manage the prescribing and distribution of addiction medications and delivery of evidence-based behavioral therapies. HHS is committed to working with states to determine if MAT coverage policies are aligned with statutory requirements so that policies do not significantly impact beneficiary access while also effectively reinforcing program integrity.

The Medicaid Drug Rebate program requires that state Medicaid programs cover all of a participating manufacturer's Covered Outpatient Drugs when prescribed for a medically accepted indication. As a result, states must cover all formats of MAT medications that are Covered Outpatient Drugs produced by participating manufacturers when prescribed for a

### Page 3

medically accepted indication. HHS will work to ensure that state Medicaid agencies are complying with these requirements so that beneficiaries are able to access effective MAT medications.

The GAO's recommendation and HHS' response is below.

#### GAO Recommendation

The Administrator of CMS should determine the extent to which state Medicaid programs are in compliance with federal requirements to cover MAT medications in all formats and take actions to ensure compliance, as appropriate.

#### HHS Response

HHS concurs with the GAO's recommendation. HHS will examine the extent to which state Medicaid programs are in compliance with the requirements of the Medicaid Drug Rebate program as it relates to coverage of MAT medications. HHS will take actions to ensure compliance, as appropriate, within our authority.

---

---

## GAO's Mission

The Government Accountability Office, the audit, evaluation, and investigative arm of Congress, exists to support Congress in meeting its constitutional responsibilities and to help improve the performance and accountability of the federal government for the American people. GAO examines the use of public funds; evaluates federal programs and policies; and provides analyses, recommendations, and other assistance to help Congress make informed oversight, policy, and funding decisions. GAO's commitment to good government is reflected in its core values of accountability, integrity, and reliability.

---

## Obtaining Copies of GAO Reports and Testimony

The fastest and easiest way to obtain copies of GAO documents at no cost is through our website. Each weekday afternoon, GAO posts on its [website](#) newly released reports, testimony, and correspondence. You can also [subscribe](#) to GAO's email updates to receive notification of newly posted products.

---

## Order by Phone

The price of each GAO publication reflects GAO's actual cost of production and distribution and depends on the number of pages in the publication and whether the publication is printed in color or black and white. Pricing and ordering information is posted on GAO's website, <https://www.gao.gov/ordering.htm>.

Place orders by calling (202) 512-6000, toll free (866) 801-7077, or TDD (202) 512-2537.

Orders may be paid for using American Express, Discover Card, MasterCard, Visa, check, or money order. Call for additional information.

---

## Connect with GAO

Connect with GAO on [Facebook](#), [Flickr](#), [Twitter](#), and [YouTube](#).  
Subscribe to our [RSS Feeds](#) or [Email Updates](#). Listen to our [Podcasts](#).  
Visit GAO on the web at <https://www.gao.gov>.

---

## To Report Fraud, Waste, and Abuse in Federal Programs

Contact FraudNet:

Website: <https://www.gao.gov/fraudnet/fraudnet.htm>

Automated answering system: (800) 424-5454 or (202) 512-7700

---

---

## Congressional Relations

Orice Williams Brown, Managing Director, [WilliamsO@gao.gov](mailto:WilliamsO@gao.gov), (202) 512-4400,  
U.S. Government Accountability Office, 441 G Street NW, Room 7125,  
Washington, DC 20548

---

## Public Affairs

Chuck Young, Managing Director, [youngc1@gao.gov](mailto:youngc1@gao.gov), (202) 512-4800  
U.S. Government Accountability Office, 441 G Street NW, Room 7149  
Washington, DC 20548

---

## Strategic Planning and External Liaison

James-Christian Blockwood, Managing Director, [spel@gao.gov](mailto:spel@gao.gov), (202) 512-4707  
U.S. Government Accountability Office, 441 G Street NW, Room 7814,  
Washington, DC 20548



**Please Print on Recycled Paper.**