

Report to Congress: Utilization Management of Medication-Assisted Treatment in Medicaid

OCTOBER 2019



MACPAC

Medicaid and CHIP Payment
and Access Commission

About MACPAC

The Medicaid and CHIP Payment and Access Commission (MACPAC) is a non-partisan legislative branch agency that provides policy and data analysis and makes recommendations to Congress, the Secretary of the U.S. Department of Health and Human Services, and the states on a wide array of issues affecting Medicaid and the State Children's Health Insurance Program (CHIP). The U.S. Comptroller General appoints MACPAC's 17 commissioners, who come from diverse regions across the United States and bring broad expertise and a wide range of perspectives on Medicaid and CHIP.

MACPAC serves as an independent source of information on Medicaid and CHIP, publishing issue briefs and data reports throughout the year to support policy analysis and program accountability. The Commission's authorizing statute, 42 USC 1396, outlines a number of areas for analysis, including:

- payment;
- eligibility;
- enrollment and retention;
- coverage;
- access to care;
- quality of care; and
- the programs' interaction with Medicare and the health care system generally.

MACPAC's authorizing statute also requires the Commission to submit reports to Congress by March 15 and June 15 of each year. In carrying out its work, the Commission holds public meetings and regularly consults with state officials, congressional and executive branch staff, beneficiaries, health care providers, researchers, and policy experts.

Report to Congress: Utilization Management of Medication-Assisted Treatment in Medicaid

OCTOBER 2019

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The Honorable Mike Pence
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The Honorable Nancy Pelosi
Speaker of the House
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Dear Mr. Vice President and Madam Speaker:

On behalf of the Medicaid and CHIP Payment and Access Commission (MACPAC), I am pleased to submit this report to Congress on *Utilization Management of Medication-Assisted Treatment in Medicaid*.

In 2018, Congress, in the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act, P.L. 115-271), directed MACPAC to conduct a study of state Medicaid utilization management policies that may affect access to medication-assisted treatment (MAT). This report responds to that directive.

MAT combines medication with counseling or behavioral therapies to treat individuals with various substance use disorders, most notably opioid use disorder (OUD). Given the strong evidence of MAT's effectiveness in promoting health and preventing relapse and overdose, many state Medicaid agencies have enacted policies to enhance access to such treatment. At the same time, concerns have arisen as to whether utilization management policies, which states use to ensure appropriate care, control costs, and prevent waste, fraud, and abuse, are creating barriers to essential care.

MACPAC's analysis looked at national trends and considered the approaches taken by eight states—Arkansas, Illinois, Maine, Missouri, Tennessee, Utah, Washington, and West Virginia—under both fee for service and managed care. We also sought to differentiate various utilization management techniques and the extent to which they affect the ability of beneficiaries to obtain care when they are ready to seek treatment.

Overall, we found that utilization management policies vary widely among states, but the extent to which these policies pose barriers to MAT access is unclear. For example, some states have removed medications used in MAT from preferred drug lists, which may make it more difficult for patients with Medicaid to gain access to these drugs. At the same time, we found a trend toward reduced use of prior authorization, which would ease an important barrier to access.

Our analysis further suggests that although more Medicaid beneficiaries are getting needed treatment, a large treatment gap remains. Medicaid prescriptions for MAT medications increased substantially from 2013 to 2017: buprenorphine

prescriptions nearly tripled, from approximately 1.8 million to 5.2 million, and naltrexone prescriptions more than quadrupled, from 99,000 to 444,000. At the same time, less than half (44 percent) of Medicaid beneficiaries under age 65 with OUD received any substance use disorder treatment in 2017.

Chapter 1 of this report provides more information about the components of MAT, including medications used for opioid and alcohol use disorders and the role of counseling. It also summarizes federal regulations related to these medications. Chapter 2 describes Medicaid coverage of the components of MAT in all 50 states and the District of Columbia. Chapter 3 presents the findings of our review of state utilization management policies and how these policies have been changed. In Chapter 4, we describe how managed care organizations are complying with federal law that permits them to apply utilization control policies for MAT. In the final chapter, we focus on state programs that influence access to MAT but are not, strictly speaking, utilization management techniques: prescription drug monitoring programs and pharmacy and provider lock-in programs.

MACPAC is committed to providing in-depth, non-partisan analyses of Medicaid and CHIP policy, and we hope this report will prove useful to Congress as it considers future policy developments affecting Medicaid. This document fulfills our statutory mandate to report within one year of the enactment of the SUPPORT Act.

Sincerely,



Melanie Bella, MBA
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Special thanks to Medicaid officials from Arkansas, Illinois, Maine, Missouri, Tennessee, Utah, Washington, and West Virginia for taking the time to speak with us regarding their state's MAT utilization management policies. Their comments and feedback helped provide significant detail and clarity as to how these policies are developed and implemented.

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Utilization Management of Medication-Assisted Treatment in Medicaid

Key Points

- State Medicaid programs implement utilization management policies to ensure the delivery of appropriate care and to address other goals, such as controlling costs and reducing the potential for fraud, waste, and abuse of program resources.
- As Medicaid programs seek to increase access to medication-assisted treatment (MAT) for beneficiaries with substance use disorders, concerns have arisen as to whether utilization management policies create barriers to access.

Major findings

- In this statutorily required report, MACPAC analyzes Medicaid utilization management policies, looking at both national trends and state-level policies. Overall, we found that such policies vary widely not only among states but also within states for different medications.
- It is difficult to assess the extent to which these policies affect MAT access. Beneficiary access is also influenced by other factors, including stigma and the availability of providers trained and authorized to prescribe such medications.
- Utilization management policies for MAT may be more stringent than those for other types of services given concerns about the potential for the diversion of controlled substances.
- States and managed care organizations (MCOs) typically apply more utilization management policies—particularly prior authorization—to medications than to counseling.
- Generally, states apply fewer utilization management policies to medications used to treat alcohol use disorder than to those used to treat opioid use disorder.
- Although drugs placed on a state’s preferred drug list are not typically subject to prior authorization, some states still require prior authorization for certain preferred MAT drugs.
- Medicaid MCO utilization management policies for MAT are consistent with federal regulations that permit MCOs to impose such policies.

State policies are changing

- Fewer states assigned preferred status to MAT drugs in 2018 than in 2011–2013, which may affect care.
- On the other hand, the number of states requiring prior authorization for these drugs decreased over the same time period.

- Some states have eliminated lifetime limits and requirements that patients undergo psychosocial counseling when prescribed certain drugs.

Use of MAT is growing but barriers to treatment still exist

- More Medicaid beneficiaries are getting needed treatment. Medicaid prescriptions for MAT medications increased dramatically from 2013 to 2017: buprenorphine prescriptions nearly tripled, from approximately 1.8 million to 5.2 million, and naltrexone prescriptions more than quadrupled, from 99,000 to 444,000.
- However, a large treatment gap remains. In 2017, less than half (44 percent) of Medicaid beneficiaries under age 65 with opioid use disorder received any substance use disorder treatment.

Overview: Utilization Management of Medication-Assisted Treatment in Medicaid

Medicaid has been at the center of the opioid epidemic that has gripped the nation over the past several years. As noted in MACPAC's March 2017 report to Congress, compared to individuals covered by other sources of insurance, Medicaid beneficiaries have higher rates of opioid use disorder (OUD), are prescribed opioids at higher rates, and have a higher risk of overdose and other adverse health outcomes (MACPAC 2017).

Medicaid is fighting the opioid epidemic on a variety of fronts. Coverage of substance use disorder (SUD) treatment and supportive services varies from state to state. States are working to integrate the treatment of SUDs with physical health, as well as with other social programs. States also are implementing programs to reduce opioid overprescribing with the goal of preventing OUD from developing in the first place (MACPAC 2017).

As part of this effort, many state Medicaid agencies have enacted policies to promote access to medication-assisted treatment (MAT). MAT combines medication with counseling or behavioral therapies to treat individuals with OUD; the evidence for its effectiveness in promoting health and preventing relapse and overdose is strong (NASEM 2019). MAT can also be used to treat individuals with alcohol use disorder (OSG 2016).

But despite evidence of its efficacy, widespread adoption of MAT by Medicaid and other payers faces certain obstacles. These obstacles include stigma, low provider payment rates, lack of provider training, insufficient availability of providers with relevant training and capacity across geographic areas, restrictive state scope-of-practice laws, and preferences among some providers and patients for abstinence-based approaches to SUD treatment (Hinde et al. 2018, Jones et al. 2018).

Certain populations, such as those in the criminal justice system or in residential treatment facilities, may have limited access to treatment (NASEM 2019). In addition, Medicaid beneficiaries may experience more difficulty finding a practice that will take them as a new patient or that can provide rapid access to treatment than patients with private insurance or willing to pay out of pocket (Beetham et al. 2019). Finally, Medicaid utilization management policies may also be creating unnecessary barriers to further adoption of MAT (Sadwith et al. 2019).

States use utilization management policies to ensure the delivery of appropriate care, but also to address other goals, such as reducing the potential for fraud, waste, and abuse and controlling program costs. Although utilization management policies are used for a variety of medications and services for other conditions, utilization management policies for MAT may be more stringent given concerns about the potential for the diversion of controlled substances.

This report responds to a statutory requirement in Section 1014 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act, P.L. 115-271) that MACPAC conduct a study on MAT utilization control policies that may affect access to clinically appropriate treatment. Our analysis looked at national trends and considered the approaches taken by specific states under both fee for service (FFS) and managed care. We also sought to differentiate various utilization management techniques and the extent to which they affect the ability of beneficiaries to obtain care when they are ready to seek treatment.

Overall, we found that utilization management policies vary widely among states but found it difficult to assess the extent to which these policies pose barriers to MAT access. For example:

- States and managed care organizations (MCOs) typically apply more utilization management policies—particularly prior authorization—to medications than to counseling.
- Generally, states apply fewer utilization management policies to medications used to treat alcohol use disorder than those used to treat OUD. Specifically, few states apply quantity or dosing limits for alcohol use disorder drugs.
- Although drugs placed on a state’s preferred drug list typically are not subject to prior authorization, some states still require prior authorization for certain preferred MAT drugs.
- Fewer states assigned preferred status to MAT drugs in 2018 than in 2011–2013. For example, 44 states assigned preferred status to oral naltrexone in 2018, down from 50 states and the District of Columbia in 2011–2013, which may be making it more difficult for beneficiaries to access this drug.
- On the other hand, the number of states requiring prior authorization for MAT medications decreased from 48 in 2011–2013 to 30 in 2018.
- State Medicaid agencies are also changing other utilization management policies, such as eliminating lifetime limits and removing requirements that patients undergo psychosocial counseling when prescribed certain drugs.

We also found that Medicaid prescriptions for MAT medications increased dramatically from 2013 to 2017: buprenorphine prescriptions nearly tripled, from approximately 1.8 million to 5.2 million, and

naltrexone prescriptions more than quadrupled, from 99,000 to 444,000 (Clemans-Cope 2019).

These trends suggest that more people are getting needed treatment. Although more people are receiving medications for OUD, a large treatment gap remains. In 2017, only 44 percent of Medicaid beneficiaries under age 65 with OUD received any SUD treatment (Orgera 2019).

Our study found that, with the increase in drug prescriptions, states are implementing stricter utilization management policies for opioids, and some of these policies may also apply to MAT medications:

- Eight states implemented policies in 2016 that require providers to check prescription drug monitoring programs before prescribing any controlled substance (Blackman 2017).
- States are adding quantity or dosing limits. From 2011–2013 to 2018, the number of states applying quantity limits for MAT medications increased from 3 to 16 states for extended-release injectable naltrexone, and from 34 to 46 states for buprenorphine-naloxone. Some states cited concerns about patient safety in justifying these measures.

The net effects of these state policy changes on access to MAT are unclear.

It is also important to note that other factors also influence the availability of MAT. Unlike other chronic illnesses, SUDs are widely stigmatized, which can affect provider willingness to offer MAT. Federal regulations designating provider types and places of service where MAT can be delivered also affect access. These regulations include the waiver requirement for buprenorphine prescribing and strict rules for opioid treatment programs (OTPs) that administer methadone.

Our review of managed care contracts found no evidence that MCOs are imposing utilization controls that are more stringent than permitted under federal law.

Below we provide an overview of the study requirements and MACPAC's approach to data collection and analysis. Chapter 1 provides more information about the components of MAT, including medications used for opioid and alcohol use disorders and the role of counseling. It also summarizes federal regulations related to these medications. Chapter 2 describes Medicaid coverage of the components of MAT in all 50 states and the District of Columbia. Chapter 3 presents the findings of our review of state utilization management policies and how these policies have been changed. In Chapter 4, we describe how MCOs are complying with federal law that permits them to apply utilization control policies for MAT. In the final chapter, we focus on state programs that influence access to MAT but are not, strictly speaking, utilization management techniques: prescription drug monitoring programs and pharmacy and provider lock-in programs.

Statutory Mandate for the MACPAC Study

The SUPPORT Act requires MACPAC to conduct a study of state Medicaid utilization control policies for MAT that may hinder or promote access to clinically appropriate treatment of SUDs (Appendix). Specifically, MACPAC's examination of policies and procedures that are applied in both Medicaid FFS and managed care arrangements must do the following:

- identify policies that limit an individual's access to MAT through prescription quantity limits or refill limits that apply without evaluating individual instances of fraud, waste, and abuse;
- include an inventory of utilization control policies and related protocols for ensuring access to medically necessary treatment; and

- determine whether Medicaid MCO utilization control policies and procedures for MAT are consistent with federal regulations that permit MCOs to impose such policies, provided that the affected services are sufficient in amount, duration, and scope to reasonably achieve their purpose and are authorized for individuals with chronic conditions in a manner that reflects their ongoing need.

To respond to this mandate, MACPAC reviewed available data on how utilization management of MAT is used in Medicaid programs and conducted interviews with industry experts, clinicians, and state officials.¹ We also examined in detail the utilization management policies of eight states to supplement our review of other data sources (Box O-1). These states were chosen to reflect diversity across several dimensions, including: whether the state had an approved SUD demonstration waiver under Section 1115 of the Social Security Act; the number of covered MAT medications and services in the state's SUD treatment continuum; recent changes to and known variations in utilization management policies for MAT medications; geography; and whether behavioral health services were delivered through managed care or FFS.

To verify the information collected from policy documents, MACPAC conducted brief telephone interviews with Medicaid program officials from all eight states, including medical directors, pharmacy staff, and behavioral health program managers. To further understand how utilization management policies for MAT are used, we interviewed relevant staff from the Centers for Medicare & Medicaid Services and representatives and members of trade associations including the American Society of Addiction Medicine, the Association for Community Affiliated Plans, and the Association for Behavioral Health and Wellness.

BOX 0-1. Eight States Selected for Medication-Assisted Treatment Utilization Management Review

Arkansas. In early 2019, Arkansas implemented the Provider-led Arkansas Shared Savings Entity (PASSE) program in an effort to shift service delivery for enrollees with significant behavioral health needs to a managed care model. Arkansas is one of two states in our review whose Medicaid program does not cover methadone treatment in opioid treatment programs (OTPs). Two buprenorphine formulations have preferred status on the state's Medicaid preferred drug list, but they require prior authorization.

Illinois. Nearly 80 percent of Illinois Medicaid enrollees are enrolled in managed care. Effective January 2017, by state legislative mandate, all medication-assisted treatment (MAT) drugs approved by the Food and Drug Administration for opioid use disorder (OUD) and alcohol use disorder must be covered through both fee for service (FFS) and managed care without prior authorization or lifetime limits. In addition, methadone treatment in OTPs is covered under both FFS and managed care. The state received federal approval in 2018 for a behavioral health demonstration under Section 1115 of the Social Security Act that includes substance use disorder (SUD) treatment and recovery support services.

Maine. Half of Medicaid beneficiaries in Maine receive services through a primary care case management model. MAT services are delivered in office-based settings, OTPs, and opioid health homes. Pharmacy and counseling services are delivered through FFS. In February 2019, Maine announced that it will apply for a Section 1115 SUD demonstration.

Missouri. Nearly all Missouri Medicaid beneficiaries are enrolled in managed care. However, pharmacy and SUD treatment services (including MAT) are delivered through FFS.

Tennessee. Nearly all Medicaid beneficiaries in Tennessee are enrolled in managed care, but the pharmacy benefit is delivered through FFS. Tennessee is one of two states in our review whose Medicaid program does not cover methadone treatment in OTPs. Two buprenorphine-naloxone products have preferred status on the state's Medicaid preferred drug list, but they require prior authorization. In June 2019, Tennessee applied for a Section 1115 SUD demonstration.

Utah. Nearly all Medicaid enrollees in Utah are enrolled in managed care. The pharmacy benefit for SUD drugs and OTP services are delivered through FFS. The state operates prepaid mental health plans for behavioral health services, although these plans do not cover inpatient withdrawal management. In March 2019, Utah received approval for a Section 1115 SUD demonstration.

Washington. Nearly all Medicaid beneficiaries in Washington are enrolled in managed care. Integrated managed care (IMC) plans operate behavioral health services-only plans for beneficiaries not eligible for managed care; for counties without IMC plans, behavioral health services are generally carved out to behavioral health organizations. The state has an approved Section 1115 SUD demonstration.

West Virginia. More than 80 percent of Medicaid beneficiaries in West Virginia are enrolled in managed care; however, OTP services, which the state recently began paying for, are paid for under FFS. The state has an approved Section 1115 SUD demonstration.

The approach and data sources used for different study elements are described below.

Quantity and refill limits. To identify quantity limits and refill limits placed on MAT medications, we relied on the findings of a 2018 study sponsored by the Substance Abuse and Mental Health Services Administration (SAMHSA), *Medicaid Coverage of Medication-Assisted Treatment for Alcohol and Opioid Use Disorders and of Medication for the Reversal of Opioid Overdose* (SAMHSA 2018). The study analyzed 2018 coverage and utilization management policies for MAT medications in Medicaid FFS and selected MCOs in the 50 states, the District of Columbia, Puerto Rico, and the U.S. Virgin Islands.

Inventory of utilization control policies.

The SAMHSA study also identified MAT medications and the number of states with utilization management policies that rely on preferred status, prior authorization, step therapy, and quantity limits (SAMHSA 2018). We supplemented the findings of this study with our own analysis of policies in eight states. For the counseling component of MAT, we drew on MACPAC work that documented coverage of SUD treatment services in all 50 states and the District of Columbia (MACPAC 2018). We then reviewed publicly available documents (e.g., provider manuals and member benefit handbooks) to identify frequency limits, rules affecting eligibility of providers, and prior authorization requirements. For states that carve out some or all of the behavioral health benefit to a managed behavioral health organization (BHO), MACPAC also reviewed BHO policies.² For states with MCOs or BHOs, we reviewed the most recently available documents of the plan with the largest Medicaid enrollment.

MCO policies and procedures. To determine whether MCO policies and procedures are consistent with federal regulations related to state Medicaid MCO contracts, we reviewed contract language in the selected states and identified instances in which contracts specify additional conditions beyond the federal requirements.

Study limitation. Prescription drugs and counseling services are subject to the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (P.L. 110-343). This law generally prevents certain health insurance plans that provide behavioral health or SUD benefits from applying limits on those benefits that are more restrictive than the limits applied to medical or surgical benefits. However, although this law applies to Medicaid coverage of medications and services that are used in MAT, a review of the law and an analysis of medical and surgical benefits in comparison with behavioral health benefits at the state level is beyond the scope of this report.

Endnotes

¹ MACPAC's examination of utilization management for MAT included a panel discussion at the January 2019 Commission meeting. Panelists brought perspectives from clinical settings, health plans, and state Medicaid programs. They discussed MAT utilization management policies in Medicaid and the effect of these policies on beneficiary access to treatment (Alvanzo 2019, Hoover 2019, San Bartolome 2019).

² In a carve out, the managed care organization excludes certain specialty services from its coverage, and management and delivery of these services is assumed by a different organization.

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Chapter 1:

Regulation and Use of Medication- Assisted Treatment

CHAPTER 1: Regulation and Use of Medication-Assisted Treatment

National evidence-based treatment guidelines recommend the use of medication-assisted treatment (MAT), which combines medication with counseling or behavioral therapies, for individuals with opioid use disorder (OUD). When used correctly, MAT for OUD can increase patient retention in treatment, restore healthy functioning, lessen criminal activity, and reduce infectious disease transmission and the risk of overdose and death (SAMHSA 2018a, OSG 2016). A National Academies of Sciences, Engineering, and Medicine report stated simply: “FDA-approved medications to treat opioid use disorder are effective and save lives” (NASEM 2019).

The U.S. Food and Drug Administration (FDA) has approved several medications to treat OUD and alcohol use disorder.¹ Other federal agencies regulate conditions under which some medications for treatment of OUD can be prescribed and dispensed. For example, federally designated opioid treatment programs (OTPs) are overseen by the Substance Abuse and Mental Health Services Administration (SAMHSA) and they must also register with the U.S. Drug Enforcement Administration and meet state licensing requirements (SAMHSA 2015a, 2015b).

Each medication approved for the treatment of OUD or alcohol use disorder has specific physiological effects and its own risks and benefits. Each drug is not necessarily interchangeable with any other drug (VA/DoD 2015). For example, some medications work by reducing cravings or by blocking or blunting the rewarding effects of opioids or alcohol; one produces negative effects if alcohol is consumed; and some may require withdrawal or abstinence for a period of time before they can be used. Clinical guidelines note that the prescriber and patient should share the decision in selecting a treatment, considering the patient’s preferences, resources, motivating factors, and stage of change;

past treatment history; potential for relapse; other medical and psychiatric problems; pregnancy; and treatment setting (ASAM 2015, SAMHSA and NIAAA 2015). MAT must be highly individualized, and treatment duration varies based on the medication and the person (ASAM 2015, SAMHSA 2018a).

This chapter describes available medications for OUD and alcohol use disorder, including physiological effects and formulations (Table 1-1). We also discuss federal regulation of MAT drugs and clinical guidelines for appropriate use of these medications.

Medications for Opioid Use Disorder Treatment

There are three FDA-approved medications for OUD treatment: methadone, buprenorphine, and naltrexone. These medications can be described as agonists, partial agonists, or antagonists. Agonists, such as methadone, produce euphoric effects to relieve withdrawal symptoms and reduce or even extinguish cravings. Partial agonists, such as buprenorphine, also produce euphoric effects to diminish withdrawal symptoms, but these effects are weaker than the effects of full agonists like methadone. In contrast, antagonists, such as naltrexone, prevent the brain from responding to opioids. Some of these medications may be available in a variety of formulations, such as oral tablets, extended-release injections, and implantable devices. Some formulations are also available in generic form.

The dispensing and prescribing of methadone and buprenorphine are subject to specific federal requirements. Naltrexone is not subject to such requirements (SAMHSA 2018b).²

Methadone

Methadone is an opioid agonist that binds to and activates the brain’s opioid receptors and has been used for decades to treat OUD (SAMHSA 2018b).³ It is used to suppress withdrawal symptoms

and control opioid cravings and blunts or blocks euphoric effects of other opioids if, for example, a patient were to take another opioid (SAMHSA 2018a, SAMHSA 2015a).

Methadone for the treatment of OUD may only be dispensed in highly regulated OTP facilities (Box 1-1). Labeling by the FDA also indicates that methadone may only be dispensed in oral form, in accordance with federal OTP standards (42 CFR 8.12).

Methadone is recommended for patients who are physiologically dependent on opioids, who are able to give informed consent, and who have no specific contraindications for agonist treatment when prescribed as part of a plan that includes psychosocial intervention. In addition, methadone is recommended for patients who may benefit from daily supervision in an OTP or for those who have unsuccessfully attempted OUD treatment with buprenorphine (ASAM 2015). Because unsupervised administration can lead to misuse and diversion, clinical guidelines state that methadone administration should be monitored until the patient’s clinical response and behavior

demonstrates that the dispensing of non-monitored doses is appropriate (ASAM 2015).

A person under age 18 must have undergone two documented unsuccessful attempts at short-term withdrawal management or drug-free treatment within a 12-month period to be eligible for maintenance treatment, and must document consent for maintenance treatment in writing from a parent, legal guardian, or responsible adult (42 CFR 8.12).⁴

Methadone can be used successfully for years at a time. Research also shows that long-term methadone maintenance treatment is more effective than short-term withdrawal management (VA/DoD 2015).

Buprenorphine

Buprenorphine is a partial opioid agonist that binds to and activates the brain’s opioid receptors, but produces a less intense opioid-like effect than methadone. Like methadone, it reduces withdrawal symptoms and cravings and blunts or blocks the euphoric effects of other opioids (SAMHSA 2018a, ASAM 2015). Generally, buprenorphine has fewer

TABLE 1-1. Medications for Opioid Use Disorder and Alcohol Use Disorder

Medication	Treatment use		Formulation		
	Opioid use disorder	Alcohol use disorder	Oral	Injectable	Implantable
Methadone ¹	✓	–	✓	–	–
Buprenorphine ²	✓	–	✓ ³	✓	✓
Naltrexone	✓	✓	✓	✓	–
Acamprosate	–	✓	✓	–	–
Disulfiram	–	✓	✓	–	–

Notes: ✓ Check indicates that the medication meets the criterion. – Dash indicates that the medication does not meet the criterion.

¹ Methadone may only be dispensed in opioid treatment programs certified by the Substance Abuse and Mental Health Services Administration (SAMHSA) and registered as narcotic treatment programs with the U.S. Drug Enforcement Administration (DEA).

² Buprenorphine may only be prescribed or dispensed in an office-based setting by a provider with a waiver from the DEA, per the Drug Addiction Treatment Act of 2000 (P.L. 106-310).

³ Oral formulations of buprenorphine may be tablets or film.

Source: SAMHSA 2018a, SAMHSA and NIAAA 2015.

BOX 1-1. Federal Regulation of Opioid Treatment Programs

When used for opioid use disorder treatment, methadone may be ordered and dispensed only through an opioid treatment program (OTP) that has been certified by the Substance Abuse and Mental Health Services Administration (SAMHSA) and registered as a narcotic treatment program with the U.S. Drug Enforcement Administration.

OTPs provide the patient with a structured environment and daily interaction with treatment providers. Federal regulations require these facilities to be able to provide adequate medical, counseling, vocational, educational, and other assessment and treatment services, either on-site or by referral through a formal agreement. Counseling must be provided by a program counselor qualified by education, training, or experience to assess the psychological and sociological background of patients, to contribute to the appropriate treatment plan for the patient, and to monitor patient progress.

Counseling services must be available at the primary facility unless the program sponsor has entered into a formal documented agreement with a private or public agency, organization, practitioner, or institution to provide these services to patients enrolled in the OTP (SAMHSA 2018b).

potential drug interactions than methadone, and is available in several formulations (SAMHSA 2018a). Buprenorphine may be prescribed or dispensed in an office-based setting, but only by a practitioner who has met certain federal requirements (SAMHSA 2018a, MACPAC 2017, ASAM 2015).

Like methadone, buprenorphine can be used successfully for years at a time. Research shows that long-term treatment is more effective than quick tapering with buprenorphine (VA/DoD 2015).

Below we summarize the types of buprenorphine formulations available and the federal regulations that apply to buprenorphine prescribers. Clinical guidelines and the FDA labeling for this drug are also discussed.

Formulations. Buprenorphine comes in oral, injectable, and implantable formulations. Formulations for daily oral use commonly include naloxone, a drug that is used to reverse opioid overdose. Including naloxone reduces the risk of misuse if the medication is crushed or dissolved because naloxone blunts buprenorphine's opioid effects and induces withdrawal symptoms

(SAMHSA 2018a). The sublingual tablet formulation of buprenorphine without naloxone is, however, preferred in certain situations: when starting treatment, for pregnant patients, and for patients with liver impairment or sensitivity to naloxone (SAMHSA 2018a, ASAM 2015).⁵

A monthly extended-release injectable formulation is available for treatment of moderate to severe OUD for patients who have begun treatment with an oral buprenorphine product and who have been on a stable dose for at least seven days.⁶ A subdermal implant version of buprenorphine, which releases a continuous low dose of the medication into the bloodstream for six months, is appropriate for individuals who are already stable on a moderate to low dose of buprenorphine.⁷

Prescribing requirements. Buprenorphine was the first medication for treating OUD that was allowed by the FDA to be prescribed or dispensed in an office-based setting. Under the Drug Addiction Treatment Act of 2000 (DATA 2000, P.L. 106-310), practitioners prescribing buprenorphine in general medical settings are subject to certain federal

requirements, including mandatory training and a limit on the number of patients to whom they may prescribe. Qualifying practitioners must obtain a DATA 2000 waiver to prescribe buprenorphine in settings such as offices, community hospitals, health departments, OTPs, or correctional facilities (SAMHSA 2019). Waivered prescribers may treat no more than 30 patients in the first year, but can request permission to increase this number to 100 patients in the second year; after one year at the 100-patient limit, they can request permission to increase their patient load to 275 patients (42 CFR 8.610). Federal law requires practitioners prescribing buprenorphine to be able to provide psychosocial counseling on-site or demonstrate that they have the capacity to refer patients to counseling (42 CFR 8.12(f)(5)(iii)).

The Comprehensive Addiction and Recovery Act of 2016 (P.L. 114-198) expanded DATA 2000 by allowing nurse practitioners and physician assistants to obtain a waiver. The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act, P.L. 115-271) further eased buprenorphine prescribing restrictions by raising the initial patient limit to 100 for practitioners with additional credentialing or who operate in a qualified practice setting. It also expanded the list of eligible practitioners to include clinical nurse specialists, certified nurse midwives, and certified registered nurse anesthetists, allowing them to prescribe through October 2023.

Recommended use. Clinical guidelines note that patients should be experiencing mild to moderate opioid withdrawal before taking the first dose of buprenorphine to reduce the risk of precipitated withdrawal, which can occur when an opioid agonist is replaced by a partial agonist or antagonist (ASAM 2015). Generally, buprenorphine initiation should occur at least 6–12 hours after the last use of heroin or other short-acting opioids, or 24–72 hours after the last use of long-acting opioids (e.g., methadone). Patients should be seen frequently at the beginning of their treatment. Visits are recommended at least weekly until patients are

determined to be stable. Prescribers should test patients for buprenorphine, substances such as heroin, and prescription medications—including benzodiazepines—which have dangerous drug interactions with opioids. There is no recommended time limit for treatment, which should continue for as long as patients are benefiting (ASAM 2015).

FDA labeling recognizes that buprenorphine can be misused in a manner similar to other opioids. Treatment should be initiated with supervised administration and progress to unsupervised administration based on the patient’s stability. When determining the prescription quantity for unsupervised administration, prescribers must consider the patient’s level of stability, the security of the patient’s home situation, and other factors likely to affect the ability to manage supplies of take-home medication. Multiple refills should not be prescribed early in treatment or without appropriate patient follow-up visits (Indivior 2018).

Naltrexone

Naltrexone is an opioid antagonist that binds to opioid receptors but does not activate them. It is used to prevent relapses, because an individual on naltrexone who uses opioids will not experience the sought-after opioid effects. Naltrexone differs from methadone and buprenorphine in that it can be prescribed and dispensed in any setting by any clinician with prescribing authority (SAMHSA 2018b). Practice guidelines recommend psychosocial treatment in conjunction with naltrexone but there are no federal requirements (ASAM 2015).

The oral formulation of naltrexone has shown limited effectiveness because of poor adherence and the requirement of 7 to 14 days of opioid abstinence before initiation (SAMHSA 2018a). Its use should be reserved for highly motivated individuals whose adherence can be monitored and enforced.

The extended-release injectable formulation reduces but does not eliminate challenges with patient adherence to treatment and also requires

the patient to have undergone opioid withdrawal (SAMHSA 2018a, OSG 2016, ASAM 2015, Bagalman 2015, VA/DoD 2015). Patients using extended-release injectable naltrexone formulations must be opioid-free at the time of initial administration. Medication is then delivered every four weeks.

There is no recommended length of treatment with either the oral or the injectable formulation of naltrexone. Treatment duration depends on clinical judgment and the patient's individual circumstances. Naltrexone is also a recommended treatment for preventing relapse in OUD. Because there is no physical dependence associated with naltrexone, it can be stopped abruptly without causing withdrawal symptoms (ASAM 2015).

Medications for Alcohol Use Disorder Treatment

Acamprosate, disulfiram, and naltrexone are FDA-approved for use in alcohol use disorder treatment. These medications help maintain abstinence, reduce the risk of relapse, and reduce heavy drinking (SAMHSA 2018b). Any providers working within their scope of practice may prescribe these medications. There are no federal requirements for counseling, although counseling is typically recommended by clinical guidelines for treating alcohol use disorder.

Some evidence suggests that treatment for alcohol use disorder should continue for at least 6 to 12 months (SAMHSA and NIAAA 2015). Because alcohol use disorder is a chronic disease, medications may be needed for longer periods of time or for multiple episodes (SAMHSA and NIAAA 2015). Additionally, some patients may benefit from taking medications for short time periods to help them manage extremely stressful situations that may elicit cravings (SAMHSA and NIAAA 2015).

Acamprosate

Taken orally three times a day, acamprosate reduces symptoms of craving. It is indicated for individuals abstinent at initiation of treatment and may be most effective among individuals motivated for complete abstinence and when provided over a long period of time (SAMHSA and NIAAA 2015).

Disulfiram

Disulfiram is taken as a daily tablet and was the first medication approved to treat alcohol use disorder. When alcohol is consumed by an individual taking disulfiram, the drug causes unpleasant effects, such as flushing, throbbing headache, nausea, and vomiting, for 24 to 30 hours. Because disulfiram triggers an adverse reaction upon drinking alcohol, it may lead to poor adherence and is considered more appropriate for individuals who are highly motivated to remain abstinent and who can be treated in situations where another person, such as a family member, supervises the taking of the medication (OSG 2016, SAMHSA and NIAAA 2015).

Naltrexone

Naltrexone blocks the euphoric effects of alcohol intoxication and reduces cravings, helping individuals remain motivated to stay in treatment. It is available in a daily tablet or a monthly extended-release injection. The injection is more effective for patients who do not adhere well to a daily oral regimen. Both formulations may have the greatest benefit if a patient can discontinue drinking several days before treatment initiation (SAMHSA 2018b, OSG 2016, SAMHSA and NIAAA 2015). Only the oral formulation has a generic version.

Behavioral Therapies

Behavioral therapies such as psychosocial treatment complement medications for substance use disorder (SUD) and are meant to help patients develop healthier and more productive coping mechanisms and recognize how their behaviors affect their ability to support long-term recovery. Psychosocial treatment may include a needs assessment, supportive counseling, connections to existing family support systems, and referrals to community services. Family involvement in treatment, including members of the patient's social network (e.g., a spouse or partner, friends, clergy, employer, or case manager), provides strong support for patient recovery; family members also benefit (ASAM 2015).

Generally, behavioral therapies, such as cognitive-behavioral therapy, contingency management, individual therapy, and group counseling, can be delivered in any setting (SAMHSA 2018a, OSG 2016, CMS 2014).⁸ Factors such as the number of sessions and patient adherence may affect the benefit derived by the patient (SAMHSA 2018a).

Clinical guidelines indicate that patients initiating MAT should be seen weekly until they are stable and experience meaningful reductions in or abstinence from illicit drug use. Visits may then occur less frequently, from twice a month to once a month or less. Patient adherence to treatment should also be monitored with periodic and random drug testing, with the frequency of testing for each patient determined by the provider (SAMHSA 2018a, ASAM 2015).

Nationally recognized treatment guidelines recommend that psychosocial treatment be offered alongside pharmacotherapy when treating either alcohol use disorder or OUD (SAMHSA 2018b, 2018c; ASAM 2015; VA/DoD 2015). However, research also indicates that some patients respond well to medication and medical management alone and may not require behavioral therapy (NASEM 2019).

Endnotes

¹ There are currently no FDA-approved medications to treat marijuana, amphetamine, or cocaine use disorders.

² Because opioid agonists and partial agonists produce effects that are similar to the effects of opioids, they are regulated by the Controlled Substances Act (P.L. 91-513) and may only be dispensed through opioid treatment programs or by authorized prescribers in office-based opioid treatment settings. By contrast, opioid antagonist medications produce no opioid-like effects of their own and are not covered under the Controlled Substances Act, so providers do not need special authority to prescribe these medications (SAMHSA 2018b, Mee-Lee et al. 2013).

³ Methadone comes in several oral formulations: tablet, tablet for suspension, concentrate, and solution.

⁴ A maintenance dose is the amount of methadone a patient requires to prevent opioid withdrawal symptoms without inducing euphoria. Patients are typically started on methadone at a low dosage, which is gradually increased until the maintenance dose is reached, usually in the 60–120 milligram range.

⁵ The American Society of Addiction Medicine guidelines state that the maintenance dose of buprenorphine can range from 4 to 24 milligrams per day, but that maintenance doses are usually 8 milligrams or more, up to the FDA-approved limit of 24 milligrams per day. There is little information regarding the efficacy of higher doses (ASAM 2015).

⁶ Because of the risk from intravenous self-administration, the injection is only available from providers who are certified in the Sublocade Risk Evaluation and Mitigation Strategy (REMS) program and who obtain the medication through a restricted distribution program (Indivior 2019).

⁷ Because of risks associated with insertion and removal, the implant is only available from providers who have completed a live training program and become certified in the Probuphine REMS program (Titan 2019).

⁸ Many types of therapies are used in SUD treatment. Cognitive-behavioral therapy teaches coping skills and techniques to identify and modify dysfunctional thinking, and usually involves 12 to 24 weekly individual sessions. Contingency management gives material rewards to

individuals demonstrating positive behavior changes (e.g., participating in treatment activities or testing drug-free in urine screens). Individual therapy helps individuals learn skills to maintain recovery, address other mental health issues, promote medication adherence, and pursue goals related to family, work, or school. Group counseling provides peer support and feedback and encourages the development of social and problem-solving skills. Motivational enhancement therapy uses motivational interviewing techniques to help individuals resolve any ambivalence about stopping substance use. The Matrix Model is a 16-week structured program that includes relapse prevention, family therapy, group therapy, drug education, and self-help. Family therapy is conducted with partners, children, and others to support an individual's behavior change. Finally, twelve-step facilitation therapy is designed to prepare individuals to engage in programs such as Alcoholics Anonymous or Narcotics Anonymous (SAMHSA 2018a, OSG 2016).

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Chapter 2:

Medicaid Coverage of Medication-Assisted Treatment

CHAPTER 2: Medicaid Coverage of Medication-Assisted Treatment

States use different Medicaid authorities to cover medication-assisted treatment (MAT). The medication itself is generally covered through the optional Medicaid prescription drug benefit under Section 1905(a)(12) of the Social Security Act (the Act).¹ Counseling may be covered under the optional Medicaid rehabilitative services benefit under Section 1905(a)(13) of the Act.

Although all state Medicaid programs cover prescription drugs, coverage of behavioral health services varies. States are required to cover certain mandatory services, such as medically necessary inpatient hospital services, outpatient hospital services, rural health clinic services, and physician services, but each state defines its own medical necessity criteria for receipt of services. For example, a life-threatening drug overdose requiring an emergency room visit would be covered under the mandatory outpatient hospital services benefit and subsequent hospitalization would be covered under the mandatory inpatient hospital services benefit. Ongoing substance use disorder (SUD) therapy after release from a hospital could be covered under the rehabilitative services benefit, which states have the option of covering for adults.²

This chapter summarizes Medicaid coverage of the two components of MAT for SUD: medications and counseling.

Coverage of Medications

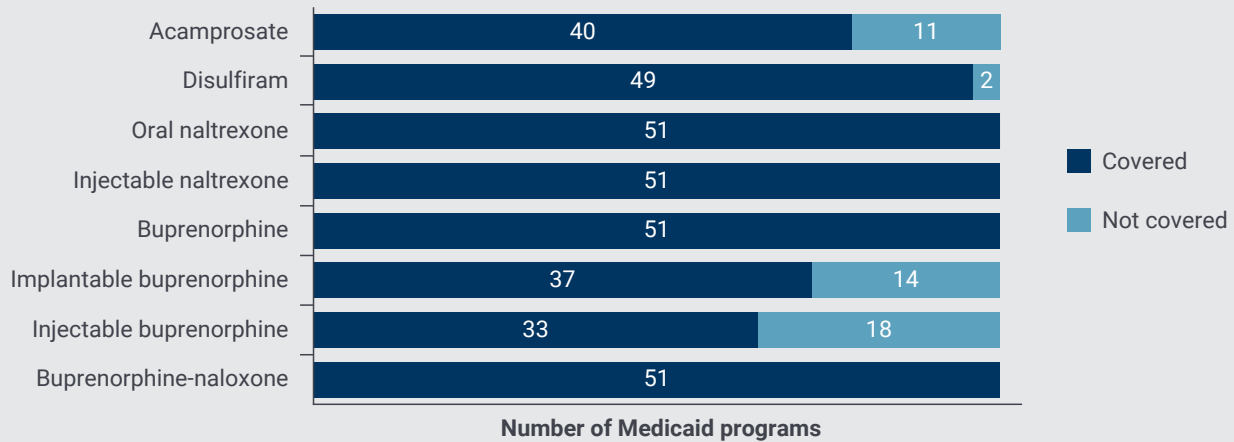
Medicaid coverage of outpatient prescription drugs is an optional benefit that all states have elected to provide.³ When covering such drugs, states must generally cover all drugs approved by the U.S. Food and Drug Administration (FDA) if their manufacturers participate in the Medicaid Drug Rebate Program and the drugs are prescribed

for a medically accepted indication.⁴ Outpatient prescription drugs are generally those that are dispensed by pharmacies; drugs provided and billed as part of a bundled service are not included in this category.⁵ Because methadone is dispensed only in an opioid treatment program as a bundled clinic service, it is not considered an outpatient prescription drug and Medicaid programs are not obligated to cover it when used in MAT (SAMHSA 2018). When states do cover methadone in MAT, given that it is covered as a part of a medical service and not as a pharmaceutical benefit, certain benefit limitations that apply to medications covered under the prescription drug benefit generally do not apply (SAMHSA 2018).⁶ Injectable formulations of naltrexone and the injectable and implantable formulations of buprenorphine, which are administered in a clinician's office, may be considered covered outpatient drugs if the payment is calculated separately from the clinician fee (MACPAC 2018).

Oral formulations of buprenorphine and naltrexone are covered by Medicaid as outpatient prescription drugs. Currently, Medicaid programs in all states and the District of Columbia pay for buprenorphine and naltrexone when used to treat opioid use disorder (OUD) (Figure 2-1) (SAMHSA 2018). Acamprosate, disulfiram, and oral formulations of naltrexone used for treatment of alcohol use disorder are also covered by Medicaid as outpatient prescription drugs.

Under the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act, P.L. 115-217), states must explicitly include MAT for OUD as a Medicaid-covered service for a five-year period beginning October 1, 2020.⁷ States can be exempted from this requirement if before October 1, 2020, they can satisfactorily certify that covering all eligible individuals in the state is not feasible due to a shortage of qualified MAT providers or treatment facilities willing to provide services under contract either with the state or with a managed care organization working with the state under Section 1903(m) or Section 1905(t)(3) of the Act.

FIGURE 2-1. State Medicaid Program Coverage of Medications for Alcohol and Opioid Use Disorder, 2018



Notes: Totals include the District of Columbia but exclude U.S. territories. Methadone is excluded from this figure because it is not considered an outpatient drug.

Source: MACPAC, 2019, analysis of SAMHSA 2018.

Coverage of Counseling Services

In 2018, 49 states and the District of Columbia offered some form of SUD counseling services, such as individual, group, or family therapy, to beneficiaries age 21–64 (MACPAC 2018). Coverage of SUD counseling services varies by state, but is generally consistent with the American Society of Addiction Medicine Criteria for level 1.0 outpatient services, defined as fewer than nine hours of service per week for recovery or motivational enhancement therapies or strategies (MACPAC 2018).⁸ Services at this intensity are appropriate for individuals who need motivating and monitoring strategies to support their ongoing recovery (Mee-Lee et al. 2013).

State coverage for these services also varies among population groups. In states that have expanded Medicaid to non-disabled adults under age 65, beneficiaries enrolled on this basis are entitled to coverage of SUD treatment services as an essential health benefit. Expansion states generally offer the same SUD treatment benefit to all

enrollees regardless of eligibility category, despite the coverage not being mandatory except for the expansion group (MACPAC 2018).

States typically elect to cover outpatient counseling services under the state plan rehabilitative services option because it offers flexibility in delivering recovery-oriented SUD services (42 CFR 440.130). States offering outpatient SUD services under this option can decide which services to cover, in which settings, and by whom (e.g., physicians, social workers, psychologists, or others).⁹ Services may include individual or group therapy, recovery support, and relapse-prevention training. Intensive services, including partial hospitalization, can also be covered under this option (SAMHSA 2013). Some states also offer behavioral health services through telemedicine or telehealth, which may improve access to treatment, particularly for beneficiaries residing in rural areas (ASPE 2019).

The structure of SUD counseling benefits varies by state. For instance, some states pay for counseling services provided by both licensed and unlicensed providers, while others require all providers to be

licensed. New York covers outpatient SUD services under the state plan rehabilitative services option and allows roughly a dozen different types of unlicensed and licensed practitioners to deliver individual and group counseling services to beneficiaries with SUD.¹⁰ Services may be delivered in several settings, including provider offices, the community, an individual's home, or on a mobile basis (CMS 2019a).¹¹ In comparison, Vermont covers individual, family, and group counseling under its state plan and authorizes nine different types of individual practitioners to deliver these services.¹² All SUD providers in Vermont must be licensed by the state and must be working within their scope of practice for their services to be covered (CMS 2019b).

Endnotes

¹ Methadone for the treatment of opioid use disorder may only be dispensed in highly regulated opioid treatment programs. Unlike other medications used in MAT, it is not considered an outpatient prescription drug under Medicaid.

² Children under age 21, however, would receive this benefit under the early and periodic screening, diagnostic, and treatment (EPSDT) benefit, which requires states to make available all medically necessary services covered under Section 1905(a) of the Social Security Act to correct or ameliorate their physical or mental conditions.

³ Coverage of prescription drugs is mandatory only for the Medicaid expansion population.

⁴ A medically accepted indication means any use for a covered outpatient drug that is approved under the Federal Food, Drug, and Cosmetic Act (P.L. 75-717) or that is supported by one or more citations included or approved for inclusion in one of the following three compendia: American Hospital Formulary Service Drug Information, United States Pharmacopeia-Drug Information, or the DRUGDEX Information System (§ 1927(k)(6) of the Social Security Act).

⁵ A drug provided as part of a bundled service may be considered a covered outpatient drug if the state's payment for the administration of these drugs separates the drug cost from the clinician fee.

⁶ These optional benefit limitations may include prior authorization requirements or quantity limits (§ 1927(d) of the Social Security Act).

⁷ MAT is defined as a service combining any FDA-approved drug, including methadone, or any biological product licensed under the Public Health Service Act to treat opioid use disorders and counseling services or behavioral therapy.

⁸ According to ASAM, level 1.0 services are provided in regularly scheduled sessions that are usually nine hours a week or less and allow for individualized treatment which may include screening, evaluation, counseling and ongoing recovery and disease management services (Mee-Lee et al. 2013).

⁹ States determine who is eligible for a service through the development of medical necessity criteria.

¹⁰ In New York, outpatient SUD services can be provided by both licensed and unlicensed providers. Licensed practitioners permitted to deliver these services include: social workers, mental health counselors, marriage and family therapists, psychoanalysts, registered nurses, creative arts therapists, physician assistants, practical nurses, nurse practitioners, physicians, and psychologists. Only physicians, psychiatrists, nurse practitioners, physician assistants, and registered nurses may provide medication management functions.

Unlicensed providers providing addiction services either must be credentialed as alcoholism and substance abuse counselors, alcoholism and substance abuse counselor trainees, or recovery peer advocates or be under the supervision of a qualified health professional. Qualified health professionals include a range of licensed or credentialed health care providers including: credentialed alcoholism and substance abuse counselors, licensed master social workers, licensed clinical social workers, nurse practitioners, occupational therapists, physicians, physician assistants, registered nurses, psychologists, certified rehabilitation counselors, therapeutic recreation specialists, licensed marriage and family therapists, and licensed mental health counselors (CMS 2019a).

¹¹ New York's SUD outpatient benefit has certain service limitations. Services may not be provided in an inpatient or outpatient hospital setting. An individual may receive multiple outpatient SUD services on a single day; however, providers may not receive payment for delivering the same service to a beneficiary more than once in a given day.

(e.g., two individual sessions, two group sessions); or more than two different services provided in a single day, except for medication administration, medication management, complex care management, collateral visit, and peer support services (CMS 2019a).

¹² In Vermont, the following practitioners are identified in the state plan: certified alcohol and drug counselors, licensed alcohol and drug counselors, apprentice addiction professionals, clinical mental health counselors, clinical social workers, marriage and family therapists, nurses, physicians, and psychologists (CMS 2019b).

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Chapter 3:

Review of Medicaid Utilization Management Policies

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Utilization management is a set of techniques used by insurers and health plans to limit unnecessary care, address fraud, waste, and abuse, and promote cost-effective alternatives for certain services or treatments (Buck and Silverman 1996, IOM 1989). These techniques are used to manage utilization of a wide variety of services, including prescription drugs, imaging, diagnostic tests, and surgical procedures.

In this chapter, we report the results of our review of Medicaid utilization management policies used for medication-assisted treatment (MAT). After discussing the goals of these policies, we describe various techniques and consider how they affect access to treatment. Specifically, we examine the use of prior authorization (including reauthorization and step therapy), preferred drug lists (PDLs), quantity and refill limits, prescription co-payments, and limits on counseling services. We also look at policies specific to methadone-based programs, changes in utilization management policies over time, and MAT access and utilization management in substance use disorder (SUD) demonstrations allowed under Section 1115 of the Social Security Act (the Act).

We found the following in our review:

- State Medicaid agencies and managed care organizations (MCOs) typically apply more utilization management policies—particularly prior authorization—to medications than to counseling services. The policies for MAT medications are applied more frequently to drugs for opioid use disorder (OUD) than drugs for alcohol use disorder, which are rarely subject to quantity or dosing limits.
- Prior authorization for MAT drugs is generally considered a barrier to access, but the degree to which it affects access depends on the

specific criteria used. Use of prior authorization for MAT drugs is changing: some states are removing prior authorization requirements in an effort to increase access to treatment, although the majority (30 states in 2018) still require prior authorization for at least one MAT medication. While drug formulations with preferred status are typically not subject to prior authorization, several states require prior authorization for certain preferred MAT drugs.

- State Medicaid programs are improving access to MAT by removing some utilization management policies, such as prior authorization, lifetime limits, and counseling requirements. On the other hand, citing patient safety concerns, some are adding other policies, such as quantity limits. These particularly apply to buprenorphine-naloxone formulations for OUD.
- Fewer states are assigning preferred status to MAT drugs. For example, the number of states assigning preferred status to oral naltrexone decreased from 50 states and the District of Columbia in 2011–2013 to 44 states in 2018, which may make it more difficult for beneficiaries to access this drug.

Goals of Utilization Management

State Medicaid agencies and MCOs implement utilization management policies to achieve multiple goals: reducing diversion and misuse, controlling costs, and ensuring access to clinically appropriate drugs. Section 1927(d) of the Act specifically allows states to limit Medicaid coverage of outpatient drugs through the use of PDLs and prior authorization (both described in more detail below).¹ States generally have discretion to determine which criteria to focus on when developing their utilization management policies (42 CFR 456).² For prescription drugs, decisions may be based on a drug's safety profile,

contraindications, cost, efficacy when compared to other drugs, and risk of misuse and diversion (42 CFR 456). In addition, states may require providers to check the prescription drug monitoring program (PDMP) before prescribing medications to treat OUD, both to prevent certain drug combinations that would be harmful to patients and to identify potential misuse (CMS 2016). Although implementation of these policies has reduced drug spending, it is less clear how these policies have affected patient outcomes or quality of care (Das et al. 2017, Puig-Junoy and Moreno-Torres 2007).

Some utilization management policies focus primarily on reducing fraud and diversion of prescription opioids, including MAT medications. A 2009 report by the U.S. Government Accountability Office found substantial amounts of fraudulent purchases, inappropriate prescribing, and diversion of controlled substances within the Medicaid program (GAO 2009). Recent data, however, found declining diversion rates for methadone (Jones et al. 2016). In addition, rates of misuse for buprenorphine-naloxone, which was developed in part as a deterrent to misuse, are lower than rates for buprenorphine alone (Lofwall and Walsh 2014).

States also consider spending on MAT drugs when developing utilization management policies for these medications (Patt 2018, Jung et al. 2016, PBMI 2014, Motheral 2011). In some states, buprenorphine is one of the most expensive drugs covered by Medicaid (Clark et al. 2011). In 2017, the buprenorphine-naloxone sublingual film formulation (Suboxone) was among the top 10 drugs by spending for state Medicaid programs (CMS 2019a). On the other hand, pharmacotherapy for OUD is associated with lower total health care costs due to reduced emergency department use and hospitalizations (Murphy and Polsky 2016).

When determining which utilization management techniques to implement, policymakers must weigh the harm from drug diversion against the consequences of limiting access to effective

treatment (SAMHSA 2018a). For example, there is evidence that illicitly obtained buprenorphine has been used by individuals to self-treat opioid withdrawal after trying and failing to access treatment (Lofwall and Walsh 2014, Lofwall and Havens 2012). Policies such as urine drug testing, periodic tablet and film counts, and checking the state's PDMP could reduce diversion concerns. In addition, opioid treatment programs (OTPs) and providers waived to prescribe buprenorphine to up to 275 patients must have formal diversion control programs (SAMHSA 2018b).

Utilization Management Tools

States use a variety of mechanisms to manage use of services and have flexibility to set their own utilization management criteria. Some of these policies may particularly affect initial access to MAT. Others are more likely to affect access to ongoing treatment. It is not always clear, however, whether Medicaid utilization management policies for MAT drugs differ from those for other outpatient drugs. In developing utilization management policies, states also must consider their obligations under the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA, P.L. 110-343).³

Prior authorization

Prior authorization is considered an important tool for payers to ensure appropriate use of health care services (Townley and Dorr 2017). Processes typically require providers to submit information to insurers to justify the clinical need and suitability of the drug for treating the patient before the patient can begin using the medication or for continuation of treatment, with limited exceptions for emergency situations (Schneiter 2016, AMCP 2012).

Medicaid prior authorization policies vary by state and by type of medication, but more states impose them for OUD drugs (particularly buprenorphine) than for alcohol use disorder drugs. For example,

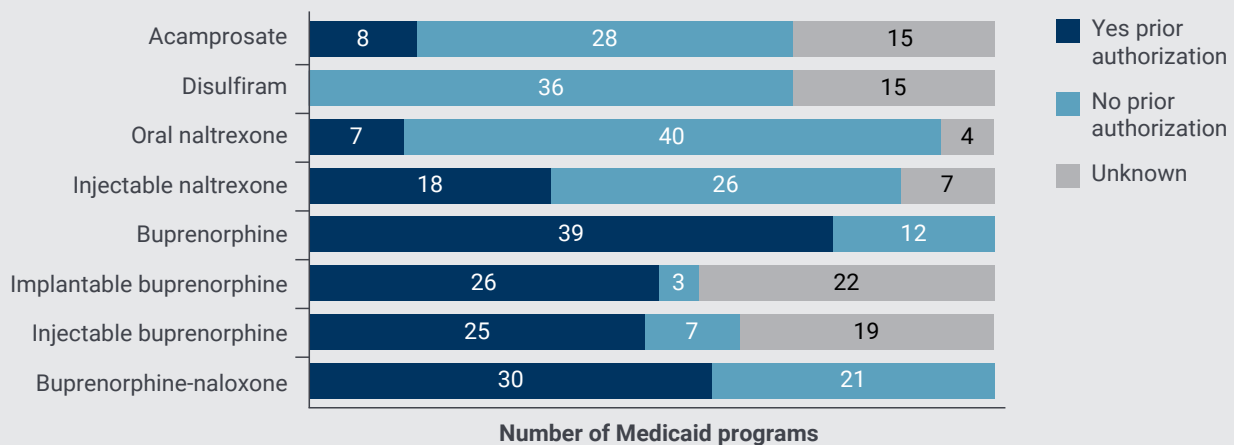
39 states and the District of Columbia require prior authorization for buprenorphine and 30 states require it for buprenorphine-naloxone, both used in MAT for OUD; just 8 states require prior authorization for acamprosate and none require it for disulfiram (Figure 3-1).

Of the eight states whose policies we reviewed in detail, only Maine, Arkansas, and Washington require prior authorization for alcohol use disorder drugs. Seven of those eight states require prior authorization for at least one form of MAT medication—at minimum for buprenorphine or one of the buprenorphine-naloxone combination products. With the exception of Illinois, policies in these states are more restrictive for buprenorphine than for other products (Appendix 3A). We also found that two states require prior authorization for naltrexone products. Buprenorphine prescribers enrolled in Tennessee’s MAT Network can use a streamlined prior authorization process that includes an option to submit the request electronically (TennCare 2018a) (Box 3-1).

Documentation requirements for prior authorization vary by state. Following are examples of the type of information and documentation that prescribers must submit to get MAT drugs approved for their patients:

- Tapering plans.** In Tennessee, Medicaid beneficiaries taking buprenorphine-naloxone sublingual tablets start with 8 milligrams twice a day for six months. If they have achieved maximum benefit from treatment, beneficiaries then taper to 2 milligrams three times a day, while also continuing psychosocial services as needed (Magellan 2019a, TennCare 2018b).
- Documentation or results of drug screening tests.** Arkansas and Maine require documentation of current urine screen test results and evidence of engagement in behavioral health counseling or recovery-oriented support services (Maine DHHS 2019a, Arkansas Medicaid 2018).
- Provider attestation of querying the PDMP database.** In Tennessee, before

FIGURE 3-1. Medicaid Prior Authorization Requirements for Medications for Alcohol and Opioid Use Disorders, 2018



Notes: Totals include the District of Columbia but exclude U.S. territories. Methadone is excluded from this figure because it is not considered an outpatient drug.

Source: MACPAC, 2019, analysis of SAMHSA 2018a.

BOX 3-1. Tennessee Medicaid Provider Network Requirements and Utilization Management Policies for Medication-Assisted Treatment

In 2018, the Tennessee Medicaid program and its three managed care organizations (MCOs) implemented a structured network for prescribers of both buprenorphine and naltrexone to balance enhanced access to medication-assisted treatment (MAT) and clinical integration with concurrent efforts to reduce drug diversion. The program encourages providers to prescribe MAT by offering them incentives such as enhanced formulary access, additional learning resources, and a more streamlined process for requesting prior authorization (TennCare 2018a). Specifically, providers in the MAT network must agree to:

- provide counseling or make referrals to counseling;
- provide patient education on the proper use of MAT medications;
- administer drug urine screens to evaluate a patient’s progress in treatment;
- create and maintain a drug diversion control plan;
- engage with a local care coordination resource to facilitate communication between prescribers and counselors; and
- check the state’s prescription drug monitoring program before prescribing MAT.

Providers who participate in the network receive care coordination support from MCOs, are authorized to prescribe additional MAT medications (specifically, generic sublingual buprenorphine-naloxone tablets and Bunavail buprenorphine-naloxone buccal film), and can bill the MCOs for MAT services (TennCare 2018a).

prescribing oral naltrexone, providers must have reviewed the state’s PDMP database within the past 30 days and must document the patient’s negative urine drug screen or naloxone challenge test (TennCare 2018c).⁴

- **Evidence that a patient is being referred to or is receiving psychosocial treatment with their medications.** When counseling requirements are incorporated into prior authorization processes, providers might have to document dates of service or submit progress notes. In Arkansas, patients receiving MAT medication must also receive at least one behavioral health therapy session per month (Arkansas DMS 2018, Arkansas Medicaid 2018).

Even when prior authorization is required for a covered outpatient drug, states must allow dispensing of at least a 72-hour supply of the drug (§ 1927(d)(5)(b) of the Act). Such so-called emergency override policies allow a pharmacist to make a clinical determination regarding the patient’s medical needs and provide a short-term, emergency supply of medication. This policy typically applies if the patient is in immediate need of a specific medication and the prescriber cannot be reached or is unable to request prior authorization from the state Medicaid program. Among the eight states we reviewed, the supply of medication that states can make available to beneficiaries through emergency override ranges from 3 days in Tennessee to 34 days in Washington (Magellan 2019b, WSHCA 2016).

Specific prior authorization policies. We looked specifically at two types of prior authorization: reauthorization and step therapy. States and MCOs may require providers to submit information periodically to reauthorize a drug, for example, documentation that the medication provides a clinical benefit, that the patient is compliant with continued treatment, or that the drug is being prescribed according to U.S. Food and Drug Administration (FDA) guidelines. Reauthorization, also referred to as a continuation or a restart, is typically required for maintenance medications, and some states may include MAT medications in that category (ASAM 2015).

Arkansas, Tennessee, and Utah require reauthorization for MAT drugs beyond the initial authorization period. In Arkansas, reauthorization is required for oral buprenorphine and buprenorphine-naloxone (Arkansas Medicaid 2018). These three states all require documentation including chart notes, urine drug screen test results, and dates of behavioral health counseling visits. The length of the initial authorization ranges from three months in Tennessee to six months in Arkansas and Utah (Magellan 2019c, UDOH 2019a, Arkansas Medicaid 2018). The reauthorization period for these three states ranges from three months in Arkansas and Tennessee to three years in Utah.⁵

Under step therapy policies, sometimes referred to as fail first, states and MCOs approve payment for a drug only if another drug (generally one that is less expensive) was tried first but failed to achieve its therapeutic benefit. In applying for prior authorization when step therapy is required, providers often need to provide documentation of a patient's unsatisfactory response to the first-line drug (Vogt et al. 2011).

Step therapy requirements are most often applied to implantable and injectable buprenorphine formulations and injectable naltrexone, likely due to their higher cost than the oral formulations and the lack of generic versions (SAMHSA 2018a). Use of step therapy may result in delayed treatment (Rinaldo and Rinaldo 2013). While research on the

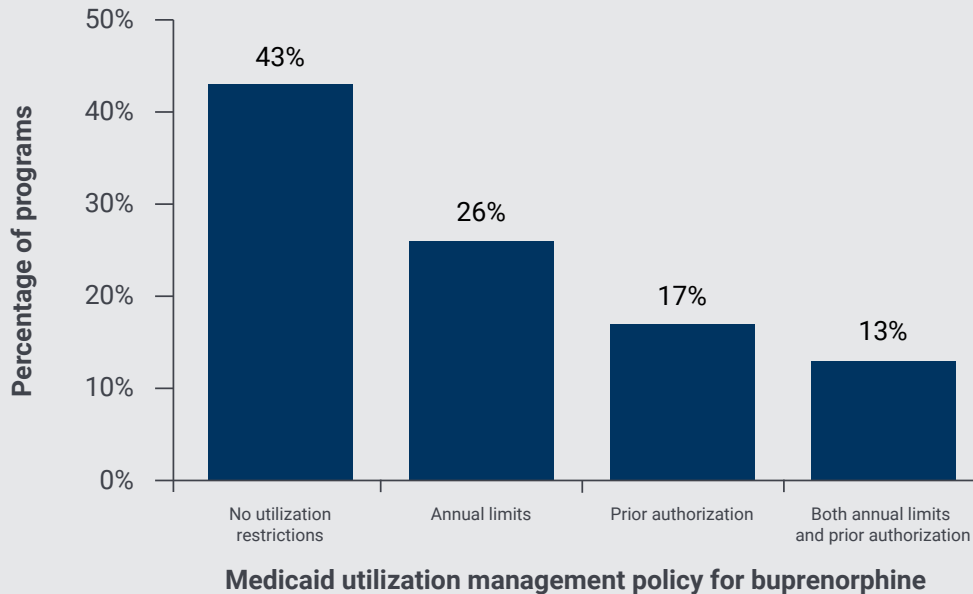
effect of step therapy on access to MAT is limited, one study found that these policies impeded access to psychiatric medication among patients dually eligible for Medicaid and Medicare (West et al. 2009).

Four of the eight states we reviewed use step therapy for OUD drugs. Of these, three use step therapy for buprenorphine-naloxone combination products. For example, Missouri requires a documented trial period for, or documented adverse reaction to, one preferred MAT drug before a non-preferred drug can be approved (MO HealthNet 2016). Utah has a similar step therapy policy (UDOH 2019b). None of the states we reviewed use step therapy for alcohol use disorder drugs.

Effects on access. Some argue that prior authorization inhibits, rather than supports, access to evidence-based care by creating additional hurdles for patients and prescribers that delay initiation of care when patients are ready to seek treatment for OUD, which, in turn, can reduce treatment retention (Sadwith et al. 2019, Sharfstein 2017, OSG 2016, SAMHSA-HRSA CIHS 2014, Quest et al. 2012, Netherland et al. 2009). The degree to which such policies affect patient access to MAT may vary based on documentation requirements and the timeliness of approvals. For example, a requirement that a provider submit patient visit notes may be more burdensome than a requirement to attest to offering counseling to patients.

Two recent studies of buprenorphine prescribing support the argument that prior authorization policies create barriers to access (Andrews et al. 2019, Kermack et al. 2017). One study, using data from the 2014 and 2017 National Drug Abuse Treatment System Survey, found that the proportion of SUD treatment programs offering buprenorphine was higher in states that did not impose any utilization management policies on the drug; in comparison, the proportion of providers offering buprenorphine was lower when states imposed prior authorization (Figure 3-2) (Andrews et al. 2019).

FIGURE 3-2. Utilization Management Policies by Share of Substance Use Treatment Programs Offering Buprenorphine, 2014 and 2017



Notes: Data are from the 2014 and 2017 National Drug Abuse Treatment System Survey, a nationally representative panel survey of addiction treatment programs in the U.S. Data were collected through an Internet-based survey of Medicaid agencies in all 50 states and the District of Columbia in two waves in 2014 and 2017. Analyses were limited to the 672 programs that accepted Medicaid.

Source: Andrews et al. 2019.

Preferred drug lists

Decisions about what drugs are placed on the state's PDL and the design or review of accompanying utilization management policies are made at the state level by expert committees, often referred to as pharmacy and therapeutics (P & T) committees (§ 1927(d)(4) of the Act). P & T committees meet regularly and consider information such as clinical practice guidelines, clinical trial data, and recommendations from providers when making decisions (AMCP 2009). A drug may be preferred because it is less expensive or because it is therapeutically superior with respect to clinical safety or effectiveness. For example, PDL decisions about buprenorphine-naloxone may take into account factors such as comparative costs of different formulations and the potential for diversion (Harper 2017).

Medicaid programs in 49 states and the District of Columbia place at least one covered MAT medication on their PDL (SAMHSA 2018a). On average, states assign preferred status to four or more MAT medications for alcohol use disorder and OUD (SAMHSA 2018a). Methadone is usually not considered eligible for preferred status because it is typically covered as a medical service rather than an outpatient drug (SAMHSA 2018a). Within states, PDLs for fee for service (FFS) and managed care can be different; however, some Medicaid programs are now moving toward uniform clinical protocols or uniform PDLs for MAT across delivery systems (KFF 2018).⁶

Buprenorphine-naloxone combination products are the most common MAT medications to be assigned preferred status (49 states and the District of Columbia) (SAMHSA 2018a). However, the specific

buprenorphine-naloxone formulation preferred varies by state, and this can affect patient access when a patient's preferences or clinical needs are not met by the preferred formulation. For example, only two states (California and Illinois) currently assign preferred status to implantable buprenorphine.

All eight states we reviewed assign preferred status to at least two MAT medications, with one of those being a buprenorphine or buprenorphine-naloxone formulation. Five states—Arkansas, Missouri, Tennessee, Utah, and West Virginia—do not include acamprosate or disulfiram, used to treat alcohol use disorder, on their PDLs. Illinois has some of the least restrictive utilization control policies of the states we reviewed, assigning preferred status to all MAT medications, for OUD as well as alcohol use disorder, and not requiring prior authorization for any of them (Goyal 2019; see also Appendix 3A).

Generally, prescribers need to seek prior authorization only for non-preferred drugs. However three states in our review—Arkansas, Tennessee, and Utah—assign preferred status to certain MAT drug formulations, but still require prior authorization (Appendix 3A, Tables 3A-6, 3A-9, 3A-10, 3A-11).⁷ Such policies may be confusing for beneficiaries and providers, add to administrative burden, and create a barrier to treatment.

Quantity and refill limits

State Medicaid programs may impose restrictions on the quantity of medication dispensed per prescription or on the number of refills (§ 1927(d)(6) of the Act). These restrictions can include limits on the number of prescriptions that can be filled in a given time period (e.g., daily, monthly) or on the dose of the medications.⁸ Quantities may be limited to a 30-day supply, or for mail-order prescriptions, a 90-day supply. For MAT, some states limit the daily dosage of oral buprenorphine-naloxone formulations that can be dispensed. States may also impose different dosage limits depending on how long an enrollee has been in treatment. With quantity limits, a prescriber may be able to use a prior authorization process to request medication dosages or amounts outside of the established limits.

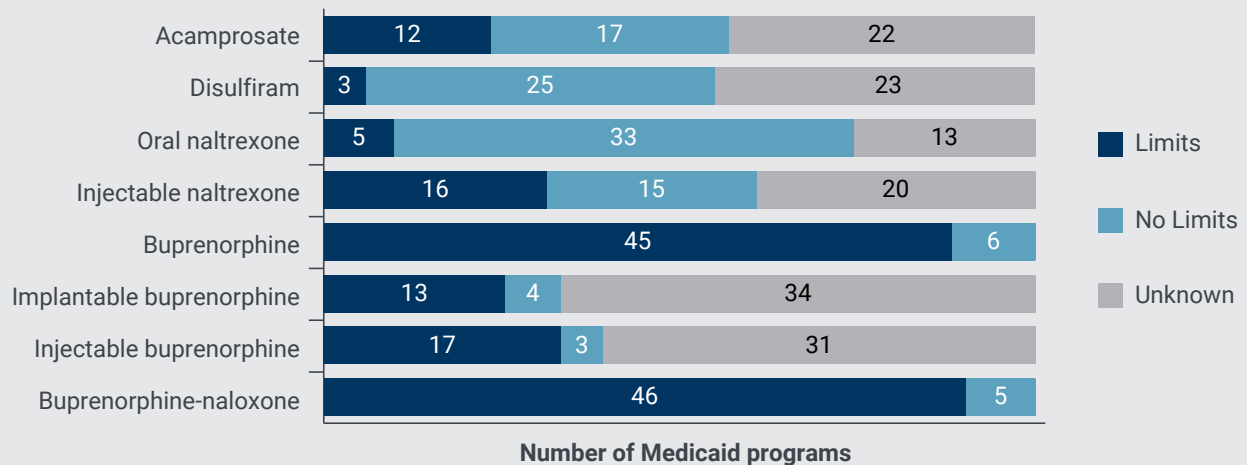
When appropriately tied to patient needs, quantity and refill limits can serve as tools to ensure patient safety and quality of care (Hoover 2019). Dosing limits should correspond to clinically recommended dosages. Dosing and refill limits present an opportunity for providers to engage with patients on a regular basis during their course of treatment (Rinaldo and Rinaldo 2013).

Such limits may also affect access to OUD treatment (Rinaldo and Rinaldo 2013). Limits should be flexible enough to accommodate the appropriate quantity and dosing for a patient's specific phase of treatment (e.g., treatment initiation, stabilization, or maintenance) (SAMHSA 2004). Moreover, the use of lifetime limits does not reflect the consensus that OUD is a chronic disease and may require long-term treatment for some patients (Rinaldo and Rinaldo 2013). As noted earlier, evidence-based treatment guidelines indicate that there is no recommended time limit for treatment with certain MAT medications (ASAM 2015).

More states apply quantity limits for OUD drugs than for alcohol use disorder drugs. For example, 46 states and the District of Columbia apply quantity limits or maximum daily doses for buprenorphine-naloxone combination products (used for OUD), while 5 states have similar policies in place for oral naltrexone (used for both OUD and alcohol use disorder), and 3 states have similar policies for disulfiram (used for alcohol use disorder only) (Figure 3-3).⁹

Seven of the eight states we reviewed use quantity limits for at least one form of MAT medication, typically in the form of daily or monthly dose limits. None apply quantity limits to acamprosate or disulfiram. Three states—Arkansas, Utah, and West Virginia—limit doses for certain buprenorphine or buprenorphine-naloxone formulations to 24 milligrams per day, consistent with FDA guidelines (Indivior 2018a). Washington allows providers to prescribe doses for buprenorphine-naloxone up to 32 milligrams per day; higher doses are permitted with prior authorization (WSHCA 2018). For buprenorphine-naloxone, Washington typically

FIGURE 3-3. Medicaid Quantity or Dosing Limit Requirements for Medications for Alcohol and Opioid Use Disorders, 2018



Notes: Totals include the District of Columbia but exclude U.S. territories. Methadone is excluded from this figure because it is not considered an outpatient drug.

Source: MACPAC, 2019, analysis of SAMHSA 2018a.

has the least restrictive dosing limits, and Tennessee has the most restrictive.¹⁰ In terms of number of days of medication allowed per prescription, two states—Arkansas and Maine—limit enrollees to a 30-day supply of buprenorphine, buprenorphine derivatives, or naltrexone per month or per billing period.

In the eight states we reviewed, three (Arkansas, Illinois, and Tennessee) apply limits on the number of prescriptions that may be filled, ranging from three to five prescriptions per month, regardless of medication type. Arkansas will consider increasing this number to a maximum of six prescriptions for medically necessary maintenance medications. All three states exempt certain populations (e.g., children under age 21) or drugs, such as family planning medications, from these restrictions (Magellan 2019d, Illinois DHFS 2016, Arkansas Medicaid 2019).

In 2018, only 2 states (Maine and New York) had lifetime limits for buprenorphine-naloxone, down from 11 states in 2011–2013 (Maine DHHS 2019b; SAMHSA 2018a, 2014). In 2019, Maine removed this limit for methadone and buprenorphine-naloxone for MAT (Alford 2019).

Prescription co-payments

Prescription co-payments are out-of-pocket costs incurred by beneficiaries when filling a prescription. Federal Medicaid regulations allow co-payments of up to \$4 for preferred drugs and \$8 for non-preferred drugs for individuals with incomes at or below 150 percent of the federal poverty level (FPL). For individuals with higher incomes, states may require cost sharing up to 20 percent of the cost of the drug for non-preferred drugs (42 CFR 447.53). States may exclude certain populations from cost sharing (e.g., individuals residing in nursing facilities), and certain drugs (e.g., family planning and smoking cessation medications) are excluded by federal law from this requirement (42 CFR 447.56).

An analysis of data from the 2013–2014 National Drug Abuse Treatment System Survey indicates that cost sharing for Medicaid beneficiaries was required for buprenorphine in 16 states and the District of Columbia, and for oral naltrexone in 13 states and the District of Columbia (Grogan et al. 2016).

Seven of the eight states we reviewed require co-payments for all prescription drugs, including

MAT medications. Co-payments are typically \$1.50–\$2.00 for generic drugs and \$3.00 for brand name drugs. In Illinois, beneficiaries covered under managed care are not subject to co-payments for any covered drugs. Similarly, Washington does not impose co-payments for prescription drugs in either FFS or managed care. Maine uses a separate co-payment structure for MAT for methadone; payments cannot exceed \$2.00 per day, per service, or \$2.00 per week (Maine DHHS 2019b).

Multiple studies have found that co-payments can decrease the use of appropriate, medically necessary services and cause enrollees to delay care (MACPAC 2015). This is also true for MAT co-payments; implementation of such policies for prescription drugs reduces use for all drug classes (Burns et al. 2016, Hartung et al. 2008).

Limits for counseling services

As noted above, Medicaid utilization management policies are not limited to prescription drugs: both FFS programs and MCOs may impose limits on the number of MAT counseling visits, limit the duration of treatment, or require prior authorization or referrals from primary care physicians.

All eight states we reviewed offer both individual and group therapy as an outpatient SUD benefit. Of these eight states, five required either referral or prior authorization for MAT counseling or they applied quantity limits.

- In Maine, individual SUD therapy is limited to three hours per week for 30 weeks in a 40-week period (Maine DHHS 2019b).
- In Illinois, there is no limit to outpatient visits under FFS, but limits vary under managed care, with the largest plan requiring prior authorization to exceed 20 outpatient behavioral health visits (Meridian Health 2019).
- In Missouri, prior authorization is required for outpatient behavioral health therapy under both FFS and managed care (Missouri DSS 2019, WellCare of Missouri 2013).

- In Arkansas, prior authorization is required for more than 12 visits, and referral from a primary care provider is required after 3 counseling visits (Arkansas DMS 2018). The Arkansas Medicaid program does not automatically deny medication for patients who are not receiving counseling; instead it asks providers for documentation that the patient has a treatment plan or is making other attempts to receive behavioral therapy (Neuhofel 2019).
- West Virginia requires prior authorization for counseling services.

Requiring counseling as a condition for receiving medication is often cited as a barrier to accessing MAT (NASEM 2019, Rinaldo and Rinaldo 2013). Although beneficiaries with an OUD may have concurrent medical and mental health needs that require more intensive and long-term counseling, policies that make receipt of medication contingent on undergoing psychosocial treatment can delay or prevent access to treatment if counseling is not available (Rinaldi and Rinaldi 2013, McCarty et al. 1999). Some patients may prefer not to have concurrent counseling services and therefore choose not to initiate or continue medication (Burns et al. 2016, Dugosh et al. 2016). Some patients may respond well to medication or medical management alone, without requiring behavioral therapy (NASEM 2019, SAMHSA 2018b).

Sixteen states require psychosocial treatment as a condition for receiving buprenorphine (SAMHSA 2018a). States requiring counseling impose different terms, for example:

- In Maine, patients enrolled in the state's Opioid Health Home program are required to attend an individual or group counseling session for at least one hour per week during the 60-day treatment initiation phase, with less frequent counseling sessions required during the stabilization and maintenance phases. Referral and documentation of counseling compliance is also required for patients receiving office-based opioid treatment (Alford 2019).

- In West Virginia, counseling can be delivered individually or in a group, according to a treatment plan created by the beneficiary, counselor, and physician. During the first 12 months of treatment, beneficiaries are required to attend a minimum of four hours of therapy per month; after 12 months, the mandatory minimum is one hour of therapy per month (WV DHHR 2018b). Moreover, if there is no record of counseling visits for beneficiaries receiving MAT medication, the state will contact the prescriber listed on the beneficiary's coordination of care agreement to discuss whether medication should be continued (Parsons 2019).
- In Missouri, Medicaid beneficiaries enrolled in FFS are limited to one individual psychotherapy session per day, or five sessions per month (MO Health Net 2019).¹¹

Methadone

Because methadone is dispensed only in OTPs, utilization management policies differ from other MAT drugs. Forty-one states and the District of Columbia pay for OTP services (SAMHSA 2018b). At least three states—Connecticut, Maine, and North Carolina—require prior authorization for methadone maintenance in OTP settings (SAMHSA 2018b). In Maine, methadone patients are also subject to a so-called soft 24-month lifetime limit, although the state offers unlimited 12-month extensions to patients who meet the state's medical necessity criteria for continued methadone treatment (Maine DHHS 2019b, SAMHSA 2018b).

Of the eight states we reviewed, six states (excluding Arkansas and Tennessee) pay for OTP services. In Maine, OTPs dispensing methadone must develop individual service plans and must apply quantity limits for initial doses (Maine DHHS 2019b). Providers must develop diversion control plans and consult the state's PDMP prior to initial treatment and before changing dosages—this is the case for all MAT prescribers and facilities in Maine (Maine DHHS 2019b).

In January 2018, West Virginia began paying OTPs through a Section 1115 SUD demonstration, with no prior authorization required. Patients receiving methadone for OUD must attend at least four hours of behavioral therapy per month during their first 12 months of treatment and one behavioral therapy session per month after that, although providers have some discretion in continuing medication for patients who do not meet these requirements.

Policy Trends

In recent years, state Medicaid programs and Medicaid MCOs have reduced use of certain utilization management policies. To quantify how states have altered their policies for MAT drugs, MACPAC compared findings from SAMHSA's 2018 report on Medicaid coverage and utilization management policies for MAT medications with the findings from SAMHSA's 2014 report (SAMHSA 2018a, 2014).

Although the 2014 SAMHSA report did not capture all formulations of the MAT drugs discussed in the 2018 report and the difference in methods of the two reports preclude direct comparisons, we were able to identify general changes in policies for acamprosate, disulfiram, oral naltrexone, extended-release naltrexone, and buprenorphine-naloxone.¹² We found the following:

- during both reporting periods, utilization management techniques were applied to buprenorphine-naloxone more than to other MAT drugs;
- fewer states assigned preferred status to acamprosate, disulfiram, and oral naltrexone in 2018 than in 2011–2013;
- the number of states that required prior authorization for disulfiram, oral naltrexone, and buprenorphine-naloxone declined over the same time period; and

- the number of states applying quantity or dosing limits increased for nearly all MAT drugs.

We discuss these findings in greater detail below.

Changes in preferred drug lists

Fewer states placed MAT drugs on their PDLs in 2018 than in 2011–2013, with the exception of extended-release naltrexone and buprenorphine-naloxone (Figure 3-4). For example, in 2011–2013, all 50 states and the District of Columbia listed oral naltrexone as a preferred drug and in 2018, 44 states assigned preferred status to this drug. The number of states assigning preferred status to disulfiram declined by the highest percentage over this time period (SAMHSA 2018a, 2014).

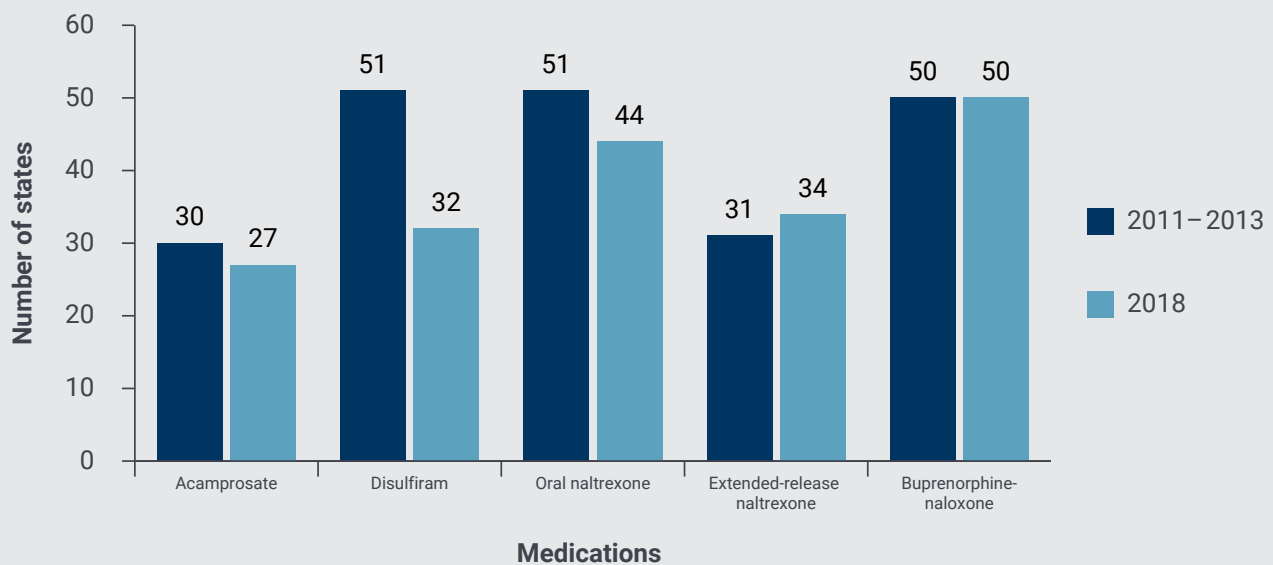
the exception of acamprosate and extended-release naltrexone (Figure 3-5). Notably, the number of states requiring prior authorization for buprenorphine-naloxone decreased from 48 in 2011–2013 to 30 in 2018 (SAMHSA 2018a, 2014).

Pennsylvania is among the states that have changed their prior authorization policies to make MAT more readily accessible. In 2017, Pennsylvania held an opioid summit that brought together payers and health plans, including many that participate in Medicaid managed care. Notably, the state asked all payers to eliminate prior authorization for most MAT drugs. All Medicaid MCOs were required to implement the recommendations from the summit (Hoover 2019) (Box 3-2).

Changes in prior authorization

The number of states that require prior authorization for MAT drugs has declined, with

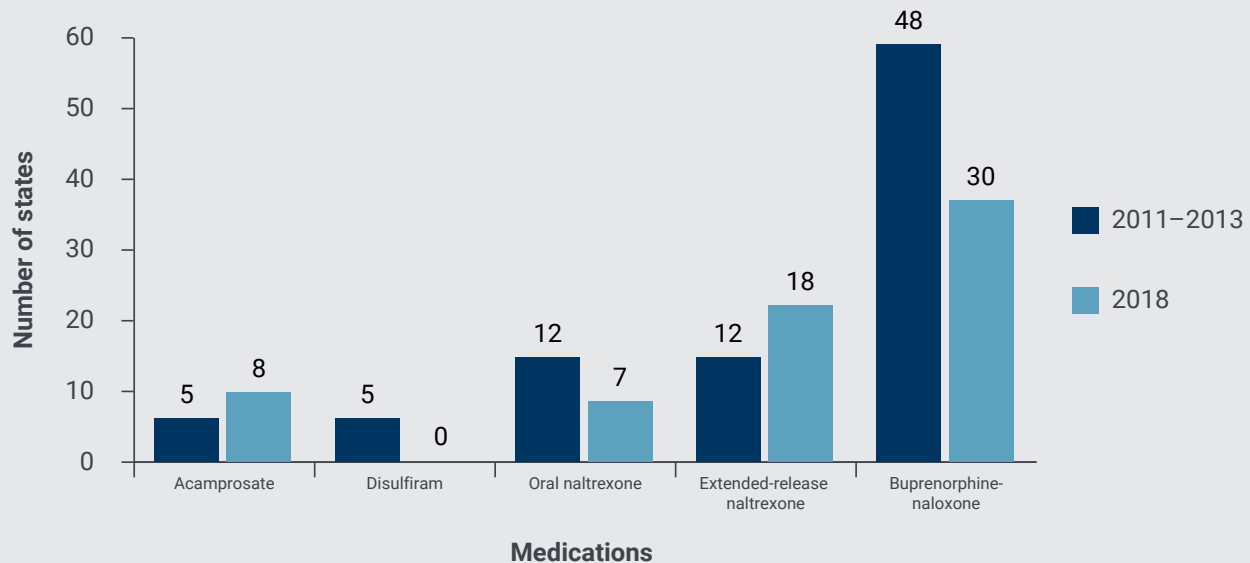
FIGURE 3-4. Number of States Assigning Preferred Status to Certain Medication-Assisted Treatment Drugs, 2011–2013 and 2018



Notes: Totals include the District of Columbia but exclude U.S. territories.

Source: SAMHSA 2018a, 2014.

FIGURE 3-5. Number of States Requiring Prior Authorization for Certain Medication-Assisted Treatment Drugs, 2011–2013 and 2018



Notes: Totals include the District of Columbia but exclude U.S. territories.

Source: SAMHSA 2018a, 2014.

Changes in quantity and refill limits

States are applying additional quantity or dosing limits to all MAT medications except disulfiram (Figure 3-6). Specifically, 46 states apply quantity or dosing limits to buprenorphine-naloxone, up from 34 states in 2011–2013. One justification states give for applying quantity and dosing limits to buprenorphine-naloxone is their concern for patient safety (Hoover 2019, San Bartolome 2019). Sixteen states applied quantity or dosing limits to extended-release naltrexone in 2018, up from three states in 2011–2013. (SAMHSA 2018a, 2014).

MAT access and utilization management under Section 1115 SUD demonstrations

The Section 1115 SUD demonstration opportunity offers states a pathway to pay for SUD treatment services in certain residential and inpatient settings. But the ability to pay for SUD treatment in residential and inpatient settings is only one component

of these demonstrations; they also provide an opportunity for states to develop a continuum of care and improve access to clinically appropriate SUD care, including MAT (CMS 2017). Demonstration components relevant to MAT access include covering critical levels of care and ensuring that residential providers offer their patients access to MAT (CMS 2017). States must also report on certain performance measures and milestones, including the number of beneficiaries with claims for MAT drugs, the number of providers enrolled in the Medicaid program who are qualified to provide buprenorphine and methadone treatment, and beneficiary initiation of treatment and engagement in MAT, including beneficiaries with OUD (CMS 2019b).

A few early data points from California and Virginia, early adopters of the Section 1115 opportunity, are promising.

California. The California Department of Health Care Services made the decision to eliminate prior authorization requirements for buprenorphine in 2015 (KHN 2019). Claims analysis demonstrates

BOX 3-2. Changes in Prior Authorization Policies in Pennsylvania

Pennsylvania adopted several policies in 2018 that removed prior authorization for drugs used to treat opioid use disorder in both managed care and fee for service (FFS):

- One formulation of buprenorphine-naloxone is now available without prior authorization. Medicaid MCOs and the state's FFS program may require prior authorization for buprenorphine products in three situations: when they are not used in combination with naloxone, when they are used in combination with benzodiazepines and other central nervous system depressants, and when the prescriptions are for doses that exceed daily dose limits.
- Prior authorization is prohibited for oral naltrexone and methadone.
- Prior authorization is eliminated for outpatient drug and alcohol counseling. Documentation of participation in counseling will now be verified only for requests that exceed the quantity limits.

Since these changes were made, the state has lost a point of contact with some beneficiaries. However, the number of buprenorphine and oral naltrexone prescriptions in Pennsylvania increased by nearly 25 percent from 2017 to 2018, which may be due in part to the elimination of prior authorization requirements for these drugs (Hoover 2019).

that the rate of Medi-Cal beneficiaries who received buprenorphine nearly quadrupled from the final quarter of 2014 to the third quarter of 2018. In comparison, the rate for methadone remained largely unchanged from the end of 2014 through the final quarter of 2017; however, the state expects to see increased use of methadone because an increase in the number of OTPs is underway as part of the state's Section 1115 demonstration (KHN 2019).

Virginia. A component of Virginia's demonstration is the development of a new delivery system model, the preferred office-based opioid treatment (OBOT) clinic. Preferred OBOT clinics receive higher payment rates to provide coordinated care to beneficiaries while adhering to MAT treatment guidelines. The state also quadrupled payment for the counseling component of MAT (MACPAC 2018, VCU 2018a).

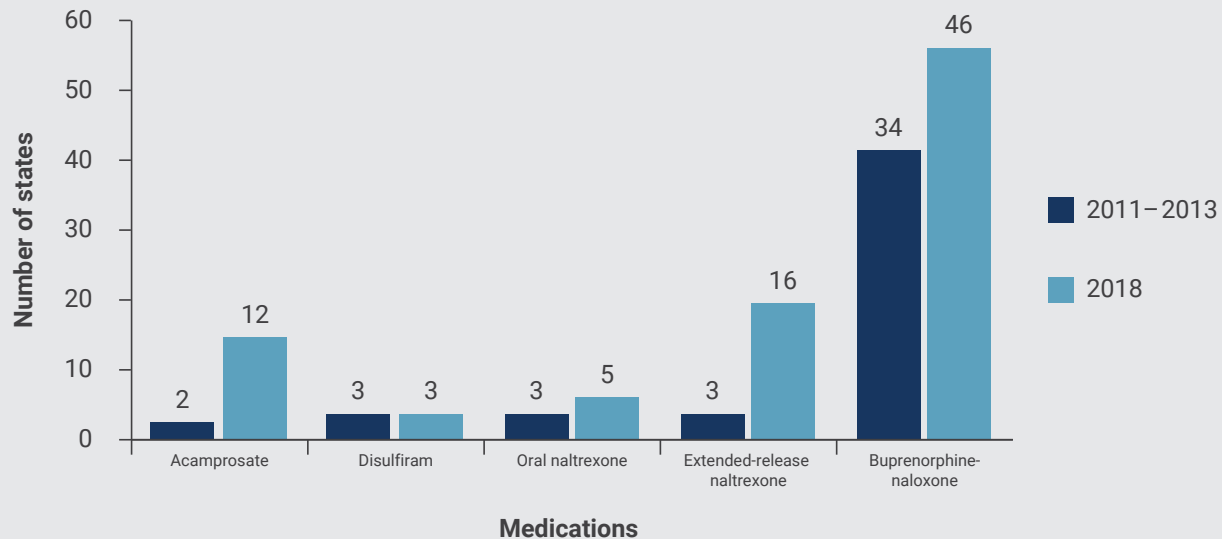
The use of buprenorphine to treat OUD, and the likelihood that beneficiaries will receive other SUD services in addition to buprenorphine, has increased since the implementation of the demonstration. During the first 12 months of the demonstration, the

number of members receiving pharmacotherapy for OUD increased by 34 percent (VCU 2018a).

During the first five months of the demonstration, beneficiaries receiving buprenorphine through the new preferred OBOT clinics were more likely to receive counseling and other services than patients using other providers. Specifically, 72 percent of beneficiaries who were prescribed buprenorphine from a preferred OBOT clinic provider received at least one other OUD service (e.g., psychotherapy, counseling, or partial hospitalization) (VCU 2018b). In comparison, 48 percent of buprenorphine users who obtained buprenorphine from other prescribers received at least one other OUD service, which is still a substantial improvement over beneficiary use of such services prior to the demonstration's implementation—before the demonstration began, 30 percent of beneficiaries using buprenorphine received an additional OUD service that was consistent with MAT standards (VCU 2018b).

It is unclear whether the application of utilization management policies for MAT will be taken into

FIGURE 3-6. Number of States Applying Quantity or Dosing Limits to Certain Medication-Assisted Treatment Drugs, 2011–2013 and 2018



Notes: Totals include the District of Columbia but exclude U.S. territories.

Source: SAMHSA 2018a, 2014.

account as other states develop strategies to expand access to SUD treatment. In addition, it may be difficult to conclude which aspects of a state's Section 1115 demonstration (e.g., increasing payment rates for existing SUD services, adding additional SUD services) have the greatest impact on beneficiary access to SUD treatment, including MAT.

Endnotes

¹ States may subject any covered outpatient drug to prior authorization as long as the state responds to requests in a timely manner.

² The Centers for Medicare & Medicaid Services do not allow so-called hard limitations on the amount, duration, and scope of services a beneficiary can access due to medical necessity. If a state imposes limits, it must demonstrate with claims data that even with limits imposed, the needs of at least 90 percent of beneficiaries in affected eligibility groups will be met.

³ MHPAEA prevents certain health insurance plans that provide behavioral health or SUD benefits from applying limits on those benefits that are more restrictive than the limits applied to medical or surgical benefits. The effect of this law on utilization management decisions and beneficiary access to MAT falls outside the scope of this study.

⁴ A naloxone challenge test may be performed prior to initiation of treatment to assess opioid dependence, because prescribing guidelines call for an individual to be opioid-free before starting the drug. In a naloxone challenge, a provider administers a small injection of naloxone. If the patient shows signs of opioid withdrawal following the injection, initiation of treatment with naltrexone may be delayed (Alkermes 2013).

⁵ In Utah, if medication is required beyond the initial 180-day period, providers must submit an annual attestation that the patient's medical record includes diagnosis of opioid dependence, a description of psychosocial support the patient will receive or is receiving, and a treatment plan detailing management and potential for tapering or discontinuation (UDOH 2019a).

- ⁶ States may also require MCOs to adhere to a uniform formulary for some or all drugs, although federal requirements allow providers to request coverage of non-preferred drugs through a prior authorization process (§ 1927(d)(4) of the Act) (KFF 2018).
- ⁷ In Arkansas, this requirement applies to buprenorphine sublingual tablets and buprenorphine-naloxone sublingual film; in Tennessee, it applies to buprenorphine-naloxone tablets and buccal film (Magellan 2019e, Arkansas DMS 2018).
- ⁸ The early and periodic screening, diagnostic, and treatment (EPSDT) benefit requires that children receive any Medicaid-coverable service in any amount that is medically necessary, regardless of whether the service is covered in the state plan (§ 1905(r) of the Act).
- ⁹ Medical necessity forms in Arkansas for Vivitrol (naltrexone for extended-release injectable suspension) and Suboxone (buprenorphine and naloxone sublingual film) include quantity limits that are consistent with FDA dosing guidelines, which recommend administering Vivitrol every four weeks at 380 milligrams (one vial) and taking Suboxone every day at the 12 milligrams buprenorphine and 3 milligrams naloxone dosage (Alkermes 2018, Arkansas Medicaid 2018, Indivior 2018b, RBP 2011).
- ¹⁰ The Tennessee Medicaid program has specific quantity limits for several buprenorphine and buprenorphine-naloxone products whose prescribing guidelines indicate that dosages are to be tapered after six months (Magellan 2019a). For example, beneficiaries taking buprenorphine-naloxone sublingual tablets start with 8 milligrams twice a day for six months and then taper to 2 milligrams three times a day (Indivior 2018a).
- ¹¹ We note that the behavioral health services manual we reviewed did not make clear whether this applies to counseling for MAT only or to all types of psychotherapy and whether these limits also apply to members enrolled in managed care.
- ¹² MACPAC compared findings from the 2018 SAMHSA report, *Medicaid Coverage of Medication-Assisted Treatment for Alcohol and Opioid Use Disorders and of Medication for the Reversal of Opioid Overdose* with findings from the 2014 SAMHSA report, *Medicaid Coverage and Financing of Medications to Treat Alcohol and Opioid Use Disorders*, which

includes information on utilization management policies for 2011–2013 (SAMHSA 2018a, 2014). It is not possible to draw comparisons for all formulations of MAT medications, because some formulations of buprenorphine products discussed in the 2018 report came to market only after the 2014 report was issued.

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APPENDIX 3A: Medicaid Policies for Selected Drugs Used in Medication-Assisted Treatment by State

The following tables present a summary of Medicaid policies for coverage and utilization management of selected drugs used in medication-assisted treatment (MAT) for eight states. These eight states were chosen to reflect diversity across several dimensions, including: whether the state had an approved Section 1115 substance use disorder (SUD) demonstration; the number of covered MAT medications and services in the state's SUD treatment continuum; recent changes to and known variations in utilization management policies for MAT medications; geography; and whether behavioral health services are delivered through managed care or fee for service.

TABLE 3A-1. Medicaid Fee-for-Service Policies for Acamprosate by State, 2019

Policy type	Total	Arkansas	Illinois	Maine	Missouri	Tennessee ¹	Utah	Washington	West Virginia
Drug is covered by Medicaid	8	✓	✓	✓	✓	✓	✓	✓	✓
Drug is covered with preferred status	3	–	✓	–	–	✓	–	✓	–
Prior authorization required	1	–	–	✓	–	–	–	–	–
Step therapy required	–	–	–	–	–	–	–	–	–
Limits on number of prescriptions	1	–	–	–	–	✓	–	–	–
Quantity or dose limits	–	–	–	–	–	–	–	–	–
Lifetime limits	–	–	–	–	–	–	–	–	–

Notes: ✓ Check indicates that the state is implementing this policy. – Dash indicates that the state is not implementing this policy.

¹ Although Tennessee Medicaid limits prescriptions of this drug to five per beneficiary per month, providers can request a limit override in certain high-risk situations.

Sources: MACPAC, 2019, analysis of state policy documents and e-mail correspondence with states.

TABLE 3A-2. Medicaid Fee-for-Service Policies for Disulfiram (Generic) by State, 2019

Policy type	Total	Arkansas	Illinois	Maine	Missouri	Tennessee ¹	Utah	Washington	West Virginia
Drug is covered by Medicaid	8	✓	✓	✓	✓	✓	✓	✓	✓
Drug is covered with preferred status	4	–	✓	✓	–	✓	–	✓	–
Prior authorization required	–	–	–	–	–	–	–	–	–
Step therapy required	–	–	–	–	–	–	–	–	–
Limits on number of prescriptions	1	–	–	–	–	✓	–	–	–
Quantity or dose limits	–	–	–	–	–	–	–	–	–
Lifetime limits	–	–	–	–	–	–	–	–	–

Notes: ✓ Check indicates that the state is implementing this policy. – Dash indicates that the state is not implementing this policy.

¹ Although Tennessee Medicaid limits prescriptions of this drug to five per beneficiary per month, providers can request a limit override in certain high-risk situations.

Sources: MACPAC, 2019, analysis of state policy documents and e-mail correspondence with states.

TABLE 3A-3. Medicaid Fee-for-Service Policies for Disulfiram (Antabuse) by State, 2019

Policy type	Total	Arkansas ¹	Illinois	Maine	Missouri	Tennessee ²	Utah	Washington	West Virginia
Drug is covered by Medicaid	8	✓	✓	✓	✓	✓	✓	✓	✓
Drug is covered with preferred status	2	–	✓	✓	–	–	–	–	–
Prior authorization required	2	✓	–	–	–	–	–	✓	–
Step therapy required	–	–	–	–	–	–	–	–	–
Limits on number of prescriptions	1	–	–	–	–	✓	–	–	–
Quantity or dose limits	–	–	–	–	–	–	–	–	–
Lifetime limits	–	–	–	–	–	–	–	–	–

Notes: ✓ Check indicates that the state is implementing this policy. – Dash indicates that the state is not implementing this policy.

¹ Arkansas requires prior authorization for brand name prescriptions of this drug but not for generic.

² Although Tennessee Medicaid limits prescriptions of this drug to five per beneficiary per month, providers can request a limit override in certain high-risk situations.

Sources: MACPAC, 2019, analysis of state policy documents and e-mail correspondence with states.

TABLE 3A-4. Medicaid Fee-for-Service Policies for Naltrexone Tablet (Generic) by State, 2019

Policy type	Total	Arkansas	Illinois	Maine	Missouri	Tennessee ¹	Utah	Washington	West Virginia
Drug is covered by Medicaid	8	✓	✓	✓	✓	✓	✓	✓	✓
Drug is covered with preferred status	5	–	✓	✓	✓	✓	–	✓	–
Prior authorization required	1	–	–	–	–	✓	–	–	–
Step therapy required	–	–	–	–	–	–	–	–	–
Limits on number of prescriptions	1	–	–	–	–	✓	–	–	–
Quantity or dose limits	2	✓	–	–	–	–	✓	–	–
Lifetime limits	–	–	–	–	–	–	–	–	–

Notes: ✓ Check indicates that the state is implementing this policy. – Dash indicates that the state is not implementing this policy.

¹ Although Tennessee Medicaid limits prescriptions of this drug to five per beneficiary per month, providers can request a limit override in certain high-risk situations.

Sources: MACPAC, 2019, analysis of state policy documents and e-mail correspondence with states.

TABLE 3A-5. Medicaid Fee-for-Service Policies for Extended-Release Injectable Naltrexone (Vivitrol) by State, 2019

Policy type	Total	Arkansas	Illinois	Maine	Missouri	Tennessee ¹	Utah	Washington	West Virginia
Drug is covered by Medicaid	8	✓	✓	✓	✓	✓	✓	✓	✓
Drug is covered with preferred status	7	–	✓	✓	✓	✓	✓	✓	✓
Prior authorization required	1	✓	–	–	–	–	–	–	–
Step therapy required	–	–	–	–	–	–	–	–	–
Limits on number of prescriptions	2	✓	–	–	–	✓	–	–	–
Quantity or dose limits	–	–	–	–	–	–	–	–	–
Lifetime limits	–	–	–	–	–	–	–	–	–

Notes: ✓ Check indicates that the state is implementing this policy. – Dash indicates that the state is not implementing this policy.

¹ Although Tennessee Medicaid limits prescriptions of this drug to five per beneficiary per month, providers can request a limit override in certain high-risk situations.

Sources: MACPAC, 2019, analysis of state policy documents and e-mail correspondence with states.

TABLE 3A-6. Medicaid Fee-for-Service Policies for Buprenorphine Tablet (Generic) by State, 2019

Policy type	Total	Arkansas	Illinois	Maine	Missouri	Tennessee ¹	Utah	Washington	West Virginia
Drug is covered by Medicaid	8	✓	✓	✓	✓	✓	✓	✓	✓
Drug is covered with preferred status	1	✓	–	–	–	–	–	–	–
Prior authorization required	5	✓	–	✓	✓	✓	–	✓	–
Step therapy required	2	–	–	–	✓	✓	–	–	–
Limits on number of prescriptions	1	–	–	–	–	✓	–	–	–
Quantity or dose limits	3	✓	–	–	–	✓	✓	–	–
Lifetime limits	–	–	–	–	–	–	–	–	–

Notes: ✓ Check indicates that the state is implementing this policy. – Dash indicates that the state is not implementing this policy.

¹ Although Tennessee Medicaid limits prescriptions of this drug to five per beneficiary per month, providers can request a limit override in certain high-risk situations.

Sources: MACPAC, 2019, analysis of state policy documents and e-mail correspondence with states.

TABLE 3A-7. Medicaid Fee-for-Service Policies for Implantable Buprenorphine (Probuphine) by State, 2019

Policy type	Total	Arkansas	Illinois	Maine	Missouri	Tennessee ¹	Utah	Washington	West Virginia
Drug is covered by Medicaid	8	✓	✓	✓	✓	✓	✓	✓	✓
Drug is covered with preferred status	1	–	✓	–	–	–	–	–	–
Prior authorization required	4	✓	–	✓	✓	–	–	✓	–
Step therapy required	1	–	–	–	✓	–	–	–	–
Limits on number of prescriptions	1	–	–	–	–	✓	–	–	–
Quantity or dose limits	–	–	–	–	–	–	–	–	–
Lifetime limits	–	–	–	–	–	–	–	–	–

Notes: ✓ Check indicates that the state is implementing this policy. – Dash indicates that the state is not implementing this policy.

¹ Although Tennessee Medicaid limits prescriptions of this drug to five per beneficiary per month, providers can request a limit override in certain high-risk situations.

Sources: MACPAC, 2019, analysis of state policy documents and e-mail correspondence with states.

TABLE 3A-8. Medicaid Fee-for-Service Policies for Extended-Release Injectable Buprenorphine (Sublocade) by State, 2019

Policy type	Total	Arkansas	Illinois	Maine	Missouri	Tennessee ¹	Utah	Washington	West Virginia
Drug is covered by Medicaid	8	✓	✓	✓	✓	✓	✓	✓	✓
Drug is covered with preferred status	2	–	✓	–	–	–	✓	–	–
Prior authorization required	4	✓	–	✓	✓	–	–	✓	–
Step therapy required	2	–	–	–	✓	–	–	–	✓
Limits on number of prescriptions	1	–	–	–	–	✓	–	–	–
Quantity or dose limits	–	–	–	–	–	–	–	–	–
Lifetime limits	–	–	–	–	–	–	–	–	–

Notes: ✓ Check indicates that the state is implementing this policy. – Dash indicates that the state is not implementing this policy.

¹ In Tennessee, coverage of extended-release injectable buprenorphine is available through the medical benefit.

Sources: MACPAC, 2019, analysis of state policy documents and e-mail correspondence with states.

TABLE 3A-9. Medicaid Fee-for-Service Policies for Buprenorphine-Naloxone Tablet (Generic) by State, 2019

Policy type	Total	Arkansas	Illinois	Maine	Missouri	Tennessee ¹	Utah	Washington	West Virginia
Drug is covered by Medicaid	8	✓	✓	✓	✓	✓	✓	✓	✓
Drug is covered with preferred status	3	–	✓	–	–	✓	–	✓	–
Prior authorization required	6	✓	–	✓	✓	✓	✓	–	✓
Step therapy required	2	–	–	–	✓	–	✓	–	–
Limits on number of prescriptions	1	–	–	–	–	✓	–	–	–
Quantity or dose limits	5	✓	–	–	–	✓	✓	✓	✓
Lifetime limits	–	–	–	–	–	–	–	–	–

Notes: ✓ Check indicates that the state is implementing this policy. – Dash indicates that the state is not implementing this policy.

¹ Buprenorphine-naloxone sublingual tablets are preferred for providers within the medication-assisted treatment (MAT) provider's network only. Buprenorphine-naloxone sublingual tablets are non-preferred for all other TennCare providers. Although Tennessee Medicaid limits prescriptions of this drug to five per beneficiary per month, providers can request a limit override in certain high-risk situations. (Buprenorphine-naloxone buccal film is the only MAT drug exempt from this limit.)

Sources: MACPAC, 2019, analysis of state policy documents and e-mail correspondence with states.

TABLE 3A-10. Medicaid Fee-for-Service Policies for Buprenorphine-Naloxone Buccal Film (Bunavail) by State, 2019

Policy type	Total	Arkansas	Illinois	Maine	Missouri	Tennessee ¹	Utah	Washington	West Virginia
Drug is covered by Medicaid	8	✓	✓	✓	✓	✓	✓	✓	✓
Drug is covered with preferred status	2	–	✓	–	–	✓	–	–	–
Prior authorization required	7	✓	–	✓	✓	✓	✓	✓	✓
Step therapy required	2	–	–	–	✓	–	✓	–	–
Limits on number of prescriptions	–	–	–	–	–	–	–	–	–
Quantity or dose limits	6	✓	–	✓	–	✓	✓	✓	✓
Lifetime limits	–	–	–	–	–	–	–	–	–

Notes: ✓ Check indicates that the state is implementing this policy. – Dash indicates that the state is not implementing this policy.

¹ Buprenorphine-naloxone buccal film is the only medication-assisted treatment (MAT) drug exempt from the monthly prescription limit that Tennessee Medicaid imposes on beneficiaries receiving MAT.

Sources: MACPAC, 2019, analysis of state policy documents and e-mail correspondence with states.

TABLE 3A-11. Medicaid Fee-for-Service Policies for Buprenorphine-Naloxone Sublingual Film (Suboxone) by State, 2019

Policy type	Total	Arkansas	Illinois	Maine	Missouri	Tennessee ¹	Utah	Washington ²	West Virginia
Drug is covered by Medicaid	8	✓	✓	✓	✓	✓	✓	✓	✓
Drug is covered with preferred status	7	✓	✓	✓	✓	–	✓	✓	✓
Prior authorization required	3	✓	–	–	–	✓	✓	–	–
Step therapy required	1	–	–	–	–	✓	–	–	–
Limits on number of prescriptions	1	✓	–	–	–	–	–	–	–
Quantity or dose limits	6	✓	–	✓	–	✓	✓	✓	✓
Lifetime limits	–	–	–	–	–	–	–	–	–

Notes: ✓ Check indicates that the state is implementing this policy. – Dash indicates that the state is not implementing this policy.

¹ Although Tennessee Medicaid limits prescriptions of this drug to five per beneficiary per month, providers can request a limit override in certain high-risk situations. (Buprenorphine-naloxone buccal film is the only medication-assisted treatment (MAT) drug exempt from this limit.)

² The generic version of buprenorphine-naloxone sublingual tablet is also covered without preferred status, with prior authorization required, and with quantity limits.

Sources: MACPAC, 2019, analysis of state policy documents and e-mail correspondence with states.

TABLE 3A-12. Medicaid Fee-for-Service Policies for Buprenorphine-Naloxone Sublingual Tablet (Zubsolv) by State, 2019

Policy type	Total	Arkansas	Illinois	Maine	Missouri	Tennessee ¹	Utah	Washington	West Virginia
Drug is covered by Medicaid	8	✓	✓	✓	✓	✓	✓	✓	✓
Drug is covered with preferred status	1	–	✓	–	–	–	–	–	–
Prior authorization required	7	✓	–	✓	✓	✓	✓	✓	✓
Step therapy required	3	–	–	–	✓	✓	✓	–	–
Limits on number of prescriptions	–	–	–	–	–	–	–	–	–
Quantity or dose limits	6	✓	–	✓	–	✓	✓	✓	✓
Lifetime limits	–	–	–	–	–	–	–	–	–

Notes: ✓ Check indicates that the state is implementing this policy. – Dash indicates that the state is not implementing this policy.

¹ Although Tennessee Medicaid limits prescriptions of this drug to five per beneficiary per month, providers can request a limit override in certain high-risk situations. (Buprenorphine-naloxone buccal film is the only medication-assisted treatment (MAT) drug exempt from this limit.)

Sources: MACPAC, 2019, analysis of state policy documents and e-mail correspondence with states.

TABLE 3A-13. Medicaid Fee-for-Service Policies for Methadone in Opioid Treatment Programs by State, 2019

Policy type	Total	Arkansas	Illinois	Maine ¹	Missouri	Tennessee	Utah	Washington	West Virginia
Drug is covered by Medicaid	6	–	✓	✓	✓	–	✓	✓	✓
Prior authorization required	1	–	–	✓	–	–	–	–	–
Step therapy required	–	–	–	–	–	–	–	–	–
Limits on number of prescriptions	–	–	–	–	–	–	–	–	–
Quantity or dose limits	5	–	–	✓	✓	–	✓	✓	✓
Lifetime limits	–	–	–	–	–	–	–	–	–

Notes: ✓ Check indicates that the state is implementing this policy. – Dash indicates that the state is not implementing this policy.

Attributing preferred status to methadone for medication-assisted treatment is not possible given federal restrictions on dispensing and access.

¹ Maine removed lifetime limits for methadone in 2019.

Sources: MACPAC, 2019, analysis of state policy documents and e-mail correspondence with states.

Chapter 4:

Managed Care Compliance with Federal Law

CHAPTER 4: Managed Care Compliance with Federal Law

The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (P.L. 115-271) directs MACPAC to determine whether Medicaid managed care organization (MCO) utilization control policies and procedures for medication-assisted treatment (MAT) are consistent with federal regulations that permit MCOs to impose such policies (42 CFR 438.210). Specifically, federal regulations allow MCOs to apply limits to certain services as long as the affected services are sufficient in amount, duration, and scope to reasonably achieve their purposes.¹ Given that more than two-thirds of all Medicaid beneficiaries are enrolled in comprehensive managed care arrangements, these utilization control policies may affect the majority of patients receiving MAT.²

Findings for Services Delivered through Managed Care Arrangements

To examine this issue, we conducted an in-depth review of the policies in eight states—Arkansas, Illinois, Maine, Missouri, Tennessee, Utah, Washington, and West Virginia—to determine whether their utilization control policies for MAT are consistent with federal regulations. For the six states that use comprehensive risk-based managed care—Illinois, Missouri, Tennessee, Utah, Washington, and West Virginia—we reviewed Medicaid managed care contracts, provider manuals, member benefit handbooks, and preferred drug lists for each state’s largest Medicaid managed care plan by beneficiary enrollment.³

We found that MCO contracts in these states allow for utilization control policies consistent with

federal regulations. A more detailed assessment of how MCOs implement such policies, including how these policies influence utilization and access to MAT, was not possible given available resources.

Three states in our review (Illinois, Utah, and Washington) cover behavioral health services separately through a behavioral health organization (BHO) or similar arrangement. For example, Utah operates prepaid mental health plans for behavioral health services other than inpatient withdrawal management. In Washington, integrated managed care (IMC) plans operate behavioral health services-only plans for beneficiaries not eligible for managed care; for counties without IMC plans, behavioral health services are generally carved out into BHOs. By January 1, 2020, IMC plans will be available in all counties in the state.

Among these three states, Washington was the only one we reviewed that had specific managed care contract language that included utilization review for substance use disorder treatment, although it does not specifically mention review of MAT services:

The [Utilization Management] Contractor shall require authorization decisions for behavioral health services are made [sic] by Washington licensed behavioral health professionals except when there is no Washington resources [sic] for specialty review. Contractor staff described in this subsection shall review any behavioral health Adverse Benefit Determination (denial) based on medical necessity, including any decision to authorize a service in an amount, duration or scope that is less than requested (WSHCA 2019).

The two other states in our policy review—Arkansas and Maine—do not use comprehensive risk-based managed care. Arkansas covers beneficiaries through fee-for-service (FFS) arrangements but provides behavioral health services separately through a BHO. Maine operates a primary care case management model.

Comparison of Managed Care and Fee-for-Service Policies

We also looked at differences within states between FFS and managed care. We found that requirements for prior authorization for MAT are often inconsistent between a state's FFS plan and different MCOs, although some states are moving toward uniform clinical protocols (KFF 2018). Of the six states with managed care arrangements, Missouri, Tennessee, and Utah carve the pharmacy benefit out of their contracts, so MACPAC was able to compare MAT medication policies for only three states—Illinois, Washington, and West Virginia.

Generally, we found that policies such as assigning preferred status on the PDL, prior authorization, and quantity limits were consistent across managed care and FFS for drugs used to treat opioid use disorder (OUD) and alcohol use disorder. For example, utilization control policies are consistent across delivery systems in Illinois following a 2017 legislative mandate that prohibited prior authorization for MAT medications for all insurers.

In some cases, however, policies differed by drug. For drugs used to treat alcohol use disorder, MACPAC found that utilization management policies were slightly less restrictive under managed care. In Washington, the MCO we reviewed assigns preferred status to the brand version of disulfiram, making it available without prior authorization. In comparison, the state's FFS program requires prior authorization for this drug.

For drugs used to treat OUD, MACPAC found that in Washington and West Virginia, MCOs used stricter utilization management policies for MAT than policies applied under FFS. In Washington, one MCO assigns preferred status to the buprenorphine-naloxone tablet but requires prior authorization for doses above a certain daily threshold; the state's FFS program does not have such dosing limits. In West Virginia, most medications are carved out into FFS, but MCOs are responsible for covering physician-administered drugs. The state's largest MCO requires prior authorization for all injectable

drugs, including naltrexone and buprenorphine formulations (UniCare 2017). In comparison, the state's FFS program covers these two drugs without prior authorization.

MACPAC found that policies varied in states in which behavioral health services are delivered through both managed care and FFS. In Illinois, for instance, there is no limit to outpatient visits under FFS, but limits differed across MCOs, with the largest plan requiring prior authorization to exceed 20 outpatient behavioral health visits (Meridian Health 2019). In Missouri, beneficiaries covered through FFS are subject to quantity limits for individual psychotherapy services, but it is unclear whether these limits also apply to beneficiaries enrolled in managed care. The state's managed care contract indicates that a member's treatment (including psychological counseling) should not be interrupted or delayed by the prior authorization process, but it does not specifically refer to MAT (MO HealthNet 2016).

In Arkansas, newly launched care coordination programs for individuals with complex behavioral health care needs cannot be more restrictive than traditional Medicaid in terms of utilization management policies, including clinical edits, prior authorization, preferred drug lists (PDL), and supply limits.⁴

Endnotes

¹ Some argue that restrictions such as limits on the duration of treatment are inconsistent with clinical guidelines and should not exist, regardless of regulatory authority.

² MACPAC analysis of managed care enrollment nationally found that as of July 1, 2016, 67.5 percent of all Medicaid beneficiaries were enrolled in comprehensive managed care plans. This type of coverage also includes Programs of All-Inclusive Care for the Elderly (MACPAC 2018).

³ The six states that use comprehensive managed care vary in how they deliver certain benefits. Some states deliver all services through managed care. Other states provide behavioral health services through a BHO but cover

prescription drugs, including MAT medications, through either FFS or risk-based managed care.

⁴ The Provider-led Arkansas Shared Savings Entity program was launched in March 2019.

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Chapter 5:

Other State Programs Affecting Prescribing

CHAPTER 5: Other State Programs Affecting Prescribing

As part of their effort to curb the opioid epidemic, states and the federal government are implementing policies that step up prescription monitoring. These policies apply to all prescription opioids, and some states also use them to monitor the prescribing of drugs used in medication-assisted treatment (MAT). The enforcement of these policies may affect patient access to MAT medications even if that is not the main policy goal. In this chapter, we discuss three state activities that may influence access to MAT but are not, strictly speaking, utilization management techniques: drug utilization review (DUR), prescription drug monitoring programs (PDMPs), and pharmacy and provider lock-in programs.

Information in this chapter comes from a review of state policy documents, federal guidance, and current literature about these programs and their effect on patient access to MAT medications as well as from our detailed review of policies in eight states: Arkansas, Illinois, Maine, Missouri, Tennessee, Utah, Washington, and West Virginia.

Drug Utilization Review

All state Medicaid programs are required to operate a DUR program to monitor prescribing patterns to ensure that prescriptions are medically necessary, to reduce the likelihood of adverse events, and to identify patterns of fraud, waste, and abuse (§ 1927(g) of the Social Security Act). In addition, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act, P.L. 115-271) contains requirements for states to implement several Medicaid DUR policies, many of which are specific to opioid prescribing.

State DUR programs may include opioid prescribing controls; managing the use of antipsychotics

in children; and other policies to identify fraud, waste, and abuse at the prescriber, pharmacy, and beneficiary level (MACPAC 2019). Some states use findings from retrospective DUR activities to implement corrective actions, such as prescriber and pharmacy educational intervention programs (CMS 2018).

DUR is a two-phase process consisting of prospective and retrospective screening and monitoring of prescription drug claims. Prospective reviews must incorporate point-of-sale review, drug counseling, and profiling patients' current drug regimens. Retrospective monitoring includes, but is not limited to, using predetermined standards to monitor a number of prescribing practices, such as incorrect drug dosage, clinical misuse, therapeutic duplication, and therapeutic appropriateness of a drug.

State Medicaid agencies must describe their retrospective DUR policies in their state plans. Generally, retrospective DUR must occur through the state's Medicaid Management Information System (MMIS) or an electronic drug claims processing system that is integrated with the state's MMIS (42 CFR 456.709). States typically use contractors to conduct this work and coordinate with a DUR board to determine the appropriate retrospective DUR criteria, for instance, concurrent prescribing of opioids and benzodiazepines (CMS 2018).

States are not specifically required to conduct DUR for MAT medications, but some of them do. After expanding access to office-based MAT in 2015, Washington used retrospective monitoring to identify underutilization of injectable naltrexone (WSHCA 2017). In late 2016, the state removed authorization criteria and required all contracted Medicaid managed care organizations (MCOs) to cover this formulation in retail pharmacy settings to improve access to treatment (CMS 2018). Indiana uses retrospective DUR to flag concurrent prescribing of opioids (including MAT medications) and benzodiazepines, and then sends providers a faxed letter in near real time to notify them of the risks of such combinations (CMS 2018).

Retrospective DUR strategies, such as claims review, do not present immediate barriers to MAT access because these reviews are conducted after a drug has been dispensed. Some state Medicaid programs have indicated that they use retrospective DUR to monitor prescribing habits that may pose a safety risk to patients and that they use a more tailored approach to engage both patients and providers (Hoover 2019, San Bartolome 2019). This shift away from up-front utilization management techniques such as prior authorization toward more targeted analytical approaches for claims review may actually improve access to treatment (Hoover 2019, San Bartolome 2019).

Prescription Drug Monitoring Programs

PDMPs are statewide and sometimes interstate electronic databases that document dispensing of controlled substances in order to reduce inappropriate prescribing (such as concurrent opioid and benzodiazepine prescribing) that can lead to drug overdoses. While policies vary by state, physicians and pharmacists may have access to these databases and are expected to consult them to help identify prescribers and patients who may be engaging in fraud or misusing controlled substances (CMS 2018). PDMPs have been shown to be an effective tool for changing prescriber and beneficiary behavior related to opioids (Fink et al. 2018, CDC 2017). The Substance Abuse and Mental Health Administration encourages opioid treatment programs (OTPs) to use PDMPs “as an additional resource to maximize safety of patient care pursuant to applicable state guidelines” (SAMHSA 2011).

The SUPPORT Act includes two provisions to address access to and use of PDMPs. First, the law clarifies that in states in which Medicaid agencies are permitted to access PDMP data, the agency may share data with Medicaid-enrolled providers and Medicaid MCOs and make it easier for them to access this data (§ 1016 of the SUPPORT Act). The SUPPORT

Act also requires providers to check a qualified PDMP before prescribing Schedule II controlled substances to a Medicaid beneficiary, effective October 1, 2021 (§ 5042 of the SUPPORT Act).

Payers and providers have pointed out some drawbacks of PDMPs (CMS 2018). First, the administrative burdens associated with using a PDMP may limit prescriber use of these programs (CMS 2018). PDMPs may also lack complete information on medications used for treating substance use disorder (SUD) (MACPAC 2018). As well, OTPs may share information with PDMPs only when patient consent has been obtained, consistent with federal confidentiality regulations (42 CFR Part 2).

As of 2017, 49 states and the District of Columbia operated a PDMP; Medicaid programs in 30 of these states are permitted to query the PDMP database to review prescribing data, and prescribers in 15 of these states are required to access patient history in the database before prescribing controlled substances, as specified in provider agreements with the state Medicaid agency (CMS 2018).

As noted above, we looked at the use of PDMPs in eight states, finding that seven allow providers to access their PDMP. (Missouri does not have a PDMP.) In Maine, prescribers must check the state’s PDMP before writing prescriptions for methadone, buprenorphine, and naltrexone products as well as any other controlled substance (Maine DHHS 2017). Providers in West Virginia are also required to check the PDMP before prescribing controlled substances; in Washington, providers must check the PDMP before prescribing buprenorphine at the start of treatment, every three months during the initiation phase, and at least every six months during the stabilization phase (CMS 2018, WSHCA 2018).

Providers in several states in our study reported challenges in using PDMPs to monitor prescribing patterns.¹ In Illinois, Tennessee, and West Virginia, providers can only view one patient at a time. In Illinois, not all pharmacies submit data in

a timely manner and there is no way to verify that a prescriber checked the PDMP prior to writing a prescription. The Utah Medicaid program is limited by state statute in how it may access and use data from the PDMP, and Washington struggles with low uptake of PDMP usage by prescribers (CMS 2018).

Overall, we found that states have concerns related to the administrative burden and usage of PDMPs, but there is limited evidence regarding PDMPs' effect on patient access to MAT.

Pharmacy and Provider Lock-in Programs

Lock-in programs, sometimes referred to as patient review and restriction programs, require patients who are considered to be at risk for misusing certain drugs, including opioids, to obtain and fill prescriptions from designated pharmacies and prescribers. These programs are intended to prevent so-called pharmacy or doctor shopping. At-risk patients are identified based on criteria such as the number of prescriptions and pharmacies a patient has visited to obtain controlled substance prescriptions (CMS 2016). Once identified, a beneficiary typically can receive prescriptions from only one prescriber and only one pharmacy.

Federal regulations allow state Medicaid programs to require patients to obtain services from a designated provider if they determine that patients are utilizing services at a frequency or amount that is not medically necessary (42 CFR 431.54). However, the Centers for Medicare & Medicaid Services advise states to limit the lock-in period to a reasonable period and ensure that patients still have access to quality services. Most states typically lock in beneficiaries for either 12 or 24 months, at which point beneficiaries are re-evaluated for continuance in the lock-in program (CMS 2018). Given that Medicaid beneficiaries experience opioid use disorder (OUD) at higher rates than individuals who are privately insured,

federal and state policymakers are focusing on Medicaid lock-in programs as part of a strategy to reduce opioid misuse and ultimately drug overdose (MACPAC 2017, Roberts and Skinner 2014).²

Medicaid beneficiaries are typically enrolled in a lock-in program because they meet a state-defined threshold of controlled substance prescription fills, use different prescribers of controlled substances, or use multiple pharmacies in a specified time period. These thresholds vary and are defined by each state. For example, Maryland enrolls beneficiaries with six or more prescriptions for controlled substances and three or more pharmacies or prescribers (Maryland Department of Health 2019). In comparison, Wyoming sets a threshold at two or more controlled substance prescriptions from different prescribers and the use of two or more pharmacies within a designated time period (Pew 2016a). Because there is wide variation in criteria, there is no consensus on best practice for these programs (Pew 2016b, Roberts and Skinner 2014, CDC 2012).

Restricting beneficiaries to a single provider or pharmacy may impede access to MAT. These programs have the potential to lock in beneficiaries who are not misusing opioids (e.g., those receiving buprenorphine as a part of MAT) and thus create additional access barriers for beneficiaries seeking treatment for OUD. For example, it is not uncommon for a prescriber to make several buprenorphine dosage adjustments in the early stages of treatment, resulting in multiple prescriptions at varying dosages until the appropriate dosing is achieved. In this situation, the likelihood that a beneficiary may get locked in increases because they are receiving multiple prescriptions within a certain time frame (Gertner 2018). When beneficiaries are locked in, their choice of prescribers, pharmacies, or both is limited, potentially impeding their access to SUD treatment.

Forty-five states and the District of Columbia operate lock-in programs for beneficiaries who misuse controlled substances (CMS 2018).³ All eight states included in our study operate lock-in programs that

restrict beneficiaries to either a single pharmacy or a single prescriber. In Tennessee, state Medicaid rules consider any beneficiary who has used buprenorphine products for office-based opioid addiction treatment within the previous six months appropriate for the state pharmacy lock-in program, but it is unclear whether the beneficiary is required to participate (TennCare 2018). To be released from a lock-in program in Tennessee, the beneficiary must meet several criteria, including abstaining from receiving any narcotic medications while on buprenorphine for SUD for at least six consecutive months (TennCare 2018).

State-level evaluations have shown that lock-in programs can help reduce Medicaid expenditures and the use of controlled substances (CDC 2012, OKHCA 2009). But research has not established a link between lock-in programs and lower diversion rates, lower rates of SUDs, increased engagement in SUD treatment, or reduced overdose deaths among Medicaid beneficiaries (ASAM 2016). The Centers for Disease Control and Prevention have called for additional evaluations of lock-in programs to examine their impact on health-related outcomes, including hospitalizations and overdose deaths (CDC 2012).

Lock-in programs could be used to help promote more appropriate care for beneficiaries and improved access to MAT, for example, by providing referrals to pain specialists or SUD treatment providers when it is deemed clinically appropriate (ASAM 2016, Pew 2016b). However, most Medicaid fee-for-service lock-in programs do not connect beneficiaries to such care (Gertner 2018, Roberts and Skinner 2014). A 2016 survey by The Pew Charitable Trusts found that only two states offered referrals to SUD treatment and only one state made referrals to pain specialists (Pew 2016b).

Endnotes

¹ In 2017, the Centers for Medicare & Medicaid Services issued guidance to states on Section 1115 SUD demonstrations, with requirements that states implement strategies to increase utilization and improve the functionality of PDMP as part of the demonstrations (CMS 2017).

² The Comprehensive Addiction and Recovery Act of 2016 (PL 114-198) established a controlled substance lock-in program for Medicare Part D prescription drug plans, which took effect in January 2019. Private payers have also recently established lock-in programs in response to the opioid epidemic (Roberts et al. 2016).

³ Arizona, California, Florida, Iowa, and South Dakota are the exceptions.

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Appendix

Statutory Requirement for MACPAC Study from the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (P.L. 115-271)

SEC. 1014. MACPAC STUDY AND REPORT ON MAT UTILIZATION CONTROLS UNDER STATE MEDICAID PROGRAMS.

- (a) STUDY.—The Medicaid and CHIP Payment and Access Commission shall conduct a study and analysis of utilization control policies applied to medication-assisted treatment for substance use disorders under State Medicaid programs, including policies and procedures applied both in fee-for-service Medicaid and in risk-based managed care Medicaid, which shall—
- (1) include an inventory of such utilization control policies and related protocols for ensuring access to medically necessary treatment;
 - (2) determine whether managed care utilization control policies and procedures for medication-assisted treatment for substance use disorders are consistent with section 438.210(a)(4)(ii) of title 42, Code of Federal Regulations; and
 - (3) identify policies that—
 - (A) limit an individual’s access to medication-assisted treatment for a substance use disorder by limiting the quantity of medication-assisted treatment prescriptions, or the number of refills for such prescriptions, available to the individual as part of a prior authorization process or similar utilization protocols; and
 - (B) apply without evaluating individual instances of fraud, waste, or abuse.
- (b) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Medicaid and CHIP Payment and Access Commission shall make publicly available a report containing the results of the study conducted under subsection (a).

Biographies of Commissioners

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Thomas Barker, JD, is a partner at Foley Hoag, LLP, where he specializes in Medicaid and Medicare regulatory, coverage, and reimbursement issues and is a member of the executive committee. He also has a pro bono law practice focusing on health care issues facing immigrants. Previously, he held

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Darin Gordon is president and CEO of Gordon & Associates in Nashville, Tennessee, where he provides health care-related consulting services to a wide range of public- and private-sector clients. Previously, he was director of Medicaid and CHIP in Tennessee for 10 years, where he oversaw various program improvements, including the implementation of a statewide value-based purchasing program. During this time, he served as president and vice president of the National Association of Medicaid Directors for a total of four years. Before becoming director of Medicaid and CHIP, he was the chief financial officer and director of managed care programs for Tennessee's Medicaid program. Mr. Gordon received his bachelor of science degree from Middle Tennessee State University.

Christopher Gorton, MD, MHSA, was formerly president of public plans at Tufts Health Plan, a non-profit health plan in Massachusetts, Rhode Island, and New Hampshire, as well as CEO of a regional health plan that was acquired by the Inova Health System of Falls Church, Virginia. Other positions held include vice president for medical management and worldwide health care strategy for Hewlett Packard Enterprise Services and president and chief medical officer for APS Healthcare, a behavioral health plan and care management organization based in Silver Spring, Maryland. After beginning his career as a practicing pediatrician in FQHCs in Pennsylvania and Missouri, Dr. Gorton served as chief medical officer in the Pennsylvania Department of Public Welfare. Dr. Gorton received his degree in medicine from Columbia University's College of Physicians and Surgeons and his master of health systems administration from the College of Saint Francis in Joliet, Illinois.

Stacey Lampkin, FSA, MAAA, MPA, is an actuary and principal with Mercer Government Human Services Consulting, where she has led actuarial work for several state Medicaid programs. She previously served as an actuary and assistant deputy secretary for Medicaid finance and analytics at Florida's Agency for Health Care Administration and as an actuary at Milliman. She has also served as a member of the Federal Health Committee of the American Academy of Actuaries (AAA), as vice chairperson of AAA's uninsured work group, and as a member of the Society of Actuaries project oversight group for research on evaluating medical management interventions. Ms. Lampkin is a fellow of the Society of Actuaries and a member of the AAA. She received her master of public administration from Florida State University.

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Biographies of Staff

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Kacey Buder, MPA, is a senior analyst. Prior to joining MACPAC, she worked in the Center for Congressional and Presidential Studies at American University and completed internships in the office of U.S. Senator Ed Markey and at the U.S. Department of Health and Human Services (HHS). Ms. Buder holds a master of public administration and a bachelor of arts in political science, both from American University.

Kathryn Ceja is the director of communications. Previously, she served as lead spokesperson for Medicare issues in the Centers for Medicare & Medicaid Services (CMS) press office. Prior to her tenure in the press office, Ms. Ceja was a speechwriter for the Secretary of HHS as well as the speechwriter for a series of CMS administrators. Ms. Ceja holds a bachelor of arts in international studies from American University.

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Ryan Greenfield, MPP, is a senior analyst. Prior to joining MACPAC, Mr. Greenfield worked as a senior program analyst in the HHS Office of the Assistant Secretary for Financial Resources, focused on Medicaid financing, payment, and

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