

# Report to Congress on Medicaid and CHIP

**JUNE 2018**



**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.

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and Access Commission



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**June 15, 2018**

The Honorable Mike Pence  
President of the Senate  
S-212 The Capitol  
Washington, DC 20510

The Honorable Paul Ryan  
Speaker of the House  
H-232 The Capitol  
Washington, DC 20515

**Dear Mr. Vice President and Mr. Speaker:**

On behalf of the Medicaid and CHIP Payment and Access Commission (MACPAC), I am pleased to submit the June 2018 Report to Congress on Medicaid and CHIP.

The June report takes an in-depth look and makes recommendations on two issues that are front and center in national health policy: the high cost of prescription drugs and the opioid epidemic. In addition, given Medicaid's role as the nation's largest payer for long-term services and supports (LTSS), the Commission considers the implications of the growing trend of delivering these services through managed care.

**Improving operations of the Medicaid Drug Rebate Program.** High rates of growth in Medicaid spending for prescription drugs have been of great concern to policymakers. Although the rate of growth in prescription drug spending has slowed since 2015, the sector is still expected to experience the fastest average annual spending growth among major health care goods and services over the next 10 years.

In Chapter 1, the Commission focuses on targeted improvements to the Medicaid Drug Rebate Program—the primary lever states and the federal government have to reduce spending on drugs—and makes two recommendations to:

- close a loophole in current law that allows a manufacturer to sell its authorized generic at a low price to a corporate subsidiary, reducing the rebate obligation for its brand drug; and
- give the Secretary of the U.S. Department of Health and Human Services clear authority to impose intermediate financial sanctions on manufacturers that misclassify a brand drug as a generic to lower their rebate payments.

**Confidentiality regulations and care integration in Medicaid.** The first of two June report chapters examining Medicaid and the opioid epidemic, Chapter 2 analyzes federal law and regulations on confidentiality of patient records related to substance use disorder—known as Part 2. Medicaid beneficiaries have been disproportionately affected by the opioid epidemic, accounting for roughly half of opioid-related overdose deaths in some states.

Part 2 has been criticized as confusing, restrictive, and challenging to implement. In the Commission's view, additional guidance would be a meaningful step to help providers, payers, and patients understand their legal rights and obligations and opportunities for information sharing that would facilitate integration of care. The Commission makes two recommendations to clarify current regulations to both facilitate information exchange and protect patient privacy.

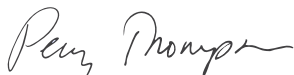
**Access to substance use disorder treatment in Medicaid.** Building on foundational work in MACPAC's June 2017 report, our review of Medicaid coverage for SUD treatment shows that only 12 states pay for the full continuum of clinical services. States can cover many of these services under state plan authority but choose not to for a variety of reasons. Often, the institutions for mental diseases (IMD) exclusion is cited as a barrier to paying for residential services. But states may pay for services in these settings under some conditions through Section 1115 demonstrations and managed care; eliminating the IMD exclusion would not address other gaps in coverage or address low provider participation.

An effective Medicaid response to the opioid epidemic requires a robust care delivery system in which the full continuum of care is covered and beneficiaries have access to specialty SUD providers. Section 1115 SUD demonstrations provide an opportunity for states to adopt comprehensive strategies to improve access to clinically appropriate SUD care, but many states have not taken advantage of this opportunity or other Medicaid authorities to reduce gaps in the continuum of care. Evaluations from these demonstrations may provide additional insight to states that have not yet expanded SUD benefits.

**Managed long-term services and supports: Status of state adoption and areas of program evolution.** Chapter 3 reflects on Medicaid's role as the nation's largest payer for LTSS and the growing trend to deliver these services through managed care. While states typically adopt managed care for LTSS (MLTSS) after gaining experience with managed care for acute care, the complex needs of people who receive LTSS and the wide range of services they use makes implementation of MLTSS more complex. The Commission observes that adoption of new quality measures and efforts to improve encounter data have potential to improve evaluation and oversight activities. The chapter concludes by identifying issues that the Commission will continue to explore and monitor with regard to MLTSS.

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 development affecting these programs. This document fulfills our statutory mandate to report each year by June 15.

Sincerely,



Penny Thompson, MPA  
Chair



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## Executive Summary: June 2018 Report to Congress on Medicaid and CHIP

The Medicaid and CHIP Payment and Access Commission (MACPAC) June 2018 *Report to Congress on Medicaid and CHIP* dives into two issues that are front and center in national health policy: the high cost of prescription drugs and the opioid epidemic. In addition, given Medicaid's role as the nation's largest payer for long-term services and supports (LTSS), the Commission considers the implications of the growing trend of delivering these services through managed care.

High rates of growth in Medicaid spending for prescription drugs have been of great concern to policymakers. Although the rate of growth in prescription drug spending has slowed since 2015, the sector is still expected to experience the fastest average annual spending growth among major health care goods and services over the next 10 years. In Chapter 1, the Commission focuses on targeted improvements to the Medicaid Drug Rebate Program—the primary lever states and the federal government have to reduce spending on drugs—and makes two recommendations.

With Congress acting on multiple bills to address the opioid epidemic as the June report goes to print, two chapters offer an in-depth examination of Medicaid policy on substance use disorder (SUD) treatment. Chapter 2 takes a close look at whether federal regulations governing consent to share SUD-related patient records—regulations that have been criticized as confusing, restrictive, and challenging to implement—might also act as barriers to integrated care. In Chapter 2, the Commission makes two recommendations to ensure that federal regulations concerning patients' SUD-related information do not unnecessarily stifle the exchange of information among providers, payers, and patients.

In Chapter 3, the Commission turns its attention to the growing role of managed care in serving Medicaid beneficiaries who receive LTSS. State Medicaid programs increasingly are using managed care as one of several strategies to improve care coordination and manage costs for populations with complex health care needs and disproportionately high Medicaid expenditures. Chapter 3 offers a status report on state adoption of managed LTSS (MLTSS), describing what we currently know about program outcomes and the complexity that LTSS adds to the operation of Medicaid managed care, and highlighting emerging MLTSS trends such as increasing enrollment of people with intellectual or developmental disabilities.

Chapter 4 returns to Medicaid policy on SUD treatment, describing barriers Medicaid beneficiaries with SUDs face when trying to access treatment. MACPAC's review of state Medicaid coverage for SUD treatment shows that only 12 states pay for the full continuum of clinical services. States can cover many of these services under state plan authority but choose not to for a variety of reasons. Often the institutions for mental diseases (IMD) exclusion is cited as a barrier to paying for residential services, but states may currently pay for these services under some conditions through Section 1115 demonstrations and managed care. Eliminating the IMD exclusion would not address other gaps in coverage or address low provider participation.

While Section 1115 demonstration programs in California and Virginia show promise with new approaches to increase availability of SUD treatment in IMD settings, building treatment capacity, and raising provider rates, not all states are well positioned to take advantage of the opportunities offered under this waiver authority.

A brief summary of each chapter follows.

## CHAPTER 1: Improving Operations of the Medicaid Drug Rebate Program

High rates of spending growth for prescription drugs have been of great concern to state and federal Medicaid officials. In 2014, Medicaid prescription drug spending experienced its highest rate of growth in almost three decades. This high growth rate was primarily due to increased spending for hepatitis C drugs and expanded Medicaid enrollment under the Patient Protection and Affordable Care Act (ACA, P.L. 111-148, as amended). Although spending growth slowed in both 2015 and 2016 due to increases in drug rebates, lower rates of growth in enrollment, and a decline in hepatitis C drug spending, over the next 10 years prescription drugs could see the fastest average annual spending growth of any major health care good or service due to growth in high-cost specialty drugs.

Chapter 1 begins by describing current Medicaid prescription drug policy and the rebates established under the Medicaid Drug Rebate Program, which was created under the Omnibus Budget Reconciliation Act of 1990 to ensure that Medicaid pays a net price consistent with the lowest price manufacturers charge other payers for the drug. Medicaid drug rebates are defined in statute and based on average manufacturer price. In general, manufacturers pay a lower rebate to the federal and state governments for a generic drug than they pay for brand drugs, which have a higher price.

The drug rebate program is primarily responsible for state and federal government reductions in Medicaid drug spending because Medicaid cannot make use of the full range of utilization management tools available to Medicare or commercial insurance. This is because, in exchange for the rebates, state Medicaid programs generally must cover all of a participating manufacturer's drugs.

Chapter 1 discusses specific concerns regarding the pricing of authorized generic drugs—a version of a brand drug that the brand manufacturer itself

produces and sells at a lower price than its brand drug—and federal oversight of the rebate program. The Commission makes two recommendations to ensure more accurate drug rebates.

First, the Commission recommends that Congress remove the statutory requirement that manufacturers blend the average manufacturer price of a brand drug and its authorized generic to ensure that manufacturer rebates are based on the drug as priced to wholesalers and pharmacies. This recommendation would close an apparent loophole in current law that allows a manufacturer to sell its authorized generic at a low price to a corporate subsidiary to reduce its rebate obligation for its brand drug.

Second, the Commission recommends giving the Secretary of the U.S. Department of Health and Human Services (the Secretary) clear authority to impose intermediate financial sanctions on manufacturers that misclassify a brand drug as a generic to lower their rebate payments. Although misclassifications are rare, they may have led to substantial losses in rebates. Currently, the Secretary may address instances of misclassification only by terminating a manufacturer's participation in the rebate program, which would be disruptive to Medicaid beneficiaries' access to valuable therapies. Authority to impose financial penalties would give the Secretary an enforcement mechanism while protecting beneficiary access to prescription medications.

Looking ahead, the Commission will focus on whether additional policy levers may be needed—and if so, what form they should take—to help manage prescription drug spending while also ensuring that Medicaid beneficiaries can continue to benefit from advances in scientific research.

## CHAPTER 2: Confidentiality Regulations and Care Integration in Medicaid and CHIP

As part of its foundational work on behavioral health disorders and Medicaid's response to the

opioid epidemic, MACPAC has identified the need for improved integration of SUD, mental health, and physical health services. People with SUDs often have serious comorbidities, such as other behavioral health disorders, cardiovascular disease, cancer, hepatitis C, and HIV. Fragmentation of care can result in inappropriate use of services, poor health status, and increased costs.

Federal law on confidentiality of SUD-related patient records (42 USC § 290dd-2) and its implementing regulations (42 CFR Part 2)—together usually referred to as Part 2—can act as a barrier to integrated care. Part 2 requirements are generally stricter than those imposed by the Health Insurance Portability and Accountability Act of 1996 (HIPAA, P.L. 104-191), which governs disclosure for most other health information and which generally allows information to be shared among health care providers and payers for payment, treatment, and health care operations without patient consent.

Loosening Part 2 privacy regulations is controversial. Many clinicians, state Medicaid officials, and other stakeholders support aligning consent standards more closely with HIPAA standards, arguing that the regulations hinder the exchange of information and thus undermine the provision of whole-person care. In addition, lack of comprehensive patient information may hamper delivery system reform efforts to hold providers and health plans accountable for health costs and outcomes.

But many patient advocates warn that creating more avenues for sensitive health information to be disclosed without patient consent could harm patients and discourage individuals from seeking care for SUDs. Unlike other chronic illnesses, SUDs are widely stigmatized. Disclosure of SUD-related information can have serious consequences, including criminal arrest, prosecution, and incarceration; loss of employment, housing, or child custody; discrimination by medical professionals; and denial of life or disability insurance.

Chapter 2 draws on a review of publicly available information and the views of participants in an

expert roundtable that MACPAC convened in November 2017 to better understand how Part 2 affects care delivery for Medicaid and State Children’s Health Insurance Program (CHIP) beneficiaries with SUDs, and possible ways to promote information sharing. Most stakeholders agree that Part 2 regulations are confusing, restrictive, and challenging to implement. Additional clarifying guidance on the existing regulations would be a meaningful step toward helping providers, payers, and patients understand their rights and obligations under the current law as well as existing opportunities for information sharing. The Commission makes two recommendations to clarify Part 2 to address this barrier to integrated care:

- The Secretary of Health and Human Services should direct relevant agencies to issue joint subregulatory guidance that addresses Medicaid and CHIP provider and plan needs for clarification of key 42 CFR Part 2 provisions.
- The Secretary should direct a coordinated effort by relevant agencies to provide education and technical assistance on 42 CFR Part 2. Such efforts should target state Medicaid and CHIP programs, health plans, primary care and specialty providers, patients and their families, and other relevant stakeholders.

### CHAPTER 3: Managed Long-Term Services and Supports: Status of State Adoption and Areas of Program Evolution

State Medicaid programs increasingly use managed care as one of several strategies to improve care coordination and manage spending for populations with complex health care needs and disproportionately high Medicaid expenditures. As of January 2018, 24 states operate MLTSS programs, up sharply from just 8 states in 2004. Although much of this growth has been fairly recent, a few states have operated MLTSS programs for

many years, and in some cases, several decades. In fiscal year 2015, an estimated \$29 billion, or 18 percent of Medicaid LTSS spending, was for MLTSS programs.

Even though states typically adopt managed care for LTSS after they have gained experience with managed care for acute care benefits, the complex needs of people who receive LTSS and the wide range of services they use make implementation of MLTSS more complex than managed care for acute care. Chapter 3 provides an overview of MLTSS, reviews results of MACPAC's initial work in this area, and identifies gaps in our knowledge about what drives success in MLTSS programs. The discussion includes highlights of state MLTSS programs and outcomes, but there are few systematic studies evaluating whether MLTSS programs are meeting their intended goals. States, managed care plans, providers, and beneficiary advocates have all identified potential benefits of MLTSS and the challenges of operating these programs, but the lack of baseline data prior to the changeover to MLTSS and standardized LTSS quality measures have limited our ability to compare states' experiences and outcomes.

This chapter begins with background information on Medicaid-covered LTSS and Medicaid beneficiaries who receive LTSS. It then provides a status report on state adoption of MLTSS programs, a discussion of the range of goals that states are trying to achieve through MLTSS programs, and an overview of federal regulations specific to these programs. Next, it describes how MLTSS programs are implemented and operated, what is currently known about program outcomes, and highlights emerging trends.

As new states implement MLTSS and the programs of early adopters mature, more states are enrolling people with intellectual or developmental disabilities into MLTSS and integrating Medicaid MLTSS with Medicare benefits for beneficiaries who are dually eligible for Medicare and Medicaid. States are also continuing to refine other aspects of their MLTSS

programs, such as network adequacy requirements, payment approaches, and quality measures.

Adoption of new LTSS quality measures and recent efforts to improve MLTSS encounter data offer the potential to improve evaluation and oversight activities in the future. The chapter concludes by identifying issues that the Commission will explore and monitor as its deliberations on MLTSS continue.

## CHAPTER 4: Access to Substance Use Disorder Treatment in Medicaid

Medicaid beneficiaries have been disproportionately affected by the opioid epidemic, accounting for roughly half of all opioid-related overdose deaths in some states. Compared to privately insured adults, Medicaid beneficiaries have a higher rate of opioid use disorder (OUD) and are prescribed pain relievers more often than individuals with other sources of insurance. The introduction of cheaper, more potent opioid alternatives, such as fentanyl, to the illicit drug supply also has created a higher risk of overdose for Medicaid beneficiaries.

State Medicaid programs are using a variety of approaches to respond to the opioid crisis, but Medicaid beneficiaries continue to face barriers when trying to access SUD treatment. Chapter 4 builds on analysis in the June 2017 report to Congress, which found that access to care may be impeded by factors ranging from fears about the stigma of having an SUD to a fragmented and poorly funded delivery system.

Ensuring Medicaid beneficiaries have access to SUD treatment requires that services along a continuum of care are covered, that they are affordable to the beneficiary, and that they are designed to meet the unique needs of the population. In addition, providers must also be available to provide appropriate care when needed.

In examining Medicaid coverage of SUD services, MACPAC's review of state policies shows that only 12 states pay for the full array of clinical services, which includes outpatient and residential



treatment with varying degrees of intensity, as well as medication-assisted treatment. The largest gaps in coverage of clinical services are for partial hospitalization and residential services, creating barriers to critical treatment for individuals with life-threatening withdrawal potential.

States can cover many of these services under state plan authority but choose not to for a variety of reasons. Moreover, although the institutions for mental diseases (IMD) exclusion is often cited as a barrier to paying for residential services, states may currently pay for these services under some conditions through Section 1115 demonstrations and managed care. Eliminating the IMD exclusion would not address other gaps in coverage or address low provider participation.

Twenty-three states have sought federal approval for Section 1115 demonstrations to implement comprehensive strategies to improve SUD care. The chapter highlights the early progress that California and Virginia are making under these waivers. Other states have neither taken advantage of this opportunity nor used other Medicaid authorities to reduce gaps in covered benefits. The inadequate supply of SUD treatment facilities and low provider participation rates in Medicaid also affect access to treatment. Although the analysis focuses on the treatment of OUD, many of the concerns described in Chapter 4 apply to treatment of other SUDs that trouble many communities, such as those associated with cocaine and methamphetamines. The chapter concludes by identifying areas for further study.



Chapter 1:

# Improving Operations of the Medicaid Drug Rebate Program

# Improving Operations of the Medicaid Drug Rebate Program

## Recommendations

- 1.1 To ensure that manufacturer rebates are based on the price of the drug available to wholesalers and pharmacies, Congress should remove the statutory requirement in section 1927(k)(1)(C) that manufacturers blend the average manufacturer price of a brand drug and its authorized generic.
- 1.2 Congress should give the Secretary of Health and Human Services the authority to level intermediate financial sanctions to compel drug manufacturers to submit accurate drug classification data and strengthen enforcement actions. These authorities could include clear authority to reclassify an inappropriately classified drug and to level civil monetary penalties for the submission of inaccurate drug classification data.

## Key Points

- State and federal policymakers are looking for ways to control prescription drug spending, which is expected to grow faster than other health care goods and services over the next 10 years.
- This report focuses on specific improvements to the existing Medicaid Drug Rebate Program. Future work will focus on the merits of broader structural changes to Medicaid policy.
- Under the Medicaid Drug Rebate Program, drug manufacturers must enter into a Medicaid national drug rebate agreement. In exchange for the rebates, state Medicaid programs must generally cover all of a participating manufacturer's drugs.
- Medicaid drug rebates are defined in statute and calculated based on average manufacturer price (AMP). There are different rebate formulas for brand and generic drugs; brand drugs receive a larger rebate.
- The law requires a manufacturer to average the price of its authorized generic with the brand drug in calculating its brand drug's AMP. This requirement creates a loophole in which a manufacturer could sell its authorized generic at a low price to a corporate subsidiary to lower its brand drug's AMP, thus lowering the manufacturer's rebate obligation. Recommendation 1.1 is meant to close this loophole.
- Under the rebate program, manufacturers are responsible for classifying their products as brand or generic drugs. Other than terminating a manufacturer's rebate agreement, which could have negative repercussions on beneficiary access, the Secretary has limited statutory authority to address a misclassification.
- Recommendation 1.2 reflects the Commission's view that the Secretary needs additional enforcement powers to address misclassifications of drugs. The clear authority to impose financial penalties would give the Secretary an enforcement mechanism while protecting beneficiary access to prescription medications.

# CHAPTER 1: Improving Operations of the Medicaid Drug Rebate Program

High rates of spending growth for prescription drugs over the past few years have been of great concern to state and federal Medicaid officials. Medicaid prescription drug spending increased 24.6 percent in 2014, reaching its highest rate of growth since 1986. This high rate of growth was primarily due to increased spending for hepatitis C drugs and enrollment growth associated with the expansion of Medicaid under the Patient Protection and Affordable Care Act (ACA, P.L. 111-148, as amended) (Martin et al. 2016). The rate of drug spending growth slowed to 13.6 percent in 2015 and to 5.5 percent in 2016 (Hartman et al. 2017). Spending growth in 2015 was tempered by an increase in drug rebates compared to the prior year, and slower enrollment growth and a decline in spending for hepatitis C drugs further reduced drug spending growth in 2016 (Hartman et al. 2017, Martin et al. 2016). Even with the recent slowing of spending growth, controlling prescription drug spending remains a focus for policymakers because prescription drugs are expected to experience the fastest average annual spending growth among major health care goods and services over the next 10 years due to the anticipated growth of high-cost specialty drugs (Cuckler et al. 2018). As policymakers attempt to rein in expenditures, however, they must also consider how such efforts would affect Medicaid beneficiaries' access to therapies that extend lives and improve health and functional status.

Many factors can affect spending for Medicaid outpatient drugs. Total Medicaid drug spending reflects the number of prescriptions filled and the amount paid per prescription. Average drug spending per person reflects the enrollment mix (the mix of conditions being treated and the distribution of drugs across different therapeutic classes),

the volume and intensity of services (the average number of drugs taken per person and the mix of brand and generic drugs), and the net prices paid for those services (i.e., the price paid to the pharmacy to purchase and dispense the drug minus any manufacturer rebates).

Efforts to control Medicaid spending on prescription drugs can focus on reducing the net price per unit, reducing utilization, or changing the mix of drugs used; these strategies can be pursued alone or in combination. Not all of these factors are within the control of program administrators, providers, or patients. Medicaid, like other payers, is affected by how manufacturers establish the market price of drugs as well as by their decisions about when and under what circumstances to bring their drugs to market. Additionally, while most payers seek to obtain rebates from drug manufacturers and control the use and mix of drugs, Medicaid is limited in its ability to use these cost control strategies. Reductions in Medicaid drug spending have been achieved by states and the federal government primarily through the Medicaid Drug Rebate Program. Under this program, Medicaid receives larger rebates than most other payers, including rebates based on the best price received by other payers. But Medicaid cannot make use of the full range of utilization management tools available to other payers, such as restricted formularies, tiered formularies, and cost sharing, to manage the utilization and mix of drugs.

MACPAC's inquiry into the rising costs of prescription drugs has focused on two separate but related issues: identifying specific improvements to the existing rebate program, which is the focus of this chapter, and developing ideas that might form the basis of more far-reaching recommendations in future reports. In the course of our inquiry, we have reached out to Medicaid directors, pharmacy benefit managers, managed care plans, federal agencies, and others. We plan to extend this conversation into the year ahead to learn whether additional policy levers may be needed—and if so, what form they should take—to help manage prescription drug spending while also ensuring that Medicaid

beneficiaries can continue to benefit from advances in scientific research.

This chapter presents the Commission's recommendations on the way the Medicaid Drug Rebate Program treats authorized generics and on gaps in the current oversight regime. Specifically:

- To ensure that manufacturer rebates are based on the price of the drug available to wholesalers and pharmacies, Congress should remove the statutory requirement in section 1927(k)(1)(C) that manufacturers blend the average manufacturer price of a brand drug and its authorized generic.
- Congress should give the Secretary of Health and Human Services the authority to level intermediate financial sanctions to compel drug manufacturers to submit accurate drug classification data and strengthen enforcement actions. These authorities could include clear authority to reclassify an inappropriately classified drug and to level civil monetary penalties for the submission of inaccurate drug classification data.

The chapter begins by describing current Medicaid prescription drug policy and the rebates established under the Medicaid Drug Rebate Program. It continues by detailing specific concerns regarding the pricing of authorized generic drugs and federal oversight of the program. It then presents the rationale for the Commission's recommendations for steps that Congress should take to mitigate these issues. The chapter concludes by outlining the Commission's plans for future work in this area, including examining Medicaid's existing ability to manage drug utilization and spending, exploring whether Medicaid could benefit from additional tools available to other payers, and monitoring the development of strategies for managing spending on specialty drugs, such as value-based purchasing arrangements.

## Medicaid Drug Rebate Program

Coverage of outpatient prescription drugs is an optional benefit that all state Medicaid programs have elected to provide (§ 1905(a)(12) of the Social Security Act (the Act)). Outpatient prescription drugs are typically those that may be obtained only by prescription and are dispensed by pharmacies. They do not include drugs provided and billed as part of other services such as inpatient hospital or nursing facility stays.<sup>1</sup>

The net price that Medicaid pays for a particular outpatient prescription drug reflects two components—the initial payment to the pharmacy and the rebates Medicaid receives from manufacturers. States set pharmacy payment policy within broad federal guidelines and requirements.<sup>2</sup> The rebates that Medicaid receives are substantial and result in Medicaid paying one of the lowest net prices of any payer (OIG 2015, GAO 2014). In fiscal year (FY) 2016, Medicaid spent approximately \$60.8 billion on outpatient prescription drugs and collected \$31.2 billion in rebates for net drug spending of \$29.6 billion (MACPAC 2017). Net spending for outpatient prescription drugs accounted for about 5.4 percent of total Medicaid benefit spending.

The Medicaid Drug Rebate Program was created under the Omnibus Budget Reconciliation Act of 1990 (P.L. 101-508) with the purpose of ensuring that Medicaid pays a net price that is consistent with the lowest or best price that manufacturers charge other payers for the drug. Under the program, a drug manufacturer must enter into a Medicaid national drug rebate agreement with the Secretary of the U.S. Department of Health and Human Services (the Secretary) in order for states to receive federal funding for using the manufacturer's products (§ 1927(a)(1) of the Act).<sup>3</sup> In exchange for the rebates, state Medicaid programs must generally cover all of a participating manufacturer's drugs when prescribed for a medically accepted indication, although the states

may limit the use of some drugs through preferred drug lists (PDLs), prior authorization, and quantity limits.<sup>4</sup>

Amounts collected under the federal rebate program are shared by the federal government and states based on each state's current federal medical assistance percentage (FMAP). The Centers for Medicare & Medicaid Services (CMS) calculates a unit rebate amount (URA) for each drug based on a specific formula defined in statute for that category of drug and provides this URA to each state. The state then multiplies the URA by the number of units of each drug purchased during the rebate period and submits a rebate invoice to the drug manufacturer.<sup>5</sup> The state collects the rebate dollars from the manufacturer and reports the total rebate amount as an offset to the drug expenditures on the CMS-64 quarterly expense report used to determine the federal and state share of Medicaid spending.

States collect the federal Medicaid rebate each quarter from manufacturers through a process that is separate from their payments to pharmacies (§ 1927(c) of the Act). This means that every state receives the same federal rebate amount for each unit of a particular drug regardless of how much they pay a pharmacy. Therefore, the net unit price (initial payment to pharmacy minus the rebate) for a Medicaid drug will vary by state because of differing pharmacy reimbursement calculations and other state-specific supplemental rebate arrangements.

Medicaid drug rebates are calculated based on average manufacturer price (AMP). AMP is defined as the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to retail community pharmacies and by retail community pharmacies that purchase drugs directly from the manufacturer (§ 1927(k)(1) of the Act).<sup>6</sup>

There are separate rebate formulas for single source and innovator multiple source drugs (i.e., brand-name drugs) versus non-innovator multiple source drugs (i.e., generic drugs).<sup>7</sup> For purposes of simplicity, this chapter refers to single source and innovator multiple source drugs as brand drugs and

refers to non-innovator multiple source drugs as generic drugs or generics.

## Rebate formula for brand drugs

The rebate amount for brand drugs has two components: a basic rebate amount and an additional inflationary component. The basic rebate amount is calculated as the greater of 23.1 percent of AMP or AMP minus best price (Table 1-1). Best price is statutorily defined as the lowest price available to any wholesaler, retailer, provider, or paying entity, excluding certain governmental payers (§ 1927(c)(1)(C) of the Act).<sup>8</sup>

For blood clotting factor drugs and drugs approved by the U.S. Food and Drug Administration (FDA) exclusively for pediatric indications, the ACA created a different minimum rebate percentage. For these drugs, the minimum rebate percentage is 17.1 percent of AMP instead of 23.1 percent of AMP.

An additional rebate based on an inflationary component is added if the increase in a drug's AMP exceeds the increase in the Consumer Price Index for All Urban Consumers (CPI-U) over time (Table 1-1). The inflationary component is equal to the amount that the drug's current quarter AMP exceeds its baseline AMP trended to the current period by the CPI-U.<sup>9</sup> This inflationary rebate limits the increase in the net price of any drug to the rate of inflation. The total rebate amount cannot exceed 100 percent of AMP (§ 1927(C)(2)(D) of the Act). The inflationary rebate has become an increasingly large portion of the overall brand drug rebate. A recent report by the U.S. Department of Health and Human Services (HHS) Office of the Inspector General (OIG) found that more than half (54 percent) of total brand drug rebates for a sample of brand drugs in 2012 was attributable to the inflationary component (OIG 2015).

The ACA established an alternative rebate formula for drugs that are considered to be line extensions of brand drugs that are in oral solid dosage form (e.g., an extended-release version).<sup>10</sup> The statutory language in the ACA contained what some have

characterized as a drafting error that reduced the rebates owed under the alternative rebate formula for line extension drugs (HHS 2016).<sup>11</sup> In February 2018, Congress passed the Bipartisan Budget Act of 2018 (BBA 2018, P.L. 115-123), which revised the line extension formula to increase rebates. For line extension drugs, the rebate per unit has been revised to be the greater of (a) the basic and inflationary rebate for the line extension drug, or (b) the basic rebate of the line extension drug plus the product of the AMP for the line extension drug and the highest additional inflationary rebate for any strength of the original drug (expressed as a percentage of the original drug's AMP). The revised calculation for line extension drugs will apply to rebate periods beginning October 1, 2018.

## Rebate formula for generic drugs

The basic rebate amount for generic drugs is calculated as 13 percent of AMP. There is no best price provision (Table 1-1). The Bipartisan Budget Act of 2015 (P.L. 114-74) added the inflationary rebate to generic drugs, which went into effect in the quarter starting January 1, 2017 (CMS 2016a). This inflationary rebate is calculated in a similar manner to the inflationary rebate for brand drugs. For generic drugs marketed on or before April 1, 2013, the baseline AMP is equal to the AMP for the third quarter of 2014, and the baseline CPI-U is the CPI-U for September 2014. For generic drugs marketed after April 1, 2013, the baseline AMP is equal to the AMP for the fifth full calendar quarter after which the drug is marketed as a drug other than a brand drug, and the baseline CPI-U is equal to the CPI-U for the last month of the baseline AMP quarter (CMS 2016a). Similar to brand drugs, the total rebate cannot exceed 100 percent of AMP.

## Federal offset of rebates

The ACA increased the minimum rebate percentage for brand drugs from 15.1 percent to 23.1 percent of AMP, increased the rebate percentage for generic drugs from 11 percent to 13 percent of AMP, and

created an alternative rebate calculation for line extension drugs (§§ 2501(a)–2501(b) and 2501(d) of the ACA). The ACA requires states to remit the amounts attributable to these increased rebate percentages to the federal government—that is, CMS gets both the federal and non-federal shares of this rebate increase (§ 2501(a)(2) of the ACA). In a state Medicaid director letter, CMS further clarified that the offset would apply only to rebate dollars above those that would have been collected under the rebate formula in effect before implementation of the ACA (CMS 2010a).

For brand drugs, the offset is anywhere from 0 to 8 percent of AMP, depending on where the best price lies in relation to the old minimum rebate percentage of 15.1 percent and the ACA minimum rebate of 23.1 percent (Table 1-1, line (j)). For example, if AMP minus best price were equal to 20 percent of AMP, then the offset would be 3.1 percent of AMP (Table 1-1, line (j) for Drug B). Because generic drugs do not have the best price provision, CMS offsets 2 percent of AMP (the difference between 13 percent and 11 percent of AMP) for all generic drugs. For line extension drugs, the federal offset is the URA for the drug calculated using the formula established in the ACA and BBA 2018 minus the URA for the drug calculated using the formula in effect prior to the ACA; if the URA based on existing law is not greater than the URA based on prior law, then the offset does not apply.

## Supplemental rebates

Most states (46 states and the District of Columbia, as of March 2018) have negotiated supplemental rebates with drug manufacturers on top of the federal rebates (CMS 2018a).<sup>12</sup> States negotiate with manufacturers to obtain supplemental rebates, usually with one or more manufacturers of drugs that the state has determined to be therapeutically equivalent. Manufacturers provide these supplemental rebates to ensure that their products get placed on a state's PDL. Preferred drugs typically face fewer utilization management requirements than their therapeutic equivalents



**TABLE 1-1. Illustrative Example of Federal Outpatient Prescription Drug Rebate Calculations** **T 1-1**

Calculation	Drug A (brand)	Drug B (brand)	Drug C (brand)	Drug D (generic) <sup>1</sup>
(a) Current AMP per unit	\$100.00	\$100.00	\$100.00	\$20.00
(b) Best price per unit	\$88.00	\$80.00	\$70.00	N/A
<b>Basic rebate</b>				
(c) Minimum rebate • for brand drugs = $a \times 23.1\%$ • for generic drugs = $a \times 13\%$	\$23.10	\$23.10	\$23.10	\$2.60
(d) AMP minus best price = $a - b$	\$12.00	\$20.00	\$30.00	N/A
(e) Basic rebate is the greater of c or d	\$23.10	\$23.10	\$30.00	\$2.60
<b>Inflationary rebate</b>				
(f) Baseline AMP per unit	\$70.00	\$80.00	\$90.00	\$10.00
(g) CPI-U trend factor from baseline to current period	1.20	1.20	1.20	1.20
(h) Baseline AMP trended to current period = $f \times g$	\$84.00	\$96.00	\$108.00	\$12.00
(i) Inflationary rebate = $a - h$ if $h$ is less than $a$	\$16.00	\$4.00	\$0.00	\$8.00
<b>(j) ACA federal offset of rebate</b>				
	\$8.00	\$3.10	\$0.00	\$0.40
<b>(k) Total rebate = <math>e + i</math></b>				
	\$39.10	\$27.10	\$30.00	\$10.60
(l) State share = $(k - j) \times 50\%$	\$15.55	\$12.00	\$15.00	\$5.10
(m) Federal share = $(k - j) \times 50\% + j$	\$23.55	\$15.10	\$15.00	\$5.50

**Notes:** AMP is average manufacturer price. N/A is not applicable. CPI-U is Consumer Price Index for All Urban Consumers. This example uses a 50 percent federal match rate.

<sup>1</sup> The Bipartisan Budget Act of 2015 (P.L. 114-74) added the inflationary rebate to generic drugs beginning January 1, 2017.

(e.g., prior authorization), and this results in a shift in market share to the preferred drugs. Some states pursue supplemental rebate agreements on their own while others have joined multistate coalitions for negotiation purposes (CMS 2018a). The federal rebate offset does not apply to any supplemental rebates that states may receive above the increased federal rebate percentages (CMS 2010a).

## Medicaid drug rebates under managed care

The ACA extended federal Medicaid drug rebates to prescriptions paid for by Medicaid managed care plans (§ 2501(c) of the ACA). Previously, the federal rebates were only available for drugs paid for by the state on a fee-for-service (FFS) basis. Rebates for these drugs are subject to the offset in non-federal share on the rebate amounts above and

beyond those that would have been collected under the pre-ACA formulas. Plans submit Medicaid drug utilization data to the state; the state then combines this information with FFS utilization and collects the rebates from manufacturers for the entire Medicaid population. Similar to the state's ability to negotiate supplemental rebates, managed care plans can negotiate their own rebates with manufacturers.

## Authorized Generics

An authorized generic drug is a version of a brand drug that the brand manufacturer itself produces and sells, or causes to be sold, at a lower price point than the brand drug (FTC 2011).<sup>13</sup> Under the Federal Food, Drug, and Cosmetic Act (P.L. 75-717), the first true generic to challenge a brand drug's patent is granted 180 days of generic exclusivity (§ 505 of the Food, Drug, and Cosmetic Act). However, this 180-day exclusivity period does not exclude the brand manufacturer from launching its own generic (FTC 2011, citing *Teva Pharm. Indus. Ltd. v. Crawford*, 410 F.3d 51, 54 (D.C. Cir. 2005)). During this time period, the average retail price of the true generic is about 86 percent of the brand drug's retail price without a competing authorized generic and 82 percent of the brand drug's retail price with a competing authorized generic (FTC 2011). Once the 180-day period expires and other generics enter the market, the generic price drops substantially (Kirchhoff et al. 2018).

The presence of authorized generics in the market can affect the calculation of Medicaid drug rebates. The Medicaid statute generally directs manufacturers to calculate AMP based on sales to wholesalers and retail community pharmacies (§ 1927(k)(1) of the Act). The statute defines a wholesaler as any entity that engages in the wholesale distribution of drugs (§ 1927(k)(11) of the Act). The law requires manufacturers who produce an authorized generic of their brand drug and sell it to wholesalers or pharmacies to include those sales in calculating their brand drug's AMP (§ 1927(k)(1)(C) of the Act). This price, based

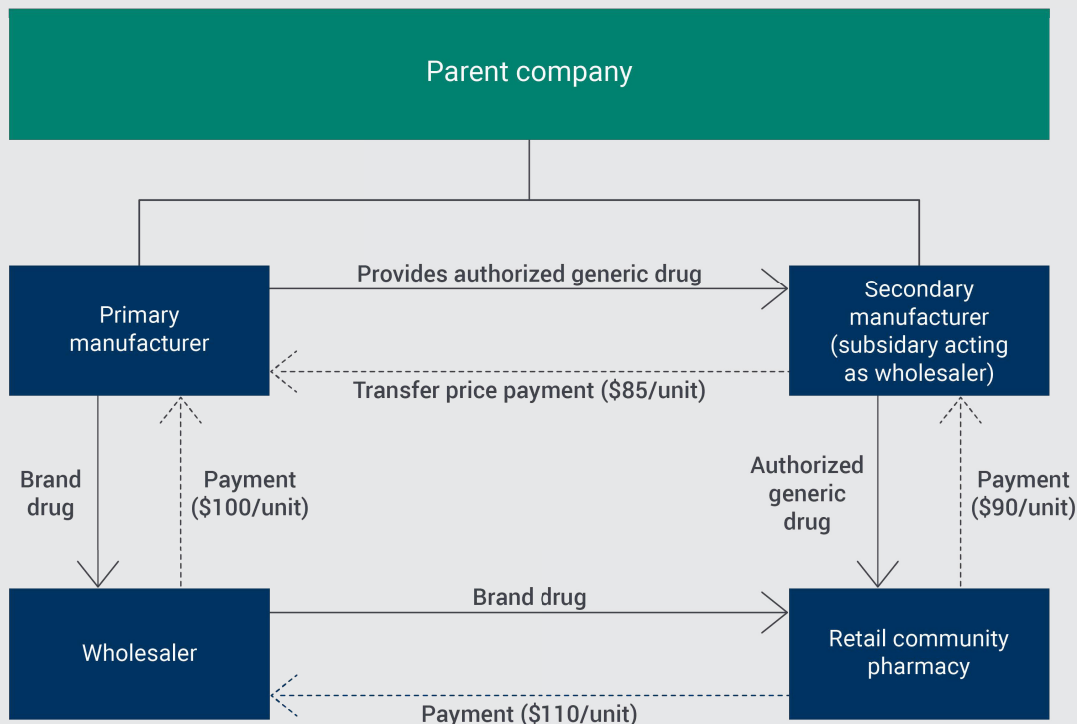
on both a brand drug and its authorized generic, is frequently referred to as a blended AMP. The statute also directs manufacturers to include their authorized generic drug's best price in their calculation of best price for the brand product. This means that if a brand drug manufacturer—referred to in this scenario as the primary manufacturer—produces an authorized generic version of its brand drug and sells it to another manufacturer—referred to as the secondary manufacturer—for distribution, the secondary manufacturer might meet the definition of a wholesaler under the statute. If so, then the primary manufacturer would be required to include the price charged to the secondary manufacturer—known as the transfer price—when calculating the AMP of its brand drug. While many secondary manufacturers are independent of primary manufacturers, manufacturers are required to calculate blended AMPs if the primary manufacturer and the secondary manufacturer have a corporate relationship, that is, if one is a subsidiary of the other (Figure 1-1).

When there is a corporate relationship between primary and secondary manufacturers, the transfer price the primary manufacturer charges its related secondary manufacturer for the drug is generally lower than the price it charges other wholesalers (HDMA 2012). When a primary manufacturer averages in a lower transfer price when calculating its brand drug's blended AMP, it lowers the drug's AMP and thus reduces the rebate (OIG 2014).<sup>14</sup>

## Oversight and Enforcement of the Medicaid Drug Rebate Program

Under the rebate program, manufacturers are responsible for providing CMS with the product and pricing information necessary to calculate rebates. The statute identifies certain data elements that are required, including AMP, customary prompt pay discounts, best price for brand drugs, and the number of units used to calculate AMP (§ 1927(b)

**FIGURE 1-1. Authorized Generic Transactions Included in Blended Average Manufacturer Price**



**Note:** AMP is average manufacturer price. A solid arrow represents the transfer of a product and a dotted arrow represents a financial transaction. In this illustrative example, the primary manufacturer would calculate a blended AMP for the brand and authorized generic drugs based on both the sales of the drug from the primary manufacturer to the wholesaler at \$100 per unit and the sales from the primary manufacturer to the secondary manufacturer (a corporate subsidiary) at \$85 per unit.

(3) of the Act). The terms of the rebate agreement specify other data that are used to identify and classify the drug, including whether the drug is a brand or generic, an authorized generic, or a line extension, as well as other information necessary to ensure that manufacturers have paid proper rebates (CMS 2018b). Manufacturers report and certify these product and pricing data via the Drug Data Reporting for Medicaid (DDR) system (OIG 2017).

Federal law provides a number of remedies in the event that a manufacturer does not comply with the reporting requirements, and several federal agencies share responsibility for enforcement. The Medicaid statute authorizes civil monetary penalties (CMPs) for manufacturers that fail to provide certain AMP and best price information on a timely basis and those that provide false

information (§ 1927(b)(3)(B)–(C) of the Act).<sup>15</sup> The OIG is responsible for auditing manufacturer price information and issuing CMPs (§ 1927(b)(3) of the Act).<sup>16</sup> The Medicaid statute also authorizes the Secretary, acting through CMS, to terminate a manufacturer’s participation in the rebate program for violating the terms of the rebate agreement or for other good cause (§ 1927(b)(4)(B)(i) of the Act). When a manufacturer is terminated, none of its drugs are eligible for federal financial participation ((§ 1903(i)(10) of the Act). CMS has stated that such a termination could have significant repercussions and potentially disrupt beneficiary access to drugs (OIG 2017). Manufacturers that report inaccurate data or pay inaccurate rebates may also be liable under the False Claims Act or other government claims, and the U.S. Department

of Justice (DOJ) is responsible for pursuing these remedies (CMS 2016b). Violations may come to the DOJ's attention either through the government's own investigation or through a qui tam action initiated by a private individual (CMS 2017a).

Aside from the above statutory authority, CMS can take administrative actions to address improperly categorized drugs; for instance, CMS issued subregulatory guidance in 2010 on the proper classification of drugs (CMS 2010b). This guidance was codified in 2016 by the covered outpatient drug final rule (CMS 2016c). The covered outpatient drug rule also specified a process for manufacturers to, in limited circumstances, appeal to CMS for approval to classify their drugs differently (CMS 2016c). Finally, the DDR system has been modified to prevent manufacturers from classifying drugs in a way that does not comply with the new regulatory requirements (OIG 2017). If CMS identifies what it believes to be a misclassification of a drug, it will contact the manufacturer to request an amended classification. However, CMS must rely on the manufacturer's willingness to change a drug's classification and has limited statutory authority in the event it disagrees with a manufacturer's classification (OIG 2017).

## Commission Recommendations

In this report, the Commission makes two recommendations to improve the operations of the Medicaid Drug Rebate Program. These should not be considered a package of recommendations; that is, the adoption of one does not require the adoption of the other.

### Recommendation 1.1

To ensure that manufacturer rebates are based on the price of the drug available to wholesalers and pharmacies, Congress should remove the statutory requirement in section 1927(k)(1)(C) that

manufacturers blend the average manufacturer price of a brand drug and its authorized generic.

#### Rationale

This recommendation would close an apparent loophole in current law that allows drug manufacturers to reduce the AMP and, therefore, the rebate obligation on certain brand drugs.

Under current law, averaging the price of brand drugs and authorized generics to arrive at a blended AMP can substantially reduce a brand drug's AMP. In 2014, the OIG analyzed the AMP of three drugs and found that the unblended AMP was more than double the blended AMP for all three (OIG 2014). In some cases, the primary and secondary manufacturer may have a corporate relationship, which allows the primary manufacturer to offer the secondary manufacturer a transfer price that is lower than the price available to other wholesalers. By including the lower transfer price of an authorized generic version of a drug sold to a subsidiary company, a drug manufacturer can lower the drug's AMP and thus reduce its rebate obligation on the drug.

The loophole that allows manufacturers to blend AMPs in such a way as to lower the rebate for a brand drug stems from two discrete statutory changes. The Deficit Reduction Act of 2005 (P.L. 109-171) required manufacturers to apply the authorized generic's best price to the brand and to blend the AMP of authorized generics with brand drugs. Five years later, the ACA added a definition of wholesaler to the Medicaid statute that includes manufacturers engaged in wholesale distribution. Nothing in the legislative history suggests that Congress intended for manufacturers to be able to use low sales prices from an authorized generic to a related corporate entity to lower the rebate on the brand drug (Senate Finance 2009a, Senate Finance 2009b, Senate Finance 2005, U.S. House of Representatives 2005).

The Commission's recommendation is meant to close this apparently inadvertent loophole and ensure that a drug's AMP reflects the actual net

price available to wholesalers and pharmacies on the open market. Manufacturers would still calculate AMP and pay rebates on both brand and authorized generic drugs, but would no longer have an avenue to use complex internal sales structures to make the AMP of a brand drug appear lower than it is. The Commission notes that this recommendation is intended to address instances when a manufacturer uses the blended AMP requirement strategically to lower the AMP of the brand drug. Accordingly, Congress may be able to craft legislation to specifically target this behavior without removing the requirement that manufacturers blend the AMP of the brand and authorized generic drug when the secondary manufacturer qualifies as an independent wholesaler.

### Implications

**Federal spending.** This recommendation is expected to reduce federal drug expenditures by increasing Medicaid drug rebates from manufacturers. The Congressional Budget Office (CBO) estimates that this recommendation would decrease federal spending by between \$0 and \$50 million in the first year and by less than \$1 billion over five years compared to the current law baseline.

**States.** This recommendation is expected to result in increased drug rebates from manufacturers, and states will receive the non-federal share of the increase in rebate dollars.

**Enrollees.** This recommendation is unlikely to have any measurable effect on enrollees.

**Drug manufacturers.** This recommendation would increase the amount of rebates that manufacturers pay on certain brand drugs that have an authorized generic available. Depending on how this recommendation is implemented, manufacturers may need to make changes to their reporting systems to accommodate the new requirements.

**Plans and providers.** This recommendation could increase some payments to providers by increasing

the federal upper limit (FUL) for some drugs. If the FDA has rated at least three drugs as being therapeutically and pharmaceutically equivalent, aggregate state payments cannot exceed 175 percent of the weighted average AMP for such drugs.<sup>17</sup> If this recommendation results in increased AMPs, it is possible that some of the affected drugs will have an associated FUL that will increase.

## Recommendation 1.2

Congress should give the Secretary of Health and Human Services the authority to level intermediate financial sanctions to compel drug manufacturers to submit accurate drug classification data and strengthen enforcement actions. These authorities could include clear authority to reclassify an inappropriately classified drug and to level civil monetary penalties for the submission of inaccurate drug classification data.

### Rationale

This recommendation calls on Congress to provide the Secretary with the authority to impose appropriate intermediate financial sanctions on manufacturers to ensure that they accurately classify their drugs. Such intermediate sanctions might include the imposition of CMPs for misclassifications, the explicit authority for HHS to change the classification of a drug, or other sanctions that Congress considers appropriate.

Although misclassifications are rare, OIG reports suggest that they may have led to substantial losses in rebates (OIG 2017, 2009). The OIG found that prior to CMS clarification of the definition of an innovator drug and non-innovator drug in the 2016 covered outpatient drug final rule, manufacturers may have misclassified some drugs in the Medicaid Drug Rebate Program as brand or generic products. As a result, drug manufacturers may not have paid the appropriate amount of rebates. In its 2017 report, the OIG found that approximately 3 percent of drugs were potentially misclassified in 2016.<sup>18</sup> When the OIG analyzed the 10 potentially misclassified drugs with the total highest payments

in 2016, it estimated that manufacturers may have owed an additional \$1.3 billion in rebates from 2012 to 2016.<sup>19</sup> In its response to the OIG report, CMS said it expects that the clarifications provided in the 2016 final rule and the changes made to the DDR will help identify and reduce these inconsistent data submissions going forward (OIG 2017).

It is not clear whether HHS has the authority to levy CMPs or other intermediate sanctions against manufacturers to compel them to correct inaccurate drug classification data. In its 2017 report, the OIG recommended that CMS pursue a means to compel manufacturers to correct inaccurate classification data. Further, the OIG stated that although it has been delegated the authority to levy CMPs in certain circumstances, it believes it lacks legal authority to levy penalties for the submission of inaccurate drug classification data (OIG 2017).

The statute provides HHS, acting through CMS, only one explicit enforcement mechanism to address instances of misclassification: terminating a manufacturer's participation in the rebate program for good cause (§ 1927(b)(4)(B)(i)). This is sometimes called the nuclear option because of its potentially disruptive effects on beneficiaries. The fact that CMS has never terminated a manufacturer that has misclassified a drug is an indication that this penalty is not a realistic option. Instead CMS relies on an informal process through which it engages with manufacturers and attempts to resolve what it considers improper classification. This system ultimately relies on manufacturers willingly changing a drug's classification, knowing that failure to do so may result in civil lawsuits and potential termination of its participation in the Medicaid program.

It is the Commission's view that while the current collaborative process is useful, the Secretary needs additional enforcement powers to address less serious instances of noncompliance—violations that do not justify terminating all of the manufacturer's products from the program but are nonetheless problematic. Given the lack of clear intermediate sanctions in statute and uncertainty as to whether

CMPs can be levied against manufacturers for inaccurate drug classification data, it is the Commission's view that Congress should provide clear authority to HHS to level CMPs for inaccurate drug classification data. The Secretary can then delegate this authority to either CMS or OIG.

The Commission considered recommending that Congress give HHS the authority to suspend a misclassified drug but determined that the threat to beneficiary access outweighed the benefits of such a measure. Suspending a drug from the program carries with it the risk of harm to beneficiaries who rely on the drug, particularly if that drug is the primary course of treatment with few therapeutic alternatives. It is the Commission's view that authority to impose financial penalties would give HHS clear enforcement authority while protecting beneficiary access to the manufacturer's product, and is therefore the more appropriate remedy for misclassification of drugs. Likewise, providing HHS the authority to reclassify a drug would allow the Secretary to address the misclassification without limiting beneficiary access to the drug. The Commission notes that Congress also has the option of pairing the authority to reclassify a drug with the authority to apply the reclassification retroactively in the DDR, thereby allowing Medicaid to collect rebates from previous quarters during which a drug was misclassified.

The current informal approach that CMS takes to correct misclassifications is a constructive first step, and any intermediate enforcement authorities should supplement, not supplant, this approach. The Commission maintains that HHS should ensure that manufacturers are afforded due process to present evidence that their classification of a drug is correct, such as provided under the narrow exceptions process established under the 2016 covered outpatient drug rule, and that HHS should provide a robust appeals process and establish protections for beneficiary access as part of any intermediate enforcement authority. HHS should be mindful of how its enforcement actions may affect beneficiaries; for many, access to prescription drugs is critically important and there may be only one

drug that meets their needs. It is the Commission's view that any intermediate sanctions authorized by Congress be paired with appropriate protections to ensure that beneficiaries are not harmed by enforcement actions.

### Implications

**Federal spending.** This recommendation could lead to increased rebates from a correction in a drug's classification or increased CMPs. However, the CBO has estimated that this recommendation will not affect federal Medicaid spending.

**States.** States could receive the non-federal share of any changes in rebate amounts. The impact on states, however, will depend largely on whether the state has a supplemental rebate agreement in place for that drug. Based on the way many states calculate supplemental rebates, an increase in federal rebates could be offset by a reduction in the amount that states receive through state supplemental rebates.

**Enrollees.** This recommendation could affect beneficiary access depending on the enforcement authority provided by Congress. Some intermediate authorities, such as the authority to suspend misclassified drugs from participation, could disrupt beneficiary access while the drug's classification is under dispute. Accordingly, the Commission maintains that financial penalties are a more appropriate remedy, one that can address misclassifications without limiting access to necessary medications.

**Drug manufacturers.** This recommendation would affect drug manufacturers that might have misclassified one or more of their drugs. Drug manufacturers could see increased scrutiny of their drug classification decisions; they could be subject to additional enforcement actions and penalties from HHS; and they could ultimately be required to pay higher rebates for these previously misclassified drugs.

**Plans and providers.** This recommendation could affect providers if the payment to the pharmacy

differs for brand and generic drugs. For example, some states have paid a different dispensing fee for brand versus generic drugs.

## Line Extension Rebate

At its December 2017 meeting, the Commission highlighted what some consider to be a drafting error in the alternative rebate calculation for line extension drugs and discussed making a recommendation to address the matter. As part of that discussion, the Commission also expressed interest in making another recommendation to remove the federal offset and allow states to share in the line extension rebate. Subsequently, Congress passed the BBA 2018, which changed the line extension rebate calculation. The BBA 2018 maintains the federal offset on the line extension rebate, so the federal government receives the entire amount of the projected increase in rebate dollars; CBO scored this provision as saving \$5.7 billion in federal spending over 10 years.

Given that Congress changed the line extension formula, the Commission discussed making a stand-alone recommendation to allow states to share in the line extension rebate at its March 2018 meeting. Although the Commission was initially interested in this recommendation as part of a package with the change to the rebate formula, the Commission decided that a stand-alone recommendation should not be made at this time and should instead be part of a larger discussion on how spending and savings should be shared between the federal government and the states.

## Next Steps

This chapter is the Commission's first step in making recommendations on Medicaid drug coverage and spending. The recommendations in this chapter focus on discrete, technical changes to the Medicaid Drug Rebate Program that improve operations without changing its overall structure.

Although these changes will improve operations, states will still face a number of challenges in managing the prescription drug benefit that warrant further work in this area. Several states have expressed interest in obtaining additional flexibility to adopt widely used commercial tools to manage increasing drug costs, such as a closed formulary that excludes certain drugs.<sup>20</sup> The Commission plans to examine how Medicaid's existing tools for managing drug utilization compare to other payers and how the use of additional tools such as closed formularies could affect state Medicaid programs and beneficiaries. Such analysis might include, for example, whether closed formularies could yield additional savings to states and how they might affect beneficiary access to treatment.

The Commission has also heard that existing drug utilization management tools are less effective at containing costs associated with high-cost specialty drugs and that additional authorities and policy options might be necessary (Brown 2017). MACPAC is currently examining whether there are drug utilization management tools or other value-based contracts used by other payers that could benefit state Medicaid programs and will continue to monitor the development of these strategies for potential use within the Medicaid program.

Additionally, the Commission has heard from state officials who expressed concern with the requirement that states cover new outpatient drugs as soon as they are approved by the FDA and enter the market. These officials stated that it can be difficult to determine appropriate coverage of these drugs without states having sufficient time to assess the effectiveness of a drug or determine coverage and prior authorization criteria that aligns with the drug's labeling and medically accepted indications. This is particularly true if a drug has been approved through an accelerated pathway with limited evidence of clinical efficacy. The Commission will conduct further analysis of this issue and evaluate possible policy solutions, such as giving states time to develop appropriate coverage criteria by allowing them to exclude a newly approved drug from coverage for a specified

period of time. Any policy option to delay coverage would need to be weighed against the potential effect on beneficiary access.

## Endnotes

- <sup>1</sup> A prescription drug provided and billed for as part of another service may be considered a covered outpatient drug if there is a direct reimbursement for the drug itself (e.g., physician-administered drugs).
- <sup>2</sup> Information on how Medicaid pays pharmacies can be found in MACPAC's May 2018 issue brief, *Medicaid Payment for Outpatient Prescription Drugs* (MACPAC 2018a).
- <sup>3</sup> In addition to a Medicaid drug rebate agreement, drug manufacturers must also enter into an agreement that meets the requirements of Section 340B of the Public Health Service Act (P.L. 102-585) and a master agreement with the Secretary of Veterans Affairs as a condition for Medicaid coverage (§ 1927(a)(1) of the Act). A drug not covered under a rebate agreement may be eligible for federal funding in limited circumstances if the state has determined that the drug is essential to the health of its beneficiaries.
- <sup>4</sup> 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)).
- <sup>5</sup> CMS calculates the URA to assist states in developing the rebate invoice, but the manufacturer remains liable for the correct calculation of the rebate.
- <sup>6</sup> The covered outpatient drug final rule in 2016 included a separate definition of AMP for the so-called 5i drugs— inhalation, infusion, instilled, implanted, or injectable drugs. These drugs are not generally sold through the same distribution channels as non-5i drugs, so the AMP for 5i drugs includes sales of a type not included in AMP calculations of non-5i drugs.
- <sup>7</sup> Generally, an innovator drug is a drug produced or



distributed under a new drug application approved by the U.S. Food and Drug Administration (FDA). Single source drugs are innovator drugs manufactured by only one company and innovator multiple source drugs are innovator drugs that have at least one generic equivalent available. Non-innovator multiple source drugs are multiple source drugs that are not innovator drugs—generally, these are drugs that have been approved under an abbreviated new drug application by the FDA.

<sup>8</sup> Best price excludes certain governmental payers such as the Indian Health Service, Department of Veterans Affairs, Department of Defense, Public Health Service (including 340B), Federal Supply Schedule, and Medicare Part D plans.

<sup>9</sup> The baseline AMP is the AMP during the quarter before the Medicaid Drug Rebate Program was started or, for new drugs, the first full quarter after the drug's market date.

<sup>10</sup> The Comprehensive Addiction and Recovery Act of 2016 (CARA, P.L. 114-198) excluded abuse-deterrent formulations of prescription drugs from the definition of line extension drugs for Medicaid rebate purposes.

<sup>11</sup> The discussion of the line extension rebate provision in the Chairman's mark for the America's Healthy Future Act of 2009, which was the precursor to the ACA that originally contained the line extension rebate, indicated the desire to treat new formulations of brand-name drugs as if they were the original product for purposes of calculating the additional inflationary rebate (Senate Finance 2009a). When a new version of an existing drug is introduced, the additional rebate obligation for that new drug would be calculated on the original drug's baseline AMP rather than on a new baseline. However, under the ACA, the alternative rebate, which is essentially the inflationary component of the original drug, gets compared to the standard rebate (basic rebate plus inflationary rebate) of the line extension drug. Because the alternative rebate calculation does not include the basic rebate, the inflationary increase of the original drug will need to be at least 23.1 percent (the minimum basic rebate amount) greater than the inflationary increase of the line extension drug to trigger the alternative rebate.

<sup>12</sup> In accordance with Section 2501(c) of the ACA, 18 states—Arizona, California, Delaware, Florida, Iowa, Kansas, Kentucky, Massachusetts, Minnesota, Nebraska, New Hampshire, New York, North Dakota, Oregon, Texas,

Virginia, Washington, and West Virginia—are expanding supplemental rebate collections to include drugs dispensed to beneficiaries who receive drugs through a managed care organization (MCO). Minnesota limits its collection of supplemental rebates for MCO enrollees to direct-acting antivirals for the treatment of hepatitis C (CMS 2018a).

<sup>13</sup> Brand drug manufacturers introduce authorized generics for a variety of reasons: to discourage third-party manufacturers from introducing generic versions of the drug, to make it less profitable for a generic manufacturer to challenge a brand drug's patent, to siphon sales from the first generic drug during the 180-day exclusivity period, or to retain market share by competing with third-party manufacturers in the generic market (FTC 2011).

<sup>14</sup> These sales are also included in determining the best price and the federal upper limit (FUL) of the drug, which provides disincentives for manufacturers to lower the transfer price beyond a certain point.

<sup>15</sup> The penalty for false information is a maximum of \$100,000 for every piece of false information. The language detailing the penalty for failure to provide timely information is unclear. It states that the amount of the penalty shall be increased by \$10,000 for every day the information is late, but does not indicate a base penalty amount.

<sup>16</sup> Every quarter, CMS transmits a list to the OIG of manufacturers that have failed to report timely data for two out of the last four quarters (OIG 2009).

<sup>17</sup> There is an exception to the FUL for drugs for which the price listed in the National Average Drug Acquisition Cost (NADAC) survey is greater than 175 percent of AMP. In such cases, the FUL for these drugs is increased to be equal to the price listed in the NADAC.

<sup>18</sup> Drugs were identified at the 11-digit national drug code level.

<sup>19</sup> All 10 drugs were classified as non-innovator products (i.e., generic) in the Medicaid file but were approved under new drug applications by the FDA and therefore should likely have been classified as innovator (i.e., brand) drugs. Manufacturers would have paid a lower base rebate amount, and would not have paid the additional inflationary rebate, when applicable, for these drugs in the years 2012–2016 because the inflationary rebate on generic drugs did not

begin until 2017. Ninety percent of the \$1.3 billion in rebates potentially lost by the misclassification was associated with only two drugs (OIG 2017).

<sup>20</sup> Two examples of states that have requested additional flexibility to manage increasing drug costs: Massachusetts has submitted a section 1115 demonstration waiver request that is still under CMS review (CMS 2017b). Arizona has submitted a letter to CMS expressing interest in additional flexibility in the coverage of drugs (AHCCCS 2017).

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## Commission Vote on Recommendations

In its authorizing language in the Social Security Act (42 USC 1396), Congress requires MACPAC to review Medicaid and CHIP program policies and make recommendations related to those policies to Congress, the Secretary of the U.S. Department of Health and Human Services, and the states in its reports to Congress, which are due by March 15 and June 15 of each year. Each Commissioner must vote on each recommendation, and the votes for each recommendation must be published in the reports. The recommendations included in this report, and the corresponding voting record below, fulfill this mandate.

Per the Commission’s policies regarding conflicts of interest, the Commission’s conflict of interest committee convened prior to the vote to review and discuss whether any conflicts existed relevant to the recommendations on improving operations of the Medicaid Drug Rebate Program. It determined that, under the particularly, directly, predictably, and significantly standard that governs its deliberations, no Commissioner has an interest that presents a potential or actual conflict of interest.

The Commission voted on Recommendation 1.1 and Recommendation 1.2 on March 1, 2018.

### Improving Operations of the Medicaid Drug Rebate Program

<p>1.1 To ensure that manufacturer rebates are based on the price of the drug available to wholesalers and pharmacies, Congress should remove the statutory requirement in section 1927(k)(1)(C) that manufacturers blend the average manufacturer price of a brand drug and its authorized generic.</p> <p>Yes: Burwell, Carter, Cerise, Cruz, Davis, Douglas, George, Gold, Gorton, Lampkin, Milligan, Retchin, Scanlon, Szilagyi, Thompson</p> <p>Not Present: Gordon, Weil</p>	<table border="1" style="background-color: #f2f2f2; border-collapse: collapse;"> <tr> <td style="padding: 5px;">15</td> <td style="padding: 5px;">Yes</td> </tr> <tr> <td style="padding: 5px;">2</td> <td style="padding: 5px;">Not Present</td> </tr> </table>	15	Yes	2	Not Present
15	Yes				
2	Not Present				
<p>1.2 Congress should give the Secretary of Health and Human Services the authority to level intermediate financial sanctions to compel drug manufacturers to submit accurate drug classification data and strengthen enforcement actions. These authorities could include clear authority to reclassify an inappropriately classified drug and to level civil monetary penalties for the submission of inaccurate drug classification data.</p> <p>Yes: Burwell, Carter, Cerise, Cruz, Davis, Douglas, George, Gold, Gorton, Lampkin, Milligan, Retchin, Scanlon, Szilagyi, Thompson</p> <p>Not Present: Gordon, Weil</p>	<table border="1" style="background-color: #f2f2f2; border-collapse: collapse;"> <tr> <td style="padding: 5px;">15</td> <td style="padding: 5px;">Yes</td> </tr> <tr> <td style="padding: 5px;">2</td> <td style="padding: 5px;">Not Present</td> </tr> </table>	15	Yes	2	Not Present
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Chapter 2:

# Substance Use Disorder Confidentiality Regulations and Care Integration in Medicaid and CHIP

# Substance Use Disorder Confidentiality Regulations and Care Integration in Medicaid and CHIP

## Recommendations

- 2.1** The Secretary of Health and Human Services should direct relevant agencies to issue joint subregulatory guidance that addresses Medicaid and CHIP provider and plan needs for clarification of key 42 CFR Part 2 provisions.
- 2.2** The Secretary should direct a coordinated effort by relevant agencies to provide education and technical assistance on 42 CFR Part 2. Such efforts should target state Medicaid and CHIP programs, health plans, primary care and specialty providers, patients and their families, and other relevant stakeholders.

## Key Points

- Disclosure of medical information about substance use disorders (SUDs) can expose individuals to harm, such as criminal prosecution and loss of employment or child custody. Such disclosures risk discouraging individuals from seeking treatment for their SUDs.
- Federal regulations (42 CFR Part 2) protect the confidentiality of certain SUD-related information. Providers generally need patient consent to share protected information, both inside and outside the health care system.
- Requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA, P.L. 104-191) that govern privacy of most other patient health information are generally less stringent, permitting providers and plans to share information for payment, treatment, and health care operations purposes without patient consent.
- Part 2 can be a barrier to integrating physical and behavioral health services for Medicaid and CHIP enrollees with SUDs. Some stakeholders contend that the rules are too restrictive, confusing, and challenging to implement, and that they limit, sometimes inadvertently, sharing of important patient information among providers and plans. Such information gaps can affect the provision of high-quality care and hamper delivery system reforms.
- Some stakeholders call for closer alignment of Part 2 with HIPAA. Others suggest that more should be done to improve stakeholder understanding of Part 2 and to develop tools to facilitate consent and disclosure processes.
- It is the Commission's view that additional subregulatory guidance could address confusion about Part 2 and highlight existing opportunities to share information. This guidance should include clear and consistent definitions about which providers and what information is subject to Part 2 and how information can be shared in a Part 2-compliant manner. Targeted education and technical assistance efforts developed in consultation with stakeholder groups is also needed.
- At this time, the Commission does not recommend alignment of Part 2 and HIPAA, but it intends to explore this issue in the future.



## CHAPTER 2: Substance Use Disorder Confidentiality Regulations and Care Integration in Medicaid and CHIP

As part of MACPAC's prior work on behavioral health disorders and Medicaid's response to the opioid epidemic, the Commission identified the need for improved integration of mental health, substance use disorder (SUD), and physical health services (MACPAC 2017, 2016). People with SUDs commonly have serious comorbidities, such as other behavioral health disorders, cardiovascular diseases, cancer, hepatitis C, and HIV (SAMHSA 2016, NIDA 2010). Fragmentation of care can affect access to care and result in inappropriate use of services, poor health status, and increased costs (MACPAC 2016).

The Commission has noted that the federal law on confidentiality of SUD-related patient records (42 USC § 290dd-2) and its implementing regulations (42 CFR Part 2)—together usually referred to as Part 2—act as a barrier to integrated care by hindering the exchange of information among the providers who treat individuals with SUDs and the payers who finance that care. Part 2 applies to information that identifies a person as having or having had an SUD and that is maintained by certain health care providers. Part 2 generally requires patients to provide explicit prior written consent to sharing of such SUD-related information, either within the health care system or outside of it. These rules are meant to minimize the risk that unauthorized disclosures of such information could expose patients to harmful consequences (SAMHSA 2017). Part 2 requirements are generally stricter than those imposed by the Health Insurance Portability and Accountability Act of 1996 (HIPAA, P.L. 104-191), a law that established privacy protections

and standards for lawful disclosures of most other health information. HIPAA generally allows information to be shared without patient consent among health care providers and payers for payment, treatment, and health care operations purposes.

Many clinicians, state Medicaid agencies, health plans, health information technology (health IT) companies, some patient advocates, and others have raised concerns in regulatory comment letters, journal articles, and other venues that the Part 2 regulations are confusing, restrictive, and challenging to implement (SAMHSA 2018a, Partnership 2017, McCarty et al. 2016, NAMD 2016). Information gaps between different providers treating the same patient or among multiple entities responsible for administering benefits can undermine the provision of whole-person care (MACPAC 2017, 2016).<sup>1</sup> Lack of comprehensive patient information may also hamper delivery system reforms, which aim to hold providers and health plans accountable for costs and health outcomes. Thus many stakeholders support relaxing consent standards to align them more closely with HIPAA standards for sharing of information among providers and payers inside the health care system (Partnership 2017, NAMD 2016). But other stakeholders, in particular certain patient advocates, warn that creating more avenues for sensitive health information to be disclosed without patient consent could harm patients and discourage individuals from seeking care for SUDs (Clark 2018, Reid 2018). Additional clarifying guidance on the existing regulations, however, would be a meaningful step to help providers, payers, and patients understand rights and obligations under the current law as well as existing opportunities for information sharing.

To better understand how Part 2 affects care delivery for beneficiaries of Medicaid and the State Children's Health Insurance Program (CHIP) who have SUDs and possible ways to promote information sharing, MACPAC conducted a review of publicly available information.<sup>2</sup> Although there is little research on this topic, comments

submitted in response to federal rulemaking and a Substance Abuse and Mental Health Services Administration (SAMHSA) public listening session on Part 2 provide many insights into the views of state Medicaid directors, SUD specialty providers, primary care providers, Medicaid managed care organizations (MCOs), and patient advocates (SAMHSA 2018a, 2018b, 2017).

In addition, in November 2017, MACPAC convened an expert roundtable of federal and state Medicaid and behavioral health officials, health care providers, legal experts, researchers, Medicaid MCOs, and patient advocates.<sup>3</sup> Roundtable participants agreed that Part 2 generally protects individuals from harms that may occur due to unauthorized disclosure of SUD treatment information. They particularly noted the importance of protecting such information from disclosure to non-health care entities without explicit consent. There was, however, less agreement on the degree to which explicit patient consent should be required for the exchange of information within the health care system for purposes of treatment, payment, and health care operations, and whether Part 2 protections that go beyond HIPAA requirements in these settings are necessary.

A key theme from the roundtable was the significant confusion among many stakeholders about the scope and applicability of Part 2, which can lead to its inconsistent application and may hamper care coordination and care transitions. As this report went to print, SAMHSA and the Office of the National Coordinator for Health Information Technology (ONC) jointly issued two fact sheets with scenarios illustrating how Part 2 may apply to certain providers, patient information, and disclosures made using electronic health information exchange. Because the Commission has not had the opportunity to review this new guidance, any discussion in this chapter regarding stakeholder confusion about the regulations' provisions and the need for subregulatory guidance does not reflect the contents of these new fact sheets.

The Commission, therefore, recommends the following actions be taken by the Secretary of the U.S. Department of Health and Human Services (the Secretary) to ensure that federal regulations do not unnecessarily stifle information exchange among providers, payers, and patients::

- The Secretary of Health and Human Services should direct relevant agencies to issue joint subregulatory guidance that addresses Medicaid and CHIP provider and plan needs for clarification of key 42 CFR Part 2 provisions.
- The Secretary should direct a coordinated effort by relevant agencies to provide education and technical assistance on 42 CFR Part 2. Such efforts should target state Medicaid and CHIP programs, health plans, primary care and specialty providers, patients and their families, and other relevant stakeholders.

Adoption of the second recommendation is contingent on adoption of the first, because educational and technical assistance activities should focus on disseminating the contents of the clarifying guidance.

The Commission will monitor U.S. Department of Health and Human Services (HHS) guidance and activities to examine whether such actions promote stakeholder understanding and information sharing under Part 2 or have an unintended effect of identifying additional impediments to care delivery and integration under Part 2. The Commission will also continue to explore whether other steps, in particular, closer alignment of Part 2 with HIPAA, could facilitate information sharing and thus improve Medicaid and CHIP beneficiaries' access to coordinated, high-quality care.

This chapter begins by providing background on the need for confidentiality protections of SUD information. It summarizes current Part 2 regulations and compares key HIPAA and Part 2 regulatory provisions. The chapter goes on to discuss the types of challenges Part 2 may pose to effective and integrated care delivery for Medicaid

and CHIP enrollees with SUDs. It then presents the rationale for the Commission's recommendations for improving the understanding and implementation of the existing Part 2 regulations and the implications of these recommendations for the federal government, states, enrollees, plans, and providers. The chapter ends by briefly outlining the Commission's plans to explore other steps Medicaid and CHIP stakeholders have suggested for addressing concerns about Part 2's effect on the delivery of care.

## The Need for Confidentiality of SUD-Related Health Information

Disclosure of SUD-related information can have serious consequences including criminal arrest, prosecution, and incarceration; loss of employment, housing, or child custody; discrimination by medical professionals; and denial of life or disability insurance. Unlike other chronic illnesses, SUDs are widely stigmatized and, depending on the substance being used, may involve criminalized behavior (AHLA 2017, Lopez and Reid 2017, SAMHSA 2017, NASEM 2016, Curtis et al. 2013). Patient advocates and providers have relayed experiences with local law enforcement officers who attempted to access SUD treatment facilities and patient records to gather information to bring criminal charges. Individuals who take methadone as part of medication-assisted treatment (MAT) for opioid use disorder have also reported being denied visitation with their children or threatened with eviction (Lopez and Reid 2017). Federal and state antidiscrimination laws that protect individuals with disabilities—such as those stemming from chronic diseases—only apply to some people with SUDs (FindLaw 2018, USCCR 2000).<sup>4</sup> In light of these circumstances, patients, providers, plans, and government health officials generally support heightened protection from unauthorized disclosure of SUD-related information outside of the health

care system (ACHP et al. 2016, LAC 2016, NAMD 2016).

Discrimination against people with SUDs can also occur within the health care system. Health professionals may have inadequate education, training, and support working with patients with SUDs. Providers, even SUD specialty providers, may view such patients as violent, manipulative, and poorly motivated to participate in their own care (van Boekel et al. 2013). Patients have reported instances of being “fired” by their physicians when their SUD was disclosed or being disparaged for taking methadone as part of MAT (Lopez and Reid 2017). Such negative attitudes and lack of empathy can perpetuate stigma, undermining a patient's feelings of empowerment and leading to poor treatment outcomes (van Boekel et al. 2013). Moreover, concern about disclosure of such sensitive information is one reason individuals with SUDs do not seek care (CBHSQ 2017, Stone 2015).

Thus, some stakeholders oppose relaxing SUD confidentiality protections, even if the changes are limited to treatment contexts. These stakeholders assert that patients should retain control over when their SUD-related information is shared and with whom (Clark 2016, Reid 2018, DASPOP 2016, EPIC 2016, LAC 2016).

## The Part 2 Regulations

The federal Confidentiality of Substance Use Disorder Patient Records regulations contained in 42 CFR Part 2 govern the confidentiality and disclosure of SUD treatment and prevention records for people receiving treatment from federally assisted programs. These regulations were first promulgated in 1975 and implement statutory requirements under the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970 (P.L. 91-616) and the Drug Abuse Prevention, Treatment, and Rehabilitation Act of 1972 (P.L. 92-255). These two laws were later consolidated in the 1992 Alcohol, Drug Abuse, and Mental Health Administration

Reorganization Act (P.L. 102-321). The law is intended to encourage individuals to seek treatment for SUDs by addressing the stigma of SUDs and concerns that individuals receiving treatment could be subject to negative consequences. Specifically, the statute (42 USC 290dd-2) includes provisions that:

- require written patient consent to disclose records of a patient’s identity, diagnosis, prognosis, or treatment information that are maintained in connection with SUD education, prevention, training, treatment, rehabilitation, or research activities or programs and that are conducted, regulated, or directly or indirectly assisted by any federal department or agency;<sup>5</sup>
- prevent, absent a court order for good cause, SUD treatment records from being acquired or used by law enforcement to investigate a patient or initiate or substantiate any criminal charges;<sup>6</sup>
- exempt from the prior written consent requirement disclosures made for the following reasons:
  - to medical personnel in case of a bona fide medical emergency, and
  - for purposes of scientific research, management and financial audits, or program evaluation, so long as any report of such activity does not directly or indirectly identify the individual patient;
- charge the Secretary with issuing regulations to carry out the law, including prescribing definitions, safeguards, and procedures, to facilitate compliance and prevent circumvention of the law.

The implementing regulations at 42 CFR Part 2 subsequently introduced several definitions and requirements, including spelling out the types of providers and information that are subject to the law, when patient consent is not required, and processes for securing and managing consent.

SAMHSA, the operating division of HHS that oversees Part 2, updated the regulations most recently in January 2017 and January 2018 (SAMHSA 2018b, 2017). SAMHSA has acknowledged that additional subregulatory guidance may be needed to clarify a number of issues, and stated in the preamble to the 2018 rule that it plans to explore additional alignment with HIPAA where possible (SAMHSA 2018b, 2017). Below we summarize key provisions of the Part 2 regulations and the preambles to the 2017 and 2018 final rules, focusing on those particularly relevant to delivery of services to Medicaid and CHIP beneficiaries.

### When patient consent is required

Providers subject to Part 2 (referred to as Part 2 programs) are generally required to obtain a patient’s prior written consent to disclose information to another individual or entity that would identify the patient as having or having had an SUD, for example, records related to SUD diagnosis, treatment, or referral for treatment.

After a patient has provided written consent to share information with a third party, the disclosure must include a notice to the recipient that the information received is protected by Part 2 and that the recipient is prohibited from redisclosing it except in accordance with Part 2 provisions (42 CFR 2.32). Entities receiving protected information may not subsequently disclose it to anyone else—including other providers and payers involved in the patient’s care—without first obtaining another written consent from the patient, or unless one of the limited exceptions to the consent requirement applies. For example, a primary care provider who receives Part 2 protected information from an SUD treatment provider generally cannot redisclose that information to a specialist or to a managed care plan unless the primary care provider obtains a new separate consent from the patient specifically authorizing such disclosure.

The regulations, consistent with the underlying statute, also prevent, absent a court order meeting

specific requirements, SUD treatment records from being acquired and used by law enforcement to investigate or prosecute a patient (42 CFR 2.12, 42 CFR 2.61).

## When patient consent is not required

There are limited circumstances under which the regulations permit information to be disclosed or redisclosed without patient consent. Protected patient information may be disclosed without consent for communications:

- among staff within a Part 2 program or between a Part 2 program and an entity with direct administrative control over the Part 2 program, so long as each staff person needs the information to carry out duties related to diagnosis, treatment, or referral for treatment of patients with SUDs (42 CFR 2.12); and
- between a Part 2 program and a qualified service organization (QSO).

QSOs are organizations that provide Part 2 programs with administrative and professional services, such as data processing; bill collecting; dosage preparation; laboratory analyses; legal, accounting, medical staffing, and other professional services; and services to prevent or treat child abuse or neglect, including training on child care and individual and group therapy. QSO services may include population management services. But the preamble to the 2017 rule specifically excludes care coordination activities from QSO services not subject to patient consent requirements because SAMHSA considers such services to have a treatment component (42 CFR 2.11–2.12).

Patient consent is also not required for certain other disclosures, including the following:

- to medical personnel in the case of bona fide medical emergencies where prior consent cannot be obtained (42 CFR 2.51);
- for research, but only if the recipient of the information is subject to and complies with rules related to HIPAA or the HHS Common

Rule for the protection of human subjects (45 CFR 46), and only if research reports exclude individually identifiable information (42 CFR 2.52);

- for Medicare, Medicaid, and CHIP audits and evaluations (42 CFR 2.53);
- to report suspected child abuse and neglect under state law (42 CFR 2.12); and
- in response to a special authorizing court order (42 CFR 2.61).

Redisclosure without patient consent is only permitted in limited circumstances, which include the following:

- recipients of protected information may redisclose the information to contractors, subcontractors, and legal representatives carrying out Medicare, Medicaid, and CHIP audits and evaluations (42 CFR 2.53); and
- an entity such as a Medicaid MCO that, pursuant to a patient’s consent, receives protected information for purposes of payment or health care operations activities, may redisclose that information to its contractors, subcontractors, and legal representatives without obtaining a separate patient consent—but only if the redisclosure is necessary for carrying out the activities for which the initial consent was granted (42 CFR 2.33).<sup>7</sup>

All of these disclosures and redisclosures must include the notice that the received information is protected by Part 2 and that further disclosure is prohibited except in accordance with Part 2 provisions.

## Providers and information subject to Part 2

Information identifying individuals as having or having had an SUD becomes subject to Part 2 when it originates with providers who are “federally assisted” and meet the definition of a “program” (42 CFR 2.12). The term “federally assisted,” in

accordance with the statute, is defined broadly and includes, but is not limited to:

- entities that receive any federal funding, even if not for SUD services;
- entities that are registered with the U.S. Drug Enforcement Administration (DEA) to dispense controlled substances for treatment of SUDs; and
- entities that hold federal tax-exempt status (42 CFR 2.12).

A “program” is defined as:

- an individual or entity (other than a general medical facility) that holds itself out as providing, and provides, SUD diagnosis, treatment, or referral for treatment;
- an identified unit within a general medical facility that holds itself out as providing, and provides, SUD diagnosis, treatment, or referral for treatment; or
- medical personnel or other staff in a general medical care facility whose primary function is the provision of SUD diagnosis, treatment, or referral for treatment and who are identified as such providers (42 CFR 2.11).

In the preamble to the 2017 final rule, SAMHSA notes that hospitals, federally qualified health centers (FQHCs), or trauma centers would generally be considered “general medical care facilities.” The preamble also states that “holds itself out” means any activity that would lead one to reasonably conclude that the individual or entity provides SUD diagnosis, treatment, or referral for treatment, including but not limited to state or federal government authorization to provide such services (e.g., being licensed, certified, or registered), advertising the provision of such services, and providing consultation activities related to such services.

Part 2 protections do not necessarily apply to records of all patients receiving SUD treatment

because some providers, such as certain primary care providers or FQHCs, may not fall under the definition of a Part 2 program. In these cases, HIPAA governs disclosure practices. A Part 2 program generally must also comply with HIPAA regulations to the extent that there is no applicable Part 2 provision for a patient’s SUD-related information, and for any non-SUD related health information held by the provider.

## Notice to patients about Part 2

A Part 2 program must, at the time of a patient’s admission, provide the patient with a written notice that includes a summary of the Part 2 confidentiality protections, the limited circumstances under which information may be disclosed without patient consent, a statement that violation of Part 2 is a crime, and contact information for reporting suspected violations (42 CFR 2.22).

## Elements of patient consent

Required elements of the patient consent to disclose information include:

- the purpose of the disclosure;
- how much and what kind of information is to be disclosed;
- the date or condition upon which consent expires; and
- the individual or entity to whom the patient allows disclosure of the protected information (42 CFR 2.31).

For the amount and kind of information to disclose, the consent form must allow patients to describe in detail which SUD-related information they want to share. The preamble to the 2017 rule suggests that this can be accomplished by providing blank spaces for patients to fill in or by providing a list of choices based on fields commonly used in medical records, including in electronic health records (EHRs).<sup>8</sup> The form may also include fields allowing patients to select to share “all my SUD information” or “none

of my SUD information,” as long as more granular options are available.

In the consent form, patients must specify who may receive the information by identifying one of the following:

- the name of an individual;
- the name of an entity, as long it has a treating provider relationship with the patient;
- the name of a third-party payer; or
- the name of an intermediary entity without a treating provider relationship that shares information with participants in that entity.

The preamble to the 2017 rule provides examples of intermediary entities that could be named on the consent form, including health information exchanges (HIEs) and entities that coordinate care, such as accountable care organizations (ACOs). If the patient names such an intermediary entity, then the patient must also name the recipient to whom the entity is ultimately sending the information, for example, a physician who participates in the HIE or ACO. The intended end recipient must be a participant in the intermediary entity. The patient can name an individual, name an entity with a treating provider relationship, or make a “general designation” of individuals or organizations, provided that they have a treating provider relationship with the patient (42 CFR 2.31). For example, as discussed in the preamble to the 2017 rule, the patient could permit the HIE to disclose information to “all my treating providers,” or to “all my current and future treating providers.”<sup>9</sup> A treating provider relationship exists, regardless of whether there has been an actual in-person encounter, when two conditions are met: (1) the patient agrees to or is legally required to be diagnosed, evaluated, or treated, or agrees to receive a consultation; and (2) an individual or entity agrees to provide or actually does provide such services to the patient (42 CFR 2.11).

## Comparison of Part 2 and HIPAA privacy provisions

While Part 2 rules dictate disclosures of SUD-related information, HIPAA regulations govern the use and disclosure of most other individually identifiable health information—that is, any information related to physical or mental health conditions, health care services, or payment for such care.<sup>10</sup> Most notably, HIPAA permits sharing without patient consent for purposes of payment, treatment, and health care operations. Part 2’s allowances for disclosure without consent are far more limited, and generally do not include disclosure for treatment purposes (Table 2-1).

## Challenges Associated with Part 2

Despite stakeholder agreement about the importance of Part 2 in protecting patients from harm that may occur from unauthorized disclosure of SUD information, and despite the recent update to Part 2, many stakeholders in public comments and at the MACPAC roundtable continue to report challenges in complying with the regulations and concerns about restrictions on information sharing (SAMHSA 2018a).

## Limits on the sharing of SUD-related health information can cause harm

Despite widespread agreement about the importance of integrating SUD treatment with other medical care, stakeholders disagree about the extent to which SUD treatment information should be shared for this purpose without patient consent. In many comment letters to SAMHSA, organizations representing Medicaid officials, providers, and plans, as well as some patient advocates, noted that the possible harms associated with withholding SUD-related information from health care providers, which can result in uncoordinated care, outweigh the risks that increased sharing of sensitive

**TABLE 2-1. Components of HIPAA and Part 2 Regulations** T 2-1

Component	HIPAA regulations	Part 2 regulations
Who must comply?	<p><b>Covered entity.</b> Any health plan, health care provider, or health care clearinghouse that electronically transmits health information in connection with transactions subject to HIPAA.</p>	<p><b>Part 2 program.</b> Any federally assisted:</p> <ul style="list-style-type: none"> <li>• individual or entity (other than a general medical facility), or identified unit in a general medical facility that holds itself out as providing, and provides, SUD diagnosis, treatment, or referral for treatment; or</li> <li>• provider in a general medical facility who is identified as and whose primary function is SUD diagnosis, treatment, or referral for treatment.</li> </ul>
What information is protected?	<p><b>Protected health information.</b> Any individually identifiable health information about past, present, or future physical or mental health or condition, care provision, or payment.</p>	<p><b>Patient identifying information.</b> Any information identifying a patient as having or having had an SUD, such as records related to SUD diagnosis, treatment, or referral for treatment.</p>
When can information be disclosed without patient consent?	<p>Circumstances include, but are not limited to:</p> <p><b>Inside health care system</b></p> <ul style="list-style-type: none"> <li>• with the exception of psychotherapy notes,<sup>1</sup> information for purposes of:                             <ul style="list-style-type: none"> <li>– treatment</li> <li>– payment</li> <li>– health operations (includes care coordination and case management)</li> </ul> </li> <li>• communications between covered entities and business associates who provide administrative and professional services to the covered entity</li> <li>• audits</li> </ul> <p><b>Outside health care system</b></p> <ul style="list-style-type: none"> <li>• law enforcement and judicial and administrative proceedings pursuant to a court order, court-ordered warrant, subpoena, and certain other situations</li> <li>• child abuse and neglect reporting</li> </ul>	<p>Circumstances include, but are not limited to:</p> <p><b>Inside health care system</b></p> <ul style="list-style-type: none"> <li>• communications:                             <ul style="list-style-type: none"> <li>– among Part 2 program staff involved in patient care</li> <li>– with QSOs providing administrative and professional services to the Part 2 program</li> </ul> </li> <li>• to medical personnel in medical emergencies</li> <li>• audits and evaluations</li> <li>• to prevent multiple enrollments in maintenance treatment or withdrawal management programs</li> </ul> <p><b>Outside health care system</b></p> <ul style="list-style-type: none"> <li>• law enforcement and judicial and administrative proceedings pursuant only to a special court order</li> <li>• child abuse and neglect reporting</li> </ul>
Are recipients of information subject to the same requirements, and can recipients share information further?	<ul style="list-style-type: none"> <li>• If recipient is a HIPAA-covered entity or business associate, then HIPAA requirements continue to apply and redisclosure is permitted under the same conditions as initial disclosures.</li> <li>• If recipient is not a HIPAA-covered entity or business associate, then HIPAA protections no longer apply and redisclosure is permitted.</li> </ul>	<ul style="list-style-type: none"> <li>• Recipients of protected information are bound by Part 2 and generally prohibited from redisclosing information without patient consent.</li> <li>• Limited exceptions include allowing redisclosure without patient consent to contractors, subcontractors, or legal representatives for:                             <ul style="list-style-type: none"> <li>– carrying out Medicaid and CHIP audits and evaluations; and</li> <li>– payment or health care operations.</li> </ul> </li> </ul>

**Notes:** HIPAA is the Health Insurance Portability and Accountability Act of 1996 (P.L. 104-191). Part 2 is 42 CFR Part 2. QSO is qualified service organization. SUD is substance use disorder. Some sensitive health data (e.g., data related to HIV/AIDS, mental health, and reproductive health) may also be subject to state laws providing additional disclosure protections. Part 2 does not apply to records exchanged within and between the U.S. Department of Veterans Affairs and the uniformed services.

<sup>1</sup> Psychotherapy notes are a mental health care provider’s notes documenting or analyzing the conversations during counseling sessions. These notes do not include summaries of diagnosis, functional status, the treatment plan, symptoms, prognosis, and progress to date.

**Sources:** 42 CFR Part 2, 45 CFR Part 164.



information could lead to disclosures that cause harm (ABHW 2016, APA 2016, MHA 2016, NAMD 2016, WHCA 2016).

Providers generally assert that effective care necessitates access to a patient's entire treatment history and current medications. When patients are unable or unwilling to accurately report on current or past medications, drug use, treatments, or health care providers, restrictions on access to such information could result in inadequate or even dangerous care, such as prescribing medications with potentially dangerous or even deadly interactions with other medications (SAMHSA 2018a, Wakeman and Friedman 2017, APA 2016, MHA 2016, ACP 2016). For example, a provider unaware of a patient's opioid use disorder history could prescribe opioids to someone in recovery, potentially contributing to a relapse (Clement and Keeton 2018). Even when a health care record reflects care that has been delivered elsewhere, if SUD treatment information has been withheld, providers may not know that the record is incomplete.

Requirements for obtaining specific consent can make it difficult to coordinate care, manage care transitions, and follow up on patient referrals,

discouraging use of integrated care models (Box 2-1). For example, an individual newly entering treatment may receive multiple SUD treatment services from different Part 2 providers (e.g., inpatient detoxification followed by residential treatment and subsequent outpatient counseling), as well as other medical care from non-Part 2 providers for hepatitis C. In order for an MCO care manager assigned to this patient to develop a comprehensive transition plan and coordinate services, each individual Part 2 program must first secure the patient's consent for a disclosure to the care manager. The care manager in turn must secure consent from the patient to then share information with the providers that make up the patient's care team (AHCCCS 2016, Anthem 2016, Beacon 2016, IN FSSA 2016, NAMD 2016). However, it may be possible for the care manager to secure a patient's consent that uses a general designation to share information with all of the patient's future treating providers. In that case, no new consents would be required to share information with a solo practice physician who is a new addition to the care team. Still, providers and payers attending MACPAC's roundtable stated that even when patients consent, the consent and disclosure process creates unnecessary delays in the sharing of essential information.

## **BOX 2-1. Examples of Part 2 Restrictions on Information Sharing in the Health Care System**

**Part 2 requirement.** A Part 2 program generally cannot share information with an outside health care provider without prior written patient consent. A provider not subject to Part 2, however, can generally provide the Part 2 program with information about a mutual patient without the patient's consent.

**Example.** Mary is a Medicaid enrollee being treated with buprenorphine for an opioid use disorder in a stand-alone SUD clinic, which is subject to Part 2. She is also getting care for hypertension from a family physician who is in private practice and is not a Part 2 program. Mary has told her family physician that she is getting treatment for her SUD. HIPAA permits the physician to give the SUD clinic updates about any changes to Mary's antihypertensive medication, without first requiring her consent. The SUD clinic, however, has not secured Mary's prior written consent to share information with her family physician, and therefore cannot provide information about her buprenorphine dosage and frequency of drug counseling sessions.

## BOX 2-1. (continued)

**Part 2 requirement.** Patients generally must consent for a Part 2 program to share SUD information with payers when filing insurance claims. Payers in most cases cannot share this information with a patient's other treating providers or use it for care coordination without a patient's consent. Payers, however, do not need consent to redisclose the protected information to contractors, subcontractors, or legal agents for payment and health care operations purposes.

**Example.** John is an enrollee in a Medicaid MCO. He uses drugs and is hospitalized following a car accident. During his stay, he meets with the hospital's addiction specialist who diagnoses his SUD and develops a treatment plan. The hospital's legal counsel previously determined that the addiction specialist is a Part 2 provider.

The hospital may submit claims to John's MCO for the physical health care portion of his stay without John's consent. However, Part 2 requires the hospital first to secure John's consent to share information with the MCO for the addiction specialist service claims. Upon receipt, the MCO is able to redisclose both the physical and SUD-related information to its third-party administrator for claims processing without John's consent.

John agrees to enter an intensive outpatient program at a local SUD clinic after discharge from the hospital. Part 2 restricts the MCO from disclosing the SUD diagnosis and treatment plan to John's primary care provider without John's consent.

The MCO would also like to have one of its in-house care managers follow up with John after he is discharged, to encourage compliance with the intensive outpatient program and discuss available services to support long-term recovery. Before sharing his information with the care manager, however, the MCO must first get John's consent.

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**Part 2 requirement.** Part 2-protected information must be segregated from the rest of a patient's medical record, including any electronic health record, and generally may only be made available with patient consent—even when a Part 2 program shares medical records with a non-Part 2 program in the same practice or health system.

**Example.** Beth is prescribed buprenorphine for her opioid use disorder by a psychiatrist in a large multispecialty practice. The practice's legal counsel has determined that the psychiatrist is a Part 2 provider. Beth relapses and develops a serious skin infection likely related to her intravenous drug use. She seeks care from the practice's dermatologist but does not disclose that she has been in SUD treatment with the practice's psychiatrist, and the dermatologist does not ask about any SUD history. Despite being part of the same practice, the dermatologist is unable to see the SUD information in Beth's medical record because she has previously chosen not to share that information with all providers in the practice. Her dermatologist cannot consider any potential antibiotic drug interactions were she to resume SUD treatment and take buprenorphine. The dermatologist also does not know to alert her psychiatrist about the infection.

**Notes:** Part 2 is 42 USC 290dd-2 and its implementing regulations 42 CFR Part 2. SUD is substance use disorder. HIPAA is the Health Insurance Portability and Accountability Act of 1996 (P.L. 104-191) and its implementing regulations 45 CFR Part 164. MCO is managed care organization. These examples illustrate requirements related to disclosures under HIPAA and Part 2 only and do not include consideration of other laws, such as state laws related to HIV/AIDS, mental health, reproductive health, and domestic violence, which may also place restrictions and conditions on disclosure of sensitive health information.

**Sources:** 42 CFR Part 2. 45 CFR Part 164.

Some stakeholders also expressed concern at the roundtable and in regulatory comments to SAMHSA that separate medical records, consent requirements and forms, and privacy regimes for SUD-related information perpetuate stigma by treating such patients and their health information differently from other patients. They argued that the separate requirements imply that SUD patients should be ashamed of their condition and that they must hide it to be treated fairly and non-prejudicially by the health care system (MHA 2016).

## Confusion over when Part 2 applies

Discussion at the MACPAC roundtable in particular and the regulatory comment letters highlighted the tremendous uncertainty among many stakeholders about when Part 2 applies and to whom. Specifically, there is confusion about:

- who is considered a treatment provider subject to Part 2;
- what parts of patient health records are covered by Part 2;
- when SUD information can be shared among staff within a Part 2 program; and
- the level of detail required in certain parts of the written patient consent to make Part 2-compliant disclosures.

Lacking more definitive guidance, providers may interpret the regulations narrowly and opt not to share Part 2 records, unnecessarily limiting other providers' access to important patient information. Concerns that offering certain services will subject them to confusing Part 2 requirements may also discourage some providers from offering SUD care. Conversely, confusion may also lead some providers to mistakenly conclude that they are not subject to Part 2.

**Defining providers subject to Part 2.** The setting in which an SUD service is provided determines in part whether a patient's SUD-related health information is protected by Part 2. SAMHSA, however, has not

published definitive subregulatory guidance that clearly enumerates which providers and settings are subject to the rule, leaving key concepts such as "holding oneself out as providing SUD care" and "general medical facility" largely open to interpretation. As a result, it is unclear whether certain providers meet the definition of a Part 2 program. Absent more definitive guidance, provider behavior can be arbitrary or inconsistent.

For example, consider the situations of a multispecialty practice that provides integrated care by employing an SUD specialist who prescribes buprenorphine for opioid use disorder as part of MAT, or a primary care provider in solo practice offering MAT. Providers with a DATA-2000 waiver from SAMHSA and the DEA to prescribe buprenorphine for MAT meet the definition of being federally assisted (42 CFR 2.12).<sup>11</sup> But in the preamble to the 2017 final rule, SAMHSA states that holding a DATA-2000 waiver does not necessarily by itself make the provider a "program" subject to Part 2. Because of this ambiguity, providers must use their own judgment to determine whether part or all of their practices' medical records fall under Part 2 limitations and protections.

At the roundtable, a clinician described the experience of an internist with addiction specialty certification who provided SUD consultations at a liver transplant clinic and an HIV clinic within the same health system. The system's attorneys recommended that the internist cease providing consultations because they concluded that this would make both clinics Part 2-covered entities. Under this interpretation, both clinics would have been required to maintain medical records systems that segregated SUD information from other medical information.

Providers also report that different attorneys, even within the same hospital or health system, may disagree on Part 2's application. SAMHSA has indicated that additional subregulatory guidance to further define the phrase "holds itself out" as providing SUD diagnosis, treatment, or referral for treatment is forthcoming but has not made any

commitments with regard to timing (SAMHSA 2017).

### **Parts of patient health records affected by**

**Part 2.** It is not necessarily clear how Part 2 applies to records for unrelated medical care delivered to patients in conjunction with SUD treatment, medical care for illnesses resulting from or associated with an SUD, or medications used to treat SUDs that may also be used in the treatment of other illnesses (APCD Council 2016, CO SIM 2016). Part 2 restrictions apply to information that would identify a patient as having or having had an SUD. Providers, however, may be unsure about what information triggers this determination. For example, a patient in an SUD treatment program may have liver disease, pancreatitis, or hypertension that is directly attributable to an SUD. According to roundtable participants and some regulatory comment letters, it can be unclear which of the diagnoses and related treatments for these illnesses are protected by Part 2, because some are more often associated with having an SUD than others. Ultimately, roundtable participants said, providers are being asked to make judgment calls that exacerbate their confusion and concerns about complying with Part 2.

SAMHSA puts the onus on the Part 2 program to provide patients with a written notice about Part 2's confidentiality protections and to explain the consent process to them (SAMHSA 2017). However, due to confusion about when the regulations apply, some providers might mistakenly think they are not subject to Part 2. In such cases, patients would not be made aware that their information should be protected. Some stakeholders at the MACPAC roundtable indicated that even when providers subject to Part 2 are aware of their obligations, they may not adequately explain the protections and the consent process to patients. This may leave patients unsure about how and what parts of their medical records are protected and how to permit the sharing of such information with other providers. To address these concerns, stakeholders have called on SAMHSA to develop a national education campaign or additional patient education requirements for Part 2 providers, including plain

language interpretations of patients' rights under Part 2 and the implications of providing consent (Northwell Health 2016, LACSAPC 2016).

**Sharing information within a Part 2 program.** The degree to which information can be shared within a Part 2 program is unclear. The regulations permit communication about protected information among staff within a Part 2 program or between Part 2 program staff and staff at an entity with direct administrative control over the Part 2 program when it is in connection with the staffs' duties to provide diagnosis, treatment, or referral for treatment for the patients with SUDs. However, SAMHSA does not further define or give examples of what it considers "direct administrative control," and in the preamble to the 2017 rule advises stakeholders to consult with legal counsel to ensure compliance. Providers that commented during the rulemaking process requested that this concept be further defined, and some even requested that communications between a Part 2 program and another entity under common ownership or control be exempt from the consent requirement (SAMHSA 2017).

**Requirements for consenting to a disclosure.** There is also confusion about the individuals and entities to whom information can be disclosed and how patients may specify what kind of information can be disclosed.

To provide greater flexibility in sharing information, including through intermediaries such as HIEs and ACOs, the 2017 Part 2 update now allows patients to make a "general designation" of an individual or entity to whom information can be disclosed, so long as that person or entity has a "treating provider relationship" with the patient. Regulatory comments by organizations representing providers and payers, however, asserted that the terms are ambiguous. For example, it is not clear whether care coordinators can be considered to have a treating provider relationship with the patient for purposes of the general designation option (SAMHSA 2017). Some stakeholders requested the general designation be expanded to include situations and relationships beyond treating providers (Rosecrance

Health Network 2017). There is also confusion about whether the general designation option is available only when coupled with disclosure through an intermediary entity, or if Part 2 programs can share information directly with providers based on a general designation in the consent form.

When providing consent, a patient must specify how much and what type of information can be shared. The preamble to the 2017 rule states that the consent form may include an option to share all of a patient's SUD information, but it must also provide the patient with specific, so-called granular, options that allow the patient to select only certain information to share. SAMHSA suggests that one way to present these options is to use information fields that generally appear in patient records. This could include diagnostic information, medications and dosages, lab tests, allergies, substance use history summary, trauma history summary, clinical notes and discharge summary, employment information, living situation and social supports, and claims and encounter data.

Stakeholders have requested that SAMHSA provide sample consent forms that comply with Part 2's granular field requirements (Reid 2018, CCC 2016, Cerner Corporation 2016). SAMHSA has stated that it is developing subregulatory guidance that might include a sample consent form, but nothing has been issued to date (SAMHSA 2017).

## Effect on Medicaid and CHIP delivery systems

In 2014, Medicaid was the largest source of insurance payment for SUD treatment, financing 21 percent of all such treatment (MACPAC 2017). Because of Medicaid's sizeable role and the fact that enrollees with SUDs often have serious comorbidities, state Medicaid agencies and MCOs are pursuing strategies to proactively manage the complex health care needs of their beneficiaries (MACPAC 2016). These initiatives seek to break down the historical silos between behavioral health care—often delivered outside of medical settings—and physical health care. The goal of integration

is to improve care coordination and transitions, and ultimately patient outcomes (MACPAC 2017, 2016; McCarty et al. 2016). But if Part 2 restrictions contribute to missing or inconsistent information in patient medical records and claims data, the success of efforts to integrate behavioral and physical health care may be affected.

Lack of information also makes it difficult to predict financial risk (as is needed under capitated payment arrangements) and to track care for high-risk, high-cost patients. For example, in states where SUD services are carved out of Medicaid managed care, MCOs may be unaware that an enrollee is being treated for SUDs. While some state agencies have developed a consent process to facilitate the flow of information between SUD treatment providers and MCOs, plans are still prohibited from further sharing information with the patient's other providers without a separate consent (DHMH 2015). This can also affect value-based payment initiatives, which hold providers accountable for patient outcomes, because providers may not have complete information about their patients or be fully aware of their medical history. A roundtable participant described a Medicaid patient-centered medical home (PCMH) program, in which the PCMH providers use claims information to help manage the care of patients attributed to their practice. Unless the patient has signed a consent form, however, SUD-related claims are suppressed. For new patients, providers have also expressed frustration about the time needed to secure consent and access to the SUD-related claims.

The 2018 rule made changes to permit Medicaid and CHIP agencies and MCOs to redisclose information without additional patient consent to contractors and subcontractors for payment and health care operations activities—but not for treatment purposes. SAMHSA explicitly excluded care coordination and case management functions from its list of permissible activities because, as discussed in the preambles to the 2017 and 2018 rules, SAMHSA deems those functions to include a treatment component. Plans and state officials argue that the benefits of including care

coordination and case management as permitted activities outweigh the risks of disclosure. They further contend that such activities contribute to patient safety, an activity that SAMHSA lists as falling under health care operations. Classifying care coordination and case management as patient safety activities rather than as treatment would allow payers to redisclose this information to contractors and subcontractors (ACAP 2016, NAMD 2016).

## Barriers to information sharing

Even when patient consent to disclose SUD treatment information within the health care system has been obtained, there are other barriers to sharing treatment information.

First, many community-based SUD treatment providers have not adopted EHRs at the same pace as the rest of the health care system (SAMHSA 2017, Williams 2013). Historically, SUD providers did not use electronic records, in part because most SUD care was largely funded through grants, so providers did not bill for individual services. Despite increased insurance participation by these providers and the increasing number of patients receiving SUD treatment who are covered by Medicaid, CHIP, or private insurance, many of these providers continue to share information only by paper, phone, or fax. Slow adoption of EHRs is also due to lack of financial incentives. Most SUD treatment providers were not eligible for the incentives available under the meaningful use program created by the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009 (Title XIII of P.L. 111-5) (SAMHSA 2017). Those ineligible included psychologists, clinical social workers, community mental health centers, psychiatric hospitals, and residential treatment centers (Dougherty et al. 2013).

Second, even when providers are using EHRs, there are several challenges with the electronic transmission of Part 2-protected data, which must be segmented from other, HIPAA-protected, health information. There are currently no

federal requirements for EHRs to include the functionality to comply with Part 2 and there is disagreement as to whether and to what degree widespread Part 2-compliant interoperability is even technically feasible. For example, ONC and SAMHSA have developed the Data Segmentation for Privacy (DS4P) standard and the Consent2Share software application to manage patient consent preferences and share Part 2-protected information electronically through EHRs and HIEs. But the Health Information Technology Standards Committee advising ONC called into question the maturity of the DS4P standard, suggesting that additional testing and refinements are needed (HITSC 2015).

Additionally, designing and maintaining systems that comply with Part 2 requirements (including incorporating updates such as those made by the 2017 and 2018 Part 2 regulatory changes) can be costly (Netsmart 2017, SAMHSA 2017, CIHS 2014, Williams 2013). As a result, many EHRs and HIEs simply omit SUD treatment information from the rest of a patient's medical record and SUD treatment providers are often excluded from participation in HIEs (RTI 2014).

Some stakeholders, particularly patient advocates who are supportive of the current Part 2 rules, hold a different view of the capability of EHRs to handle Part 2 information. They argue that state laws already require heightened protections for sharing of other sensitive health data, such as for HIV/AIDS, mental health, reproductive health, and domestic violence, so existing EHR systems must be capable of segmentation for these purposes. Similarly, under federal HIPAA regulations, psychotherapy notes maintained in an EHR must also be segregated from the rest of a patient's record. These stakeholders contend that tools such as DS4P and Consent2Share allow for the necessary segmentation of such data (Reid 2018).

Finally, prescription drug monitoring programs (PDMPs), which are meant to help providers avoid potentially fatal drug interactions, help clinicians identify patients who may be at risk for

prescription drug misuse, and identify providers with inappropriate prescribing patterns, often lack information on pharmacotherapies used to treat SUDs (ASAM 2018, State Attorneys General 2016, PDMP COE 2014). Part 2 permits opioid treatment programs that dispense methadone or buprenorphine and Part 2 providers with DATA-2000 waivers to prescribe buprenorphine to report to PDMPs, if the patient gives consent. However, SAMHSA advises these providers to not share information with PDMPs because it is SAMHSA's view that it is not feasible for PDMPs to protect such information from redisclosures prohibited by Part 2 (SAMHSA 2011). Because PDMPs often originated as a criminal justice tool, there is particular concern that law enforcement may have access to protected information (Knopf 2016).

## Commission Recommendations

In this report, the Commission makes two recommendations to address the widespread confusion among health care providers and payers of care for Medicaid and CHIP enrollees with SUDs about the ability to exchange health information for treatment purposes. Adoption of the second recommendation is contingent on adoption of the first, because educational and technical assistance activities should focus on disseminating the contents of clarifying guidance.

As this report went to print, SAMHSA and ONC jointly issued two fact sheets with scenarios illustrating how Part 2 may apply to certain providers, patient information, and disclosures made using electronic health information exchange. The Commission has not had the opportunity to review this new guidance and evaluate the extent to which it addresses our recommendations. We appreciate SAMHSA and ONC's effort and look forward to analyzing the impact of this guidance as we continue our work in this area.

### Recommendation 2.1

The Secretary of Health and Human Services should direct relevant agencies to issue joint subregulatory guidance that addresses Medicaid and CHIP provider and plan needs for clarification of key 42 CFR Part 2 provisions.

#### Rationale

This recommendation calls for subregulatory guidance from HHS to further clarify several key aspects of the Part 2 regulations that Medicaid and CHIP stakeholders have identified as ambiguous and confusing. HHS should ensure that such guidance does not add any additional complexity that would further exacerbate confusion and provider reluctance to share information. At a minimum, guidance should provide clear and consistent definitions and explanations of the following:

- which providers are covered by Part 2, including whether providers prescribing buprenorphine or SUD specialists practicing in multispecialty settings are covered;
- the meaning of the phrase “holds itself out as providing, and provides, substance use disorder diagnosis, treatment, or referral for treatment”;
- which information must be protected, including that related to non-SUD medical care delivered to patients in SUD treatment settings, medical care for illnesses associated with SUD, and medications used to treat SUD;
- which entities or individuals within a Part 2 program can share SUD information with each other without patient consent and whether SUD information must be segregated in EHRs accessible to other providers within the Part 2 program; and
- when a patient can use a general designation to identify recipients to whom information is to be disclosed, and when a treating provider

relationship exists (e.g., whether a care coordinator falls into this category).

Guidance should also include sample consent forms that specify the granularity required by Part 2 and how to opt in or out of data sharing and redisclosures.

Comments submitted in response to Part 2 rulemaking and discussions during MACPAC's expert roundtable suggest that providers and payers may be misinterpreting the regulations because of their ambiguity and complexity. This may lead to unnecessary self-imposed restrictions on information sharing, affecting delivery of whole-person care to Medicaid and CHIP enrollees with SUDs.

Clarifying Part 2 may help promote more information sharing, as currently permitted, without requiring further regulatory changes. SAMHSA has already noted that additional subregulatory guidance might be helpful in some of these areas, and Medicaid directors, MCOs, providers, and others have also requested additional clarification. Such guidance should also lead to more consistent and appropriate application of Part 2.

In developing new guidance, the Secretary should solicit input from affected stakeholders and provide opportunities for the review of draft content. The Secretary should also involve all relevant agencies and staff with a role in implementing Part 2 as well as those whose work with HIPAA, Medicaid, and CHIP intersects with Part 2. This would include, but not be limited to, SAMHSA, the Centers for Medicare & Medicaid Services (CMS), ONC, and the HHS Office for Civil Rights (OCR).

Because providers and plans are generally also subject to HIPAA privacy and disclosure requirements, guidance should discuss the interaction between HIPAA and Part 2 requirements and provide assistance in determining which rules apply in a given scenario. SAMHSA last provided such information in 2004, but has not issued an update reflecting the 2017 and 2018 changes to Part 2 (SAMHSA 2004). For compliance purposes,

HHS should give affected stakeholders sufficient time to make any necessary adjustments to their practice following issuance of subregulatory guidance.

The Commission recognizes that some stakeholders are seeking more fundamental changes that would permit sharing of most SUD-related information inside the health care system without requiring patient consent. At this time, the Commission is not prepared to make such recommendations and intends to further study and analyze issues related to the alignment of Part 2 and HIPAA requirements.

### Implications

**Federal spending.** This recommendation would not have a direct effect on federal Medicaid and CHIP spending.

**States.** Any improved information sharing as the result of clearer guidance has the potential to improve the coordination of SUD treatment and physical health care, and to support related Medicaid- and CHIP-led delivery system and payment reform initiatives. Additional guidance can help states better understand the regulations and improve their ability to exchange enrollee information with plans and providers.

**Enrollees.** For enrollees with SUDs, additional guidance that helps patients and providers better understand requirements for patient consent may improve care coordination and allay patient concerns that the sharing of their SUD treatment information may cause harm.

**Plans and providers.** This recommendation would have a direct effect on Medicaid and CHIP MCOs and providers. More definitive guidance on Part 2 would reduce confusion about which providers are subject to Part 2. Similar to the potential effects on states, better plan and provider understanding may foster more consistent and increased data sharing. This, in turn, could improve patient care and consideration of SUDs in delivery system and payment reforms promoting whole-person care.



## Recommendation 2.2

The Secretary should direct a coordinated effort by relevant agencies to provide education and technical assistance on 42 CFR Part 2. Such efforts should target state Medicaid and CHIP programs, health plans, primary care and specialty providers, patients and their families, and other relevant stakeholders.

### Rationale

Additional subregulatory guidance is necessary but not sufficient to address requests for clarification about confusing and ambiguous Part 2 provisions. In federal rulemaking, SAMHSA has recognized that education and training of staff and patients on Part 2 regulations is needed, but has yet to provide these opportunities. Given Medicaid's significant role in financing SUD treatment, it is the Commission's view that education and technical assistance is needed to ensure that: (1) providers and plans are fully aware of how and when information can be shared; and (2) beneficiaries understand under what circumstances information is protected and when and how they can provide consent to share that protected information with others. Education for patients and their families should also explain the importance of coordinated care and why the disclosure of SUD treatment information to other providers may improve care coordination and health outcomes. Such efforts could also ensure that providers, patients, Medicaid and CHIP managed care plans, state agencies, and other stakeholders understand the more recent changes to Part 2. As with the first recommendation, the Secretary should work with relevant agencies, including but not limited to SAMHSA, CMS, ONC, and OCR.

To maximize the utility of education and technical assistance efforts and further increase their reach, HHS should partner with relevant national and state stakeholder organizations to develop and disseminate information tailored to each constituency. Jointly developed efforts could create multiple channels through which to communicate information to a broader audience. For example, CMS uses informational bulletins to communicate

changes in policy; SAMHSA's Treatment Improvement Protocols are widely recognized among community-based SUD providers; and OCR has experience leading HIPAA-related education and has developed frequently asked questions documents, continuing medical education modules, and training materials for state attorneys general. Patient advocacy organizations and health care provider and health lawyer associations regularly communicate with their members through various avenues.

### Implications

**Federal spending.** This recommendation would not have a direct effect on federal Medicaid and CHIP spending.

**States.** Providing education and technical assistance to state Medicaid and CHIP officials and other related state agencies can help them better understand what patient information, such as claims data or quality metrics, can be shared with plans and providers. It may also help improve care coordination, leading to improved health outcomes for Medicaid and CHIP beneficiaries.

**Enrollees.** For enrollees with SUDs, additional education could lead to improved understanding of privacy rights. Education would also inform enrollees of the benefits to them of allowing their protected SUD health information to be shared with their other treating providers.

**Plans and providers.** This recommendation will benefit Medicaid and CHIP managed care plans and providers to the extent that it reduces confusion about what information is protected by Part 2 and the Part 2 consent requirements. With additional education and technical assistance, plans and providers may be able to develop additional Part 2-compliant processes that increase the sharing of SUD information.

## Looking Ahead

Adoption of the Commission's recommendations would be an important step to help alleviate confusion and improve existing opportunities for information sharing and care coordination. Going forward, the Commission is interested in studying additional ways to address concerns about Part 2's effects on care delivery for Medicaid and CHIP enrollees.

First, the Commission remains concerned about barriers to information sharing that negatively affect patients and intends to explore further how Part 2 could be aligned with HIPAA to allow greater sharing of information without patient consent for treatment, payment, and health care operations. The Commission recognizes that there is substantial disagreement about such changes and will therefore want to consider the potential advantages and drawbacks. This will include understanding in greater detail:

- how HIPAA protections differ from Part 2, such as provisions related to disclosures to the criminal justice system and other entities that may discriminate against individuals with SUDs;
- how HIPAA provisions support coordinated care and care integration practices;
- whether less patient control over information disclosures could affect individuals' willingness to seek SUD treatment; and
- the extent to which alignment can be achieved through regulatory changes versus requiring a statutory change.

Second, the Commission notes that the existing Part 2 regulatory framework does not address the limited functionality of most EHR systems to segment data or the low rate of EHR adoption among SUD providers. The current framework also does not adequately address the limitations on the sharing of information by most SUD treatment providers with PDMPs. The Commission

is interested in better understanding these challenges as well as proposals to address them, such as providing financial incentives for EHR adoption to behavioral health providers in Medicaid and establishing national EHR interoperability requirements.

## Endnotes

<sup>1</sup> The organization and financing of Medicaid mental health and SUD treatment services varies across states. In some states, managed care plans provide both physical and behavioral health services. In other states, some or all behavioral health services are carved out, either under a capitated arrangement to a plan with specialized expertise or under fee for service. Some states may also limit carve in or carve out arrangements to certain defined populations (MACPAC 2016). Because of the variability in Medicaid benefits and certain federal restrictions on what Medicaid can pay for, other state programs may fund some SUD treatment and recovery support services for Medicaid beneficiaries—most often through a state's substance abuse agency. These services may include residential treatment, case management, peer support, housing supports, and other recovery support services (Pew and MacArthur 2015, Woodward 2015, NASADAD 2010).

<sup>2</sup> A discussion of 42 CFR Part 2's provisions that are specific to minors and parental involvement in consent to treatment and disclosure of Part 2-protected information is beyond the scope of this chapter.

<sup>3</sup> The goal of the roundtable was not to develop recommendations, but to gain insight from a broad array of stakeholders on how to protect SUD treatment information while supporting appropriate information sharing among providers and payers. Specifically, we sought to learn more about the following: (1) why Part 2 protections are needed; (2) how Part 2 affects care delivery, information exchange, care coordination, and new delivery and payment models in Medicaid; and (3) what operational, regulatory, or statutory changes could support the integration of SUD treatment with other medical care while protecting Medicaid enrollees with SUDs from discrimination.

<sup>4</sup> For example, the Americans with Disabilities Act (P.L.

101-336) and the Fair Housing Act (Title VIII of P.L. 90-284) explicitly exclude individuals engaged in current illegal drug use; individuals entering treatment for substance use disorder would not be protected from potentially losing their jobs were this information disclosed to their employer.

<sup>5</sup> The statute explicitly excludes application to records exchanged within or between the U.S. Department of Veterans Affairs (VA) and the uniformed services. Disclosure of VA-related information is governed by 38 USC 7332.

<sup>6</sup> Good cause includes the need to avert a substantial risk of death or serious bodily harm. The statute says that in assessing good cause, the court shall weigh the public interest and the need for disclosure against the injury to the patient, to the physician-patient relationship, and to the treatment services (42 USC 290dd-2(b)(2)(C)).

<sup>7</sup> To redisclose Part 2-protected information to its contractors, subcontractors, or legal representatives, a contract or comparable legal instrument must be in place, which includes language stating that the recipient is fully bound by Part 2's provisions upon receipt of the protected information (42 CFR 2.33). The preamble to the 2018 rule includes a list of illustrative examples of permissible payment and health care operations activities. Examples include the following:

- billing, claims management, collections activities, obtaining payment under a contract for reinsurance, claims filing and related health care data processing;
- clinical professional support services (e.g., quality assessment and improvement initiatives; utilization review and management services);
- patient safety activities;
- accreditation, certification, licensing, or credentialing activities;
- underwriting, enrollment, premium rating, and other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits, and ceding, securing, or placing a contract for reinsurance of risk relating to claims for health care;
- activities related to addressing fraud, waste and abuse;
- conducting or arranging for medical review, legal services, and auditing functions;

- determinations of eligibility or coverage (e.g. coordination of benefit services or the determination of cost sharing amounts), and adjudication or subrogation of health benefit claims;
- risk adjusting amounts due based on enrollee health status and demographic characteristics; and
- review of health care services with respect to medical necessity, coverage under a health plan, appropriateness of care, or justification of charges (SAMHSA 2018b).

<sup>8</sup> In the preamble to the 2017 final rule, SAMHSA suggests that consent form field options can be taken from a generally accepted architecture, such as the Consolidated-Clinical Document Architecture (C-CDA), or document, such as the Summary of Care Record as defined by CMS for the EHR Incentive Programs.

<sup>9</sup> If the patient makes a “general designation,” the patient can request a “list of disclosures,” that is, a list of parties who received the disclosed information in the previous two years. This request must be in writing. The entity facilitating the information sharing has 30 days following receipt of the patient’s written request to provide the list, which must also include a brief description of the patient identifying information that was disclosed to each party (42 CFR 2.13).

<sup>10</sup> In addition to being subject to HIPAA, certain other sensitive health data—for example, patient data related to HIV/AIDS, mental health, reproductive health, and domestic violence—may also be subject to state laws mandating heightened disclosure protections.

<sup>11</sup> The Drug Addiction Treatment Act of 2000 (DATA 2000, P.L. 106-310) requires physicians to take a special eight-hour training course to receive a DATA-2000 waiver which authorizes them to prescribe buprenorphine as part of MAT or for withdrawal management. Depending on the waiver, a physician is limited to prescribing the drug to up to 30, 100, or 275 patients. As part of the Comprehensive Addiction and Recovery Act of 2016 (CARA, P.L. 114-198), advanced practice nurses and physician assistants can also qualify for a waiver for up to 30 patients from 2016 through 2021, but only if their state license includes prescribing authority for Schedule III, IV, or V medications for the treatment of pain (SAMHSA 2018c).

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## Commission Vote on Recommendations

In its authorizing language in the Social Security Act (42 USC 1396), Congress requires MACPAC to review Medicaid and CHIP program policies and make recommendations related to those policies to Congress, the Secretary of the U.S. Department of Health and Human Services, and the states in its reports to Congress, which are due by March 15 and June 15 of each year. The Commission is also directed to examine issues affecting Medicaid and CHIP, including the implications of changes in health care delivery in the United States and in the market for health care services on such programs. Each Commissioner must vote on each recommendation, and the votes for each recommendation must be published in the reports. The recommendations included in this report, and the corresponding voting record below, fulfill this mandate.

Per the Commission’s policies regarding conflicts of interest, the Commission’s conflict of interest committee convened prior to the vote to review and discuss whether any conflicts existed relevant to the recommendations to clarify regulations governing the exchange of health information that would identify Medicaid and CHIP enrollees as having or having had a substance use disorder. It determined that, under the particularly, directly, predictably, and significantly standard that governs its deliberations, no Commissioner has an interest that presents a potential or actual conflict of interest.

The Commission voted on Recommendation 2.1 and Recommendation 2.2 on March 1, 2018.

### Clarification of Key Provisions Governing Health Information Privacy under 42 CFR Part 2

<p>2.1 The Secretary of Health and Human Services should direct relevant agencies to issue joint subregulatory guidance that addresses Medicaid and CHIP provider and plan needs for clarification of key 42 CFR Part 2 provisions.</p> <p>Yes: Burwell, Carter, Cerise, Cruz, Davis, Douglas, George, Gold, Gorton, Lampkin, Milligan, Retchin, Scanlon, Szilagyi, Thompson</p> <p>Not Present: Gordon, Weil</p>	<table border="1" style="background-color: #f2f2f2; border-collapse: collapse;"> <tr> <td style="padding: 5px;">15</td> <td style="padding: 5px;">Yes</td> </tr> <tr> <td style="padding: 5px;">2</td> <td style="padding: 5px;">Not Present</td> </tr> </table>	15	Yes	2	Not Present
15	Yes				
2	Not Present				
<p>2.2 The Secretary should direct a coordinated effort by relevant agencies to provide education and technical assistance on 42 CFR Part 2. Such efforts should target state Medicaid and CHIP programs, health plans, primary care and specialty providers, patients and their families, and other relevant stakeholders.</p> <p>Yes: Burwell, Carter, Cerise, Cruz, Davis, Douglas, George, Gold, Gorton, Lampkin, Milligan, Retchin, Scanlon, Szilagyi, Thompson</p> <p>Not Present: Gordon, Weil</p>	<table border="1" style="background-color: #f2f2f2; border-collapse: collapse;"> <tr> <td style="padding: 5px;">15</td> <td style="padding: 5px;">Yes</td> </tr> <tr> <td style="padding: 5px;">2</td> <td style="padding: 5px;">Not Present</td> </tr> </table>	15	Yes	2	Not Present
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Chapter 3:

# Managed Long-Term Services and Supports: Status of State Adoption and Areas of Program Evolution

# Managed Long-Term Services and Supports: Status of State Adoption and Areas of Program Evolution

## Key Points

- People who use long-term services and supports (LTSS) make up a diverse group that includes all ages, with needs stemming from a wide range of physical and cognitive limitations.
- Medicaid beneficiaries who use LTSS are among the program's most vulnerable and account for a disproportionate share of Medicaid spending. In fiscal year 2013, Medicaid spending for beneficiaries who used LTSS through fee-for-service arrangements was approximately 42 percent of total Medicaid spending, despite these beneficiaries comprising only about 6 percent of Medicaid beneficiaries that year.
- In managed long-term services and supports (MLTSS) programs, states contract with managed care plans to deliver LTSS. The number of states implementing MLTSS programs grew from 8 states in 2004 to 24 states as of January 2018.
- States may operate multiple MLTSS programs, often targeting them to different populations. In total, the 24 states with MLTSS operate 41 programs.
- States can use several Medicaid authorities to implement MLTSS: either Section 1115 waivers or combining Section 1915(c) home and community-based services (HCBS) waiver authority with Section 1915(a), Section 1915(b), or Section 1932 managed care authorities. MLTSS plans must adhere to the same regulations as other Medicaid managed care plans and are subject to additional MLTSS-specific regulations and guidance.
- Whether delivering LTSS through fee for service or managed care, Medicaid programs face common challenges, such as limited HCBS workforce capacity. But even for states and plans experienced in using managed care to deliver acute care, using managed care to deliver LTSS presents a new set of challenges. For example, because Medicaid is the nation's primary payer for LTSS, the implementation of MLTSS presents a major change to the provider community, who may not have experience contracting with managed care plans.
- As states gain MLTSS experience, attention is turning to program outcomes. Although there is modest evidence of some successes, there are many unanswered questions. Limited baseline data and insufficient targeted quality measures have made evaluation difficult. Efforts to implement new quality measures and collect better encounter data may improve monitoring and oversight of MLTSS in the future.
- As MLTSS programs have evolved, their scope has expanded, with more states enrolling individuals with intellectual or developmental disabilities or aligning MLTSS with Medicare managed care for individuals who are dually eligible for Medicare and Medicaid.

# CHAPTER 3: Managed Long-Term Services and Supports: Status of State Adoption and Areas of Program Evolution

State Medicaid programs increasingly use managed care as one of several strategies to improve care coordination and manage costs for populations with complex health care needs and disproportionately high Medicaid expenditures. As of January 2018, 24 states operate managed long-term services and supports (MLTSS) programs, in which state Medicaid agencies contract with managed care plans to deliver long-term services and supports (LTSS), up sharply from just 8 states in 2004 (Lewis et al. 2018). Although much of this growth has been fairly recent, a few states have operated MLTSS programs for many years, and in some cases, several decades. In fiscal year (FY) 2015, \$29 billion, or 18 percent of Medicaid LTSS spending, was for MLTSS programs (Eiken et al. 2017).<sup>1</sup> Even though states typically adopt managed care for LTSS after they have gained experience with managed care for acute care benefits, the complex needs of people who receive LTSS and the wide range of services they use makes implementation of MLTSS more complex than managed care for acute care.

Given the growing role of managed care in serving people who receive LTSS, the Commission has undertaken a variety of activities in recent years to better understand this change and its effect on beneficiary outcomes and Medicaid LTSS spending. These activities have included site visits to states with MLTSS programs, research projects on network adequacy standards for home and community-based services (HCBS) providers and on how programs have been tailored to meet the needs of people with intellectual or developmental disabilities

(ID/DD), and presentations at MACPAC public meetings from a range of MLTSS stakeholders.

The purpose of this chapter is to provide an overview of MLTSS, review results of MACPAC's initial work in this area, and identify gaps in our knowledge about what drives success in MLTSS programs. While the discussion includes highlights of reports describing state MLTSS programs and program outcomes, there are few rigorous studies evaluating whether MLTSS programs are meeting their intended goals. States, managed care plans, providers, and beneficiary advocates all have identified potential benefits of MLTSS and the challenges of operating these programs, but lack of baseline data prior to the changeover to MLTSS and standardized LTSS quality measures have limited our ability to compare states' experiences and outcomes. Adoption of new LTSS quality measures and recent efforts to improve MLTSS encounter data offer the potential to improve evaluation and oversight activities in the future.

This chapter begins with background information on Medicaid-covered LTSS and Medicaid beneficiaries who receive LTSS. It then provides a status report on state adoption of MLTSS programs, a discussion of the range of goals that states are trying to achieve through MLTSS programs, and an overview of federal regulations specific to these programs. Next, it describes how MLTSS programs are implemented and operated, what is currently known about program outcomes, and emerging trends. As new states implement MLTSS and the programs of early adopters mature, more states are enrolling people with ID/DD into MLTSS and integrating Medicaid MLTSS with Medicare benefits for beneficiaries who are dually eligible for Medicare and Medicaid. States are also continuing to refine other aspects of their MLTSS programs, such as network adequacy requirements, payment approaches, and quality measures. The chapter concludes by raising issues that the Commission will explore and monitor as its deliberations on MLTSS continue.

## Medicaid-Covered Long-Term Services and Supports

Medicaid is the nation's largest payer for LTSS (O'Shaughnessey 2014). In FY 2015, Medicaid spent \$158 billion on LTSS, accounting for almost one-third of Medicaid benefit spending (Eiken et al. 2017). Medicaid LTSS spending growth has been modest in recent years, averaging 0.8 percent from FY 2011 to FY 2012, and 3.8 percent each year from FY 2013 to FY 2015 (Eiken et al. 2017).

### LTSS covered by Medicaid and issues spanning delivery systems

State Medicaid programs must cover services provided in nursing facilities as well as home health services (e.g., nursing services). States may also elect to cover other LTSS including HCBS and services provided in intermediate care facilities for individuals with ID/DD, and all states do (CMS 2018a, Eiken et al. 2017). States can include HCBS in their Medicaid benefit package using both state plan and waiver authorities, and most states use more than one strategy.<sup>2</sup>

HCBS are delivered on a frequent or even daily basis and meet individuals' ongoing needs for assistance with activities of daily living (ADLs), such as bathing and dressing, and with instrumental activities of daily living (IADLs), such as managing medications and preparing meals; these services can also provide supervision to assist with behavioral or cognitive limitations. HCBS comprise a wide range of services, including personal care services provided in the home, services provided at adult day centers and in residential care settings, and supported employment services. HCBS also includes supports and other resources that help individuals live in the community, such as home modifications and meal delivery. In addition, they include services that beneficiaries may self-direct, for instance, by selecting their own direct care providers or exercising control over their own budget for care.

In 2015, Medicaid programs spent a majority (55 percent) of LTSS spending on HCBS, the third consecutive year that Medicaid programs spent more on HCBS than institutional care (Eiken et al. 2017).<sup>3</sup> This reflects specific programmatic efforts by the federal government and states to rebalance spending—that is, to shift the balance of Medicaid spending from institutional to home and community-based settings. These efforts include the Balancing Incentive Program, which targeted states spending less than 50 percent of LTSS on HCBS, and the Money Follows the Person demonstration program that gave states flexibility and funding to help certain beneficiaries transition from institutions back to the community (MAG and HSRI 2013, HHS 2017a). Rebalancing also reflects efforts to comply with legal decisions. In its 1999 *Olmstead v. L.C.* ruling, the Supreme Court held that Title II of the Americans with Disabilities Act (ADA, P.L. 101-336) and its implementing regulations obligate states to administer their services, programs, and activities “in the most integrated setting appropriate to the needs of qualified individuals with disabilities” (28 CFR 35.130).<sup>4</sup> Under *Olmstead*, states must operate public programs (including Medicaid) in a non-discriminatory fashion and furnish services in the most integrated setting appropriate to an individual's needs, by delivering services to persons with disabilities in community settings rather than in institutions when possible.

As the Commission considers Medicaid's role in serving individuals with LTSS needs, it recognizes several principles important for serving this population whether the delivery system is fee for service (FFS) or managed care. These include the importance of providing opportunities for beneficiaries to exercise choice and control over their authorized services through self-directed options, person-centered planning, and the acknowledgement of the dignity of risk (i.e., the right of individuals with disabilities to take risks when exercising choice and control over their lives). These concepts, discussed in more detail later in this chapter, are necessary components for LTSS delivery systems. The design of both FFS and managed care systems also must take into

account the contributions of and support the role of beneficiaries' informal caregivers through activities such as respite care and training.

Some challenges to the delivery of LTSS are present under both FFS and managed care. For example, as the population ages, a key challenge will be state capacity to meet demand for HCBS. The number of individuals on HCBS waiting lists nationally has been increasing since at least 2006—with 656,195 on waiting lists in 2016—even as some states have eliminated waiting lists (Watts and Musumeci 2018).<sup>5</sup> In addition, high turnover and shortages among the personal care workforce present a challenge to all states, particularly as demand for HCBS grows with an aging population (Stone and Harahan 2010). Lack of affordable, accessible housing is also a limitation for Medicaid programs aiming to serve more beneficiaries in the community (HHS 2017a).

## Medicaid beneficiaries who receive LTSS

People who receive LTSS are among Medicaid's most vulnerable beneficiaries, given the complexity of their conditions and care needs, and are also among the program's most expensive. In FY 2013, Medicaid spending for beneficiaries who use LTSS under FFS arrangements was \$171.7 billion, or approximately 42 percent of total Medicaid spending, a disproportionate amount given that this group comprised only about 6 percent of Medicaid beneficiaries that year (MACPAC 2017). Medicaid beneficiaries who use LTSS include a diverse group of individuals, spanning a range of ages and having different types of physical and cognitive disabilities, who often receive such services and supports for many years, or even decades. Beneficiaries may use institutional care or HCBS, and the types and intensity of services they require vary—both across and within subgroups.

- About half of Medicaid beneficiaries receiving LTSS are adults age 65 and older (MACPAC 2014). Given beneficiary preferences to age in place at home or in a home-like setting,

about half of these beneficiaries receive HCBS (Eiken 2017). For example, a beneficiary may receive a few hours of personal care services each day for assistance with bathing, dressing, and preparing meals. These hours usually supplement support from informal caregivers such as family members and neighbors. Although older adults may need increasing levels of support as they age, sometimes necessitating a move into a nursing facility, on average older adults use LTSS for a relatively short period of time (an estimated average of 2.5 years for women and 1.5 years for men) (Favreault and Dey 2016).

- Individuals with physical disabilities can include both young and older adults with functional impairment, such as individuals with spinal cord injuries that have left them with some form of paralysis, or individuals with traumatic brain injuries. Depending on the severity of their functional limitations, they may require different levels of services, and depending on the onset of disability, they may require services for many years. These individuals may also require assistive technologies that allow them to live in the community, such as wheelchairs or equipment to assist caregivers in moving them from a bed to a wheelchair.
- Individuals with ID/DD include people with conditions such as cerebral palsy and autism that originate at a young age.<sup>6</sup> Individuals with ID/DD may require LTSS for many years, and as their needs vary substantially over their lifespan, their services vary accordingly.<sup>7</sup> For example:
  - Infants born with ID/DD or diagnosed in early childhood may receive early intervention program services and Medicaid-funded special education services. Their families often also rely upon respite services, private duty nursing, home modifications, and durable medical equipment.

- Children with ID/DD often receive school-based services.
- Young adults with ID/DD may begin to receive non-residential services in adolescence, with these services continuing throughout adulthood, including prevocational services, supported employment (e.g., use of job coaches or other supports in the community or facilities), or other day services in group and community settings.
- Young adult, middle-aged, and older people with ID/DD may receive residential services. In 2014, the majority (68 percent) of people with ID/DD receiving services lived with their families or in a home of their own, but others may have had group living arrangements (Larson et al. 2017). In particular, as individuals with ID/DD age, they may outlive family caregivers (or family caregivers may be less able to support individuals in the home as they age themselves), thus requiring individual or group living arrangements.
- Some individuals with ID/DD, including those who have concurrent mental health disorders, also need support with challenging behaviors. Medicaid LTSS includes behavior interventions, including crisis respite, crisis response teams, and positive behavior interventions and supports.
- Individuals with severe mental illness, such as bipolar disorder and schizophrenia, also receive LTSS. Although these individuals make up a relatively small percentage of enrollment in state HCBS waiver programs, they have high per capita total Medicaid expenditures (GAO 2014, MACPAC 2014).
- In addition to the populations specified above, states also provide LTSS to other individuals who have medically complex conditions. This includes individuals who are ventilator

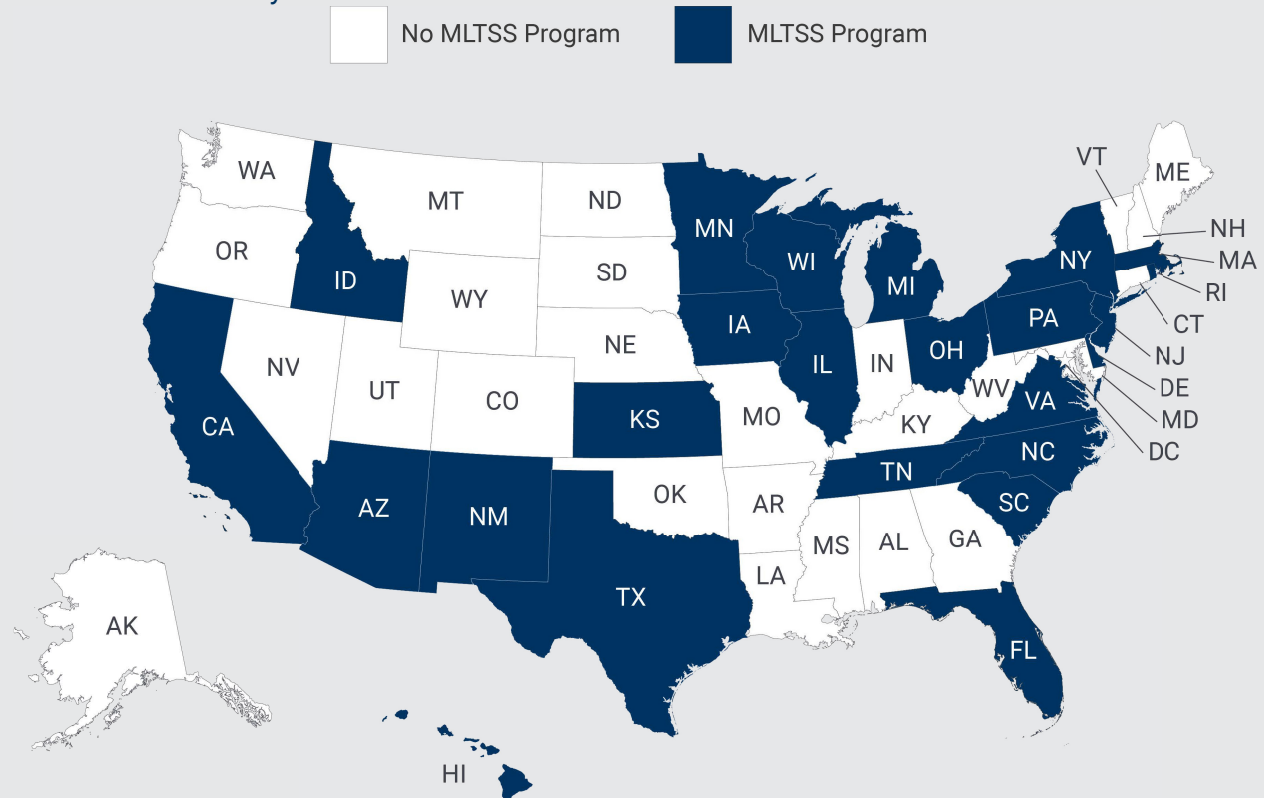
dependent and children who are medically fragile, who may require assistive equipment and aids.

## State Adoption of MLTSS and Program Design

State and federal policy makers have sought ways to manage LTSS spending growth while maintaining and improving beneficiary quality of care and quality of life. MLTSS is one tool being employed in pursuit of these goals. In MLTSS programs, states contract with plans to provide LTSS benefits, generally alongside other Medicaid benefits such as acute care services.

MLTSS programs differ in some ways from managed care programs for acute care for which there were existing private-sector models and well-established approaches for determining medical necessity. When providing managed care services to beneficiaries receiving LTSS, states must consider beneficiaries' complex and frequent service needs. Available Medicaid LTSS benefits also include non-medical services that go beyond those covered by traditional health insurance, including, for example, personal care assistance for those with ADL and IADL limitations, supported employment services for individuals with disabilities, and other services aimed at community integration. Finally, many MLTSS interventions target needs related to the social determinants of health. For example, some plans that provide MLTSS help beneficiaries locate affordable and accessible housing because it is in a plan's interest to avoid more costly institutionalization and to support more beneficiaries in the community. Although social determinants of health have been receiving greater attention across the health system, they have been recognized as an important aspect of MLTSS since the early years of these programs.

**FIGURE 3-1. State Adoption of Managed Long-Term Services and Supports Programs, January 2018**



**Notes:** MLTSS is managed long-term services and supports.

**Source:** MACPAC, 2018, analysis of Lewis et al. 2018.

### States with MLTSS

As of January 2018, 24 states operate MLTSS programs (Figure 3-1 and Appendix 3A, Table 3A-1).<sup>8</sup>

In 2017, 1.8 million beneficiaries were reported enrolled in MLTSS programs (Lewis et al. 2018).<sup>9</sup>

Arizona has operated MLTSS since 1989. Other early adopters include Wisconsin (1996) and Texas (1998) (Lewis et al. 2018). More recently, Virginia launched a statewide MLTSS program for older adults and individuals with physical disabilities on August 1, 2017, although the state had previously operated a regional MLTSS program for dually eligible beneficiaries under the Financial Alignment Initiative (FAI).<sup>10</sup> Pennsylvania began a regionally phased

implementation of a statewide MLTSS program on January 1, 2018 (PA DHS 2018a, VA DMAS 2018).

States that offer MLTSS often do so through more than one program. As of 2018, 24 states operated 41 MLTSS programs (Lewis et al. 2018). For example, the state of Tennessee operates the CHOICES program for older adults, adults with physical disabilities, and institutionalized children with disabilities. The state also operates the Employment and Community First CHOICES program for certain individuals with ID/DD.<sup>11</sup> States may also operate demonstration programs for dually eligible beneficiaries through the FAI while continuing other MLTSS programs for beneficiaries enrolled only in Medicaid or those who did not choose to enroll in an FAI demonstration program.

This is the case in New York, which has mandatory MLTSS for older adults and individuals with physical disabilities, but also operates an FAI demonstration program in which dually eligible beneficiaries may voluntarily enroll (Lewis et al. 2018).

MLTSS programs vary on a number of dimensions and each program is unique (Table 3-1). For

example, some states require mandatory enrollment of individuals who are eligible for MLTSS and others allow beneficiaries the option to remain in the FFS system. States also vary in terms of which services are included in the MLTSS benefit package (Lewis et al. 2018).

**TABLE 3-1. Selected Managed Long-Term Services and Supports Program Design Characteristics** T 3-1

MLTSS program characteristics	Description
Managed care authorities	State options include: <ul style="list-style-type: none"> <li>• Section 1115 waiver authority</li> <li>• A combination of Section 1915(a) and Section 1915(c) waiver authorities</li> <li>• A combination of Section 1915(b) and Section 1915(c) waiver authorities</li> <li>• A combination of Section 1932(a) state plan amendment and Section 1915(c) waiver authorities</li> </ul>
Contract types	<ul style="list-style-type: none"> <li>• Comprehensive managed care program that includes LTSS and non-LTSS benefits (some states limit enrollment to populations eligible for LTSS, others include all populations)</li> <li>• Plan that provides only LTSS benefits</li> <li>• Single comprehensive plan that covers Medicare and Medicaid benefits for individuals who are dually eligible for Medicare and Medicaid, such as those offered through the Financial Alignment Initiative</li> </ul>
Populations covered	<ul style="list-style-type: none"> <li>• Almost all state MLTSS programs cover older adults and individuals with physical disabilities</li> <li>• Most states exclude individuals with intellectual or developmental disabilities</li> <li>• Some states exclude children</li> <li>• Some states cover individuals with traumatic brain injuries</li> </ul>
Mandatory or voluntary enrollment	<ul style="list-style-type: none"> <li>• Many states mandate that beneficiaries in eligible populations enroll</li> <li>• Some states give beneficiaries the option of enrolling in an MLTSS plan or continuing to receive LTSS on an FFS basis</li> </ul>
Geographic reach	<ul style="list-style-type: none"> <li>• Statewide or only offered in certain regions</li> </ul>
Inclusion of institutional coverage	<ul style="list-style-type: none"> <li>• Most state MLTSS programs cover both HCBS and institutional care</li> <li>• A few states focus their MLTSS programs on beneficiaries currently receiving HCBS and they have delayed including current nursing facility residents or they limit their plans' risk for institutionalized beneficiaries</li> </ul>



**TABLE 3-1.** (continued)

MLTSS program characteristics	Description
Number of plans participating	<ul style="list-style-type: none"> <li>• State decisions on number of plans affect beneficiary choice and administrative complexity</li> </ul>
Types of plans participating	<ul style="list-style-type: none"> <li>• States can contract with for-profit, non-profit, or public entities</li> </ul>
Payment policies	<ul style="list-style-type: none"> <li>• States can make different decisions regarding payment incentives, for example, to promote HCBS</li> </ul>
Integration with Medicare benefits	<ul style="list-style-type: none"> <li>• States can align Medicaid MLTSS with Medicare Advantage dual-eligible special needs plans (D-SNPs) to integrate care for beneficiaries who are dually eligible for Medicare and Medicaid</li> </ul>

**Notes:** MLTSS is managed long-term services and supports. LTSS is long-term services and supports. FFS is fee for service. HCBS is home- and community-based services.

**Source:** MACPAC, 2018, analysis of Lewis et al. 2018, Dobson et al. 2017, Libersky et al. 2016, and Saucier et al. 2012.

### Reasons states pursue MLTSS

States implement MLTSS for a variety of reasons. In a recent survey of 12 states with MLTSS, states reported that their goals included:

- rebalancing LTSS spending—increasing the proportion of Medicaid LTSS spending used for HCBS while decreasing the proportion of spending for institutional services (12 states);
- improving beneficiary care experience by increasing care coordination to improve health and quality of life (12 states);
- reducing or eliminating HCBS waiver waiting lists to address access gaps and to provide care in the setting that the beneficiary chooses (6 states);<sup>12</sup> and
- providing budget predictability and potentially containing costs via rebalancing, efficiencies, and improved quality (7 states) (Dobson et al. 2017).

Another recent review of state documents, including waiver applications, fact sheets, contracts, and state websites, identified similar goals. The most frequently cited MLTSS goals were related to improved participant outcomes (67 percent of

MLTSS programs reviewed), followed by increased access to HCBS and improved care coordination (both 46 percent), increased efficiency (41 percent), and improved consumer choice (15 percent) (Lewis et al. 2018).

However, some states are reluctant to pursue managed care for LTSS. For example, Indiana state law prohibits Indiana’s Medicaid program from implementing MLTSS until after December 31, 2019 (Ind.Code § 12-10-11.5-8 (2017)). Such legislation may reflect resistance to MLTSS among LTSS providers and beneficiary groups. For example, a bill to implement MLTSS in Louisiana recently failed after encountering strong opposition from the state’s nursing facility industry (Allen 2017). States with small populations may also be less likely to pursue MLTSS due to low enrollment numbers that would not support adequate risk sharing, particularly for small subpopulations with high average costs per person, such as individuals with ID/DD. Some states may also be satisfied with the performance of their FFS LTSS delivery system and achieve their programmatic goals through other activities. In Oregon, 82 percent of LTSS spending in FY 2015 was for HCBS, demonstrating that the state’s FFS system is largely rebalanced (Eiken et al. 2017).

## Federal Requirements for MLTSS

Federal requirements for LTSS include those for operating managed care or providing HCBS under various Medicaid authorities as well as additional guidance and regulations developed specifically for MLTSS programs.

### Medicaid authorities used to implement MLTSS

MLTSS programs can operate under several Medicaid authorities. States may pursue different Medicaid authorities based on the different types of flexibility they provide and on other changes a state wishes to make to its Medicaid program. States must get approval from the Centers for Medicare & Medicaid Services (CMS) to deliver services through a managed care program, to provide HCBS, or both.

- Section 1115 waiver authority is the most common approach used for MLTSS (Appendix 3A, Table 3A-1). States have used this authority to waive comparability and statewideness requirements related to eligibility, benefits, service delivery, and payment methods. States often use this authority when an MLTSS program is rolled into a broader managed care system that may have many other demonstration components. Section 1115 waivers allow states to receive simultaneous approval for the delivery of services through managed care and to provide HCBS. Currently, most Section 1115 waivers must be renewed every five years.<sup>13</sup>
- States may also implement MLTSS by combining a managed care authority and an HCBS authority. For example, states can combine Section 1915(b) waiver authority, which allows states to achieve certain managed care goals and restrict beneficiary choice of providers, with Section 1915(c) waiver authority, which allows states to develop HCBS waiver services. Currently, Section

1915(b) waivers must be renewed every two years, or every five years if individuals who are dually eligible for Medicare and Medicaid are included. Section 1915(c) waiver authority is used for FFS and MLTSS to provide HCBS.<sup>14</sup>

- States can also use a combination of Section 1915(a) and Section 1915(c) authorities; the combination allows states to implement voluntary managed care plans that include HCBS.
- Finally, states can use Section 1932(a) authority, which allows states to implement mandatory managed care for all populations except individuals dually eligible for Medicaid and Medicare, American Indians and Alaska Natives, and children with special health care needs (including children eligible for Medicaid on the basis of involvement with the child welfare system) through a state plan amendment (SPA). Section 1932(a) SPAs must be paired with a Section 1915(c) waiver to operate an MLTSS program.

### Federal regulations and guidance on MLTSS

In general, MLTSS plans must adhere to the same regulations as other Medicaid managed care plans. In addition, as the MLTSS model has matured as a delivery system, CMS has released guidance targeted to MLTSS and has added specific MLTSS provisions to more general regulations for Medicaid managed care. Guidance released in May 2013 outlined what CMS referred to as key elements of an effective MLTSS program (CMS 2013). These key elements included:

- adequate planning and transition strategies, including readiness assessments at the state and managed care plan level and transition plans for beneficiaries;
- stakeholder engagement in the planning, implementation, and ongoing oversight processes;

- enhanced provision of HCBS, that is, providing opportunities for beneficiaries to live in the community, or in as integrated a setting as possible, in keeping with the requirements of the ADA and the Supreme Court’s 1999 *Olmstead* decision, which requires that states serve beneficiaries in “the least restrictive setting possible”;
- alignment of payment structures with MLTSS programmatic goals, which include improving the health and care experiences of beneficiaries, and reducing costs;
- support for beneficiaries, including enrollment counseling and an advocate or ombudsmen to help them navigate their health plans (e.g., how to handle disputes);
- person-centered processes for service planning, including participation by the beneficiary and his or her designee, and the opportunity for self-direction of HCBS;
- a comprehensive and integrated service package that covers all physical, behavioral health, and LTSS benefits or, in the absence of an integrated service plan covering all these services, contract provisions that allow and encourage coordination and referral;
- a provider network that includes qualified providers, including those who provide services that support community integration, such as employment supports;
- participant protections to safeguard beneficiaries from financial exploitation, neglect, emotional mistreatment, and to monitor critical incidents; and
- integrated LTSS and managed care quality systems that look at beneficiary outcomes in a holistic manner across services and provide sufficient oversight.

CMS codified the 2013 guidance in an update to federal managed care regulations released in May 2016 (CMS 2016).<sup>15</sup> Among provisions specific to

MLTSS, the agency set new standards related to network adequacy and quality strategies. CMS has directed states to develop and implement network adequacy standards other than time and distance for providers who travel to a beneficiary to provide care (e.g., personal care attendants). CMS has not specified any particular standards that states must use for HCBS network adequacy, nor has the agency required that states set different standards for different HCBS provider types. Instead, CMS commented that “states should establish standards based on their unique mix of services and characteristics and evaluate and amend these standards, as appropriate” (CMS 2016). However, each state is required to evaluate plans’ network adequacy at least annually, and tell CMS that the state has determined plans’ networks are in compliance with the rule. MACPAC’s 2016 analysis of HCBS network adequacy standards found that all states had such standards in place although their approaches often differed (Box 3-1).

## Operation of MLTSS Programs

The administration of MLTSS is generally similar to Medicaid managed care, but the mixture of services and the wide range of needs of beneficiaries who receive LTSS adds complexity, particularly for rate setting and care coordination.

### MLTSS implementation

The initial implementation of MLTSS and subsequent contract procurements are critical periods for beneficiaries, because disruptions in care during these transitions may cause serious harm. Many beneficiaries using LTSS need services on the day the MLTSS program begins. Even one missed personal care visit could create a hardship for a beneficiary unable to perform ADLs such as bathing and toileting. Implementation can be designed to protect beneficiaries from disruptions in care; for example, by having continuity of care periods during which plans must contract with all of a beneficiary’s

### **BOX 3-1. MACPAC Research on Network Adequacy Standards for Home- and Community-Based Services**

In 2016, MACPAC contracted with Health Management Associates (HMA) to identify existing home- and community-based services (HCBS) network adequacy standards in contracts between states and plans. HMA reviewed 33 contracts in 23 states, for established managed long-term services and supports (MLTSS) programs as well as for several programs scheduled to launch in 2017. The review of state contracts showed that all states had existing HCBS network adequacy standards in place, including measures other than time and distance for providers who travel to the beneficiary. However, these standards took many forms. The most common HCBS network standards were the following:

- continuity of care standards beyond federal time requirements (23 contracts), including standards to promote a smooth transition from a non-participating HCBS provider to a participating HCBS provider when a beneficiary is newly enrolled in a health plan, or when a provider discontinues participation in the health plan network;
- time and distance metrics (22 contracts) that establish the maximum allowable travel time or mileage between a beneficiary's residence and HCBS providers to which the beneficiary travels (e.g., adult day health and day habilitation centers);
- criteria for number of providers (16 contracts), which define a minimum number of providers by type or require reporting to the state of the total number of participating HCBS providers in a defined geographic service area;
- reporting requirements for gaps in service (14 contracts), which require reporting to the state of missed HCBS visits and gaps or delays from the time of service authorization to service delivery;
- any willing provider provisions (14 contracts), which require that plans reimburse for care delivered by any willing HCBS provider;
- rate requirements (11 contracts) that require plans to pay providers at least Medicaid fee-for-service rates; and
- single case agreement provisions (10 contracts), through which plans provide time-limited access to out-of-network providers for continuity purposes or for services that are not otherwise available from a participating network provider (also referred to as single source agreements).

HMA also found that network adequacy standards are evolving as states gain experience with MLTSS. Stakeholder interviews indicated that some standards, such as requiring a minimum number of each provider type, were considered to be a starting point for HCBS network adequacy, particularly when states first implement MLTSS, but were not the end goal. Such standards may be relatively easy to implement and enforce but were viewed as insufficient for monitoring whether beneficiaries receive the services authorized in their care plan.

Stakeholders said a preferred standard is a gaps-in-service standard, found in 14 contracts, which requires tracking—and often reporting—of instances when a beneficiary was authorized to receive a service, but the service was not provided, either on one or more dates, on time, or at all. Three states also require plans to submit annual network adequacy reports detailing the composition of their network. Plans may also be required to demonstrate their processes for monitoring the timeliness of care provided to beneficiaries and for addressing deficiencies.

existing providers. In addition to mitigating harm, minimizing disruptions can build confidence in an MLTSS program, especially amid uneasiness by stakeholders unaccustomed to managed care.

As noted above, in both guidance and regulation, CMS has stressed the importance of adequate transition planning to minimize care disruptions (CMS 2013). States determine plans' ability to begin accepting enrollees and providing services through the readiness review process, which is meant to ensure that certain procedures are in place prior to program launch. For example, one review of MLTSS programs noted that Tennessee's readiness review process included having plans demonstrate they would be able to produce state-required reports and monitor timeliness of service delivery, among other items (Lipson et al. 2012). Another review identified factors that officials in five states noted as being important to consider in readiness review, for example, ensuring that information technology systems were ready to store information on beneficiaries' service plans, submit information to providers and state systems, and support timely provider payments (Flowers 2013). State MLTSS contracts typically include provisions to promote continuity of care, such as requirements that plans pay providers Medicaid FFS rates or allow any provider willing to serve plan enrollees to receive payment during a transition period (Saucier et al. 2013).

Through site visits, interviews, listening sessions, and panel presentations, the Commission has also heard from stakeholders about several potential success factors in MLTSS implementation. First, a successful roll-out of MLTSS is carefully planned, deliberate, and incremental. An incremental approach can mean several things. It can mean beginning an MLTSS program in one geographic area, making adjustments, then moving on to the next region to give plans and states time to ramp up the program. It could also mean starting MLTSS with certain populations, such as older adults and individuals with physical disabilities, before enrolling others, such as individuals with ID/DD. Some states might first pilot MLTSS through small programs such

as the FAI before rolling out a larger program based on what they learned through the demonstration process. Other states have used a combination of such approaches.

Second, implementation of MLTSS represents a major change in the delivery system for providers, and a successful roll-out requires appropriate training. Unlike managed care for medical services, for which providers may be used to dealing with Medicaid plans and commercial insurance plans for people with employer-sponsored insurance, few payers other than Medicaid cover LTSS. Thus, transitioning to managed care may mean that, for example, instead of submitting claims to the Medicaid agency, LTSS providers must learn to contract with plans for rates—something they may have never done before—and adjust to new billing systems. This might be particularly challenging in circumstances where several managed care companies operate in the same region or state, each with its own processes and interfaces for payment and billing. On our site visits, several states emphasized the need for robust training programs to prepare the existing provider community (including private agencies, other governmental agencies, and quasi-governmental entities) for the transition to managed care.

Third, stakeholder engagement of beneficiaries, advocates, and providers is commonly cited as a key factor in successful transitions to MLTSS. As noted earlier, providers often experience the transition as a major change and thus must be prepared to ensure the prompt delivery of services on day one. Stakeholders also stress the importance of engaging beneficiaries in the planning and ongoing oversight process. States may establish advisory councils for this purpose or require plans to implement their own stakeholder groups. One state that has adopted MLTSS for individuals with ID/DD specifies the particular advocacy groups that the plans must consult. The ID/DD community is particularly engaged in advocacy work, as is discussed later in this chapter.

Finally, payment policy is important in determining the financial viability of MLTSS plans. Plans must be paid enough to incentivize participation of high quality providers. During recent interviews with stakeholders in states that have implemented MLTSS for individuals with ID/DD, we heard about instances in which payments to providers had been reduced substantially in the transition to MLTSS.

## Setting capitation rates and payment incentives

Factors involved in setting capitation payment rates for MLTSS include accounting for the range of services included, the wide variability in the needs of beneficiaries receiving LTSS, and the need to promote program goals through financial incentives. Unlike other health care services, LTSS are often used daily and may not be paid on an FFS encounter basis with clear billable units. In addition, the needs of beneficiaries receiving LTSS can be difficult to predict given the diversity of functional limitations, even among those with the same medical condition. A recent review of factors that affect the cost of MLTSS identified age, geographic region, race and ethnicity, and household composition among factors influencing the cost of LTSS (Libersky and Lipson 2016). For example, the number of individuals living in the home of a beneficiary receiving LTSS may influence the amount of personal care services needed, because household members may provide some of the needed supports for some portion of the day.

Collecting information about the diverse needs of individuals receiving LTSS can help states create risk-adjusted capitation rates, but research has identified limitations in states' ability to use information on functional needs for this purpose. As we noted in the chapter on functional assessments for LTSS in our June 2016 report to Congress, states currently use a wide range of assessments (MACPAC 2016). Some states require all MLTSS plans to use the same assessment tool to collect information on beneficiaries' functional limitations while others allow each plan to select its own

tool (MACPAC 2016). Use of validated tools can promote equity in service determination by removing some subjectivity from the assessment process. Research on rate setting in MLTSS has noted that the use of multiple tools can complicate states' ability to have comparable data across their LTSS populations (Lipson et al. 2016). Ideally, states would link data from functional assessments with encounter data, because functional limitations (e.g., information on ADLs and IADLs) are key predictors of beneficiary spending (Lipson et al. 2016). New York and Wisconsin leverage their functional assessment data for risk adjustment, but this approach has been challenging for most other states (Dominiak and Bohl 2016, Lipson 2016).

States can use payment rates to incentivize program goals such as rebalancing. To achieve this goal, many states have structured their contracts to incentivize rebalancing; for example, by including both HCBS and institutional care, and subsequently paying blended capitation rates that assume a certain mixture of both (Dominiak and Libersky 2016). Plans gain financially if they serve more beneficiaries in the community than assumed in the rate setting methodology. In addition, states can structure payment rates to adjust annually so that plans are incentivized to meet transition targets each year to make continued progress toward a goal. This is the case in Florida, which has a long-term goal of having no more than 35 percent of its MLTSS-enrolled beneficiaries residing in nursing facilities. (Kidder 2017a, 2017b).

The payment structure of MLTSS programs also permits plans to provide value-added services that target social determinants of health (Soper 2017). A recent review of eight health plans targeting dually eligible beneficiaries found plans provide value-added services to fill gaps in Medicare- and Medicaid-covered services, avoid inpatient hospital and nursing facility admissions, and improve physical health. Plans reported providing services such as housing-related supports, non-medical transportation, nutritional supports, and opportunities for socialization. For example, Tennessee allows plans to provide cost-effective

alternative services such as bed bug treatment to reduce admissions to nursing facilities (Soper 2017).

## Care coordination procedures

Care coordination is a key element of MLTSS programs. Care coordinators are typically nurses or social workers who either work for a plan or a community-based organization that contracts with the plan (Saucier and Burwell 2015). Once a beneficiary has been enrolled in an MLTSS plan, the care coordinator is responsible for assessing their needs to determine what plan-covered services the beneficiary is qualified to receive. The assessment is often conducted in the beneficiary's home. Care coordinators then work with the beneficiary to develop a care plan, connect the beneficiary to providers, ensure that these services are delivered according to the care plan, and conduct periodic reassessments of the beneficiary's needs so they can adjust the care plan as those needs change (GAO 2017a). Care coordination also enforces principles important to delivering services to people who receive LTSS, such as person-centered planning, providing opportunities for self-direction, and recognizing the dignity of risk:

- Person-centered planning relates to the way in which care planning is conducted. In a person-centered planning process, a care coordinator's goal is to help the beneficiary identify which services and supports will help achieve a beneficiary's self-identified goals. For example, if an individual with ID/DD would like to work, or would like to live independently of family members, then the care plan should reflect these goals, incorporating, for example, supportive employment or housing-related services.
- Self-direction provides people who receive LTSS with a high degree of choice over how HCBS are delivered. There are two primary approaches for self-direction. Employer authority allows individuals to recruit, hire, and train their own personal care attendant. They

may be assisted by a managed care plan or state agency in locating caregivers, or they may find their own caregiver, for example, a family member. Under the second approach, budget authority, beneficiaries oversee a budget of Medicaid funds allotted based on their level of care needs and devise their own plan of services (ICRC 2017a).

- The concept of the dignity of risk asserts that individuals with disabilities should have the ability to make decisions about their lives with the same degree of autonomy as individuals without disabilities (Lewin Group 2015). This means that the care planning and service delivery process should honor individuals' choices and not insulate them from risks, just as individuals without disabilities encounter risks in their daily lives. For example, helping individuals live in the setting of their choice is important despite the inherent risks of living alone, so care planners should find ways to mitigate the risks involved in community living rather than counseling them to live in a setting that others might consider safer.

States specify certain care coordination requirements in their contracts with MCOs. A review of 19 state MLTSS programs for older adults and individuals with physical disabilities shows a wide variety of contract requirements related to care coordination. For example, about half of the contracts required care coordinators to have previous experience serving individuals with LTSS needs or disabilities (Saucier and Burwell 2015). Other common care coordination requirements included specifying the time period within which care coordinators must make contact with new members and requiring a single point of contact for beneficiaries to coordinate across the members of the care management team (Saucier and Burwell 2015).

Although care coordination generally serves the same broad functions and states specify certain requirements, each plan may take a different approach to care coordination within the parameters set by the state. For example, plans

may employ care coordinators using one of three models:

- in-house, where plans use their own care coordination staff;
- shared function, in which plan staff perform some functions while the plan contracts out other care coordination functions to community-based organizations (CBOs) such as area agencies on aging, centers for independent living, and aging and disability resource centers; and
- delegated models, where plans contract with an outside agency to conduct care coordination (e.g., a coordinator embedded within a health provider) (Saucier and Burwell 2015).

There are advantages and disadvantages to each of these approaches. For example, in-house approaches allow plans to adjust care coordination capacity easily. However, particularly in a state with a new MLTSS program, an in-house approach may not fully take advantage of existing care coordination capacity in the community available through partnering with CBOs (Saucier and Burwell 2015).

Care coordination also varies by plan in the extent to which it is tailored to specific subpopulations of individuals who receive LTSS. Earlier this year, as part of MACPAC's examination of MLTSS programs enrolling individuals with ID/DD, staff and contractors interviewed several managed care plans on their approach to care coordination for this population. One plan used a team approach; that is, although the plan had staff with experience serving individuals with ID/DD, they did not restrict case managers to serving only individuals with ID/DD. The plan representative explained that the plan deploys individuals with expertise in particular areas to assist a case manager when a beneficiary is in need of those specialized services. In contrast, other plans may connect individuals with ID/DD with case managers who specialize in serving individuals with those conditions.

## MLTSS Outcomes and Oversight

As states gain experience with MLTSS, attention is turning to whether these programs have achieved their intended outcomes. There have been few rigorous evaluations of the effects of MLTSS implementation, and states typically do not collect the baseline data necessary for reliable and valid assessments of beneficiary outcomes (Dobson et al. 2017). Published studies show some evidence of success, but lack of standardized beneficiary-focused outcome measures has historically limited the ability to make comparisons across states. Over time, the recent efforts to develop quality measures for both LTSS generally and MLTSS specifically may result in data that will allow evaluations to say more about beneficiary and program outcomes.

### MLTSS studies and evaluations

Much of what is known about MLTSS outcomes draws from descriptive analyses of state programs and surveys of states. In a review on the value of MLTSS published by the National Association of States United for Aging and Disabilities and the Center for Health Care Strategies, 8 of 12 states reported that MLTSS had supported their rebalancing efforts. For example, Arizona, which has structured its contracts to incentivize serving beneficiaries in community settings, reported that it served 86 percent of beneficiaries in community settings. In the same survey, seven states reported that MLTSS had helped to improve enrollees' physical health. States cited surveys and encounter data as support; for example, in Florida, 60 percent of surveyed beneficiaries reported improved health (Dobson et al. 2017).

As noted earlier, a number of states cite reductions in waiting lists as a motivating factor in pursuing MLTSS. A recent report published by CMS examined the effect of MLTSS adoption on HCBS waiver waiting lists (Saucier et al. 2017). The study found that after adoption of MLTSS, two of seven states that had previously maintained waiting



lists were able to eliminate them, and another four reduced the number of individuals on waiting lists. States gave multiple reasons for the reduction or elimination of waiting lists; MLTSS was not the sole cause (Saucier et al. 2017).

A few evaluations have been conducted that focus on state MLTSS programs. A study of Texas's managed care system found that the STAR+PLUS long-term care component resulted in an estimated 3.5 percent decrease in costs between state fiscal years 2010 and 2015 compared to what was expected under FFS (Hart and Muse 2015). A 2016 evaluation found that, after controlling for individual and area-level characteristics, beneficiaries enrolled in Minnesota's integrated care program for dually eligible beneficiaries were 48 percent less likely to have a hospital stay than enrollees in its non-integrated MLTSS program, and 6 percent less likely to have an emergency room visit (Anderson et al. 2016).

As part of a broader initiative to evaluate Section 1115 waiver programs, CMS contracted with Mathematica Policy Research to conduct an evaluation of MLTSS programs (Libersky et al. 2017). Specifically, the MLTSS evaluation is focused on understanding differences in beneficiary outcomes between FFS and MLTSS. The evaluation is focused on nine outcome measures related to hospitalization, receipt of HCBS versus institutional care, and pressure ulcers. It also includes some descriptive trends across all MLTSS programs, such as spending, utilization, and enrollment data. Due to the limited availability of encounter data, the researchers are focusing on MLTSS beneficiary outcomes in only two states, Tennessee and New York, relative to comparison groups of beneficiaries in FFS in other states (Libersky et al. 2017). The interim findings of the evaluation show mixed results. Enrollment in New York's MLTSS program was associated with a reduced probability of institutionalization over its comparison group, but there was no significant effect in Tennessee. Both states demonstrated higher use of personal care services than their comparison groups. Evaluators also found an increase in hospitalizations in

Tennessee, but a decrease in New York. A final evaluation will be completed in 2019 which will incorporate additional measures that may refine these results and possibly incorporate new data or other analyses (Libersky et al. 2018).

## MLTSS quality measurement development

Successful monitoring and evaluation of the quality of care provided by MLTSS programs is partially dependent on the availability of quality measures that are appropriate for the population receiving LTSS. People who receive LTSS typically have chronic conditions and their functional ability is likely to decline over time due to the nature of their disability or age. Thus, quality measures focusing on beneficiary outcomes such as improvements in health status and function are not sufficient for monitoring LTSS programs. More appropriate LTSS quality measures include improvement in quality of life, community integration, avoidance or delay of institutionalization, and other outcomes that do not assume improvement in health and functional status. Measures must also address the varying needs of different populations; for example, certain outcomes may be more relevant to younger individuals with ID/DD (e.g., satisfaction with employment supports) than to older adults.

To date, measures used to assess LTSS quality have primarily focused on process. A 2016 inventory of state quality measurement initiatives conducted for MACPAC, found that most measures focused on compliance with waiver reporting requirements, for instance, confirming provider qualifications or that personal goals were included in service plans (SHADAC 2016). In 2013, a review of 17 MLTSS contracts similarly found that quality requirements tended to focus on processes, such as timeliness of receipt of covered services and the process of handling critical incidents, with only a few related to outcomes, such as the rate of nursing facility admission (Rivard et al. 2013).

A number of efforts are underway to develop and test quality measures for LTSS that are more

appropriate for users of these services and which may be of more interest to policymakers. These efforts place more emphasis on beneficiary experiences and outcomes, and can be used to strengthen quality oversight efforts in both Medicaid FFS and MLTSS:

- CMS developed the Experience of Care (EoC) Survey as part of the Testing Experience and Functional Tools (TEFT) demonstration. TEFT has granted nine states awards to test HCBS quality measurement tools and develop LTSS information technology infrastructure. The EoC Survey is a beneficiary survey that covers beneficiaries with all types of disabilities. Following testing by states in 2015, this survey has now been incorporated into the Consumer Assessment of Healthcare Providers and Systems (CAHPS) program as the CAHPS Home and Community-Based Services Survey. The National Quality Forum has also endorsed 19 quality measures derived from the survey. TEFT-participating states are currently collecting a second round of survey data, which is intended to give them information to assess and improve their HCBS programs (CMS 2017c).
- The National Core Indicators for Aging and Disabilities is a survey of beneficiaries that can be used in both FFS and managed care programs. Implemented in 2015, this survey was modeled after the National Core Indicators for Intellectual and Developmental Disabilities survey, which began in 1997. Both surveys focus on beneficiaries' reports of their quality of life and outcomes, and can be used across different delivery systems (Bradley et al. 2017).
- CMS contracted with the National Quality Forum to convene a group of stakeholders to identify domains for HCBS quality measure development. In 2016, NQF's report identified 11 areas where there are gaps in measurement, including areas such as service delivery and effectiveness, community inclusion, and caregiver support (NQF 2016). The

report is intended to provide priorities for the development and testing of new HCBS measures.

In addition, CMS has contracted with Mathematica Policy Research and the National Committee for Quality Assurance to develop standardized MLTSS quality measures. In the first phase, contractors reviewed existing measures and convened a technical expert panel to identify the most important measure gaps. The project recommended development and testing of eight measure concepts including assessment and care planning, rebalancing and institutional utilization, and fall risk reduction. The second phase, which is currently underway, consists of field testing the recommended measures to determine the feasibility of collecting required data elements from health plans and testing the results for validity and reliability (Ross 2017). CMS has begun making the technical specifications for the measures that have been tested available to states, beginning with the four comprehensive assessment and care planning measures. These technical specifications will allow states to implement these measures if they desire to do so (CMS 2018b).

## Federal oversight of MLTSS

With nearly half of all states implementing MLTSS for at least some subpopulations, increasing attention is being paid to federal efforts to oversee these programs. Two recent reports by the U.S. Government Accountability Office (GAO) have identified areas where federal oversight may be lacking. First, in a study of CMS's monitoring of payment rates, GAO found that five of six state MLTSS programs included payment rates that supported rebalancing through blended capitation rates. However, most of the states did not link payments directly to performance in achieving program goals, for example, by making a portion of payment conditional on their performance on outcome measures. GAO also found that CMS had not consistently required states to report on how their payment structures achieved program goals such as rebalancing (GAO 2017a). CMS's

requirements were inconsistent across study states; three were required to report on their MLTSS programs' achievement of goals related to providing HCBS and the other three were not. GAO recommended that CMS require such reporting across all states. In its response to the report, the U.S. Department of Health and Human Services (HHS) said it would release guidance clarifying that states must include certain measures related to quality of life, rebalancing, and community integration among the other measures they report on in their required managed care annual reports (GAO 2017a).

A second GAO report examined CMS's oversight of access and quality in MLTSS programs. Again, GAO found inconsistencies across states regarding CMS reporting requirements for key elements of MLTSS programs (GAO 2017b). In particular, GAO found inconsistencies in information CMS required states to report regarding network adequacy, critical incidents, and appeals and grievances. CMS officials told GAO that they do not have a consistent approach because MLTSS monitoring is customized to each state. GAO recommended, and HHS concurred, that more steps should be taken to identify and obtain information on MLTSS access and quality to make federal oversight more effective (GAO 2017b).

Even as gaps identified in federal oversight of MLTSS are addressed, oversight will be difficult without sufficient encounter data to support Medicaid claims analysis, and—as noted earlier—adequate outcome data also are needed. CMS and states are working to implement the Transformed Medicaid Statistical Information System (T-MSIS). As of March 2018, all state Medicaid agencies but one were in the production phase of T-MSIS, meaning they have begun submitting information to the system and are either up to date in their reporting or in the process of catching up (CMS 2018c). T-MSIS data are not yet available for analysis by outside entities because the agency is still testing the data for completeness and quality. However, CMS plans for T-MSIS include improved encounter data for managed care plans, including

MLTSS programs, which should assist oversight efforts.

## The Future of MLTSS

As more states pursue managed care as a delivery model for LTSS, and as existing programs mature, the MLTSS model continues to evolve. For example, we heard in our research on network adequacy that as states learned what works and found limitations to their existing approaches, the reprocurement process provided opportunities to implement new contract requirements informed by past experience. We can similarly expect continued changes in other program areas over time. In addition, the MLTSS plan market will likely evolve, particularly as larger organizations gain experience in multiple states. As noted earlier, there are opportunities to learn more about MLTSS program outcomes, such as the effect of MLTSS on access to care, and to gain insight into areas such as how plans make service plan decisions.

The Commission has begun to explore two areas of MLTSS evolution in particular. First, state interest in enrolling individuals with ID/DD into managed care is growing. However, the ID/DD population has special considerations which may influence how states approach enrollment of this group. Second, states are increasingly aligning MLTSS with Medicare benefits to integrate care for beneficiaries dually eligible for Medicare and Medicaid. One particular arrangement, aligning MLTSS with Medicare Advantage dual-eligible special needs plans (D-SNPs) may gain additional traction now that special needs plans (SNPs) have been permanently authorized.

### Enrollment of individuals with ID/DD into MLTSS programs

Throughout the 1980s and 1990s, states expanded use of HCBS waivers and also moved to implement managed care. However, for people with ID/DD, these two Medicaid program reforms occurred on

separate tracks, only intersecting in states such as Arizona and Wisconsin, which began using managed care for individuals with ID/DD in 1988 and 1999, respectively. Most states that have implemented managed care for people with ID/DD have not incorporated LTSS, and continue to cover such services under FFS. Several factors likely play a role in why services for individuals with ID/DD have historically been excluded from MLTSS:

- Managed care plans and ID/DD service providers lack experience with each other. Given that Medicaid is the dominant payer of services for individuals with ID/DD and these services have traditionally been paid on an FFS basis, many plans do not have experience working with ID/DD providers. In addition, many ID/DD providers do not have experience contracting with managed care.
- In addition to lacking experience with providers serving beneficiaries with ID/DD, managed care plans have not historically served individuals with ID/DD, who differ from other recipients of LTSS due to the types of services received (e.g., education and employment supports) and the length of time they are typically enrolled in LTSS plans. This lack of history contributes to stakeholder mistrust and resistance to moving this population to MLTSS.
- Organized and engaged ID/DD stakeholder communities exist at both the state and federal levels and they have historically resisted MLTSS. Individuals with ID/DD often need LTSS for many years, and sometimes for decades. As a result, advocates for individuals with ID/DD, including family members, professionals, and people with ID/DD themselves, are often personally involved in the provision of services and the relationships they share. In addition, strong stakeholder coalitions have been built over years of policy and program advocacy efforts to support the deinstitutionalization and community inclusion of people with ID/DD.
- Cost savings are difficult to achieve with the ID/DD population. Spending on LTSS for people

with ID/DD is largely rebalanced toward HCBS, limiting potential savings from transitioning beneficiaries to the community (Eiken et al. 2017). In addition, as life expectancy for individuals with ID/DD continues to increase, costs for this population are likely to persist or increase (AAIDD 2015).

### **Tailoring MLTSS programs for individuals with ID/DD.**

Several states have recently included individuals with ID/DD in the transitions to MLTSS, and others have indicated interest in doing so. Given that this group's needs differ from older adults and individuals with physical disabilities, the Commission recognized a need to better understand how MLTSS has been implemented for this population. In 2017, MACPAC employed HMA to review the eight state contracts representing, as of November 2017, all states administering comprehensive managed care programs or prepaid inpatient health plans including the majority or all HCBS for people with ID/DD (Arizona, Iowa, Kansas, Michigan, New York, North Carolina, Tennessee, and Wisconsin). The contract review found that ID/DD-specific provisions are more prevalent for separate programs designed for people with ID/DD than for programs that include other populations receiving LTSS. The prevalence of ID/DD-specific provisions also appears to be correlated with states that have underlying ID/DD policy goals, such as Tennessee's efforts to increase employment among people with ID/DD, and New York's focus on integration of Medicare and Medicaid services for people with ID/DD. States moving to managed care for all populations, such as Kansas and Iowa, had the fewest provisions targeted specifically to people with ID/DD.

Key findings from the contract review include:

- The most frequent ID/DD-specific requirements relate to training and experience of the case managers. For example, Tennessee case managers are required to have received training on cultural competency, family supports, transition planning for youth, health and safety training that includes acknowledgement of the

dignity of risk, housing options, and assistive technology. Kansas and New York require a care manager to have a certain amount of experience working with individuals with ID/DD.

- Three states (Kansas, North Carolina, and Tennessee) require plan staff (including senior leadership) to have ID/DD-specific experience, especially for medical directors and LTSS directors. Tennessee is the only state to require experience in integrated employment services for people with ID/DD.
- ID/DD-specific stakeholder engagement requirements are found primarily in states with MLTSS programs targeted to people with ID/DD. Arizona and New York both require ID/DD-specific advisory committees that include members and families to provide input into the plan. Tennessee goes further by identifying specific ID/DD organizations that the MCOs must include in their stakeholder engagement efforts.
- Five states include ID/DD-specific quality provisions or measures important to people with ID/DD. For example, New York includes the Council on Quality and Leadership Personal Outcome Measures in its quality improvement program, and notes that the New York State Office for People with Developmental Disabilities will develop a customized review process for outcomes of care management for individuals with ID/DD. Tennessee notes that quality monitoring will be developed by the state's Department of Intellectual and Developmental Disabilities.

In addition to reviewing contracts, HMA conducted a series of interviews with states, managed care plans, consumer advocates, and provider associations. Slow, incremental program transitions (by region, eligibility category, or both) were cited as a factor of success. Another factor cited as being important to program and policy success was stakeholder engagement, which helped overcome reluctance to the move to MLTSS,

particularly among beneficiaries and advocates. Examples of stakeholder engagement efforts that plans undertook include having a member advocate on staff, hiring family members and people with disabilities, involving advocacy and stakeholder organizations in service coordinator training and review of training materials, supporting and participating in local disability events and conferences, and hosting regularly scheduled stakeholder meetings in a variety of geographic locations.

## Integrating care for dually eligible beneficiaries

People who are dually eligible receive both Medicare and Medicaid benefits by virtue of their age or disability and low incomes. For dually eligible beneficiaries, Medicare is the primary payer of physician services, inpatient and outpatient acute care, and post-acute care. Medicaid wraps around Medicare's coverage by providing assistance with Medicare premiums and cost sharing and by covering some services that Medicare does not cover, such as LTSS. Among full-benefit dually eligible beneficiaries in FFS in 2013, 42 percent used LTSS (MACPAC and MedPAC 2018).<sup>16</sup>

Generally, care for dually eligible beneficiaries is not well integrated across Medicare and Medicaid. The two programs cover different benefits and have different program and payment rules, which can result in confusion for beneficiaries and providers. Because policies and benefits are not integrated, there are missed opportunities to help both programs reduce costs while improving the beneficiary experience. For example, better management of care transitions following an acute inpatient hospital admission (paid for by Medicare) for dually eligible beneficiaries who are receiving HCBS (paid for by Medicaid) could help reduce avoidable rehospitalizations.

In recent years, states interested in integrating care for dually eligible beneficiaries have pursued several options. The FAI, authorized under Section

3021 of the Patient Protection and Affordable Care Act (ACA, P.L. 111-148, as amended) to enable states to test models to integrate primary, acute, behavioral health, and LTSS for their dually eligible beneficiaries, is currently operating in 11 states. As of April 2018, 383,324 dually eligible beneficiaries were enrolled in the capitated model being tested in nine states (ICRC 2017b). In the capitated model, states enter into a three-way contract with CMS and the integrated Medicare-Medicaid plans. Most demonstrations are scheduled to end in 2019 or 2020 (MACPAC 2018a).

States may choose to align their managed care (including MLTSS) programs with Medicare Advantage D-SNPs. Medicare Advantage is the managed care component of Medicare and D-SNPs are a type of Medicare Advantage health plan designed specifically for dually eligible beneficiaries. Since 2008, D-SNP enrollment has grown from 829,000 to about 2 million dually eligible beneficiaries, nearly 20 percent of all dually eligible beneficiaries (MedPAC 2017).

Alignment of MLTSS and D-SNPs occurs on a continuum, ranging from limited benefit coordination to fully integrated plans, as follows:

- States may use D-SNPs to provide limited benefit coordination. Federal law requires D-SNPs to have a contract with the state Medicaid program to operate in a state; however, a state may choose not to use the D-SNP as a vehicle to closely align Medicare or Medicaid benefits.<sup>17</sup> In such cases, D-SNPs may meet only the minimum requirements to provide or coordinate Medicaid benefits required by the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA, P.L. 110-275), but states have the flexibility to impose additional requirements.<sup>18</sup> Dually eligible beneficiaries may see some benefits of shared information between the two programs, but the minimum MIPPA requirements do not provide a high degree of benefit integration.
- States may require close coordination between D-SNPs and MLTSS plans. States

may selectively contract with D-SNPs by only contracting with D-SNPs that offer MLTSS plans within their state or requiring that the MLTSS plans in their state offer a companion D-SNP. State contracts may align multiple areas of the two programs, but the beneficiary is technically enrolled in two plans. For example, Minnesota includes the D-SNP requirements in their Medicaid MLTSS contracts and Arizona establishes requirements for D-SNPs in a separate contract (Verdier et al. 2016). When one parent organization offers both an MLTSS plan and a D-SNP, states and the plan can encourage (but not require) beneficiaries to enroll in the companion D-SNP. When beneficiaries are enrolled with the same parent organization for both their Medicare and Medicaid benefits, the parent organization coordinates all of the benefits.

- States may contract with a fully integrated dual-eligible special needs plan (FIDE-SNP). In this case, beneficiaries are enrolled in a single integrated plan that typically includes LTSS, behavioral health, and other Medicaid benefits that vary by state (ICRC 2017c). These plans operate similarly to the FAI capitated plans in that Medicare and Medicaid benefits can be provided through the same parent organization, thereby providing a seamless experience to the beneficiary despite services being paid for by two different programs. The FIDE-SNP may receive an additional Medicare payment from CMS through a frailty adjustment if their beneficiaries have an average acuity level as high as beneficiaries enrolled in the Program of All-Inclusive Care for the Elderly. In Minnesota, the Minnesota Senior Health Options (MSHO) program requires that beneficiaries who choose to enroll receive all their benefits from one plan and all of the MSHO plans are FIDE-SNPs (ICRC 2017c).

D-SNP and FIDE-SNP authority was made permanent in the Bipartisan Budget Act of 2018 (P.L. 115-123).<sup>19</sup> Removing uncertainty over the future of D-SNPs could potentially prompt some

of the states that have not yet aligned MLTSS with D-SNPs to consider doing so. The law also takes other steps to promote greater integration of Medicare and Medicaid benefits through D-SNPs. It requires that D-SNPs meet one of several new requirements related to the integration of Medicaid and Medicare benefits. For example, under one option, D-SNPs coordinate LTSS, behavioral health services, or both through integration activities such as notifying the state in a timely manner when a beneficiary has been hospitalized, has visited the emergency room, or has been discharged from a hospital or nursing home. The law also directs the Secretary of HHS, through the Medicare-Medicaid Coordination Office, to establish a uniform process for disseminating information to states related to contracts with D-SNPs and to establish resources for states interested in exploring D-SNPs as a platform for integration.

## Looking Ahead

This chapter provides an overview of MLTSS in Medicaid and issues of key importance as this delivery system evolves. During the course of the Commission's work, we have identified areas for further exploration. In particular, the Commission is interested in better understanding how states are aligning MLTSS with D-SNPs to integrate care for dually eligible beneficiaries. We expect our future work to focus on identifying state activity to develop integrated care models and the key components of these models. We are especially interested in learning how states and plans have overcome barriers to integration and whether these strategies can be replicated in other states.

Another issue of concern is the adequacy of federal and state oversight efforts and the extent to which information used in federal oversight efforts reflects the breadth of information collected by states from MCOs, such as information about complaints and grievances and results of beneficiary surveys. States collect a great deal of information from plans; however, as GAO found, inconsistencies

in state reporting to CMS means that little of this information is comparable across states, and this information could be better disseminated.

We will also monitor research on the cost and quality of MLTSS programs, particularly how costs and quality of services provided in MLTSS compare to services in FFS, how different state design decisions influence outcomes, and how plans deal with the challenges of managing care and costs. We will also track CMS's efforts to develop HCBS and MLTSS quality measures, and the adoption of these measures by states. Improved outcome data would help the Commission understand the successes and challenges faced by CMS and states, and enhance our ability to advise Congress on any steps that need to be taken to improve the oversight and operation of MLTSS programs.

## Endnotes

- <sup>1</sup> The \$29 billion figure may represent an underestimate due to data limitations in spending on MLTSS. The Centers for Medicare & Medicaid Services (CMS) required states to report estimates of MLTSS spending beginning in FY 2016, which may improve future data reporting (Eiken et al. 2017).
- <sup>2</sup> For more information on how state Medicaid programs deliver LTSS and how Medicaid-covered LTSS have evolved over time, see the chapter on Medicaid's role in providing assistance with LTSS in MACPAC's June 2014 report to Congress (MACPAC 2014).
- <sup>3</sup> Medicaid beneficiaries receiving LTSS vary in the proportion of LTSS spending attributable to HCBS. For individuals with ID/DD, over 70 percent of LTSS was for HCBS in FY 2015. In contrast, only 44 percent of Medicaid LTSS spending in 2015 was for HCBS for older adults and persons with disabilities (Eiken et al. 2017).
- <sup>4</sup> *Olmstead v. L.C.* 1195.Ct. 2176 (1999).
- <sup>5</sup> In some states, individuals on waiting lists may not yet have been determined to be eligible for HCBS, and in other states, HCBS waiting lists are at least partially attributable to a lack of state funding to meet demand.

<sup>6</sup> The terms intellectual disabilities and developmental disabilities refer to different conditions. As described by the American Association on Intellectual and Developmental Disabilities, intellectual disability originates before the age of 18 and includes substantial limitations both in intellectual functioning (e.g., reasoning, learning, problem solving) and in adaptive behavior. Developmental disabilities appear before the age of 22 and are likely to persist throughout life. They include intellectual disability and other physical and cognitive disabilities that appear during childhood (AAIDD 2018).

<sup>7</sup> The closure of state-run and other public institutions over the past 50 years, along with litigation and consent decrees stemming from the *Olmstead* decision have helped to hasten the provision of HCBS for individuals with ID/DD. Spending on LTSS for people with ID/DD is now largely rebalanced toward HCBS, with 76 percent of Medicaid LTSS spending for people with ID/DD residing in the community in FY 2015 (Eiken et al. 2017).

<sup>8</sup> The state of Washington once operated an MLTSS program, but ended it in 2012 (Lewis et al. 2018).

<sup>9</sup> Enrollment estimate based on most recent year of data available, either 2016 or 2017. In addition, data for eight MLTSS programs in seven states (California, Hawaii, Massachusetts, Michigan, North Carolina, Texas, and Virginia) were unavailable (Lewis et al. 2018).

<sup>10</sup> The CMS Medicare-Medicaid Coordination Office has implemented the FAI to improve care and reduce program costs for dually eligible beneficiaries as well as to improve coordination between the Medicaid and Medicare programs. As of December 2017, 13 states participated in the FAI either under a capitated model, a managed FFS model, or an alternative model. Demonstrations in two states ended in December 2017, and 11 states continued their demonstrations into 2018 (MACPAC 2018a).

<sup>11</sup> Tennessee's enrollment of individuals with ID/DD is limited to those who became eligible as of July 1, 2016. Beneficiaries who were eligible prior to that date can continue to receive their LTSS through FFS (TN HCFA 2018).

<sup>12</sup> Section 1915(c) waivers authorize states to provide HCBS as an alternative to institutional care in nursing facilities, intermediate care facilities for individuals with intellectual

disabilities, and hospitals. States are permitted to impose caps on waiver program enrollment and average costs per person to ensure that they do not exceed the waiver's cost-neutrality limit.

<sup>13</sup> Some waivers may be extended for periods of 10 years. CMS has indicated that it will approve routine, successful, non-complex Section 1115(a) waiver extensions for up to 10 years (CMS 2017a). In December 2017, CMS approved the Mississippi family planning waiver for 10 years (CMS 2017b).

<sup>14</sup> Presently, states must use a combination of these authorities to implement MLTSS. In our March 2018 report, the Commission recommended that Congress should revise Section 1915(c) waiver authority to permit Section 1915(c) waivers to waive freedom of choice and selective contracting. In addition, the Commission recommended that Congress extend approval and renewal periods for Section 1915(b) waivers from two to five years (MACPAC 2018b).

<sup>15</sup> In a letter to governors in March 2017, HHS indicated it would review the managed care regulations to give greater weight to beneficiary outcomes and state priorities. It is currently unknown when this review will be complete and any changes to these regulations that might occur (HHS 2017b).

<sup>16</sup> Full-benefit dually eligible beneficiaries receive the full range of Medicaid benefits offered in a given state. For partial-benefit dually eligible beneficiaries, Medicaid provides assistance with Medicare premiums and cost sharing. Most dually eligible beneficiaries (72 percent) are eligible for full Medicaid benefits (MACPAC and MedPAC 2018).

<sup>17</sup> States may also choose not to contract with a prospective D-SNP.

<sup>18</sup> MIPPA, as amended by the ACA, required that Medicare Advantage organizations seeking to offer D-SNPs have a contract with the state Medicaid agency by calendar year 2013 and in each year thereafter (42 CFR 422.107). MIPPA enacted a minimum set of requirements for what D-SNP contracts must cover: (1) the Medicare Advantage organization's responsibilities, including financial obligations, to provide or arrange for Medicaid benefits; (2) the categories of eligibility for dually eligible beneficiaries to be enrolled under the D-SNP, including the targeting of specific subsets; (3) the Medicaid benefits covered under the D-SNP;



(4) the cost sharing protections covered under the D-SNP; (5) the identification and sharing of information about Medicaid provider participation; (6) the verification process of an enrollee's eligibility for both Medicare and Medicaid; (7) the service area covered under the SNP; and (8) the contracting period (CMS 2016). States can add additional requirements beyond the minimum MIPPA requirements.

<sup>19</sup> D-SNPs were originally authorized as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA, P.L. 108-173). They began operating in 2006. The authority granted under MMA expired in December 2008 but was extended by MIPPA and subsequently extended by other legislation.

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# APPENDIX 3A: State MLTSS Programs

**T 3A-1**
**TABLE 3A-1. State MLTSS Program Populations and Enrollment**

State	Program	Year implemented	Medicaid managed care authority	Eligible enrollment populations				Enrollment in 2017
				Older adults	Adults with physical disabilities	Adults with ID/DD	Children with disabilities	
Arizona	Arizona Long-Term Care System	1989	1115	✓	✓	✓	✓	60,044
California	Cal Medi-Connect	2014	1115	✓	✓	-	-	118,096
	Managed Medi-Cal Long-Term Services and Supports	2014	1115	✓	✓	✓	-	N/A
Delaware	Diamond State Health Plan Plus	2012	1115	✓	✓	-	✓	12,6661
Florida	Statewide Medicaid Managed Long-Term Care Plan	2013	1915(b)	✓	✓	-	-	93,843
Hawaii	Quest Integration	2015	1115	✓	✓	✓	✓	N/A
Idaho	Medicare-Medicaid Coordinated Plan	2014	1915(a)	✓	✓	-	-	2,4891
	MLTSS	2016	1915(b)	✓	✓	-	-	28,640
Illinois	Medicare-Medicaid Alignment Initiative	2014	1932(a)	✓	✓	-	-	52,004
	Integrated Care Program	2011	1932(a)	✓	✓	✓	-	114,365
Iowa	Health Link	2016	1915(b)	✓	✓	✓	✓	36,825 <sup>1</sup>
Kansas	KanCare	2013	1115	✓	✓	✓	✓	33,615
	One Care	2013	1115	-	✓	✓	-	17,938
Massachusetts	Senior Care Options	2004	1915(a)	✓	-	-	-	N/A
	MI Health Link	2015	1915(b)	✓	✓	✓	-	39,965
Michigan	MI Choice	2013	1915(b)	✓	✓	-	-	N/A

**TABLE 3A-1. (continued)**

State	Program	Year implemented	Medicaid managed care authority	Eligible enrollment populations					Enrollment in 2017
				Older adults	Adults with physical disabilities	Adults with ID/DD	Children with disabilities		
Michigan	Managed Specialty Services and Supports	1998	1915(b)	-	-	✓	✓	N/A	
Minnesota	Senior Care Plus	2005	1915(b)	✓	-	-	-	16,265	
	Senior Health Options	1997	1915(a)	✓	-	-	-	37,649	
New Jersey	NJ FamilyCare	2014	1115	✓	✓	-	-	28,731 <sup>1</sup>	
New Mexico	Centennial Care	2014	1115	✓	✓	✓	✓	34,947 <sup>1</sup>	
	Medicaid Advantage Plus	2016	1115	✓	✓	-	-	8,356	
New York	Fully Integrated Duals Advantage	2015	1115	✓	✓	-	-	4,468	
	Fully Integrated Duals Advantage – I/DD	2015	1915(a)	-	-	✓	-	701	
	Managed Long-Term Care Partial Cap	1998	1115	✓	✓	-	-	186,626	
	NC Innovations	2005	1915(b)	-	-	✓	✓	N/A	
Ohio	MyCare	2014	1915(b)	✓	✓	✓	-	111,994	
Pennsylvania	Community HealthChoices	2018	1915(b)	✓	✓	-	-	N/A	
	Adult Community Autism Program	2009	1915(a)	-	-	✓ <sup>2</sup>	-	147	
Rhode Island	Integrated Care Initiative, Phase 2	2015	1115	✓	✓	✓	-	13,725 <sup>1</sup>	
	Rhody Health Options	2013	1115	✓	✓	✓	-	15,234 <sup>1</sup>	
South Carolina	Healthy Connections Prime	2015	1932(a)	✓	-	-	-	11,907	
Tennessee	Employment and Community First CHOICES	2016	1115	-	-	✓	✓	1,389	
	CHOICES	2010	1115	✓	✓	-	✓ <sup>3</sup>	28,941	

**TABLE 3A-1. (continued)**

State	Program	Year implemented	Medicaid managed care authority	Eligible enrollment populations				Enrollment in 2017
				Older adults	Adults with physical disabilities	Adults with ID/DD	Children with disabilities	
Texas	STAR Kids	2016	1115	-	-	-	✓	N/A
	Dual Eligibles Integrated Care Project	2015	1115	✓	✓	✓	-	41,182
	STAR Health	2015	1915(a)	-	-	-	✓ <sup>4</sup>	30,912
	STAR+PLUS	1998	1115	✓	✓	✓	✓	519,105
Virginia	Commonwealth Coordinated Care Plus	2017	1915(b)	✓	✓	✓	✓	N/A
	Family Care	1999	1915(b)	✓	✓	✓	-	44,404
Wisconsin	Family Care Partnership	1996	1932(a)	✓	✓	✓	-	3,000

**Notes:** MLTSS is managed long-term services and supports. ID/DD is intellectual or developmental disabilities. MLTSS programs may carve certain benefits out of capitation. Enrollment data may include some beneficiaries who did not use LTSS.

✓ Check indicates population is included in an MLTSS program.

- Dash indicates that population is not included in MLTSS program. N/A indicates that enrollment data was not available.

<sup>1</sup> State enrollment figures are for 2016.

<sup>2</sup> In Pennsylvania, enrollment in the Adult Community Autism Program is limited to adults age 21 and older who have been diagnosed with autism spectrum disorder and meet certain clinical criteria.

<sup>3</sup> Includes only children who are nursing facility residents.

<sup>4</sup> Includes only children in foster care.

**Source:** MACPAC, 2018, analysis of Lewis et al. 2018, PA DHS 2018b, and NYS OPWDD 2018.



Chapter 4:

# Access to Substance Use Disorder Treatment in Medicaid

# Access to Substance Use Disorder Treatment in Medicaid

## Key Points

- Ensuring Medicaid beneficiaries have access to substance use disorder (SUD) treatment requires that services along a continuum of care are covered, affordable to the beneficiary, and designed to meet the unique needs of the population. In addition, providers must be available to provide appropriate care when needed.
- The continuum of care for individuals with an SUD should include outpatient services, intensive outpatient services, partial hospitalization, residential treatment, and medication-assisted treatment (MAT). SUD treatment also should be offered in non-specialty settings such as primary care.
- MACPAC's review of state Medicaid coverage for SUD treatment services shows that only 12 states pay for the full continuum of clinical services, which includes MAT, outpatient treatment and residential treatment at varying degrees of intensity.
- The largest gaps in state clinical service coverage are for partial hospitalization and residential treatment. This creates a barrier to critical treatment for individuals with life-threatening withdrawal potential.
- Although the institutions for mental diseases (IMD) exclusion is often cited as a barrier to paying for residential services, states may currently pay for these services under some conditions through Section 1115 demonstrations and managed care.
- Twenty-three states have sought federal approval for Section 1115 demonstrations to implement comprehensive strategies to improve SUD care. Others have neither taken advantage of this opportunity nor used other Medicaid authorities to reduce gaps in the continuum of care.
- An inadequate supply of SUD treatment facilities and low provider participation rates in Medicaid also affect access to treatment:
  - Roughly 40 percent of counties do not have an outpatient SUD treatment program. Gaps are more pronounced for partial hospitalization and short-term residential treatment, with less than 15 percent of providers offering these services.
  - About 6 in 10 specialty SUD treatment facilities accept Medicaid, but there is wide variation among states, with Medicaid participation as low as 29 percent.
- In some states, Medicaid payment rates are low; paying for certain levels of care may do little to improve access. Rates must be set at a sufficient level to attract a supply of providers.
- Early results from Section 1115 SUD demonstrations in California and Virginia indicate that implementing comprehensive strategies that include covering additional services and undertaking efforts to attract new providers can improve access to SUD treatment.

## CHAPTER 4: Access to Substance Use Disorder Treatment in Medicaid

The opioid epidemic continues to ravage families and communities across the country. In 2016, drug overdose deaths in the United States increased by 21.4 percent over the previous year, with nearly two-thirds of these deaths involving opioids obtained by prescription, illicitly, or in some cases both (Vivolo-Kantor et al. 2018).

Medicaid beneficiaries have been disproportionately affected by the opioid epidemic, accounting for roughly half of all opioid-related overdose deaths in some states (McMullen 2016, Sharp and Melnik 2015, Whitmire and Adams 2010, CDC 2009). Compared to privately insured individuals, Medicaid beneficiaries age 18–64 have a higher rate of opioid use disorder (OUD) and are prescribed pain relievers more often than individuals with other sources of insurance. The introduction of cheaper, more potent opioid alternatives, such as fentanyl, to the illicit drug supply has also resulted in a higher risk of overdose for Medicaid beneficiaries (MACPAC 2017a).

State Medicaid programs are using a variety of approaches to respond to the opioid crisis, but Medicaid beneficiaries continue to face barriers when trying to access substance use disorder (SUD) treatment. As MACPAC noted in the June 2017 report to Congress, access to care may be impeded by factors ranging from fears about the stigma of having an SUD to a fragmented and poorly funded delivery system. Medicaid-participating providers and practitioners trained in providing medication-assisted treatment (MAT) remain in short supply, and gaps in the continuum of care persist (MACPAC 2017a). Federal regulations meant to protect the privacy of individuals with SUDs have also been cited as a potential impediment to care coordination; further work and recommendations on this topic can be found in Chapter 2 of this report.

An effective SUD treatment system provides access to a continuum of care, but gaps in the continuum

often limit access to treatment. Ensuring access to care requires that services are covered, that they are affordable to the beneficiary, and that they are designed to meet the unique needs of the population. Providers must also be available to provide appropriate care when needed (MACPAC 2011). The delivery system must have an adequate supply of providers located where patients are, and these providers must also be willing to participate in the Medicaid program and accept new patients. All of these components are important to beneficiaries' ability to obtain timely access to treatment.

In this chapter, the Commission extends its analysis of the care delivery system for Medicaid beneficiaries with OUDs, using industry standards for evidence-based care to characterize the SUD continuum of care. We note that as of April 2018, only 12 states cover a full continuum of care. While policymakers have focused on the role played by the Medicaid payment exclusion for institutions for mental diseases (IMD) in creating gaps in residential SUD services, the IMD exclusion is not the only reason gaps in coverage exist. Many states do not take advantage of the various legal authorities available to them, such as the state plan rehabilitation option and the health home option, to expand their SUD treatment benefit. These policy choices reflect a variety of factors, including budgetary constraints.

In this chapter, MACPAC also notes that many states have a limited supply of SUD providers, especially in rural areas. This includes both specialty SUD treatment facilities and practitioners certified to prescribe drugs used to treat OUD. While opportunities to seek Section 1115 SUD demonstrations have created momentum in certain states to create a more comprehensive approach to SUD treatment that focuses on both covered services and the availability of providers, to date, only 23 states have sought this authority.

The chapter begins with a discussion of the components of an SUD continuum of care. These components include both clinical and non-clinical services that address short-term needs, including withdrawal services, as well as services that

support long-term recovery for those with an SUD. It then details Medicaid's coverage of these services and describes the availability of SUD treatment providers, including their participation rates in Medicaid. The chapter describes opportunities available to states to develop an SUD delivery system and highlights the early progress two states are making under Section 1115 SUD demonstrations. Although this analysis focuses on the treatment of OUD, the continuum of care, as well as many of the concerns described here, apply to treatment of other SUDs such as those associated with cocaine and methamphetamines, that continue to trouble many communities.

The chapter concludes by identifying areas for further study. The Commission has already begun work to assess state coverage of recovery support services for Medicaid beneficiaries with an SUD. MACPAC is also interested in further exploring the availability of MAT to Medicaid beneficiaries; and analyzing access to SUD services for certain populations such as older adults, parents or prospective parents, individuals involved in the criminal justice system, and adolescents with an SUD.

## Components of a Substance Use Disorder Continuum of Care

Providing access to treatment services along a continuum of care is important for effective treatment and an individual's continued recovery. Because the severity of an individual's SUD influences the type and intensity of services needed, a continuum of care that offers progressive clinical treatment, such as outpatient services and MAT, and non-clinical supports, such as recovery services, is needed. These services enable individuals to manage their SUDs over an extended period of time as their treatment needs change (Mee-Lee et al. 2013). For example, an individual with multiple comorbid SUDs, such as alcohol, benzodiazepines,

and opioids, is more likely to need inpatient or medically monitored residential levels of care to safely address withdrawal management. For an individual with OUD alone, however, withdrawal management and transition to maintenance medications can often be safely and effectively addressed in an outpatient setting (Olsen 2018). Compared to residential environments, outpatient environments allow sustained connections to support systems, including interactions with family, spouses, children, and others. Receiving treatment in an outpatient environment can also allow individuals to keep their jobs.

### Clinical services

For this report, the Commission selected criteria developed by the American Society of Addiction Medicine (ASAM) as a framework to analyze coverage of SUD treatment services. The ASAM criteria comprise a set of guidelines for assessing and making treatment decisions for individuals with addiction and co-occurring conditions, including service planning, placement, continued stay, transfer, and discharge decisions (ASAM 2014).<sup>1</sup> These guidelines are referenced by both private and public payers to determine medical necessity for treatment. In addition, the Centers for Medicare & Medicaid Services (CMS) requires states applying for Section 1115 SUD demonstrations to use either the ASAM criteria or similar nationally recognized guidelines. The majority of states also require Substance Abuse and Mental Health Administration (SAMHSA) block grant-funded providers to use the ASAM criteria when determining a patient's treatment needs (Grogan et al. 2016).

Appropriate SUD treatment can differ depending on the severity of an individual's disorder, co-occurring mental health conditions, treatment goals, and other factors, such as readiness to change and relapse potential. Accordingly, the ASAM criteria identify five broad levels of service across the SUD treatment continuum: early intervention, outpatient treatment, intensive outpatient services or partial hospitalization, residential inpatient services, and medically managed intensive inpatient services.

Within the five broad levels, there are additional gradations, resulting in nine discrete levels of care that each have specific treatment and provider requirements (Table 4-1). Each of these nine levels of care reflects differing degrees of service intensity that correspond to a specific service. For example, within ASAM level 2.0, there are two discrete levels of outpatient care that range from 9 or more hours of service per week in an intensive outpatient program (ASAM level 2.1) to 20 or more hours of service per week in a partial hospitalization program (ASAM level 2.5). At both levels, services may include family therapy, group counseling,

medication management, and other strategies to engage patients in their recovery process.

The ASAM criteria also define a multidimensional assessment framework that assists providers in creating a patient’s individualized treatment plan and identifying the clinically appropriate level of care for that individual.<sup>2</sup> To ensure appropriate patient placement, states with approved Section 1115 SUD demonstrations must require providers to use a patient placement assessment tool, such as one based on the ASAM criteria framework, to assess an individual’s treatment needs.

**TABLE 4-1. Summary of the American Society of Addiction Medicine Criteria Levels of Care for Adults** T 4-1

ASAM level of care		Functional limitations of individual
<b>0.5 Early intervention</b>		
0.5 Early intervention	Assessment and education for at-risk individuals who do not meet diagnostic criteria for substance use disorder.	None or minimal.
<b>1.0 Outpatient services</b>		
1.0 Outpatient services	Fewer than nine hours of service per week for recovery or motivational enhancement therapies or strategies.	Needs motivating and monitoring strategies to support recovery.
<b>2.0 Intensive outpatient services/partial hospitalization</b>		
2.1 Intensive outpatient services	Nine or more hours of service per week to treat multidimensional instability.	Minimal risk of severe withdrawal. Mild emotional, behavioral, or cognitive complications. Has variable engagement in treatment.
2.5 Partial hospitalization	Twenty or more hours of service per week for multidimensional instability not requiring 24-hour care.	Moderate risk of severe withdrawal. Mild to moderate emotional, behavioral, or cognitive complications. Has poor engagement in treatment.
<b>3.0 Residential inpatient services</b>		
3.1 Clinically managed low-intensity residential services	Twenty-four-hour structure with available trained personnel; at least five hours of clinical service per week or as step-down from more intensive care.	No withdrawal risk or minimal or stable withdrawal. Problems in the application of recovery skills, self-efficacy, or lack of connection to the community systems of work, education, or family life.

**TABLE 4-1. (continued)**

ASAM level of care		Functional limitations of individual
3.3 Clinically managed population-specific high-intensity residential services	Twenty-four-hour care with trained counselors to stabilize multidimensional imminent danger. Less intense milieu and group treatment for those with cognitive or other impairments unable to use full active milieu or therapeutic community.	At minimal risk of severe withdrawal. Limitations are primarily related to cognitive impairment, which can be either temporary or permanent. Limitations may result in problems in interpersonal relationships, emotional coping skills, or comprehension.
3.5 Clinically managed high-intensity residential services	Twenty-four-hour care with trained counselors to stabilize multidimensional imminent danger and prepare for outpatient treatment. Able to tolerate and use full active milieu or therapeutic community.	At minimal risk of severe withdrawal. Multiple limitations, which may include criminal activity, psychological problems, impaired functioning, and disaffiliation from mainstream values.
3.7 Medically monitored intensive inpatient services	Twenty-four-hour nursing care with physician availability for significant problems in acute intoxication, withdrawal potential, or both; biomedical conditions and complications; above symptoms may or may not be accompanied by emotional, behavioral, or cognitive conditions and complications. Counselor availability 16 hours per day.	At high risk of withdrawal. Subacute biomedical and emotional, behavioral, or cognitive problems.
<b>4.0 Medically managed intensive inpatient services</b>		
4.0 Medically managed intensive inpatient services	Twenty-four-hour nursing care and daily physician care for severe, unstable problems in acute intoxication, withdrawal potential, or both; biomedical conditions and complications; above symptoms may or may not be accompanied by emotional, behavioral, or cognitive conditions and complications. Counseling available to engage patient in treatment.	At high risk of withdrawal. Acute biomedical and emotional, behavioral, or cognitive problems.

**Note:** ASAM is American Society of Addiction Medicine. The ASAM criteria comprise a set of guidelines for assessing and making treatment decisions for individuals with addiction and co-occurring conditions. The criteria describe nine discrete levels of care, each with specific treatment and provider requirements. For a full description of the levels of care, see *The ASAM criteria: Treatment criteria for addictive, substance-related, and co-occurring conditions* (<https://www.asam.org/resources/the-asam-criteria/text>).

**Source:** Mee-Lee et al. 2013.

**Application to individuals eligible for Medicaid.** The ASAM criteria can be used to determine the level of care needed by adults and adolescents regardless of insurance status. They also take into account the unique needs of subpopulations that are often covered by Medicaid, including adults age 65 and older who are dually eligible for Medicaid and Medicare; parents or prospective parents, including

pregnant women; and individuals in the criminal justice system, a traditionally uninsured population that now may be eligible for Medicaid coverage upon release in states that adopted the Medicaid expansion to the new adult group under the Patient Protection and Affordable Care Act (ACA, P.L. 111-148, as amended) (Box 4-1).

### **BOX 4-1. Application of the American Society of Addiction Medicine Criteria: Select Adult Populations**

**Older adults.** The American Society of Addiction Medicine (ASAM) criteria note that older adults are more likely to struggle with social isolation, which can hinder their recovery process, and describe additional services older adults may need for recovery support. For example, twelve-step programs may alleviate their isolation issues. Older adults are also more likely than the general population to have chronic health conditions that require multiple medications. Often those drugs can interact with medications used to treat opioid use disorder. Finally, extra attention to discharge planning may be needed to link individuals to aging services or other community supports, particularly if they are caring for an aging partner.

**Parents or prospective parents.** The ASAM criteria identify additional considerations for this subpopulation. In many instances, parents or prospective parents with a substance use disorder (SUD) may need therapy that includes family members. For example, additional counseling may need to be arranged for a parenting couple or for extended family members, including a non-custodial parent. Sometimes concurrent treatment with the parent and child is necessary.

According to the ASAM criteria, the accepted standard of care is to provide opioid-addicted pregnant women access to medication-assisted treatment (MAT). Such treatment can stabilize the pregnant woman and protect the fetus from episodes of withdrawal. When initiating MAT, providers must counsel the woman regarding neonatal abstinence syndrome and ensure connections to prenatal care.

The ASAM criteria also recommend helping connect patients to supportive relationships and services early in treatment, including supportive family members and public programs like Temporary Assistance for Needy Families (TANF). Navigating these services can be overwhelming for parents or prospective parents and, for individuals leaving inpatient treatment, connections to these services before discharge are critical to continued recovery.

**Individuals involved in the criminal justice system.** The ASAM criteria acknowledge that the objectives of public safety and desirable clinical outcomes may not always align with an individual's treatment needs. The court system often mandates specific levels of care, such as residential treatment. This typically occurs due to a misconception that residential treatment is superior to other levels of SUD care. The court system may also mandate specific lengths of stay for populations involved in the criminal justice system. However, fixed lengths of stay are not person-centric and do not account for the individual's specific treatment needs.

### BOX 4-1. (continued)

Therapy may need to be further personalized for this population to address the behaviors that are related to their criminal offenses. If an individual relapses while participating in community-based, court-ordered treatment, conducting a multidimensional assessment and intensifying the level of clinical services needed for an individual may be warranted in lieu of incarceration. Additional support may be needed to reintegrate the individual in the community during the transition from a prison or jail setting. Support might include referrals to safe housing resources, job readiness training, and employment services.

**Notes:** ASAM is American Society of Addiction Medicine. The ASAM criteria comprise a set of guidelines for assessing and making treatment decisions for individuals with addiction and co-occurring conditions. For a full description of the criteria, see *The ASAM criteria: Treatment criteria for addictive, substance-related, and co-occurring conditions* (<https://www.asam.org/resources/the-asam-criteria/text>). For individuals involved in the criminal justice system, mandated treatment times required by the court system may conflict with medical necessity standards for payers, including state Medicaid programs and managed care organizations. In some instances, court-mandated treatment may also prohibit certain treatment modalities, specifically medication-assisted treatment.

**Source:** Mee-Lee et al. 2013.

Although the ASAM criteria mention additional factors that providers may need to consider when initiating treatment for an individual from one of these special populations, other variables may also inform treatment needs. The ASAM criteria recommend that a multidimensional assessment be conducted to account for the distinct needs of the individual. For example, parents may need to receive outpatient rather than residential treatment to remain connected to their community so they can maintain employment or remain in contact with children, extended family, or other individuals or organizations in their support system.

**Treatment progression.** As individuals move through the continuum, appropriate transitions between levels of treatment are important for ensuring continuity of care. In general, a patient with a severe SUD should stay engaged for at least one year in the treatment process; this may involve participation in three to four different programs or services with varying intensities. A typical progression for an individual with a severe SUD, where withdrawal potential is life-threatening, might start with three to seven days in a medically managed withdrawal program followed by a period

of intensive 24-hour care in a residential treatment program. Care could continue after discharge from residential treatment, first in an intensive outpatient program that meets two to five days a week for a few months and then in a traditional outpatient program that meets less frequently. Such an approach would be responsive to patients' changing needs as they gradually develop the ability to self-manage their SUDs. For patients whose living situations are not conducive to recovery, outpatient services may need to be provided in conjunction with non-clinical services such as housing (OSG 2016). It is important to note that recovery is not always linear and individuals often move from less intensive to more intensive settings during their recovery.

## Variation in Medicaid SUD Coverage by State

Medicaid's role in the coverage and financing of SUD treatment varies considerably across states. Nearly all state Medicaid programs offer some form of SUD services; however, most do not cover all of



the levels of care described in the ASAM criteria for adults age 21–64. The largest gaps in coverage exist for residential SUD treatment (Appendix 4A-1). In part, this may be attributable to the IMD exclusion, especially in states where the majority of residential treatment facilities are considered IMDs. (A detailed discussion of the IMD exclusion occurs later in this chapter.)

Coverage gaps also exist at other levels of care, even where there are no federal Medicaid policy barriers that affect a state's ability to pay for a given service (Appendix 4A-1). Many SUD services are optional under the Medicaid statute, and states may opt not to cover these for a variety of reasons. For example, gaps in coverage of partial hospitalization may reflect state policies designed to mirror those of Medicare. In other cases, state Medicaid programs may deliberately choose not to cover services available to beneficiaries through the use of non-Medicaid funding sources. State Medicaid programs often work with other agencies, such as the single state substance use authority that receives block grants for prevention, treatment, and recovery support from SAMHSA to ensure that block grant funding complements Medicaid-financed care.

In addition, the services that are provided to Medicaid beneficiaries vary among Medicaid eligibility groups. In states that expanded Medicaid to the new adult group, these beneficiaries are entitled to coverage of 10 essential health benefits, including SUD treatment services (CMS 2017a).<sup>3</sup> For children enrolled in Medicaid, states must pay for SUD treatment when it is medically necessary, as required by the early and periodic screening, diagnostic, and treatment (EPSDT) benefit.<sup>4</sup> Although coverage for behavioral health services such as SUD treatment is not mandatory in separate CHIP, as of 2013, nearly all states covered some form of outpatient and inpatient SUD treatment (MACPAC 2015, Cardwell et al. 2014).

To determine whether states offer a full SUD continuum of care, the Commission used the ASAM criteria and the levels of care it describes as a

framework. Specifically, the Commission reviewed state documentation including Medicaid state plans, provider manuals, enrollee handbooks, fee schedules, Section 1115 SUD demonstrations, and other publicly available materials to independently align service descriptions with the ASAM levels of care. In instances where publicly available information was insufficient to determine coverage, MACPAC contacted states directly. MACPAC's categorization of state-level coverage approximates the closest level of care described by the ASAM criteria.<sup>5</sup>

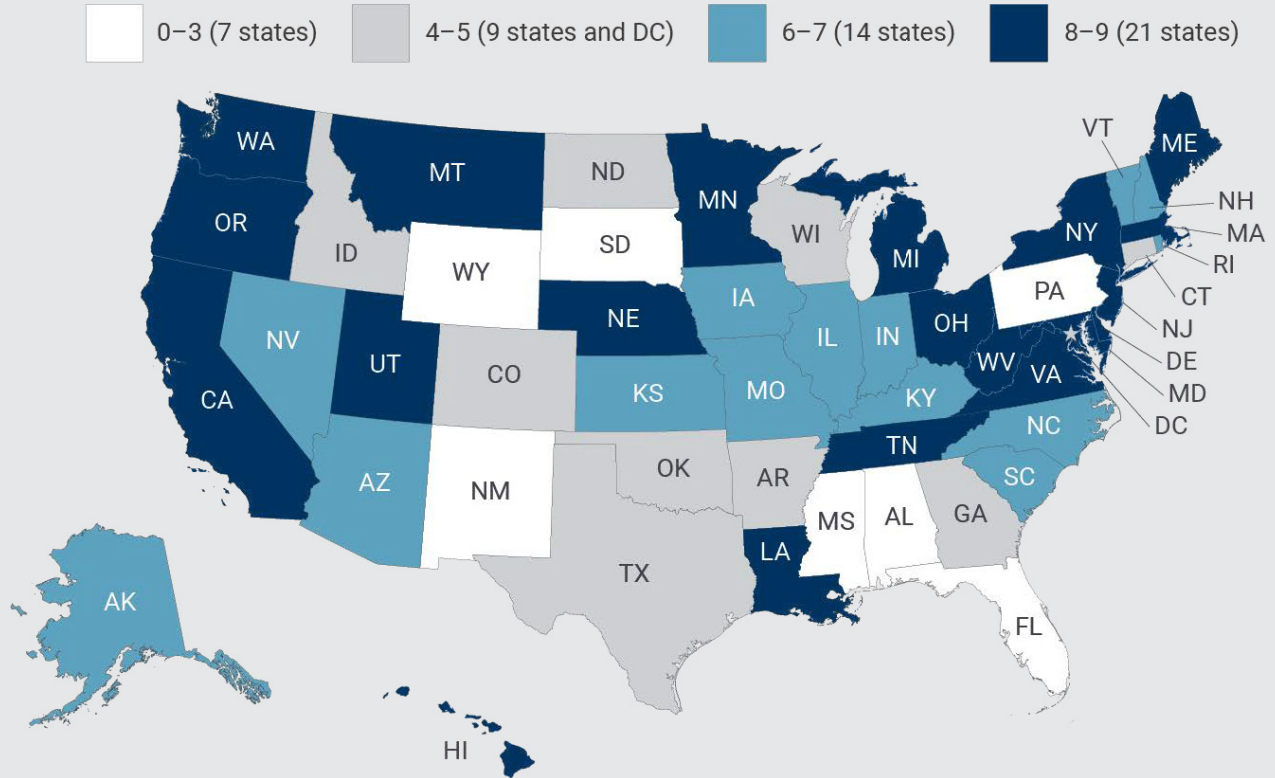
Our analysis found that most states have gaps in SUD coverage, covering on average just six of the nine levels of care described by the ASAM criteria (Figure 4-1). Nearly half of states (24) provide four to seven levels of care. Seven states cover up to three levels of care. Only 12 states offer the full continuum of care, that is, each of the nine ASAM levels of care (Appendix 4A-1).

Gaps in care can be categorized by the number of services covered in a given state. Of the seven states that offer zero to three services, none pay for residential SUD treatment. Most also do not pay for early intervention (ASAM level 0.5), intensive outpatient services (ASAM level 2.1), or partial hospitalization services (ASAM level 2.5). In many instances, these states only pay for outpatient services (ASAM level 1.0) and medically managed intensive inpatient treatment (ASAM level 4.0), creating substantial gaps in the continuum.

Nine states and the District of Columbia pay for four to five services. All of them pay for outpatient services (ASAM level 1.0), and all but one state pays for early intervention (ASAM level 0.5). Only two states do not pay for intensive outpatient treatment (ASAM level 2.1). Most of these states do not pay for partial hospitalization (ASAM level 2.5) and five pay for only one of the levels of care for residential SUD treatment identified by the ASAM criteria.

Fourteen states cover six to seven services and all of them pay for outpatient services (ASAM level 1.0). Only one state does not pay for early intervention (ASAM level 0.5) and intensive

**FIGURE 4-1. State Medicaid Program Coverage of American Society of Addiction Medicine Criteria Levels of Care, 2018**



**Notes:** ASAM is American Society of Addiction Medicine. The ASAM criteria comprise a set of guidelines for assessing and making treatment decisions for individuals with addiction and co-occurring conditions. The criteria describe nine discrete levels of care, each with specific treatment and provider requirements. For a full description of the levels of care, see *The ASAM criteria: Treatment criteria for addictive, substance-related, and co-occurring conditions* (<https://www.asam.org/resources/the-asam-criteria/text>). Estimate of the number of states covering services in the ASAM criteria levels of care is based on MACPAC’s analysis of coverage under state plan authority and approved Section 1115 substance use disorder (SUD) demonstrations. Many state Medicaid agencies do not use the ASAM criteria to determine SUD treatment coverage or require providers to use them for patient assessment purposes. For residential treatment services, states use a variety of terms to describe coverage. For the purposes of this analysis, states providing low-intensity or long-term residential treatment were classified as covering ASAM level 3.1; those providing medium-intensity residential SUD treatment were classified as covering ASAM level 3.5; and states covering high-intensity or short-term residential treatment were classified as providing ASAM level 3.7.

**Sources:** MACPAC, 2018, analysis of Medicaid state plan and Section 1115 demonstration coverage. Mee-Lee et al. 2013.

outpatient services (ASAM level 2.1). The majority of these states pay for partial hospitalization (ASAM level 2.5). Most of these states also pay for at least two of the levels of care defined by ASAM that are considered residential SUD treatment (ASAM level 3.0).

### Coverage of residential treatment and the IMD exclusion

The largest coverage gaps in the continuum of care are for intensive outpatient or partial hospitalization (ASAM level 2.0) and residential treatment (ASAM level 3.0). Most states (43 states and the District of Columbia) pay for intensive outpatient services (ASAM level 2.1); however, partial hospitalization

(ASAM level 2.5) is covered in only 33 states. Thirty-eight states and the District of Columbia cover at least one level of residential SUD care described by the ASAM criteria. Seventeen states cover all four residential levels of care. Sixteen states and the District of Columbia pay for two or three services. Five states pay for just one level of residential SUD care.

Identifying gaps in coverage for residential treatment is of particular interest given that Medicaid programs are not allowed to receive federal payment for inpatient care provided to individuals age 21–64 who are patients in an IMD. An IMD is defined as a hospital, nursing facility, or other institution of more than 16 beds that is primarily engaged in providing diagnosis, treatment, or care of persons with mental diseases. The Medicaid IMD exclusion is one of the few instances in the Medicaid program in which federal financial participation (FFP) is not available for medically necessary and otherwise covered services for certain Medicaid beneficiaries receiving treatment in a specific setting.

Although the IMD exclusion applies to residential SUD treatment facilities of more than 16 beds, states can still pay for residential SUD treatment for this population in facilities with 16 beds or fewer. In fact, many states that pay for residential SUD services do so in facilities of this size. Nevertheless, in 2015, CMS recognized that the IMD exclusion was acting as a barrier to accessing SUD treatment in these settings and offered states two pathways to pay for IMD stays under certain circumstances: as an in-lieu-of service in managed care settings and through Section 1115 demonstrations.<sup>6</sup>

**Managed care.** Under current managed care regulations, states may receive FFP for capitation payments made on behalf of an enrollee age 21–64 who is receiving inpatient treatment in an IMD for a short-term stay of no more than 15 days during the period of the monthly capitation payment, so long as the facility is a hospital providing SUD inpatient care or a subacute care facility providing SUD crisis residential services. The 15-day limit was selected

based on multiple data sources and to ensure that during the month in which a capitation payment is made, beneficiaries are eligible to receive services in the community (CMS 2016). This regulation does not extend to states that provide SUD services in a fee-for-service delivery system or non-risk-based managed care arrangements.

Although some states have welcomed the opportunity to provide crisis residential SUD services in IMDs for the limited time period allowed, other states view the 15-day limit as too rigid.<sup>7</sup> Prior to the issuance of the current managed care regulations in 2016, managed care organizations (MCOs) had historically used in-lieu-of services to pay Medicaid benefits in alternate settings without day limits. CMS estimates that in 2010, approximately 17 states were using the in-lieu-of provision to pay for services in IMDs and another 9 states were potentially using this provision (GAO 2017). Thus, when the 15-day limit was imposed, some states viewed this action as more restrictive. Some stakeholders have further criticized the 15-day limit as being arbitrary and not meeting the needs of individuals with an SUD.

CMS has advised that Medicaid managed care plans should not be used to pay for services for which coverage and payment are prohibited by Medicaid statute (CMS 2016). Absent a change in statute, it is unclear if federal regulations could be further revised to pay for IMD services for longer periods of time. In an ideal environment, Medicaid MCOs would implement day limits for residential SUD services that reflect what is medically necessary. CMS advised that Section 1115 demonstrations are available to states seeking to provide services beyond the 15-day limit.

**Section 1115 demonstrations.** In July 2015, CMS issued guidance allowing states to receive FFP for SUD care in IMDs under a Section 1115 demonstration, if they could demonstrate that residential service providers meet the ASAM criteria (CMS 2015). On November 1, 2017, CMS sent a letter to state Medicaid directors outlining a number




of changes to the policy (discussed later in this chapter) (CMS 2017c).

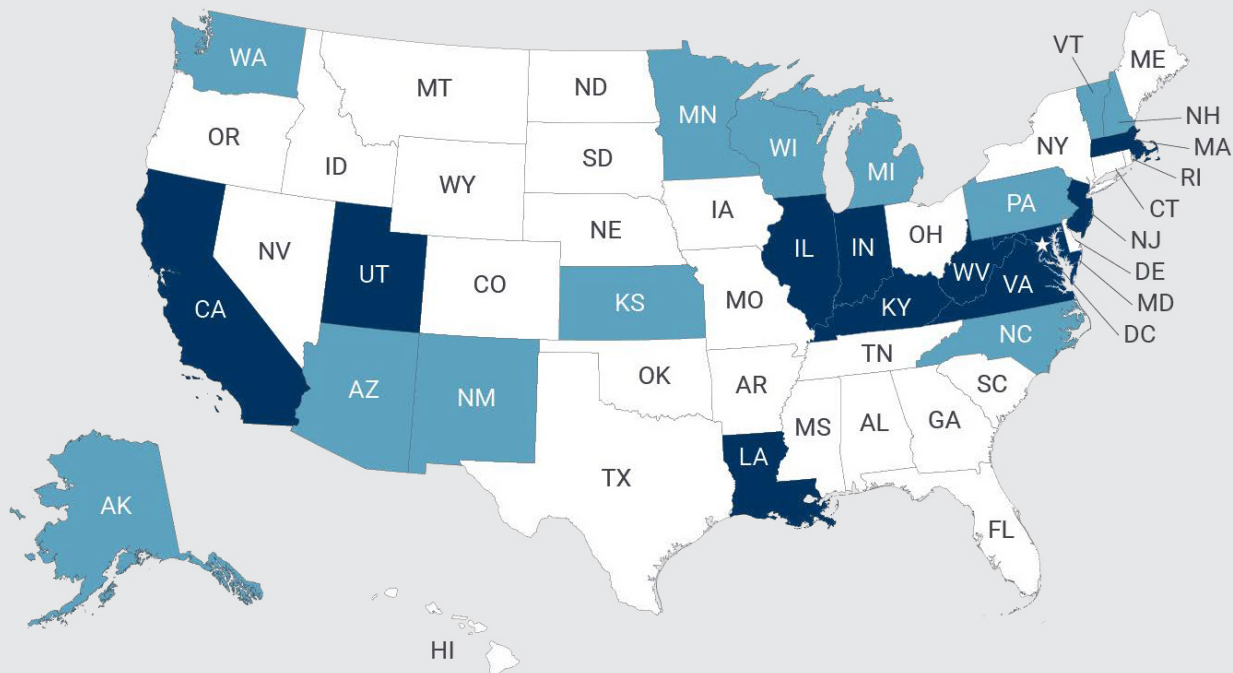
To date, 23 states have sought authority via Section 1115 to provide residential SUD treatment in IMDs (Figure 4-2). In addition to paying for services in IMDs, some states are undertaking broader delivery system reforms. California, Maryland, Virginia, and West Virginia have approved demonstrations under the 2015 guidance. Massachusetts also has an approved demonstration under that guidance and an additional amendment to further expand their authority is pending approval. Illinois, Indiana, Kentucky, Louisiana, New Jersey, and Utah have received approval under the 2017 guidance, and West Virginia agreed to meet the reporting

and evaluation requirements under the new guidance. Several states—Alaska, Arizona, Kansas, Michigan, New Hampshire, New Mexico, North Carolina, Pennsylvania, Vermont, Washington, and Wisconsin—have pending Section 1115 applications or amendments seeking similar demonstration authority (CMS 2018).

Demonstration design components vary, with some states instituting day limits for IMD stays under approved and pending Section 1115 demonstrations. Generally, states have to maintain an average length of stay of 30 days. Of the 23 approved or pending demonstrations, more than half do not have explicit day limits in their special terms and conditions or demonstration

**FIGURE 4-2. States with Approved or Pending Section 1115 Substance Use Disorder Medicaid Demonstrations, 2018**

 Approved (11 states)     Pending (12 states)     No waiver (27 states and DC)



**Note:** This map reflects states with approved or pending Section 1115 substance use disorder demonstrations as of May 23, 2018.

**Source:** MACPAC, 2018, analysis of Section 1115 substance use disorder Medicaid demonstrations (CMS 2018).

applications. Day limits in states that do have explicit day limits in their approved demonstrations range from 30- to 90-day stays. In Massachusetts, the average length of stay in SUD treatment for individuals admitted to residential programs (ASAM levels 3.1, 3.5, and 3.7) during state fiscal year 2015 was 16.1 days (CMS 2017b). In comparison, California has reported the majority (56.2 percent) of residential treatment admissions resulted in lengths of stay of 30 days or longer (Urada et al. 2017). It may be difficult for states to determine an appropriate length of stay for residential SUD treatment because there is limited information on the association between specific lengths of stay and therapeutic gains, and about whether individuals with OUD have better treatment results in residential settings than in outpatient settings. The ASAM criteria acknowledge that further research is needed to predict typical lengths of stay for residential SUD treatment.

## Medicaid coverage of medication-assisted treatment

For individuals who have an OUD, current evidence-based guidelines recommend the use of MAT, which combines medication with counseling, behavioral therapies, and recovery support services (VA/DoD 2015, ASAM 2015).<sup>8</sup> The use of MAT was described in detail in MACPAC's June 2017 report (MACPAC 2017a).

Much of the policy discussion about MAT has focused on state policies for drug coverage, specifically, the coverage of the three medications approved to treat OUD: buprenorphine, methadone, and naltrexone. However, drug coverage must be evaluated in combination with the treatment settings paid for by state Medicaid programs. In many instances, the setting MAT is delivered in, such as an opioid treatment program (OTP) or primary care office, is as important as the medication selected to treat an individual.

**Payment for OUD medications.** Although prescription drug coverage is not a federally mandated Medicaid benefit, all states and the

District of Columbia offer this benefit, which includes some coverage of medications used to treat SUD. Currently, all states and the District of Columbia pay for buprenorphine and 48 states and the District of Columbia pay for naltrexone. States are not required to pay for methadone in the treatment of OUD; however, 37 states and the District of Columbia cover methadone treatment services in Medicaid (Appendix 4A, Table 4A-1) (KFF 2018).

**MAT treatment settings.** Depending on a patient's individual needs, MAT can be used at many levels of care defined by the ASAM criteria. Each of the levels of care corresponds to treatment services that include counseling and therapy, and the intensity of those treatment services varies at each level of care. A partial hospitalization or residential SUD program could have a physician on-site to prescribe buprenorphine or naltrexone as a complement to the intensity of therapy the individual is receiving. In some instances, a program could also obtain certification to function as an OTP.<sup>9</sup>

OTPs provide an appropriate setting for individuals who require a structured environment and daily interaction with their treatment providers. In accordance with federal law, OTPs are the only setting in which methadone can be dispensed for the treatment of OUD, and they must be certified and regulated by SAMHSA (Bagalman 2015). OTPs, in addition to offering daily, supervised dosing of methadone, are increasingly offering buprenorphine. OTP services must also include clinically appropriate counseling and therapy. If states choose not to pay for OTP services, Medicaid beneficiaries with OUD will not have access to methadone. (The limited availability of OTPs is discussed later in this chapter.)

MAT can also be provided in a general medical office. Office-based treatment provides medication on a prescribed weekly or monthly basis and is limited to buprenorphine and naltrexone. Federal law requires practitioners prescribing buprenorphine to offer psychosocial counseling, and if that counseling is not available on-site, they must demonstrate that they have the existing referral

relationships to refer patients to counseling (MACPAC 2017a). Practitioners prescribing buprenorphine in general medical settings are also limited in the number of patients to whom they may prescribe.<sup>10</sup>

Naltrexone can be prescribed in any setting by any clinician with the authority to prescribe medication. For practitioners offering naltrexone, there is no federally mandated counseling requirement. However, the ASAM criteria indicate that psychosocial treatment is recommended in conjunction with naltrexone. Office-based treatment with buprenorphine or naltrexone may not be suitable for individuals requiring daily dosing and supervision or for individuals with active alcohol use disorders or those who use sedatives due to potentially deadly drug interactions.

## Non-clinical services

Due to the chronic nature of SUDs, individuals may need additional non-clinical services to support their recovery. For instance, an individual's living environment, school, or work situation affects their ability to engage in treatment. Similarly, the support of friendships and social institutions can increase the likelihood of successful recovery. Availability of transportation, child care, and housing also contribute to an individual's recovery environment (Mee-Lee et al. 2013).

Recovery supports are non-clinical services that are used to address an individual's environment and provide emotional and practical support to maintain remission. Individuals who both participate in treatment and take advantage of support services typically have better long-term outcomes than individuals who do only one of these things. Recovery supports are offered through both treatment programs and community organizations and are conducted by trained case managers, recovery coaches, and peers. Supports include peer support, supported employment, mutual aid groups such as 12-step groups, recovery housing, recovery checkups, telephonic case monitoring, and recovery community centers (OSG 2016). Recovery support

services may be needed even after clinical services, such as outpatient treatment, end.

In 2015, 14 states covered some form of peer support for SUDs and 9 states and the District of Columbia covered some form of supported employment under state plan authority (MACPAC 2017a). MACPAC is conducting additional research to examine state policies for covering recovery support services, including which populations are eligible for such services, and how coverage of these services complements coverage for the levels of care described by ASAM.

## Access to SUD Services in Medicaid

In addition to covering services, a robust delivery system must also ensure that treatment is readily available in an individual's community. Below we describe the availability of treatment in various settings and states, including outpatient, intensive outpatient, partial hospitalization, and residential treatment. The extent to which existing SUD treatment facilities participate in Medicaid is also examined. In general, the supply of these providers is limited, especially in rural areas, and the number of SUD treatment providers accepting Medicaid is low.

Two key factors influence the availability of providers: provider supply and provider participation in Medicaid. Overall, the availability of SUD providers is influenced by the distribution of providers, including the types of services offered by an SUD treatment facility, as well as state policies and providers' responses to those policies (e.g., provider payment, willingness to accept Medicaid, and workforce issues such as scope of practice). Each of these factors is explained in more detail below, including commonly used measures to describe access. Key factors related to provider availability include:

- the number and type of SUD providers in areas where Medicaid beneficiaries reside;

- the number and type of these providers participating in Medicaid;
- the settings used by Medicaid beneficiaries receiving SUD care; and
- policies enacted at the federal and state levels that influence provider participation, such as payment methodologies and how well they work.

Most individuals receive SUD treatment in outpatient settings and most commonly from specialty SUD treatment providers. However, the supply of these providers, especially for services such as partial hospitalization and residential SUD treatment, is low.

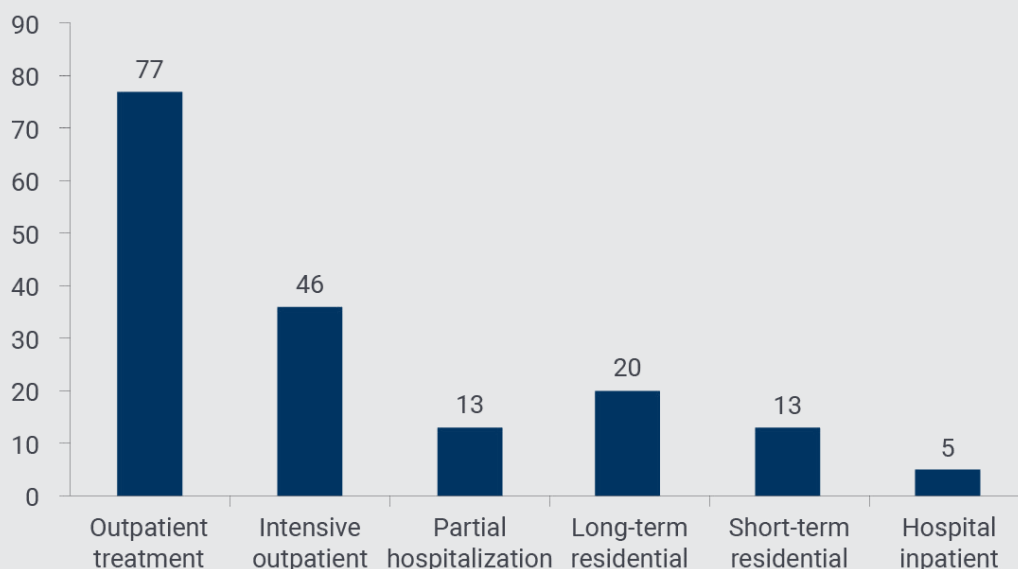
### Provider supply

Although no comprehensive source of data on the supply of professionals available to treat individuals with an SUD is available, multiple sources point to a shortage of trained providers (Cummings et al.

2014, OSG 2016, Rosenblatt et al. 2015). In 2016, nearly three-quarters of U.S. counties had severe shortages of psychiatrists and other types of health professionals needed to treat mental health and SUD services (OSG 2016). SUD treatment facilities provide more intense services—such as intensive outpatient services, partial hospitalization, and short-term residential treatment—less often than outpatient services (Figure 4-3). Although the degree to which SUD treatment facilities offer services varies, the majority of SUD treatment facilities provide outpatient services. Partial hospitalization and residential services, which are necessary for people with high withdrawal potential, are offered less frequently than outpatient services.

Little information is available regarding the settings in which Medicaid beneficiaries receive SUD treatment. Data sources not specific to Medicaid suggest that of individuals currently seeking SUD treatment on a given day, the overwhelming majority (91 percent) are receiving services in an outpatient setting; 8 percent receive non-hospital based

**FIGURE 4-3.** Percentage of Substance Use Disorder Treatment Facilities Offering Certain Services, 2016



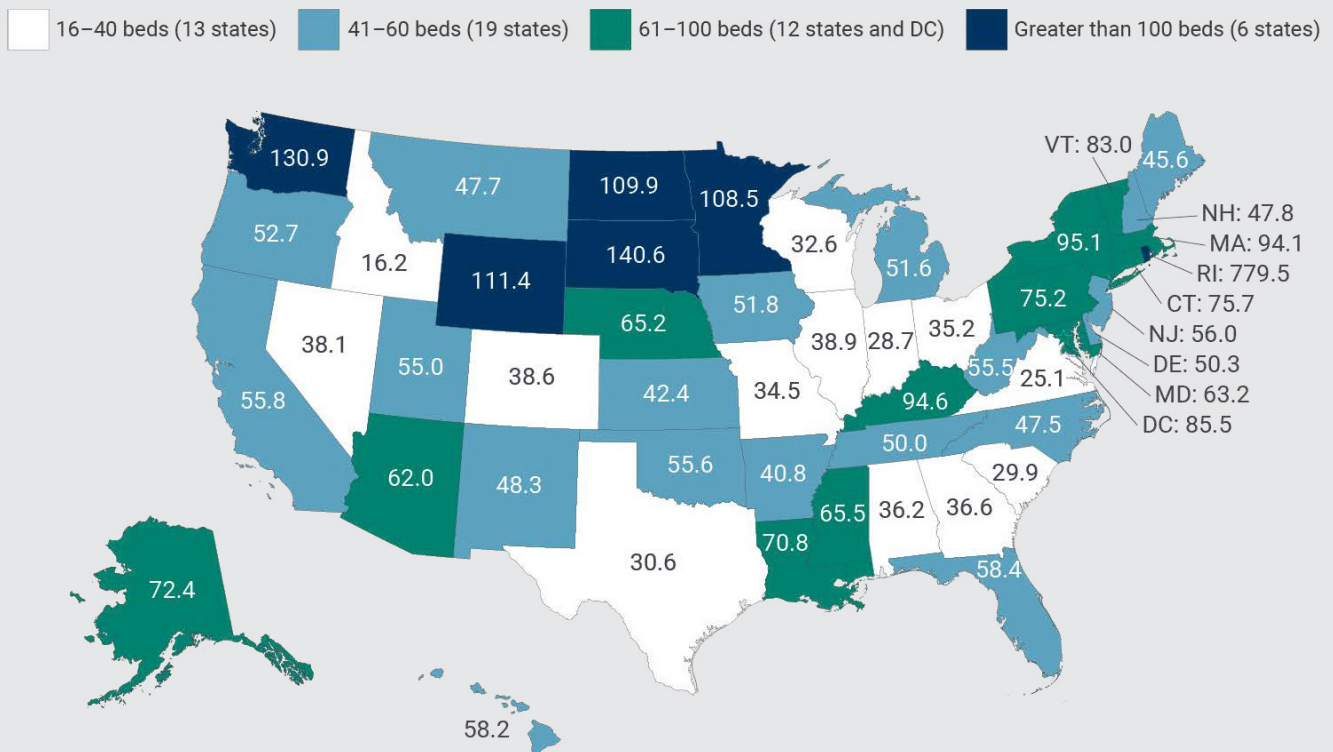
Source: MACPAC, 2018, analysis of SAMHSA 2017.

residential SUD treatment; and 1 percent receive inpatient hospital treatment (SAMHSA 2017).

An August 2017 study by the U.S. Government Accountability Office (GAO) found wide variation in SUD treatment capacity across states, with the

number of beds per 100,000 adults ranging from 16.2 in Idaho to 779.5 in Rhode Island in 2015 (Figure 4-4). GAO found that some small facilities maintained waiting lists or turned individuals away when beds were unavailable (GAO 2017).

**FIGURE 4-4. Number of Inpatient and Residential Substance Use Disorder Beds per 100,000 Adults by State, 2015**



Source: GAO 2017.

For the general population, access to providers offering MAT for OUD is also limited. Only 2.7 percent of specialty SUD facilities report that they offer all three forms of MAT. Eight states do not have any SUD facilities offering all three forms of MAT regardless of payer and 14 states do not have a facility offering all three forms of MAT that also accepts Medicaid (Jones et al. 2018). OTPs are mostly located in urban areas and often require patients to visit daily for on-site administration of

methadone, limiting the ability of rural patients to access such treatment (Dick et al. 2015).

In addition, few practitioners are authorized to prescribe buprenorphine. As of 2012, only 18,225 (2.2 percent) of U.S. physicians had obtained the federal waiver necessary to prescribe this medication. Generally, these physicians were concentrated on the East and West Coasts, with limited access in the middle of the country (Rosenblatt et al. 2015). However, the number of



practitioners capable of prescribing buprenorphine has been steadily increasing. As of March 2018, 47,446 practitioners, including physicians, nurse practitioners, and physician assistants, had obtained a waiver to prescribe buprenorphine. Presently, 72 percent of these providers are certified to prescribe buprenorphine to up to 30 patients, 19.3 percent are certified to prescribe to up to 100 patients, and 8.4 percent are certified to prescribe to up to 275 patients (SAMHSA 2018). Although practitioners are certified to prescribe up to a certain number of patients, studies have shown that practitioners generally prescribe well under their current patient limit (Thomas et al. 2017).

Despite limited access to MAT providers in some areas, spending data suggest that MAT is increasingly being used to treat Medicaid beneficiaries for OUD. Between 2011 and 2017 the number of buprenorphine units paid for by Medicaid increased 180 percent, from 51.7 million to 144.9 million units. Between 2011 and 2016, the number of naltrexone units paid for by Medicaid increased 244 percent, from 2.4 million to 8.3 million units. However, it is difficult to attribute increased naltrexone use to the treatment of OUD alone because it is also approved to treat alcohol use disorder (Clemans-Cope and Epstein 2018). Ultimately, additional research is needed to determine if Medicaid beneficiaries are using OTP services, whether there is variation in MAT utilization among state Medicaid programs, and whether Medicaid beneficiaries are accessing the counseling component of MAT.

## Provider participation

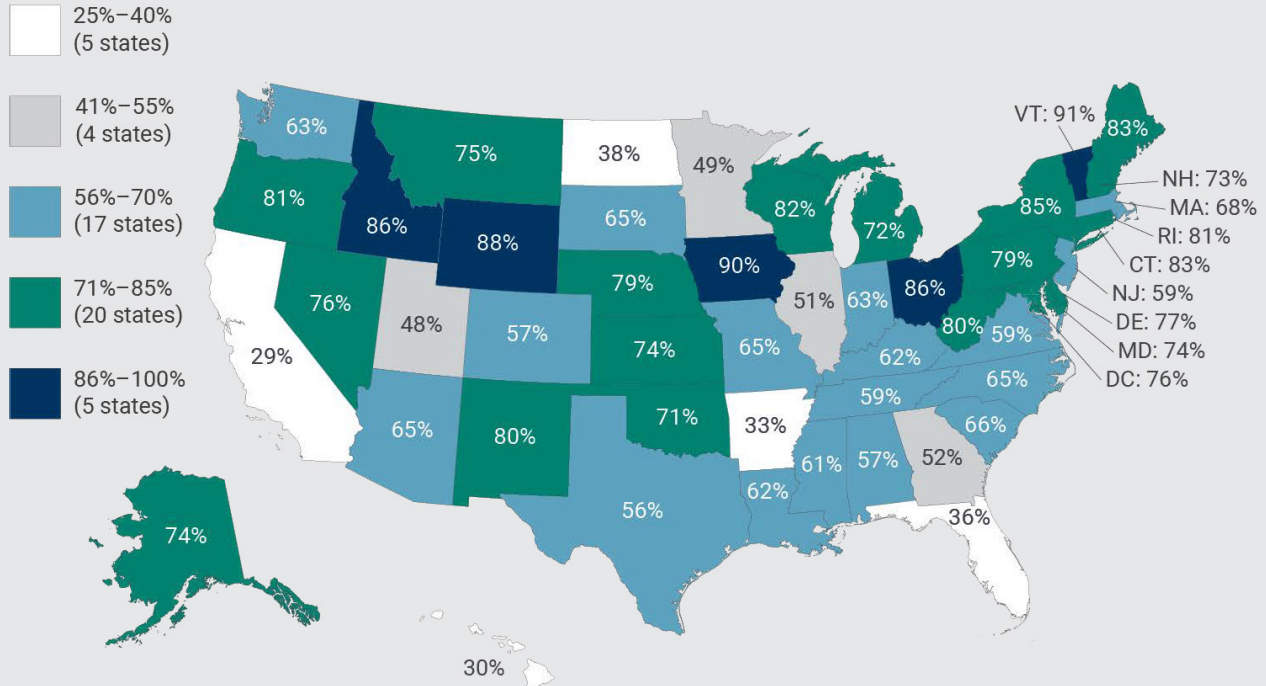
Low SUD provider participation in Medicaid also affects beneficiaries' access to SUD treatment. The SAMHSA National Survey of Substance Abuse Treatment Services (N-SSATS) survey data indicate that in 2016, 62 percent of specialty SUD facilities reported accepting Medicaid, which was lower than the acceptance rate for private insurance (68 percent) (SAMHSA 2017).<sup>11</sup> SUD provider participation in Medicaid also varies greatly by state (Figure 4-5). At the state level, specialty SUD

provider participation in Medicaid ranges from 29 percent in California to 91 percent in Vermont. One study noted that 60 percent of U.S. counties have at least one outpatient SUD facility that accepts Medicaid, although this rate is lower in many southern and midwestern states. Counties with a higher percentage of black, rural, or uninsured residents are less likely to have one of these facilities (Cummings et al. 2014).

About half of the specialty SUD treatment facilities that offer outpatient treatment participate in Medicaid, but providers of more intensive services are much less likely to be available to Medicaid beneficiaries (Figure 4-6). Facilities may offer services across multiple ASAM levels of care; therefore, the percentage of facilities accepting Medicaid is not necessarily indicative of the percentage of facilities that accept Medicaid payment for a specific level of service. For example, a provider offering two services, partial hospitalization (ASAM level 2.5) and outpatient treatment (ASAM level 1.0), may report accepting Medicaid, but the state Medicaid program may only cover one of the services. Facilities offering partial hospitalization and different intensities of residential services (ASAM level 3.0) accept Medicaid at a lower rate overall.<sup>12</sup>

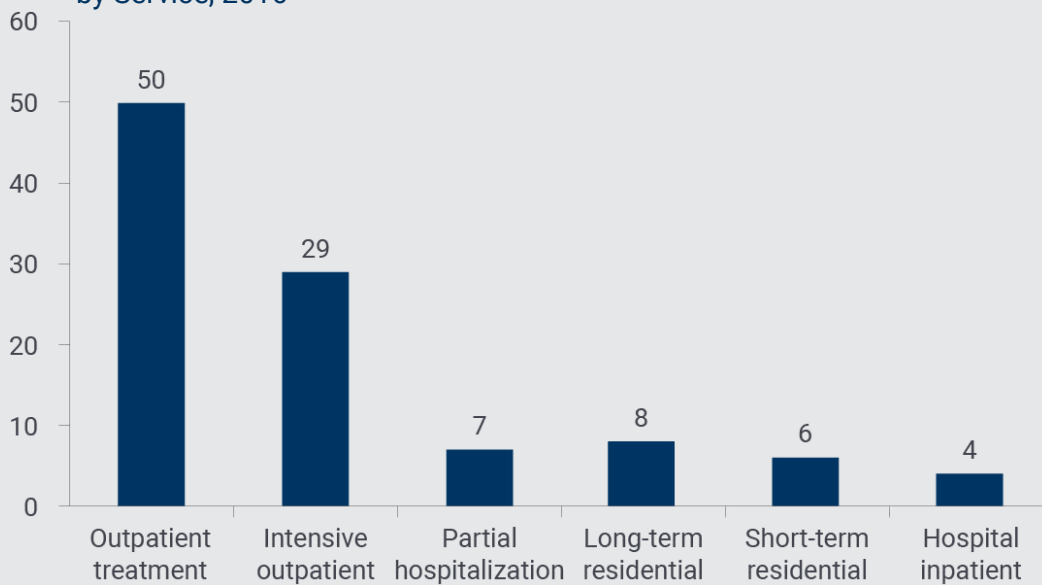
Lower Medicaid participation rates among specialty SUD treatment providers may reflect additional barriers. Different credentialing requirements for Medicaid MCOs may be burdensome for certain providers, who then choose not to participate in Medicaid. In an effort to address these concerns, some states, such as Virginia, have instituted uniform credentialing requirements across all MCOs. Similarly, many SUD treatment providers do not hold the medical licenses required by some payers and traditionally, many of these providers have not contracted with insurers (ASPE 2015, SAMHSA 2012). A 2012 survey also found that many specialty SUD treatment providers did not have adequate information technology systems needed to bill insurers, which posed a challenge to providing care to individuals newly covered under the ACA (Andrews et al. 2015).

**FIGURE 4-5.** Percentage of Substance Use Disorder Treatment Facilities Accepting Medicaid, by State, 2016



Source: MACPAC, 2018, analysis of SAMHSA 2017.

**FIGURE 4-6.** Percentage of Substance Use Disorder Treatment Facilities Accepting Medicaid, by Service, 2016



Source: MACPAC, 2018, analysis of SAMHSA 2017.

Although we know that approximately 69 percent of physicians in the United States reported accepting new Medicaid-enrolled patients in 2016, it remains unclear how many physicians, physician assistants, and nurse practitioners who are authorized to prescribe buprenorphine are participating in the Medicaid program (Hing et al. 2015). Additional research is needed to determine the actual availability of buprenorphine-prescribing clinicians to Medicaid beneficiaries.

## Opportunities to Improve the SUD Delivery System

MACPAC has previously documented that federal law offers state Medicaid programs several avenues to build or expand their SUD continuum of care (MACPAC 2017a). States can cover all of the levels of care described in the ASAM criteria through their state plan. However, many states do not do so, resulting in gaps in coverage for partial hospitalization and residential treatment in particular. Barriers to care often extend beyond the IMD exclusion.

Section 1115 SUD demonstrations are another option available to states to address gaps. The experience to date of states that are in the early phases of implementing Section 1115 SUD demonstrations indicates that a multipronged strategy can promote the full continuum of care, provide access to specialty SUD providers, and incentivize provider participation in Medicaid (Urada et al. 2017, VDMAS 2018).

Below we discuss recent Section 1115 SUD demonstration guidance and how states are using demonstrations to improve their SUD continuum of care.

### Section 1115 SUD demonstration development

Much attention has been paid to the Section 1115 SUD demonstration opportunity because it

allows states to pay for treatment in IMD settings. But relief from the IMD exclusion is only one component of such demonstrations. To receive approval and FFP for IMD services, states must develop a comprehensive strategy to improve their SUD delivery system that goes beyond payment for residential treatment. Guidance issued by CMS in November 2017 requires states seeking a demonstration to cover critical levels of care including outpatient, intensive outpatient, MAT, residential, inpatient, and medically supervised withdrawal management. Inpatient and residential SUD care must supplement and coordinate with community-based care that is part of a broader continuum. States must also implement provider requirements and meet stringent reporting requirements (Box 4-2).

As such, many of the Section 1115 demonstrations that have been approved thus far include broad strategies to improve access to and quality of SUD treatment services. California's demonstration requires a strategy to coordinate and integrate across systems of care, and Maryland's demonstration includes a strategy to integrate physical and behavioral health outcomes over the course of the demonstration. Other states, including West Virginia and Kentucky, have Section 1115 demonstrations that expand the use of methadone treatment. Some states, including West Virginia and Massachusetts, are also providing recovery support services such as peer support through their demonstrations.

### Section 1115 demonstration findings

Although several demonstrations have been approved by CMS, few have been implemented long enough to be evaluated. Two states—California and Virginia—were early adopters of Section 1115 SUD demonstrations. In addition to offering insight on the provision of residential treatment in IMD settings, these states are taking additional steps, such as capacity building and raising provider rates, to increase the availability of SUD treatment providers.

## BOX 4-2. Section 1115 Substance Use Disorder Medicaid Demonstration Requirements, 2017

In November 2017, CMS issued revised guidance outlining parameters for states to obtain a Section 1115 demonstration to pay for short-term inpatient and residential substance use disorder (SUD) treatment services in institutions of mental diseases (IMDs). The 2017 guidance replaced guidance that was issued in July 2015 and requires states to meet the following criteria:

- **Provider capacity.** Within 12 months of approval, states must complete an assessment of the availability of providers enrolled in Medicaid and accepting new patients at the following levels of care: medication-assisted treatment (MAT), outpatient, intensive outpatient, residential, inpatient, and medically supervised withdrawal management.
- **Phased-in provider requirements.** Between 12 and 24 months following demonstration approval, states must ensure that residential providers meet the ASAM criteria or other nationally recognized, evidence-based SUD-specific program standards, and that residential providers offer their patients access to MAT. During the initial implementation period, interim provider qualifications included in the demonstration's special terms and conditions will be used so that states can receive federal financial participation (FFP) as they work toward implementing the national standard.
- **Patient placement criteria.** Between 12 and 24 months following demonstration approval, states must require providers to use an evidenced-based, SUD-specific patient assessment tool. Within 24 months of demonstration approval, states must also ensure that there is an independent utilization management approach that ensures beneficiaries have access to services at the appropriate level of care, that interventions are appropriate for the diagnosis and level of care, and that there is an independent process for reviewing placement in residential settings.
- **Opioid prescribing, naloxone, and prescription drug monitoring.** Throughout the course of the demonstration, states must implement opioid prescribing guidelines and other strategies to prevent opioid abuse. They must also expand coverage of and access to naloxone for overdose reversal. Strategies to increase the use of prescription drug monitoring programs and to improve their functionality are also required.
- **Care coordination strategies.** Between 12 and 24 months following demonstration approval, states must implement policies to ensure that residential and inpatient facilities link beneficiaries, especially those with an OUD, with community-based services and supports following stays in these facilities.
- **Evaluation and reporting.** Through their regular Section 1115 demonstration reports, states are required to include information on performance measures and milestones. CMS is developing a standardized set of reporting requirements and performance measures for these SUD demonstrations, but has not said when they will be finalized and is still determining which measures will be required and which will be optional. However, the agency is expected to draw from existing measures, such as the Medicaid adult core set. Performance measures are tied to demonstration goals, including improved adherence to treatment, and reduced use of emergency department and inpatient hospital settings.

## BOX 4-2. (continued)

States must report on progress toward meeting six standardized milestones, some of which must be met within 12 and 24 months of demonstration approval, and some that may be met over the course of the demonstration.<sup>13</sup> States are also required to conduct independent interim and final evaluations that address the milestones, performance measures, and other data. States are subject to a deferral of payment of \$5 million per item if they fail to submit an acceptable and timely evaluation design or file required reports in a timely manner.

- **Demonstration approval and FFP.** FFP for services in IMDs is contingent upon CMS approval of each participating state's implementation plan detailing how the state will meet the six milestones; it may be withheld if states do not make adequate progress toward meeting the milestones and goals agreed upon by the state and CMS. States also must be in full compliance with budget neutrality requirements at the end of the demonstration period or CMS will recover the difference from the state. CMS will take achievement of milestones and performance measure targets into consideration if a state requests an extension of its demonstration.

Source: CMS 2017c.

**California.** CMS approved California's Drug Medi-Cal Organized Delivery System Section 1115 demonstration in August 2015.<sup>14</sup> Through the demonstration, California is restructuring SUD services to operate an organized delivery system that provides a continuum of SUD care that the state has modeled after the ASAM levels of care, facilitates the use of evidence-based practices in SUD treatment, and increases the coordination of SUD treatment with other systems of care.

Prior to approval of California's demonstration, each of the state's 58 counties was responsible for providing Medi-Cal beneficiaries a limited set of SUD treatment services. The services could be offered by the local county health department or, if a county chose not to administer services, by providers who contracted directly with the California Department of Health Care Services. The waiver represents a major change for counties choosing to participate; it requires local jurisdictions to move away from administering services or contracting the administration of block grants and become specialty managed care plans (Hunt and Hamblin 2017). As of March 2018, 40 counties in the state

have opted to participate in the demonstration, and 10 of them have already executed contracts.

In addition to offering Medi-Cal beneficiaries coverage for additional SUD services, select counties have undertaken substantial capacity building efforts to set up new providers for certain levels of care (Box 4-3).

**Virginia.** Elements of Virginia's Section 1115 SUD demonstration were first described by MACPAC in Chapter 2 of the June 2017 report to Congress (MACPAC 2017a). The demonstration included the expansion of SUD treatment benefits to cover the entire continuum of care, which was modeled after the ASAM criteria. In addition, the Commonwealth quadrupled payment for partial hospitalization, intensive outpatient services, and the counseling component of MAT. Virginia also moved SUD services into managed care to promote integration of physical and behavioral health services.

Virginia implemented these benefit expansions on April 1, 2017, and has released evaluation results from the first five months of the demonstration (Box 4-4). It is important to note that expanding

### **BOX 4-3. Early Results: California’s Section 1115 Substance Use Disorder Demonstration, 2017**

California’s substance use disorder demonstration is being implemented in phases and three counties had fully approved contracts with the state at the end of June 2017. Early evaluation findings were based on stakeholder surveys and interviews that took place between July 1, 2016, and June 30, 2017. The evaluation did not include claims data analysis; however, some data was available from the state’s outcomes measurement system. Future analyses will include claims data, which should provide additional insight into the effects of the state’s Section 1115 demonstration. Highlights of the existing evaluation include the following:

- **Access to a continuum of care.** Stakeholders reported concerns about the ability to expand the availability of medical detoxification and withdrawal management and residential treatment. They cited provider certification and upfront costs as examples of challenges to capacity expansion, but also noted that barriers to facility certification had been reduced over the previous year.
- **Care transitions.** After release from residential treatment, patients did not typically move along the continuum of care to receive additional treatment. Of all beneficiaries initially admitted to residential treatment in 2016, only 13.4 percent were moving along the continuum of care in a timely manner (e.g., a transfer to another level of care within 14 days).
- **Evidence-based practices.** The majority of counties reported using two of five evidence-based practices listed in the state’s Section 1115 demonstration special terms and conditions; however, stakeholders reported that implementing the use of evidence-based practices was challenging.
- **Coordination with other systems of care.** Coordination of services with Medi-Cal managed care plans is a required component for participation in the demonstration. This requires counties to contract with managed care plans. Counties with early participation under the waiver had greater coordination of services than the rest of the state

**Source:** Urada et al. 2017.

coverage to additional levels of care, including IMD settings, was necessary; Virginia also had to increase payment rates to ensure adequate provider participation. The Commonwealth is still working to attract additional providers in certain parts of Virginia.

**Broader implications.** After reviewing Section 1115 SUD waiver applications, the Commission notes a number of elements common to states that have

obtained demonstration approval to date. In general, these states:

- already pay for the majority of the levels of care modeled after the ASAM criteria;
- pay for certain ASAM levels of care using non-Medicaid funding streams; or
- use the ASAM criteria or another standard within their health care system.

### **BOX 4-4. Early Results: Virginia’s Section 1115 Substance Use Disorder Demonstration, 2017**

Virginia’s early Section 1115 substance use disorder (SUD) results are derived from the first five months of the demonstration, April–August 2017. The evaluation compares SUD service utilization to the previous calendar year (April–August 2016) and shows a 63 percent increase in the number of Medicaid beneficiaries with an SUD diagnosis receiving any SUD treatment service. The number of beneficiaries with an opioid use disorder (OUD) receiving any OUD service increased by 51 percent. This increased utilization resulted in a \$10 million (32 percent) increase in SUD treatment service spending. Emergency department visits related to SUDs declined by 31 percent during the evaluation period; however, total emergency department visits for all Medicaid members decreased over the same time period.

For beneficiaries accessing residential SUD treatment (ASAM levels 3.1, 3.5, and 3.7), including those in IMD settings, the average length of stay was 11.5 days across all residential treatment settings. Additional measures will be included in future reports to CMS, including claims and encounter-based measures that capture whether individuals are continuing in treatment.

Since its Section 1115 SUD demonstration was approved, Virginia has seen a dramatic increase in the number of providers participating in the Medicaid program. For example, the number of residential SUD providers participating in Medicaid increased from 4 to 77. The number of OTPs participating in Medicaid also increased from 6 to 29. However, there are still areas of the state where access to residential SUD treatment remains limited. For an area to be considered accessible there must be at least two providers within 30 miles for urban areas, or within a driving distance of 60 miles for rural areas. Southwest Virginia, an area that has been particularly affected by the opioid epidemic, generally lacks access to residential levels of care.

**Source:** VDMAS 2018.

Medicaid programs that currently pay for six or more levels of care already pay for at least one level of residential care described by the ASAM criteria. Therefore, they may be better positioned than states paying for fewer levels of care to use a demonstration to pay for SUD treatment in an IMD. Because these states currently pay for at least one level of residential SUD treatment under their state plan, residential SUD providers may already be enrolled with the Medicaid program in their states and participating in managed care networks. This can reduce administrative burdens to expand service capacity, such as those described by California.

Even if states are covering fewer than six levels of care, other factors may enhance their ability to expand coverage of SUD treatment, such as whether they are using state-only funding or federal block grants to offer services along the ASAM continuum of care that are not otherwise paid for by Medicaid. States that already pay for certain levels of care through non-Medicaid funds may be uniquely poised to create a new Medicaid service under a Section 1115 demonstration because there is an existing infrastructure of providers. For example, both Massachusetts and Maryland have expanded treatment under such demonstrations to pay for levels of care that were previously funded by another state agency.

States that currently use the ASAM criteria may also be better positioned to expand services and may be more capable of meeting the provider requirements under CMS Section 1115 demonstration guidance because they will not have to spend additional time and resources on provider education. Many clinicians and programs still struggle to understand the ASAM criteria, as evidenced by providers that advertise as 30-day programs (Mee-Lee et al. 2013). Although the majority of states already require SAMHSA-funded providers to use the ASAM criteria when determining a patient's treatment needs, it appears that additional work is needed to familiarize providers with the criteria. For example, California has sponsored provider training on the ASAM criteria as a part of its Section 1115 SUD demonstration (Urada et al. 2017). CMS also acknowledged this in issuing revised Section 1115 demonstration criteria by allowing for phased-in provider requirements over a two-year period.

Section 1115 SUD demonstrations may also allow an incremental approach to offering the ASAM continuum of care. For example, prior to its demonstration approval, Maryland did not pay for residential SUD treatment for adults. Effective July 1, 2017, the state began paying for residential care modeled after ASAM levels 3.3, 3.5, and 3.7. In January 2019, the state will begin to pay for a level of care meant to meet ASAM level 3.1. West Virginia is also taking an incremental approach: on January 1, 2018, the state began to pay for methadone treatment services, and on July 1, 2018, it will fully implement the demonstration by paying for residential treatment services.

Finally, some states may not seek a Section 1115 SUD demonstration because they can offer a full continuum of care through their state plan. However, even when using state plan authority, states may need to take additional steps to ensure there is access to a continuum of care. For instance, a state may offer coverage, but there may not be an adequate number of specialty SUD facilities to provide care, and low payment rates may deter providers from participating. For these states, increasing Medicaid provider participation might

require increasing rates or changing their rate setting methodology to interest existing providers to participate in the Medicaid program. If providers do not exist for a certain level of care, states will have to develop strategies to convince existing providers to expand their service offerings or to attract new providers to the state.

## Conclusions

Medicaid plays a critical role in responding to the opioid epidemic. Although much effort has been expended to make federal grant dollars available to states and communities to address different aspects of the opioid epidemic, it is important to note that Medicaid spending on health care services for individuals with OUD is much larger than other federal grants available for states to address the opioid epidemic and has the potential to make a greater impact on the availability of services (Grady et al. 2018).<sup>15</sup>

An effective Medicaid response to the opioid epidemic requires a robust care delivery system. States must pay for the full continuum of care, access to specialty SUD providers must be available, and these providers must participate in Medicaid. Section 1115 SUD demonstrations provide an opportunity for states to comprehensively improve access to clinically appropriate SUD care, but many states have not taken advantage of this opportunity or other Medicaid authorities to reduce gaps in the continuum of care. As evaluation results from Section 1115 SUD demonstrations are made available, lessons learned from states may provide additional insight to states that have yet to expand their SUD Medicaid benefit.

Medicaid's response to the opioid epidemic is limited in several states, in part, due to narrow coverage or payment policies. As noted earlier in the chapter, gaps in coverage are present at several levels of care, not just those that could be explained by the IMD exclusion. These include lack of coverage for partial hospitalization, which offers critical support to individuals who are



ready to receive care in the community, and lack of coverage for methadone treatment in OTPs, a treatment setting necessary for individuals who need the structure of daily dosing to support their recovery. Moreover, while repealing the IMD exclusion could help eliminate barriers to residential treatment, the availability of such resources could also inadvertently divert attention from addressing gaps at outpatient levels of care or result in individuals being placed in institutional settings when they could be more appropriately served in the community.

For many levels of care, especially those that require residential treatment and partial hospitalization, which are covered by fewer state Medicaid programs, there is also a shortage of SUD treatment facilities. This creates additional challenges for beneficiaries when they are trying to access services. Few specialty SUD treatment facilities offer levels of care that support individuals who have higher relapse potential, including intensive outpatient, partial hospitalization, and residential treatment. Even fewer specialty SUD providers accept Medicaid. In some states, Medicaid rates of payment are low, and paying for certain levels of care may do little to improve clinically appropriate access to treatment. Rates must be set at a level to attract a sufficient supply of providers.

## Next Steps

In the course of the Commission's work in this area, several key areas for future inquiry have emerged. First, the Commission is interested in better understanding the extent to which states are providing non-clinical SUD treatment services to Medicaid beneficiaries. We expect future work and contracted research projects to focus on identifying coverage of recovery support services at the state level. Next, the Commission is interested in gaining insight into the availability of MAT to Medicaid beneficiaries and the variations in coverage by state, including the coverage of methadone. The degree to which MAT utilization among Medicaid beneficiaries

is influenced by preferred drug status and policies that require counseling in combination with office-based therapy is also unknown. A more nuanced understanding of MAT utilization at the state level will help us further assess gaps in treatment. In addition, the Commission is interested in analyzing access to SUD services for special populations identified by ASAM, such as older adults, parents or prospective parents, and individuals involved in the justice system, as well as adolescents with an SUD.

While this report offers numerous findings related to access to levels of care described by the ASAM criteria and medications used to treat OUD, additional work is needed to determine whether these benefits are delivered in systems where behavioral and physical health are integrated. Even when the full continuum of care is paid for, many states deliver SUD treatment services in systems that are not integrated with the rest of the health care system. The Commission is interested in how Medicaid delivery systems, including managed care and fee-for-service programs, affect the identification of the need for SUD treatment and the access to such treatment by Medicaid beneficiaries.

Finally, MACPAC will continue to monitor state efforts to expand their SUD continuum of care through Section 1115 demonstrations and other relevant Medicaid authorities. As approved demonstrations mature, access to demonstration evaluations will help the Commission understand the successes and challenges faced by CMS and states in addressing the opioid epidemic.

## Endnotes

<sup>1</sup> ASAM is a non-profit professional medical society dedicated to improving the quality of and access to addiction care. The society represents more than 5,100 physicians, clinicians, and associated professionals in the field of addiction medicine. ASAM publishes its clinical guidelines in *The ASAM Criteria: Treatment Criteria for Addictive, Substance-Related and Co-Occurring Conditions* (Mee-Lee et al. 2013). The guidelines were first published in 1991 and have been updated three times, most recently in 2013

(ASAM 2014).

<sup>2</sup> ASAM considers several patient factors when determining placement: intoxication or withdrawal potential; biomedical conditions and complications; emotional, behavioral, or cognitive conditions and complications; readiness to change; relapse, continued use, or continued problem potential; and recovery or living environment (Mee-Lee et al. 2013).

<sup>3</sup> Medicaid beneficiaries in the new adult group are entitled to coverage of SUD treatment services as an essential health benefit; however, coverage of SUD treatment has traditionally been an optional benefit. MACPAC found in its analysis that states that expanded Medicaid generally offered the same SUD benefit not only to the new adult group but to all enrollees regardless of eligibility category.

<sup>4</sup> Under EPSDT, states must provide access to any Medicaid-coverable service in any amount that is medically necessary, regardless of whether the service is covered in the state plan (CMS 2013). Children eligible for Medicaid must be provided periodic screenings, known as well-child exams. One required element of this screening is a comprehensive health and developmental history including assessment of physical and mental health development. This includes an age-appropriate mental health and substance use health screening. If, during a routine screening, a provider determines that there may be a need for further assessment, a child should be furnished additional diagnostic and treatment services. The screening may also trigger the need for a further assessment to diagnose or treat a substance use condition.

<sup>5</sup> During this review, MACPAC found that many states use the ASAM criteria within their state plan or other materials as a way to self-describe services. MACPAC also found that some Medicaid agencies do not reference the ASAM criteria, or another standard, to describe SUD treatment coverage. As a result, additional research is needed to determine whether states are consistently applying the ASAM criteria. ASAM is in the process of creating a program that will certify the delivery of addiction care and offer a way to verify that delivery is consistent with the guidelines described in the ASAM criteria.

<sup>6</sup> An in-lieu-of service is one that is not included under the state plan, but is a clinically appropriate, cost-effective substitution for a similar, covered service. In August

2017, CMS issued subregulatory guidance on this in-lieu-of provision, noting that states do not need to submit a state plan amendment to provide in-lieu-of IMD services to managed care beneficiaries. CMS also clarified the circumstances under which capitation payments can be made. Specifically, when an IMD stay is more than 15 days but spans across two consecutive months, payments may be made as long as the stay is no more than 15 days in each month. If a beneficiary is a patient in an IMD beyond the allowed 15-day stay in a single month, states may make prorated capitation payments to managed care organizations (MCOs) to cover only the days within the month when the enrollee is not a patient in an IMD (CMS 2016).

<sup>7</sup> Of 39 states that currently operate managed care programs, 26 states reported on the Kaiser Family Foundation's annual budget survey that they planned to use the in-lieu-of provision in fiscal year 2017, 2018, or both years; 5 states said that they would not use this provision; and the response for 8 states could not be categorized clearly. States were also asked whether they believed that the managed care rules allowed them to meet the needs of individuals with SUD and 12 states said they were unsure and 8 states said that it did. The majority of states (19) expressed concern that federal rules do not meet the needs of Medicaid beneficiaries with SUDs and many states said that the 15-day limit was too restrictive (Gifford et al. 2017).

<sup>8</sup> Three medications are approved by the U.S. Food and Drug Administration (FDA) for MAT of alcohol use disorder—acamprostate, disulfiram, and naltrexone (CMS 2014). There are currently no FDA-approved medications to treat addiction to cannabis, cocaine, or methamphetamine (CMS 2014).

<sup>9</sup> Methadone use for treatment of OUD can be provided only in specially designated OTPs certified and regulated by SAMHSA's Center for Substance Abuse Treatment.

<sup>10</sup> Qualifying practitioners must obtain a Drug Addiction Treatment Act of 2000 (DATA 2000) waiver to prescribe buprenorphine in an office-based setting. Qualifying practitioners include physicians, nurse practitioners, and physician assistants. Practitioners who receive a DATA 2000 waiver may treat 30 patients in their first year under the waiver and may increase to 100 patients after one year upon submission of a notice to the Secretary of Health and Human Services. Physicians who have prescribed buprenorphine to

100 patients for at least one year can now apply to increase their patient limits to 275 under new federal regulations.

<sup>11</sup> SAMHSA administers N-SSATS, which, among other things, captures a one-day census across all SUD facilities. N-SSATS is limited to treatment facilities that (1) are licensed, certified, or otherwise approved for inclusion in the Directory by their State Substance Abuse Agencies, and (2) responded to the 2016 N-SSATS. The N-SSATS collects data from institutional providers, not individual providers (SAMHSA 2017).

<sup>12</sup> N-SSATS does not fully align with the levels of care described by the ASAM criteria and sometimes a level of care is used to describe more than one service setting. For example, residential short-term treatment is described by N-SSATS as being similar to ASAM level 3.5; however N-SSATS also uses ASAM level 3.5 to describe hospital inpatient treatment (MACPAC classified it as level 3.7 for its analysis). Residential long-term treatment is described by N-SSATS as being similar to ASAM levels 3.1 or 3.3 (MACPAC classified it as level 3.1).

<sup>13</sup> The six demonstration milestones are: (1) access to critical levels of care for OUD and other SUDs; (2) widespread use of evidence-based, SUD-specific patient placement criteria; (3) use of nationally recognized, evidenced-based SUD program standards to set residential treatment provider qualifications; (4) sufficient provider capacity at each level of care; (5) implementation of comprehensive treatment and prevention strategies to address opioid abuse and OUD; and (6) improved care coordination and transitions between levels of care (CMS 2017c).

<sup>14</sup> California's Medicaid program is called Medi-Cal.

<sup>15</sup> The federal government declared the opioid epidemic a public health emergency and made over \$500 million of OUD-targeted funding available to states in 2017. The Bipartisan Budget Act of 2018 (P.L. 15-123) added \$3 billion per year in opioid funding to the federal budget for 2018 and 2019; and the President's budget calls for \$10 billion to be allotted across multiple agencies to address the opioid crisis. Although this is a substantial amount of funding, program spending for Medicaid beneficiaries with an OUD in 2013 was more than \$9 billion. The 2013 spending level does not reflect increased enrollment under the ACA when Medicaid was expanded in many states to cover adults

under age 65 with incomes less than or equal to 138 percent of the federal poverty level (Grady et al. 2018).

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# APPENDIX 4A: State Coverage of Substance Use Disorder Services

**TABLE 4A-1. Medicaid State Plan and Section 1115 Waiver Coverage of Substance Use Disorder Services, April 2018** **T 4A-1**

State	Early intervention (ASAM level 0.5)	Outpatient services (ASAM level 1.0)	Intensive outpatient services (ASAM level 2.1)	Partial hospitalization (ASAM level 2.5)	Clinically managed low-intensity residential services (ASAM Level 3.1)	Clinically managed population-specific high-intensity residential services (ASAM level 3.3)	Clinically managed high-intensity residential services (ASAM level 3.5)	Medically monitored intensive inpatient services (ASAM level 3.7)	Medically managed intensive inpatient services (ASAM level 4.0)	Selected medication-assisted treatment therapies		
										Buprenorphine	Methadone	Naltrexone
<b>Total</b>	<b>44</b>	<b>50</b>	<b>44</b>	<b>33</b>	<b>27</b>	<b>22</b>	<b>34</b>	<b>29</b>	<b>44</b>	<b>51</b>	<b>38</b>	<b>49</b>
Alabama	✓	✓	-	-	-	-	-	-	✓	✓	-	✓
Alaska	✓	✓	✓	-	-	✓	-	✓	✓	✓	✓	✓
Arizona	✓	✓	✓	✓	-	-	✓	-	✓	✓	✓	✓
Arkansas	-	✓	✓	-	-	-	✓	-	✓	✓	-	-
California <sup>1</sup>	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Colorado	✓	✓	-	-	✓	-	✓	-	✓	✓	✓	✓
Connecticut	✓	✓	✓	✓	-	-	-	-	✓	✓	✓	✓
Delaware	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
District of Columbia	✓	✓	✓	-	✓	-	✓	-	-	✓	✓	✓
Florida	✓	✓	-	-	-	-	-	-	-	✓	✓	✓
Georgia	✓	✓	✓	-	-	-	-	✓	✓	✓	✓	✓
Hawaii	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Idaho	✓	✓	✓	-	-	-	-	-	✓	✓	-	✓
Illinois <sup>2</sup>	-	✓	✓	✓	-	-	✓	✓	✓	✓	-	-
Indiana	✓	✓	✓	✓	✓	-	✓	-	✓	✓	✓	✓
Iowa	✓	✓	-	-	✓	✓	✓	✓	✓	✓	-	✓
Kansas	✓	✓	✓	-	✓	-	✓	-	✓	✓	✓	✓

**TABLE 4A-1. (continued)**

State	Early intervention (ASAM level 0.5)	Outpatient services (ASAM level 1.0)	Intensive outpatient services (ASAM level 2.1)	Partial hospitalization (ASAM level 2.5)	Clinically managed low-intensity residential services (ASAM Level 3.1)	Clinically managed population-specific high-intensity residential services (ASAM level 3.3)	Clinically managed high-intensity residential services (ASAM level 3.5)	Medically monitored inpatient services (ASAM level 3.7)	Medically managed intensive inpatient services (ASAM level 4.0)	Selected medication-assisted treatment therapies		
										Buprenorphine	Methadone	Naltrexone
Kentucky	✓	✓	✓	✓	✓	-	✓	-	✓	✓	-	✓
Louisiana	✓	✓	✓	-	✓	✓	✓	✓	✓	-	-	✓
Maine	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Maryland <sup>3</sup>	✓	✓	✓	✓	-	✓	✓	✓	✓	✓	✓	✓
Massachusetts	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Michigan	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Minnesota	✓	✓	✓	-	✓	✓	✓	✓	✓	✓	✓	✓
Mississippi	-	✓	-	✓	-	-	-	-	✓	✓	✓	✓
Missouri	✓	✓	✓	✓	-	-	-	✓	✓	✓	✓	✓
Montana	✓	✓	✓	✓	✓	-	✓	✓	✓	✓	✓	✓
Nebraska	✓	✓	✓	✓	✓	✓	✓	-	✓	-	-	✓
Nevada	✓	✓	✓	✓	-	✓	✓	-	✓	✓	✓	✓
New Hampshire	✓	✓	✓	✓	✓	-	✓	-	✓	✓	✓	✓
New Jersey	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
New Mexico	-	✓	✓	-	-	-	-	-	✓	✓	✓	✓
New York	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
North Carolina	✓	✓	✓	✓	-	-	✓	✓	✓	✓	✓	✓
North Dakota	✓	✓	✓	✓	-	-	-	-	✓	✓	-	✓
Ohio	✓	✓	✓	✓	✓	✓	✓	✓	-	✓	✓	✓
Oklahoma	✓	✓	✓	✓	-	-	-	-	✓	✓	✓	✓
Oregon	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓



**TABLE 4A-1. (continued)**

State	Early intervention (ASAM level 0.5)	Outpatient services (ASAM level 1.0)	Intensive outpatient services (ASAM level 2.1)	Partial hospitalization (ASAM level 2.5)	Clinically managed low-intensity residential services (ASAM Level 3.1)	Clinically managed population-specific high-intensity residential services (ASAM level 3.3)	Clinically managed high-intensity residential services (ASAM level 3.5)	Medically monitored inpatient services (ASAM level 3.7)	Medically managed intensive inpatient services (ASAM level 4.0)	Selected medication-assisted treatment therapies		
										Buprenorphine	Methadone	Naltrexone
Pennsylvania	-	✓	✓	-	-	-	-	-	✓	✓	✓	✓
Rhode Island	✓	✓	✓	✓	✓	-	-	✓	✓	✓	✓	✓
South Carolina	✓	✓	✓	✓	-	-	✓	✓	✓	-	✓	✓
South Dakota	-	-	-	-	-	-	-	-	-	✓	✓	✓
Tennessee	✓	✓	✓	✓	-	✓	✓	✓	✓	-	✓	✓
Texas	✓	✓	-	-	-	-	✓	-	✓	-	✓	✓
Utah	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Vermont	✓	✓	✓	✓	✓	-	-	✓	-	✓	✓	✓
Virginia	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Washington	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
West Virginia	-	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Wisconsin	✓	✓	✓	-	-	-	-	-	✓	✓	✓	✓
Wyoming	✓	✓	✓	-	-	-	-	-	-	✓	-	✓

**Notes:** ASAM is American Society of Addiction Medicine. The ASAM criteria comprise a set of guidelines for assessing and making treatment decisions for individuals with addiction and co-occurring conditions. The criteria describe nine discrete levels of care, each with specific treatment and provider requirements. (For a full description of the levels of care, see Mee-Lee et al. 2013.) Estimates of the number of states covering services in the ASAM levels of care are based on MACPAC’s analysis of coverage under state plan authority and approved Section 1115 substance use disorder (SUD) demonstrations. In instances where publicly available information was insufficient to determine coverage, MACPAC contacted states directly. The Commission’s analysis does not account for additional states that may be utilizing the in-lieu-of provision to provide access to IMD levels of care. Many state Medicaid agencies do not use the ASAM Criteria to determine SUD treatment coverage or require provider use for patient assessment purposes. For residential treatment services, states use a variety of terms to describe coverage. For the purposes of MACPAC’s analysis, states that indicate that they provide low-intensity or long-term residential treatment were classified as covering ASAM level 3.1; those providing medium-intensity residential SUD treatment were classified as covering ASAM level 3.5; and states covering high-intensity or short-term residential treatment were classified as providing ASAM level 3.7.

**TABLE 4A-1. (continued)**

- ✓ Indicates that a state provides services in this category.
- Indicates that a state does not provide services in this category.
- 1 California’s Medicaid program operates on a county-by-county basis. Services listed here are those approved in its Section 1115 Drug Medi-Cal waiver. Services may vary at the county or plan level.
- 2 Illinois has approval to pay for short-term residential treatment in IMDs through its Section 1115 Behavioral Health Transformation demonstration; however the special terms and conditions of the waiver do not identify levels of care used by ASAM. Therefore, information on coverage is drawn from the state’s Section 1115 demonstration application.
- 3 Maryland has approval to pay for ASAM level 3.1 through its Section 1115 HealthChoice waiver; however it does not have the authority to pay for such services until July 1, 2019.

**Sources:** For levels of care: MACPAC, 2018, analysis of Medicaid state plan and Section 1115 coverage; Mee-Lee et al. 2013, *The ASAM Criteria: Treatment criteria for addictive, substance-related, and co-occurring conditions*, third edition, Carson City, NV: The Change Companies. For medication-assisted treatment coverage: MACPAC, 2018, analysis of Section 1115 waivers and materials from Kaiser Family Foundation (KFF). 2018. Medicaid’s role in addressing the opioid epidemic. Infographic, February 27, 2018. Washington, DC: KFF. <https://www.kff.org/infographic/medicaids-role-in-addressing-opioid-epidemic/>.

# Appendix

## Authorizing Language from the Social Security Act (42 USC 1396)

### Medicaid and CHIP Payment and Access Commission

- (a) ESTABLISHMENT.—There is hereby established the Medicaid and CHIP Payment and Access Commission (in this section referred to as “MACPAC”).
- (b) DUTIES.—
- (1) REVIEW OF ACCESS POLICIES FOR ALL STATES AND ANNUAL REPORTS.—MACPAC shall—
- (A) review policies of the Medicaid program established under this title (in this section referred to as “Medicaid”) and the State Children’s Health Insurance Program established under title XXI (in this section referred to as “CHIP”) affecting access to covered items and services, including topics described in paragraph (2);
  - (B) make recommendations to Congress, the Secretary, and States concerning such access policies;
  - (C) by not later than March 15 of each year (beginning with 2010), submit a report to Congress containing the results of such reviews and MACPAC’s recommendations concerning such policies; and
  - (D) by not later than June 15 of each year (beginning with 2010), submit a report to Congress containing an examination of issues affecting Medicaid and CHIP, including the implications of changes in health care delivery in the United States and in the market for health care services on such programs.
- (2) SPECIFIC TOPICS TO BE REVIEWED.—Specifically, MACPAC shall review and assess the following:
- (A) MEDICAID AND CHIP PAYMENT POLICIES.—Payment policies under Medicaid and CHIP, including—
    - (i) the factors affecting expenditures for the efficient provision of items and services in different sectors, including the process for updating payments to medical, dental, and health professionals, hospitals, residential and long-term care providers, providers of home and community based services, Federally-qualified health centers and rural health clinics, managed care entities, and providers of other covered items and services;
    - (ii) payment methodologies; and
    - (iii) the relationship of such factors and methodologies to access and quality of care for Medicaid and CHIP beneficiaries (including how such factors and methodologies enable such beneficiaries to obtain the services for which they are eligible, affect provider supply, and affect providers that serve a disproportionate share of low-income and other vulnerable populations).
  - (B) ELIGIBILITY POLICIES.—Medicaid and CHIP eligibility policies, including a determination of the degree to which Federal and State policies provide health care coverage to needy populations.

- (C) ENROLLMENT AND RETENTION PROCESSES.—Medicaid and CHIP enrollment and retention processes, including a determination of the degree to which Federal and State policies encourage the enrollment of individuals who are eligible for such programs and screen out individuals who are ineligible, while minimizing the share of program expenses devoted to such processes.
  - (D) COVERAGE POLICIES.—Medicaid and CHIP benefit and coverage policies, including a determination of the degree to which Federal and State policies provide access to the services enrollees require to improve and maintain their health and functional status.
  - (E) QUALITY OF CARE.—Medicaid and CHIP policies as they relate to the quality of care provided under those programs, including a determination of the degree to which Federal and State policies achieve their stated goals and interact with similar goals established by other purchasers of health care services.
  - (F) INTERACTION OF MEDICAID AND CHIP PAYMENT POLICIES WITH HEALTH CARE DELIVERY GENERALLY.—The effect of Medicaid and CHIP payment policies on access to items and services for children and other Medicaid and CHIP populations other than under this title or title XXI and the implications of changes in health care delivery in the United States and in the general market for health care items and services on Medicaid and CHIP.
  - (G) INTERACTIONS WITH MEDICARE AND MEDICAID.—Consistent with paragraph (11), the interaction of policies under Medicaid and the Medicare program under title XVIII, including with respect to how such interactions affect access to services, payments, and dually eligible individuals.
  - (H) OTHER ACCESS POLICIES.—The effect of other Medicaid and CHIP policies on access to covered items and services, including policies relating to transportation and language barriers and preventive, acute, and long-term services and supports.
- (3) RECOMMENDATIONS AND REPORTS OF STATE-SPECIFIC DATA.—MACPAC shall—
- (A) review national and State-specific Medicaid and CHIP data; and
  - (B) submit reports and recommendations to Congress, the Secretary, and States based on such reviews.
- (4) CREATION OF EARLY-WARNING SYSTEM.—MACPAC shall create an early-warning system to identify provider shortage areas, as well as other factors that adversely affect, or have the potential to adversely affect, access to care by, or the health care status of, Medicaid and CHIP beneficiaries. MACPAC shall include in the annual report required under paragraph (1)(D) a description of all such areas or problems identified with respect to the period addressed in the report.
- (5) COMMENTS ON CERTAIN SECRETARIAL REPORTS AND REGULATIONS.—
- (A) CERTAIN SECRETARIAL REPORTS.—If the Secretary submits to Congress (or a committee of Congress) a report that is required by law and that relates to access policies, including with respect to payment policies, under Medicaid or CHIP, the Secretary shall transmit a copy of the report to MACPAC. MACPAC shall review the report and, not later than 6 months after the date of submittal of the Secretary’s report to Congress, shall submit to the appropriate committees of

Congress and the Secretary written comments on such report. Such comments may include such recommendations as MACPAC deems appropriate.

- (B) REGULATIONS.—MACPAC shall review Medicaid and CHIP regulations and may comment through submission of a report to the appropriate committees of Congress and the Secretary, on any such regulations that affect access, quality, or efficiency of health care.
- (6) AGENDA AND ADDITIONAL REVIEWS.—
- (A) IN GENERAL.—MACPAC shall consult periodically with the chairmen and ranking minority members of the appropriate committees of Congress regarding MACPAC’s agenda and progress towards achieving the agenda. MACPAC may conduct additional reviews, and submit additional reports to the appropriate committees of Congress, from time to time on such topics relating to the program under this title or title XXI as may be requested by such chairmen and members and as MACPAC deems appropriate.
- (B) REVIEW AND REPORTS REGARDING MEDICAID DSH.—
- (i) IN GENERAL.—MACPAC shall review and submit an annual report to Congress on disproportionate share hospital payments under section 1923. Each report shall include the information specified in clause (ii).
- (ii) REQUIRED REPORT INFORMATION.—Each report required under this subparagraph shall include the following:
- (I) Data relating to changes in the number of uninsured individuals.
  - (II) Data relating to the amount and sources of hospitals’ uncompensated care costs, including the amount of such costs that are the result of providing unreimbursed or under-reimbursed services, charity care, or bad debt.
  - (III) Data identifying hospitals with high levels of uncompensated care that also provide access to essential community services for low-income, uninsured, and vulnerable populations, such as graduate medical education, and the continuum of primary through quaternary care, including the provision of trauma care and public health services.
  - (IV) State-specific analyses regarding the relationship between the most recent State DSH allotment and the projected State DSH allotment for the succeeding year and the data reported under subclauses (I), (II), and (III) for the State.
- (iii) DATA.—Notwithstanding any other provision of law, the Secretary regularly shall provide MACPAC with the most recent State reports and most recent independent certified audits submitted under section 1923(j), cost reports submitted under title XVIII, and such other data as MACPAC may request for purposes of conducting the reviews and preparing and submitting the annual reports required under this subparagraph.
- (iv) SUBMISSION DEADLINES.—The first report required under this subparagraph shall be submitted to Congress not later than February 1, 2016. Subsequent reports shall be submitted as part of, or with, each annual report required under paragraph (1)(C) during the period of fiscal years 2017 through 2024.

- (7) AVAILABILITY OF REPORTS.—MACPAC shall transmit to the Secretary a copy of each report submitted under this subsection and shall make such reports available to the public.
- (8) APPROPRIATE COMMITTEE OF CONGRESS.—For purposes of this section, the term “appropriate committees of Congress” means the Committee on Energy and Commerce of the House of Representatives and the Committee on Finance of the Senate.
- (9) VOTING AND REPORTING REQUIREMENTS.—With respect to each recommendation contained in a report submitted under paragraph (1), each member of MACPAC shall vote on the recommendation, and MACPAC shall include, by member, the results of that vote in the report containing the recommendation.
- (10) EXAMINATION OF BUDGET CONSEQUENCES.—Before making any recommendations, MACPAC shall examine the budget consequences of such recommendations, directly or through consultation with appropriate expert entities, and shall submit with any recommendations, a report on the Federal and State-specific budget consequences of the recommendations.
- (11) CONSULTATION AND COORDINATION WITH MEDPAC.—
- (A) IN GENERAL.—MACPAC shall consult with the Medicare Payment Advisory Commission (in this paragraph referred to as “MedPAC”) established under section 1805 in carrying out its duties under this section, as appropriate and particularly with respect to the issues specified in paragraph (2) as they relate to those Medicaid beneficiaries who are dually eligible for Medicaid and the Medicare program under title XVIII, adult Medicaid beneficiaries (who are not dually eligible for Medicare), and beneficiaries under Medicare. Responsibility for analysis of and recommendations to change Medicare policy regarding Medicare beneficiaries, including Medicare beneficiaries who are dually eligible for Medicare and Medicaid, shall rest with MedPAC.
- (B) INFORMATION SHARING.—MACPAC and MedPAC shall have access to deliberations and records of the other such entity, respectively, upon the request of the other such entity.
- (12) CONSULTATION WITH STATES.—MACPAC shall regularly consult with States in carrying out its duties under this section, including with respect to developing processes for carrying out such duties, and shall ensure that input from States is taken into account and represented in MACPAC’s recommendations and reports.
- (13) COORDINATE AND CONSULT WITH THE FEDERAL COORDINATED HEALTH CARE OFFICE.—MACPAC shall coordinate and consult with the Federal Coordinated Health Care Office established under section 2081 of the Patient Protection and Affordable Care Act before making any recommendations regarding dually eligible individuals.
- (14) PROGRAMMATIC OVERSIGHT VESTED IN THE SECRETARY.—MACPAC’s authority to make recommendations in accordance with this section shall not affect, or be considered to duplicate, the Secretary’s authority to carry out Federal responsibilities with respect to Medicaid and CHIP.
- (c) MEMBERSHIP.—
- (1) NUMBER AND APPOINTMENT.—MACPAC shall be composed of 17 members appointed by the Comptroller General of the United States.
- (2) QUALIFICATIONS.—

- (A) **IN GENERAL.**—The membership of MACPAC shall include individuals who have had direct experience as enrollees or parents or caregivers of enrollees in Medicaid or CHIP and individuals with national recognition for their expertise in Federal safety net health programs, health finance and economics, actuarial science, health plans and integrated delivery systems, reimbursement for health care, health information technology, and other providers of health services, public health, and other related fields, who provide a mix of different professions, broad geographic representation, and a balance between urban and rural representation.
  - (B) **INCLUSION.**—The membership of MACPAC shall include (but not be limited to) physicians, dentists, and other health professionals, employers, third-party payers, and individuals with expertise in the delivery of health services. Such membership shall also include representatives of children, pregnant women, the elderly, individuals with disabilities, caregivers, and dually eligible individuals, current or former representatives of State agencies responsible for administering Medicaid, and current or former representatives of State agencies responsible for administering CHIP.
  - (C) **MAJORITY NONPROVIDERS.**—Individuals who are directly involved in the provision, or management of the delivery, of items and services covered under Medicaid or CHIP shall not constitute a majority of the membership of MACPAC.
  - (D) **ETHICAL DISCLOSURE.**—The Comptroller General of the United States shall establish a system for public disclosure by members of MACPAC of financial and other potential conflicts of interest relating to such members. Members of MACPAC shall be treated as employees of Congress for purposes of applying title I of the Ethics in Government Act of 1978 (Public Law 95–521).
- (3) **TERMS.**—
- (A) **IN GENERAL.**—The terms of members of MACPAC shall be for 3 years except that the Comptroller General of the United States shall designate staggered terms for the members first appointed.
  - (B) **VACANCIES.**—Any member appointed to fill a vacancy occurring before the expiration of the term for which the member’s predecessor was appointed shall be appointed only for the remainder of that term. A member may serve after the expiration of that member’s term until a successor has taken office. A vacancy in MACPAC shall be filled in the manner in which the original appointment was made.
- (4) **COMPENSATION.**—While serving on the business of MACPAC (including travel time), a member of MACPAC shall be entitled to compensation at the per diem equivalent of the rate provided for level IV of the Executive Schedule under section 5315 of title 5, United States Code; and while so serving away from home and the member’s regular place of business, a member may be allowed travel expenses, as authorized by the Chairman of MACPAC. Physicians serving as personnel of MACPAC may be provided a physician comparability allowance by MACPAC in the same manner as Government physicians may be provided such an allowance by an agency under section 5948 of title 5, United States Code, and for such purpose subsection (i) of such section shall apply to MACPAC in the same manner as it applies to the Tennessee Valley Authority. For purposes of pay (other than pay of members of MACPAC) and employment benefits, rights, and privileges, all personnel of MACPAC shall be treated as if they were employees of the United States Senate.
- (5) **CHAIRMAN; VICE CHAIRMAN.**—The Comptroller General of the United States shall designate a



member of MACPAC, at the time of appointment of the member as Chairman and a member as Vice Chairman for that term of appointment, except that in the case of vacancy of the Chairmanship or Vice Chairmanship, the Comptroller General of the United States may designate another member for the remainder of that member's term.

(6) MEETINGS.—MACPAC shall meet at the call of the Chairman.

(d) DIRECTOR AND STAFF; EXPERTS AND CONSULTANTS.—Subject to such review as the Comptroller General of the United States deems necessary to assure the efficient administration of MACPAC, MACPAC may—

- (1) employ and fix the compensation of an Executive Director (subject to the approval of the Comptroller General of the United States) and such other personnel as may be necessary to carry out its duties (without regard to the provisions of title 5, United States Code, governing appointments in the competitive service);
- (2) seek such assistance and support as may be required in the performance of its duties from appropriate Federal and State departments and agencies;
- (3) enter into contracts or make other arrangements, as may be necessary for the conduct of the work of MACPAC (without regard to section 3709 of the Revised Statutes (41 USC 5));
- (4) make advance, progress, and other payments which relate to the work of MACPAC;
- (5) provide transportation and subsistence for persons serving without compensation; and
- (6) prescribe such rules and regulations as it deems necessary with respect to the internal organization and operation of MACPAC.

(e) POWERS.—

- (1) OBTAINING OFFICIAL DATA.—MACPAC may secure directly from any department or agency of the United States and, as a condition for receiving payments under sections 1903(a) and 2105(a), from any State agency responsible for administering Medicaid or CHIP, information necessary to enable it to carry out this section. Upon request of the Chairman, the head of that department or agency shall furnish that information to MACPAC on an agreed upon schedule.
- (2) DATA COLLECTION.—In order to carry out its functions, MACPAC shall—
  - (A) utilize existing information, both published and unpublished, where possible, collected and assessed either by its own staff or under other arrangements made in accordance with this section;
  - (B) carry out, or award grants or contracts for, original research and experimentation, where existing information is inadequate; and
  - (C) adopt procedures allowing any interested party to submit information for MACPAC's use in making reports and recommendations.

- (3) ACCESS OF GAO TO INFORMATION.—The Comptroller General of the United States shall have unrestricted access to all deliberations, records, and nonproprietary data of MACPAC, immediately upon request.
  - (4) PERIODIC AUDIT.—MACPAC shall be subject to periodic audit by the Comptroller General of the United States.
- (f) FUNDING.—
- (1) REQUEST FOR APPROPRIATIONS.—MACPAC shall submit requests for appropriations (other than for fiscal year 2010) in the same manner as the Comptroller General of the United States submits requests for appropriations, but amounts appropriated for MACPAC shall be separate from amounts appropriated for the Comptroller General of the United States.
  - (2) AUTHORIZATION.—There are authorized to be appropriated such sums as may be necessary to carry out the provisions of this section.
  - (3) FUNDING FOR FISCAL YEAR 2010.—
    - (A) IN GENERAL.—Out of any funds in the Treasury not otherwise appropriated, there is appropriated to MACPAC to carry out the provisions of this section for fiscal year 2010, \$9,000,000.
    - (B) TRANSFER OF FUNDS.—Notwithstanding section 2104(a)(13), from the amounts appropriated in such section for fiscal year 2010, \$2,000,000 is hereby transferred and made available in such fiscal year to MACPAC to carry out the provisions of this section.
  - (4) AVAILABILITY.—Amounts made available under paragraphs (2) and (3) to MACPAC to carry out the provisions of this section shall remain available until expended.

## Biographies of Commissioners

**Penny Thompson, MPA (Chair)**, is principal of Penny Thompson Consulting, LLC, and provides strategic advice and solutioning services in the areas of health care delivery and payment, information technology development, and program integrity. Previously, she served as deputy director of the Center for Medicaid and CHIP Services at the Centers for Medicare & Medicaid Services (CMS). Ms. Thompson previously was director of health care strategy and planning for Hewlett Packard's health care business unit. In addition, she served as CMS's director of program integrity and as chief of the health care branch within the Office of Inspector General at the U.S. Department of Health and Human Services. Ms. Thompson received her master of public administration from The George Washington University.

**Stacey Lampkin, FSA, MAAA, MPA (Vice Chair)**, 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 in the Society of Actuaries and a member of the AAA. She received her master of public administration from Florida State University.

**Melanie Bella, MBA**, is chief of new business and policy at Cityblock Health, which facilitates health care delivery for low-income urban populations, particularly Medicaid beneficiaries and those dually eligible for Medicaid and Medicare. Previously, she served as the founding director of the Medicare-Medicaid Coordination Office at CMS, where she designed and launched payment and delivery system demonstrations to improve quality and reduce costs. Ms. Bella also was the director of the Indiana

Medicaid program, where she oversaw the State Children's Health Insurance Program (CHIP) and the state's long-term care insurance program. Ms. Bella received her master of business administration from Harvard University.

**Brian Burwell** is senior executive, government health and human services, at IBM Watson Health in Cambridge, Massachusetts. Mr. Burwell conducts research and provides consulting services, policy analysis, technical assistance in financing and delivery of long-term services and supports, and data analysis related to integrated care models for dually eligible beneficiaries and managed long-term services and supports. He has been with IBM Watson Health and its predecessor companies for 30 years. Mr. Burwell received his bachelor of arts degree from Dartmouth College.

**Martha Carter, DHSc, MBA, APRN, CNM**, is founder and chief executive officer (CEO) of FamilyCare Health Centers, a community health center serving four counties in south-central West Virginia. Dr. Carter practiced as a certified nurse-midwife in Kentucky, Ohio, and West Virginia for 20 years. She is a member of the West Virginia Alliance for Creative Health Solutions, a practice-led research and advocacy network, and she serves as the chair of the Quality Leadership Committee of the West Virginia Primary Care Association. Dr. Carter was a Robert Wood Johnson Foundation Executive Nurse Fellow in 2005–2008 and received the Robert Wood Johnson Foundation Community Health Leader award in 1999. She holds a doctorate of health sciences from A.T. Still University in Mesa, Arizona, and a master of business administration from West Virginia University in Morgantown, West Virginia.

**Frederick Cerise, MD, MPH**, is president and chief executive officer of Parkland Health and Hospital System, a large public safety-net health system in Dallas, Texas. Previously, he oversaw Medicaid and other programs for the state of Louisiana as secretary of the Department of Health and Hospitals. Dr. Cerise also held the position of medical director and other leadership roles at various health care facilities operated by Louisiana State University. He

began his career as an internal medicine physician and spent 13 years treating patients and teaching medical students in Louisiana's public hospital system. Dr. Cerise received his degree in medicine from Louisiana State University and his master of public health from Harvard University.

**Kisha Davis, MD, MPH**, is a family physician at CHI Health Care in Rockville, Maryland, and is also program manager at the Center for Applied Research in Philadelphia, Pennsylvania, where she supports projects for family physicians focused on payment reform and practice transformation to promote health system change. Previously, Dr. Davis was medical director and director of community health at CHI and was also a family physician at a federally qualified health center (FQHC) in Maryland. As a White House Fellow at the U.S. Department of Agriculture, she established relationships among leaders of FQHCs and the Women, Infants, and Children nutrition program. Dr. Davis received her degree in medicine from the University of Connecticut and her master of public health from Johns Hopkins University.

**Toby Douglas, MPP, MPH**, is senior vice president, national Medicaid at Kaiser Permanente. Previously, Mr. Douglas was senior vice president for Medicaid solutions at Centene Corporation, and prior to that, a long-standing state Medicaid official, serving for 10 years as an executive in California Medicaid. He served as director of the California Department of Health Care Services and was director of California Medicaid for six years, during which time he also served as a board member of the National Association of Medicaid Directors and as a CHIP director. Earlier in his career, Mr. Douglas worked for the San Mateo County Health Department in California, as a research associate at the Urban Institute, and as a VISTA volunteer. He received his master of public policy and master of public health from the University of California, Berkeley.

**Leanna George** is the parent of a teenager with a disability who is covered under Medicaid and a child covered under CHIP. A resident of Benson, North Carolina, Ms. George is the chair of the North Carolina Council on Educational Services for Exceptional

Children, a special education advisory council for the State Board of Education. She also serves as the secretary of the Johnston County Consumer and Family Advisory Committee, which advises the Board of the County Mental Health Center, and on the Client Rights Committee of the Autism Society of North Carolina, a Medicaid provider agency.

**Darin Gordon** is president and chief executive officer 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**, is the former president of public plans at Tufts Health Plan, a non-profit health plan in Massachusetts, Rhode Island, and New Hampshire. Previously, Dr. Gorton was CEO of a regional health plan that was acquired by the Inova Health System of Falls Church, Virginia. Other positions have included 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.

**Charles Milligan, JD, MPH**, is CEO of UnitedHealthcare Community Plan of New Mexico, a Medicaid managed care organization with enrolled members in all Medicaid eligibility categories (including dually eligible beneficiaries and adults in Medicaid expansion programs) that provides somatic, behavioral, and managed long-term services and supports. Mr. Milligan is a former state Medicaid and CHIP director in New Mexico and Maryland. He also served as executive director of the Hilltop Institute, a health services research center at the University of Maryland at Baltimore County, and as vice president at the Lewin Group. Mr. Milligan directed the 2005–2006 Commission on Medicaid and has conducted Medicaid-related research projects in numerous states. He received his master of public health from the University of California, Berkeley, and his law degree from Harvard Law School.

**Sheldon Retchin, MD, MSPH**, is professor of medicine and public health at The Ohio State University in Columbus, Ohio. Dr. Retchin's research and publications have addressed costs, quality, and outcomes of health care as well as workforce issues. From 2015 until 2017, he was executive vice president for health sciences and CEO of the Wexner Medical Center. From 2003 until 2015, he served as senior vice president for health sciences at Virginia Commonwealth University (VCU) and as CEO of the VCU Health System, in Richmond, Virginia. Dr. Retchin also led a Medicaid health maintenance organization, Virginia Premier, with approximately 200,000 covered lives. Dr. Retchin received his medical and public health degrees from The University of North Carolina at Chapel Hill, where he was also a Robert Wood Johnson Clinical Scholar.

**William Scanlon, PhD**, is a consultant for the West Health Institute. He began conducting health services research on the Medicaid and Medicare programs in 1975, with a focus on such issues as the provision and financing of long-term care services and provider payment policies. He previously held positions at Georgetown University and the Urban Institute, was managing director of health care issues at the U.S. Government Accountability Office, and served on the

Medicare Payment Advisory Commission (MedPAC). Dr. Scanlon received his doctorate in economics from the University of Wisconsin, Madison.

**Peter Szilagyi, MD, MPH**, is professor of pediatrics, executive vice chair, and vice chair for research in the Department of Pediatrics at the Mattel Children's Hospital at the University of California, Los Angeles (UCLA). Prior to joining UCLA, he served as chief of the division of general pediatrics and professor of pediatrics at the University of Rochester and as associate director of the Center for Community Health within the University of Rochester's Clinical Translational Research Institute. His research has addressed CHIP and child health insurance, access to care, quality of care, and health outcomes, including the delivery of primary care with a focus on immunization delivery, health care financing, and children with chronic disease. From 1986 to 2014, he served as chairman of the board of the Monroe Plan for Medical Care, a large Medicaid and CHIP managed care plan in upstate New York. He is editor-in-chief of *Academic Pediatrics* and has served as the president of the Academic Pediatric Association. Dr. Szilagyi received his medical and public health degrees from the University of Rochester.

**Alan Weil, JD, MPP**, is editor-in-chief of *Health Affairs*, a multidisciplinary peer-reviewed health policy journal, in Bethesda, Maryland. He is an elected member of the National Academy of Medicine and served six years on its Board on Health Care Services. He is a trustee of the Consumer Health Foundation and is the director of the Aspen Health Strategy Group. He previously served as executive director of the National Academy for State Health Policy, director of the Urban Institute's Assessing the New Federalism Project, executive director of the Colorado Department of Health Care Policy and Financing, and assistant general counsel in the Massachusetts Department of Medical Security. He received a master's degree from Harvard University's John F. Kennedy School of Government and a law degree from Harvard Law School.

**Katherine Weno, DDS, JD**, is an independent public health consultant. Previously, she held positions

at the Centers for Disease Control and Prevention, including senior advisor for the National Center for Chronic Disease Prevention and Health Promotion and director of the Division of Oral Health. Dr. Weno also served as the director of the Bureau of Oral Health in the Kansas Department of Health and Environment. Previously, she was the CHIP advocacy project director at Legal Aid of Western Missouri and was an associate attorney at Brown, Winick, Graves, Gross, Baskerville, and Shoenebaum in Des Moines, Iowa. Dr. Weno started her career as a dentist in Iowa and Wisconsin. She earned degrees in dentistry and law from the University of Iowa.

## Biographies of Staff

**Annie Andrianasolo, MBA**, is the executive administrator. She previously held the position of special assistant for global health at the Public Health Institute and was a program assistant for the World Bank. Ms. Andrianasolo has a bachelor of science in economics and a master of business administration from Johns Hopkins Carey Business School.

**Kirstin Blom, MIPA**, is a principal analyst. Before joining MACPAC, Ms. Blom was an analyst in health care financing at the Congressional Research Service. Before that, Ms. Blom worked as a principal analyst at the Congressional Budget Office, where she estimated the cost of proposed legislation on the Medicaid program. Ms. Blom has also been an analyst for the Medicaid program in Wisconsin and for the U.S. Government Accountability Office (GAO). She holds a master of international public affairs from the University of Wisconsin, Madison.

**James Boissonnault, MA**, is the chief information officer. Prior to joining MACPAC, he was the information technology (IT) director and security officer for OnPoint Consulting. At OnPoint, he worked on several federal government projects, including projects for the Missile Defense Agency, the U.S. Department of the Treasury, and the U.S. Department of Agriculture. He has nearly two decades of IT and communications experience. Mr. Boissonnault holds a master of arts in Slavic languages and literatures from The University of North Carolina and a bachelor of arts in Russian from the University of Massachusetts.

**Madeline Britvec** is a research assistant. Prior to joining MACPAC, she held internships at the U.S. Chamber of Commerce, International Bridges to Justice, and CBS Detroit. Ms. Britvec holds a bachelor of arts in economics and applied statistics from Smith College.

**Kacey Buderer, 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. Buderer 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.

**Benjamin Finder, MPH**, is a senior analyst. His work focuses on benefits and payment policy. Prior to joining MACPAC, he served as an associate director in the Health Care Policy and Research Administration at the District of Columbia Department of Health Care Finance and as an analyst at the Henry J. Kaiser Family Foundation. Mr. Finder holds a master of public health from The George Washington University, where he concentrated in health policy and health economics.

**Moira Forbes, MBA**, is a policy director focusing on payment policy and the design, implementation, and effectiveness of program integrity activities in Medicaid and the State Children's Health Insurance Program (CHIP). Previously, she served as director of the division of health and social service programs in the Office of Executive Program Information at HHS and as a vice president in the Medicaid practice at the Lewin Group. At Lewin, Ms. Forbes worked with every state on issues relating to program integrity and eligibility quality control in Medicaid and CHIP. She has extensive experience with federal and state policy analysis, Medicaid program operations, and delivery system design. Ms. Forbes has a master of business administration from The George Washington University and a bachelor's degree in Russian and political science from Bryn Mawr College.

**Martha Heberlein, MA**, is a principal analyst. Prior to joining MACPAC, she was the research manager at

the Georgetown University Center for Children and Families, where she oversaw a national survey on Medicaid and CHIP eligibility, enrollment, and renewal procedures. Ms. Heberlein holds a master of arts in public policy with a concentration in philosophy and social policy from The George Washington University and a bachelor of science in psychology from James Madison University.

**Kayla Holgash, MPH**, is an analyst focusing on payment policy. Prior to joining MACPAC, Ms. Holgash worked as a senior research assistant in the Department of Health Policy and Management at The George Washington University and as a health policy legislative intern for U.S. Senator Charles Grassley. Before that, she served as the executive manager of the Health and Wellness Network for the Homewood Children's Village, a non-profit organization in Pittsburgh, Pennsylvania. Ms. Holgash holds a master of public health from The George Washington University and a bachelor of science in public and community health from the University of Maryland.

**Joanne Jee, MPH**, is the congressional liaison and a principal analyst focusing on CHIP and children's coverage. Prior to joining MACPAC, she was a program director at the National Academy for State Health Policy, where she focused on children's coverage issues. Ms. Jee also has been a senior analyst at GAO, a program manager at the Lewin Group, and a legislative analyst in the HHS Office of Legislation. Ms. Jee has a master of public health from the University of California, Los Angeles, and a bachelor of science in human development from the University of California, Davis.

**Allissa Jones** is the administrative assistant. Prior to joining MACPAC, she worked as an intern for Kaiser Permanente, where she helped coordinate health and wellness events in the Washington, DC, area. Ms. Jones holds a bachelor of science with a concentration in health management from Howard University.

**Kate Kirchgraber, MA**, is a policy director. Prior to joining MACPAC, she led the private health insurance and Medicaid and CHIP teams at the CMS Office of Legislation. She has held health policy and budget

analysis positions on the federal and state levels, including with the U.S. Senate Committee on Finance, Office of Management and Budget, and the New York State Assembly Ways and Means Committee. She also has worked as a private consultant on Medicaid, health coverage, and financing issues. Ms. Kirchgraber has a master of arts in teaching from the State University of New York at Albany and a bachelor of arts in economics and history from Fordham University.

**Nisha Kurani, MPP**, is an analyst. Prior to joining MACPAC, Ms. Kurani was a policy associate at the Henry J. Kaiser Family Foundation. She also has held research and policy analysis positions at the University of California's Berkeley School of Public Health, the Public Policy Institute of California, and Housing and Economic Rights Advocates. Ms. Kurani holds a master of public policy from the University of California, Berkeley, and a bachelor of science in physiology and neuroscience from the University of California, San Diego.

**Erin McMullen, MPP**, is a principal analyst. Prior to joining MACPAC, she served as the chief of staff in the Office of Health Care Financing at the Maryland Department of Health. Ms. McMullen also has been a senior policy advisor in the Office of Behavioral Health and Disabilities at the Maryland Department of Health, and a legislative policy analyst for the Maryland General Assembly's Department of Legislative Services. Ms. McMullen holds a master of public policy from American University and a bachelor's degree in economics and social sciences from Towson University.

**Nevena Minor, MPP**, is a senior analyst. Prior to joining MACPAC, Ms. Minor was deputy director of the American Psychiatric Association's Department of Reimbursement Policy, focusing on Medicaid and Medicare policies affecting access to care for mental health and substance use disorders. She was also head of the federal affairs division of the American Congress of Obstetricians and Gynecologists, leading its work on physician payment and reproductive, maternal, and child health. Before that, Ms. Minor held several positions at the Heart Rhythm Society.



She has a master's degree in public policy with a concentration in health policy from The George Washington University and a bachelor of arts in sociology from Dickinson College.

**Jessica Morris, MPA**, is a principal analyst focusing on Medicaid data and program integrity. Previously, she was a senior analyst at GAO with a focus on Medicaid data systems. She also was a management analyst at the U.S. Department of Veterans Affairs (VA), a presidential management fellow at the Pittsburgh VA Medical Center, and a legislative correspondent in the U.S. Senate. Ms. Morris has a master of public administration from The George Washington University and a bachelor of arts in political science and communications from the State University of New York at Cortland.

**Robert Nelb, MPH**, is a senior analyst focusing on issues related to Medicaid payment and delivery system reform. Prior to joining MACPAC, he served as a health insurance specialist at CMS, leading projects related to CHIP and Medicaid Section 1115 demonstrations. Mr. Nelb has a master of public health and a bachelor's degree in ethics, politics, and economics from Yale University.

**Kevin Ochieng** is MACPAC's IT specialist. Before joining MACPAC, Mr. Ochieng was a systems analyst and desk-side support specialist at American Institutes for Research, and prior to that, an IT consultant at Robert Half Technology, where he focused on IT system administration, user support, network support, and PC deployment. Previously, he served as an academic program specialist at the University of Maryland University College. Mr. Ochieng has a bachelor of science in computer science and mathematics from Washington Adventist University.

**Chris Park, MS**, is a principal analyst. He focuses on issues related to managed care payment and Medicaid drug policy and has lead responsibility for MACStats. Prior to joining MACPAC, he was a senior consultant at the Lewin Group, where he provided quantitative analysis and technical assistance on Medicaid policy issues, including managed care capitation rate-setting and pharmacy-reimbursement

and cost-containment initiatives. Mr. Park holds a master of science in health policy and management from the Harvard School of Public Health and a bachelor of science in chemistry from the University of Virginia.

**Ken Pezzella, CGFM**, is the chief financial officer. He has more than 15 years of federal financial management and accounting experience in both the public and private sectors. Mr. Pezzella also has broad operations and business experience, and is a proud veteran of the U.S. Coast Guard. He holds a bachelor of science in accounting from Strayer University and is a certified government financial manager.

**Brian Robinson** is MACPAC's financial analyst. Prior to joining MACPAC, he worked as a business intern at the Joint Global Climate Change Research Institute, a partnership between the University of Maryland and Pacific Northwest National Laboratory. Mr. Robinson holds a bachelor of science in accounting from the University of Maryland.

**Anne L. Schwartz, PhD**, is the executive director. She previously served as deputy editor at *Health Affairs*; vice president at Grantmakers In Health, a national organization providing strategic advice and educational programs for foundations and corporate giving programs working on health issues; and special assistant to the executive director and senior analyst at the Physician Payment Review Commission, a precursor to the Medicare Payment Advisory Commission (MedPAC). Earlier, she held positions on committee and personal staff for the U.S. House of Representatives. Dr. Schwartz earned a doctorate in health policy from the School of Hygiene and Public Health at Johns Hopkins University.

**Rick Van Buren, JD**, is a senior analyst. Prior to joining MACPAC, he was a health insurance specialist in the CMS Office of Legislation, where he served as the lead analyst on the Medicaid drug rebate program and Medicaid managed care. Mr. Van Buren has a juris doctor from Georgetown University and a bachelor's degree in English and political science from the University of Pittsburgh.

**Kristal Vardaman, MSPH**, is a principal analyst focused on long-term services and supports and on high-cost, high-need populations. Previously, she was a senior analyst at GAO and a consultant at Avalere Health. Ms. Vardaman holds a master of science in public health from The University of North Carolina at Chapel Hill and a bachelor of science from the University of Michigan. She currently is pursuing a doctorate in public policy from The George Washington University.

**Ricardo Villeta, MBA**, is the deputy director of operations, finance, and management with overall responsibility for operations related to financial management and budget, procurement, human resources, and IT. Previously, he was the senior vice president and chief management officer for the Academy for Educational Development, a private non-profit educational organization that provided training, education, and technical assistance throughout the United States and in more than 50 countries. Mr. Villeta holds a master of business administration from The George Washington University and a bachelor of science from Georgetown University.


**Eileen Wilkie** is the administrative officer and is responsible for coordinating human resources, office maintenance, travel, and Commission meetings. Previously, she held similar roles at National Public Radio and the National Endowment for Democracy. Ms. Wilkie has a bachelor's degree in political science from the University of Notre Dame.





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