Chapter 2:

Medicaid and the Opioid Epidemic



Medicaid and the Opioid Epidemic

Key Points

- The opioid epidemic, which has reached most communities across the U.S., disproportionately affects Medicaid beneficiaries. For example:
 - Medicaid beneficiaries age 18–64 have a higher rate of opioid use disorder than privately insured individuals, comprising about 12 percent of all civilian, non-institutionalized adults in this age group but about one-quarter of those with an opioid use disorder.
 - Medicaid beneficiaries are prescribed pain relievers at higher rates than those with other sources of insurance.
 - They also have a higher risk of overdose and other negative outcomes, from both prescription opioids and illegal opioids such as heroin and illicitly manufactured fentanyl.
 - But Medicaid beneficiaries with an opioid use disorder have higher treatment rates than privately insured adults with the same condition.
- State Medicaid programs are responding to the opioid crisis by covering treatment, innovating in the delivery of care, and working to reduce misuse of prescription opioids. Medicaid programs cover many components of medication-assisted treatment (MAT), the recommended treatment for opioid use disorders under current evidence-based guidelines. However, there is considerable variation in available services across states, since many are optional under the Medicaid statute.
- States are using a variety of legal authorities to expand both the availability of treatment and the number of individuals eligible for such care. They are also working to organize and integrate physical health and substance use disorder treatment delivery systems to provide more effective care. These mechanisms include Section 1115 waivers, the health homes option, and the rehabilitation option.
- States are also focused on identifying opioid overprescribing in order to prevent opioid use disorders from developing. These approaches include prescription drug monitoring programs, patient review and restriction programs, drug utilization reviews, utilization management techniques such as quantity limits or prior authorization requirements for prescription opioids, and the use of non-opioid pain management therapies.
- Even so, many Medicaid enrollees with an opioid use disorder are still not receiving treatment. Barriers to care include individuals not perceiving the need for treatment or fearing the stigma of having a substance use disorder, a fragmented and poorly funded delivery system, privacy regulations that limit care coordination, a shortage of Medicaid-participating providers and providers trained in MAT, and gaps in the continuum of care associated with both restrictive coverage policies and the institution for mental diseases (IMD) payment exclusion.



CHAPTER 2: Medicaid and the Opioid Epidemic

Much has been written about the opioid epidemic in America and its devastating effects on families and communities. In many ways, Medicaid is at its center. The epidemic disproportionately affects Medicaid beneficiaries, and state Medicaid programs are taking the lead in identifying and tailoring strategies to prevent and treat opioid use disorder and reduce its adverse effects. In 2015, Medicaid beneficiaries age 18-64 had a higher rate of opioid use disorder than privately insured individuals: they comprised about 12 percent of all civilian non-institutionalized adults in this age group but about one-guarter of those with an opioid use disorder (SHADAC 2017). Medicaid beneficiaries are prescribed pain relievers at higher rates than those with other sources of insurance. They also have a higher risk of overdose and other negative outcomes, from both prescription opioids and illegal opioids, such as heroin and illicitly manufactured fentanyl (McMullen 2016, Zhou et al. 2016, Sharp and Melnick 2015, Whitmire and Adams 2010, CDC 2009). In addition, Medicaid beneficiaries with an opioid use disorder have higher treatment rates than privately insured with the same condition (SHADAC 2017).

Beyond the human toll, opioid misuse and opioid use disorder have large financial effects. In 2012, 81 percent of the estimated \$1.5 billion in hospital charges related to neonatal abstinence syndrome in infants born to women using opioids was billed to Medicaid (Patrick et al. 2015).¹ In 2012, inpatient hospital charges for individuals with serious infections associated with an opioid use disorder exceeded \$700 million, and Medicaid enrollees accounted for 43 percent of those hospitalizations (Ronan and Herzig 2016).

Opioids are a class of drugs that include many prescription pain relievers (such as oxycodone, hydrocodone, codeine, morphine, fentanyl, and methadone) and illegal versions such as heroin and illicitly manufactured fentanyl (CDC 2016a). While historically considered a moral failing, opioid use disorder-like other substance use disorders-is a chronic brain disease. It typically develops over time with repeated misuse of opioids and involves a three-stage cycle: binge/intoxication, withdrawal/ negative affect, and preoccupation/anticipation. It is further characterized by clinically significant impairments in health, social function, and control over opioid use; development of tolerance; and withdrawal symptoms. An opioid use disorder can range from mild to severe and from temporary to chronic. Continued use increases the severity of effects and changes brain function, persisting long after use has stopped. The extent to which these changes can be reversed, and how long that might take, is unknown. Even so, opioid use disorder can be effectively treated and managed; recurrence rates (also referred to as relapse rates) are no higher than those of other chronic illnesses such as type 2 diabetes, hypertension, or asthma (OSG 2016, ASAM 2014).

Medicaid is responding to the opioid crisis by covering treatment, innovating in the delivery of care, and working with other state agencies to reduce misuse of prescription opioids. However, there are gaps in the continuum of care, and states vary in the extent to which they cover needed treatment. An insufficient supply of providers also limits access to treatment in many locations. The delivery systems for physical health and behavioral health (which encompasses mental illness and substance use disorders) are traditionally separately organized and financed; the resulting fragmentation and lack of coordination can impede access to care and lead to inappropriate and insufficient use of services, poor health status, and increased costs (OSG 2016). The stigma associated with substance use disorders can also affect the willingness of individuals to seek help, providers to offer care, and policymakers to finance treatment.

Although the opioid epidemic has cut a broad swath through our society—affecting rich and poor, as well as urban, suburban, and rural communities—this chapter focuses on how it



affects Medicaid beneficiaries and state strategies to address this crisis. The chapter begins by documenting the prevalence of opioid use and opioid use disorder among different groups of beneficiaries, including children, pregnant women, working-age adults, older adults, and people with disabilities. It goes on to describe how Medicaid programs are covering screening and treatment services for opioid use disorder, highlighting the legal authorities that states are using to expand not only benefits but also the number of enrollees eligible for such care. It then details how Medicaid programs are working to reduce inappropriate opioid prescribing, and concludes by describing the challenges to further improving access to treatment for Medicaid beneficiaries with an opioid use disorder.

Opioid Use, Misuse, and Use Disorders: Prevalence, Comorbidities, and Adverse Outcomes

Prescription opioid misuse occurs when a person uses the drug without a prescription; in greater amounts, more often, or longer than prescribed; or in other ways contrary to the prescribing clinician's directions (Hughes et al. 2016). Opioid use disorder, an umbrella term for both pain reliever and heroin use disorders, is a brain disease that typically develops over time with repeated misuse of opioids. It is characterized by clinically significant impairments in health, social function, and control over opioid use; development of tolerance; and withdrawal symptoms that occur after stopping or reducing use.

Below, we describe the prevalence of and sociodemographic characteristics associated with opioid use, misuse, and opioid use disorder. We also present information on health conditions that can affect or be affected by opioid use, and rates of treatment for opioid use disorder. While not all the data in this section are specific to Medicaid, they are useful in understanding the scope and nature of the epidemic.

Prevalence of opioid use, misuse, and use disorder

In 2015, 2 million people (0.8 percent of civilian, non-institutionalized individuals age 12 and older in the U.S.) had a prescription pain reliever disorder, and some 12.5 million people (4.7 percent of individuals age 12 and older) had misused prescription pain relievers in the previous year (Bose et al. 2016, Hughes et al. 2016). Rates of prescription opioid use and misuse differed among population groups (Table 2-1).

Link between prescription opioids and heroin use

People who misuse opioids may turn from prescription drugs to illegal drugs, which may be cheaper and more potent; the share that do so is small, at less than 5 percent (Compton et al. 2016, Wu et al. 2011). Most heroin users, however, have a history of prescription opioid misuse (Jones et al. 2015a). For example, one study found that among people who used both prescription opioids for non-medical reasons and heroin during the previous year, 77.4 percent reported using prescription opioids before initiating heroin use (Jones 2013).² A recent study comparing data from 2001-2002 to 2012-2013 found an increase in the share of white individuals whose heroin use was preceded by non-medical use of prescription opioids. There was, however, a reduction in the percentage of non-white users who reported nonmedical prescription opioid use before initiation of heroin use over the same time span (Martins et al. 2017). The increase in heroin overdose deaths rates has occurred concurrently with an increase in prescription opioid overdoses (Jones et al. 2015a).



TABLE 2-1. Share of Prescription Pain Reliever Use and Misuse in Past Year among U.S. PersonsAge 12 and Older, by Demographic Characteristics, 2015

Demographic group	Prescription pain reliever use past year	Prescription pain reliever misuse past year			
All individuals age 12 and older	36.4%	4.7%			
Age					
12–17	22.7	3.9			
18–25	34.8	8.5			
26 and older	38.3	4.1			
Sex					
Male	33.9	5.3			
Female	38.8	4.0			
Race and ethnicity					
White	38.7	4.8			
Black	38.3	4.4			
Hispanic	30.2	5.0			
Asian	22.0	1.8			
American Indian or Alaska Native	38.7	5.6			
Native Hawaiian or other Pacific Islander	32.7	5.4			
Two or more races	44.8	8.4			
Education (among persons 18 and older)					
Less than high school	37.4	5.7			
High school graduate	38.9	4.9			
Some college or associate degree	42.8	5.7			
College graduate	38.1	3.1			
Employment status (among persons 18 and older)					
Working full time	34.9	4.8			
Working part time	36.5	5.4			
Unemployed	40.1	9.1			
Other ¹	42.4	3.7			

Notes: Prescription pain reliever use means the use of one's own prescription medication as directed by the prescribing clinician. Prescription pain reliever misuse means taking a prescription medication without a prescription; taking a prescription medication in greater amounts, more often, or longer than prescribed; or taking a prescription medication in any other way contrary to the prescribing clinician's directions. Table shows percentage of given U.S. population group with prescription pain reliever use or misuse in past year, as reported in the 2015 National Survey on Drug Use and Health (SAMHSA 2016a).

¹ Other indicates individuals not in the labor force (e.g., students, homemakers, retirees, or people not working due to disability).

Source: SHADAC 2017, Hughes et al. 2016, SAMHSA 2016a.



Prevalence of opioid disorders by insurance status

In 2015, Medicaid beneficiaries were more likely to abuse or have a dependency on an opioid in the previous year than privately insured adults age 18–64. Medicaid beneficiaries have similar rates of opioid abuse and dependence (both considered an opioid use disorder) as uninsured adults (Table 2-2). Medicaid enrollees, however, are more likely than privately insured and uninsured adults to have both used heroin in the past and had a pain reliever dependence in the previous year. They are the most likely to have ever used heroin and misused a prescription pain reliever.

Opioid use disorder occurs across all Medicaid beneficiary groups and demographics, but certain comorbid conditions, predictors of future use disorder, and outcomes differ.

Geographic differences. There has been substantial media attention on opioid misuse and opioid use disorder in rural areas (Bohner 2017, Gliha 2017, Runyon 2017, Tanner 2016). Even so, using national datasets, misuse of prescription opioids between rural and more urban areas show either similar rates of misuse or higher rates in urban and suburban areas (Lenardson et al. 2016, Rigg and Monnat 2015, SAMHSA 2013a). These statistics may mask other important differences, however. For example, studies documented a higher prevalence of prescription pain reliever misuse in certain vulnerable rural populations, such as adolescents, women who are pregnant or experiencing partner violence, and persons with co-occurring disorders. One study found higher misuse rates among specific rural subpopulations compared to their urban counterparts, including those who had less than a high school education, were uninsured, were in fair or poor health, or had low incomes (Lenardson et al. 2016, Monnat and Rigg 2015, Havens et al. 2011).

Additionally, there has been a shift in the demographics of heroin use over the past 50 years. No longer centered in inner cities and among racial minorities, heroin use is now more widespread geographically, involving primarily white men and women in their late 20s living outside of large urban areas (Cicero et al. 2014). States with the highest opioid overdose death rates also include states with large rural populations, such as Kentucky, New Hampshire, and West Virginia (Rudd et al. 2016).

Pregnant women and infants. Opioids are widely prescribed among women of childbearing age, with over one-third of Medicaid-enrolled women filling an opioid prescription annually (Ailes et al. 2015). Between 2005 and 2014, nearly 1 percent of pregnant women and 2.3 percent of non-pregnant women of reproductive age reported non-medical use of a prescription opioid in the previous 30 days. Of these women reporting non-medical use of a prescription opioid, pregnant women were more likely to receive their opioid from a doctor (46 percent) than were non-pregnant women (28 percent) (Kozhimannil et al. 2017). Infants born to women using opioids during pregnancy may experience neonatal abstinence syndrome, which manifests in the first few days of life with the following symptoms: difficulty with mobility and flexing; inability to control heart rate, temperature, and other autonomic functions; irritability; poor sucking reflex; impaired weight gain; and, in some cases, seizures (Tolia et al. 2015, Patrick et al. 2015). From 2004 to 2013, neonatal intensive care unit admissions for infants with neonatal abstinence syndrome increased from 7 cases per 1,000 admissions to 27 cases per 1,000 admissions (Tolia et al. 2015).

Adolescents. Adolescents who have an opioid prescription by 12th grade are more likely to misuse prescription opioids by the time they are 23 than those with no history of an opioid prescription (Miech et al. 2015). A history of prescription opioid misuse is also associated with initiating heroin use. Those beginning misuse of prescription opioids between the ages of 10 and 12 have the highest risk of transitioning to heroin use, and that association appears to be consistent across race, ethnicity, and income groups (Cerdá et al. 2015).



TABLE 2-2. Substance Misuse, Abuse, and Dependence in Adults Age 18–64, by Insurance Status, 2015

	Number of adults age 18–64	Percentage of all adults age 18–64	Percentage of adults age 18–64 in each coverage category		
Type of use			Medicaid	Private ¹	Uninsured
Illicit drug dependence or abuse, past year	6,674,356	3.4%	5.7%	2.4%*	5.4%
Illicit drug and alcohol abuse, past year	358,315	0.2	0.2	0.2	0.3
Illicit drug or alcohol abuse, past year	7,448,820	3.8	2.7	3.9*	4.7*
Pain reliever dependence, past year	1,430,552	0.7	1.3	0.5*	1.0
Pain reliever abuse, past year	444,013	0.2	0.5	0.1*	0.4
Misused pain reliever, past 30 days	3,309,245	1.7	2.6	1.3*	2.6
Ever misused pain reliever	24,194,171	12.4	14.0	11.7*	14.5
Misused OxyContin, past 12 months	1,581,181	0.8	1.2	0.6*	1.4
Ever used heroin	1,855,967	2.4	5.2	1.5*	3.2*
Heroin dependence, past year	555,291	0.3	0.8	0.1*	0.6
Ever used heroin and had pain reliever dependence, past year	535,853	0.3	0.8	0.2*	0.4*
Ever used heroin and ever misused pain reliever	1,123,879	1.4	3.3	0.9*	2.3*
Ever misused pain reliever and had heroin dependence, past year	164,051	0.2	0.6	0.1*	0.6

Notes: Before the 2013 release of the updated *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition* (DSM-5), substance use disorders were split into two categories, abuse and dependence (e.g., an alcohol use disorder could be either a diagnosis of alcohol abuse or a diagnosis of alcohol dependence). The DSM-5 no longer distinguishes between abuse or dependence and uses one designation for substance use disorders and measures them on a continuum from mild to moderate to severe (e.g., a mild alcohol use disorder or a severe opioid use disorder). The 2015 National Survey on Drug Use and Health (NSDUH), however, used the older definition of abuse and dependence. In this survey, pain reliever misuse means taking a prescription medication without a prescription; taking a prescription medication in greater amounts, more often, or longer than prescribed; or taking a prescription medication in any other way contrary to the prescribing clinician's directions. We used the following hierarchy to assign individuals with multiple insurance coverage sources to a primary source: Medicare, private, Medicaid, other, or uninsured. Coverage source is defined as of the time of the most recent survey interview.

¹ Private health insurance coverage excludes plans that pay for only one type of service, such as accident coverage or dental care.

* Difference from Medicaid is statistically significant at the 0.05 level.

Source: SHADAC 2017.



Working-age adults. Factors that predict misuse by working-age adults include being male, unmarried, low income, and uninsured (Cicero et al. 2014). Available research suggests that opioid deaths and opioid-related emergency department visits rise when county-level and state-level unemployment rates increase (Hollingsworth et al. 2017). A recent study found that among adults age 26 and older, unemployed individuals were most likely to misuse prescription opioids, followed by those employed full-time. Individuals not in the labor force (e.g., students, homemakers, retirees, or persons not working due to disability) were least likely to misuse a prescription opioid (Perlmutter et al. 2017). People involved with the criminal justice system, by contrast, have higher rates of substance use disorders and heroin use in particular (Evans and Sullivan 2015, Belenko et al. 2013).

Older adults. There is relatively little high-quality research on prescription opioid misuse among older adults (Maree et al. 2016). One study found that in 2012, over one-third of Medicare enrollees with Part D prescription drug coverage filled at least one prescription for an opioid, and these individuals had more comorbidities than those without an opioid prescription. Those with particularly high use of opioids were more likely to be under age 65 and receiving a low-income subsidy (MedPAC 2015).³ The Medicare population has one of the highest and fastest-growing rates of diagnosed opioid use disorder. Mortality rates among older adults also increased and surpassed rates for younger adults in 2012 and 2013 (Lembke and Chen 2016, West et al. 2015). Opioids and benzodiazepines (which are more likely to be prescribed to older adults to treat anxiety and sleep disorders) are also a high-risk combination, particularly in such older individuals (Nuckols et al. 2014, AOA and SAMHSA 2012).

People with disabilities. People with disabilities are more likely to be prescribed opioid pain relievers due to their higher rates of painful conditions, but there are no nationally representative data on opioid misuse in populations of people with disabilities (NCHS 2016). One systematic review and data synthesis found that rates of opioid misuse averaged between 21 percent and 29 percent among patients with chronic pain, and rates of addiction averaged between 8 percent and 12 percent (Vowles et al. 2015). Another systematic review of studies of opioid prescribing for patients with low back pain found that up to 25 percent of patients receiving these medications exhibited some signs of medication misuse (Martell et al 2007).

Utilization of treatment for opioid use disorder by insurance status

Medicaid beneficiaries with opioid use disorder are more likely to receive treatment than privately insured adults with the disorder, both inpatient and outpatient treatment. They are about three times more likely to receive drug or alcohol treatment in a hospital as an inpatient or in a residential treatment facility than privately insured adults, and they are almost twice as likely to receive care on an outpatient basis from a mental health center than privately insured adults. Treatment services, however, remain substantially underutilized; this is often referred to as the treatment gap. In 2015, only about 32 percent of Medicaid enrollees with an opioid use disorder were receiving treatment (Table 2-3).

It is unclear why Medicaid enrollees are more likely to receive treatment than privately insured individuals. Many factors influence whether an individual seeks care; for example, a belief that one does not need treatment, an unwillingness or inability to stop using drugs, concerns about the effect on one's job, inability to afford the cost of treatment, lack of information about treatment options, and lack of available treatment programs in the community (OSG 2016). Another possible explanation for the difference in rates of treatment between individuals covered by Medicaid and those with private insurance is that private plans may impose higher out-of-pocket costs or more stringent coverage limits, which discourage individuals from seeking care. Those with



employer-sponsored coverage may also worry that their employer will find out about their substance use disorder, and thus they do not get treatment (Bouchery et al. 2012). Differences in rates of treatment receipt were also observed by various demographic characteristics, such as age, race, and educational level (Bali 2013).

TABLE 2-3. Treatment for Substance Use Disorder among Adults Age 18–64 with Past Year Opioid Use Disorder, by Medicaid and Private Insurance Coverage, 2015

	Percentage of adults age	Percentage in each coverage category	
Treatment characteristics	18–64 with past year opioid use disorder	Medicaid	Private ¹
Currently receiving treatment or counseling	20.2%	32.3%	17.2%*
Ever received alcohol or drug treatment	56.0	64.3	49.9*
During previous 12 months			
Perceived the need for treatment or counseling for alcohol or drug use	11.4	16.0	6.1*
Perceived the need for treatment or counseling for pain reliever use disorder	7.1	N/A	N/A
Perceived the need for treatment or counseling for heroin use disorder	3.8	N/A	N/A
Received treatment in a hospital overnight as an inpatient	10.4	16.4	6.2*
Received treatment in a residential drug rehabilitation facility	11.7	21.8	7.1*
Received treatment in a drug rehabilitation facility as an outpatient	19.6	30.4	16.2*
Received treatment in a mental health center or facility as an outpatient	11.0	22.0	8.0*
Received treatment in an emergency room	5.8	9.6	4.0
Received treatment in a private doctor's office	12.7	15.4	15.4
Participated in a mutual aid group such as Alcoholics Anonymous or Narcotics Anonymous	20.2	26.0	19.0
Received treatment in another place	10.7	N/A	9.8

Notes: N/A indicates that the estimate is based on too small a sample or is too unstable to present. We used the following hierarchy to assign individuals with multiple coverage sources to a primary source: Medicare, private, Medicaid, other, or uninsured. Coverage source is defined as of the time of the most recent survey interview.

¹ Private health insurance coverage excludes plans that pay for only one type of service, such as accident coverage or dental care.

* Difference from Medicaid is statistically significant at the 0.05 level.

Source: SHADAC 2017.



Opioid use disorder and comorbidities

It is important to note that there are health factors that can exacerbate disorders and make effective treatment difficult. For example, comorbidities such as mental illness or misuse of other substances may interfere with a patient's ability to seek care (e.g., they are too weak to travel, or these conditions interfere with adherence). In addition, other conditions may be the main focus of a patient's treatment, with opioid use disorder being ignored or considered less critical to treat. For example:

- Heroin use, in particular, is associated with other serious health conditions. When people inject heroin with shared needles, they are at risk of serious, long-term viral infections such as HIV, hepatitis C, and hepatitis B. Intravenous drug use can also cause bacterial infections of the skin, bloodstream, and heart (CDC 2015).
- People who use other substances are more likely to misuse pain relievers (Bose et al. 2016). For example, 5.9 percent of past-year alcohol users also misused prescription pain relievers during the same time period. Among past-year heroin users age 12 and older, 72.1 percent had misused prescription pain relievers during the same time period. Of people age 12 and older who used marijuana in the past year, 16.2 percent also misused prescription pain relievers during the same time period (Bose et al. 2016). A significant percentage of heroin users meet diagnostic criteria for disorders involving other drugs (Jones et al. 2015a).
- There is a higher prevalence of opioid use disorder among individuals with anxiety or mood disorders, such as major depressive disorder or bipolar disorder, than in individuals without these conditions (NIDA 2010). Among the 19.6 million adults age 18 and older in 2015 with a past-year substance use disorder, 2.3 million (11.9 percent) also had a serious

mental illness during the same period (Bose et al. 2016).

Mortality associated with opioid use

Although opioids are useful for pain control when used appropriately, their mood-enhancing effects and addictive properties can lead to misuse, opioid use disorder, and negative outcomes, such as increased risk of brain and organ damage and death. National statistics on opioid-related death rates specific to the Medicaid population are not available, but drug overdose deaths in the United States overall nearly tripled from 1999 to 2014 (Rudd et al. 2016). During this period, overdose death rates were highest among the 25 to 54 age group. Overdose death rates for non-Hispanic whites and American Indian or Alaskan Natives were higher than rates for non-Hispanic blacks and Hispanics, and men were more likely to die from an overdose than women (although the mortality gap between men and women is closing) (CDC 2016b). State-level data on opioid overdose deaths show Medicaid beneficiaries have a higher risk of overdose and adverse effects from both prescription opioids and illegal versions, including heroin and illicitly manufactured fentanyl (McMullen 2016, Zhou et al. 2016, Sharp and Melnick 2015, Whitmire and Adams 2010, CDC 2009).

Death rates vary by type of opioid. There is progress in preventing methadone deaths: death rates declined by 9.1 percent from 2014 to 2015 (Figure 2-1). During the same time period, however, overdose deaths associated with other synthetic opioids increased by 72.2 percent (most likely due to greater availability of illicitly manufactured fentanyl), while natural or semisynthetic opioid death rates increased by 2.6 percent (Rudd et al. 2016, Gladden et al. 2016).⁴ Heroin death rates increased by 20.6 percent overall and across all demographic groups and regions. Of the 28 states with high-quality data permitting state-level analysis, 16 experienced increases in death rates involving synthetic opioids other than methadone,



and 11 saw increases in heroin death rates. West Virginia had the highest death rate associated with opioid use, followed in descending order by New Hampshire, Kentucky, Ohio, and Rhode Island. The largest overall changes in rates of death from synthetic opioids other than methadone occurred in Massachusetts, New Hampshire, Ohio, Rhode Island, and West Virginia; the largest overall changes in rates of heroin deaths were in Connecticut, Massachusetts, Ohio, and West Virginia. New Mexico, Oklahoma, and Virginia saw decreases in rates of deaths due to natural or semisynthetic opioids, while increases occurred in Massachusetts, New York, North Carolina, Ohio, and Tennessee (Rudd et al. 2016).



Notes: Other opioids in this figure include natural opioids (e.g., morphine and codeine), semisynthetic opioids (e.g., oxycodone, hydrocodone, hydromorphone, and oxymorphone), and synthetic opioids other than methadone

(e.g., tramadol and fentanyl).

Source: MACPAC, 2017, analysis of Centers for Disease Control and Prevention 1999–2015 multiple cause of death data.



Medicaid's Response to the Opioid Epidemic

Medicaid is fighting the opioid epidemic on a variety of fronts. State Medicaid programs cover substance use disorder treatment and supportive services to varying degrees. They are working to integrate care for physical health and treatment for substance use disorders across providers and with other social programs. They also are implementing programs to reduce opioid overprescribing in order to prevent opioid use disorder from developing in the first place. Many of these efforts are being undertaken in conjunction with other state and federal initiatives, such as the National Governors Association's Compact to Fight Opioid Addiction and the Centers for Medicare & Medicaid Services (CMS) Opioid Misuse Strategy (CMS 2017a, NGA 2016).

Medicaid coverage of diagnosis and treatment for opioid use disorder

State Medicaid programs cover many services that are considered effective in identifying and intervening in misuse, responding to overdoses, and diagnosing and treating opioid use disorder. Below, we describe three components that contribute to this success: screening and early intervention, naloxone use, and medicationassisted treatment.

Coverage varies considerably across states, in part because many of these services are optional under the Medicaid statute. Such services include counseling, services provided by licensed clinical social workers, targeted case management, medication management, clinic services, prescription drugs, and peer and recovery supports.⁵ States that expanded Medicaid to the new adult group have different obligations to these beneficiaries: alternative benefit plans offered to the new adult group must cover 10 essential health benefits, including mental health and substance use disorder services (CMS 2017b). Although mental health parity requirements prohibit Medicaid managed care organizations and alternative benefit plans from imposing financial and treatment limitations to mental health and substance use disorder benefits that are more stringent than those imposed on medical and surgical benefits, parity requirements apply only to covered benefits and do not create an obligation to provide them (CMS 2013).

Screening and early intervention. Because of the prevalence of substance use disorders and the fact that most individuals with such a disorder are not aware of the need for treatment, it is important for clinicians, including primary care providers, to screen for misuse and disorders, engage patients, and provide interventions and referrals for additional care as needed. Thirtyfour states and the District of Columbia covered some component of screening, intervention, and referral under Medicaid in 2012 (Townley and Dorr 2017, Shapiro et al. 2013). Current guidelines of the American Academy of Family Physicians, the American Academy of Pediatrics, and the American College of Obstetricians and Gynecologists call for universal and ongoing screening for substance use and mental health issues in both adults and adolescents (OSG 2016).6 The United States Preventive Services Task Force (USPSTF) recommends that primary care providers screen adults for alcohol misuse and provide brief behavioral counseling interventions as an evidencebased practice (USPSTF 2013). The USPSTF is currently reviewing new evidence and is potentially updating its recommendation regarding screening and intervention for illicit drug use in adults, including pregnant women, and adolescents. The USPSTF had previously found insufficient evidence regarding the utility of screening and intervention in the general population (USPSTF 2016).

Overdose prevention. Naloxone reverses or blocks the effects of opioids, reducing the likelihood of overdose death or injury, such as brain and other organ damage. All states cover naloxone (MACPAC 2016a). In addition, 26 state Medicaid programs listed naloxone on their preferred drug lists or



Medication-assisted treatment. For individuals who already have an opioid use disorder, current evidence-based guidelines recommend the use of medication-assisted treatment (MAT), which combines medication with counseling, behavioral therapies, and recovery support services (VA/ DoD 2015, ASAM 2015). When used correctly, MAT is cost-effective and can reduce or eliminate illicit opioid use, restore healthy functioning, lessen criminal activity, reduce infectious disease transmission, and lead to significant reductions in inpatient and detoxification use (OSG 2016, Baser et al. 2011). Medicaid coverage of MAT components, as described below, varies considerably.

Medications. Three medications are currently approved by the U.S. Food and Drug Administration (FDA) for use in MAT of opioid use disorder: methadone, buprenorphine, and naltrexone. While all states now cover at least one of these three, many do not cover all. State Medicaid policies on these drugs as of 2015 were as follows:

- methadone-30 states and the District of Columbia covered methadone (MACPAC 2016a);
- buprenorphine—all 50 states and the District of Columbia covered at least one formulation of buprenorphine (Grogan et al. 2016); and

 naltrexone-49 states and the District of Columbia covered at least one formulation of naltrexone under Medicaid state plan authority (MACPAC 2016a).

MACPAC

Each medication has its own known risks and benefits, and, depending on an individual's treatment plan, they may not be interchangeable (VA/DoD 2015).⁷ Clinical guidelines note that the clinician and patient should share the decision in selecting a treatment, basing it on patient preferences, resources, past treatment history, and treatment setting (ASAM 2015). There is not yet sufficient research to recommend a specific length of time for MAT, but arbitrary maintenance periods (e.g., 90 or 180 days), followed by detoxification from methadone or buprenorphine, are rarely effective and may lead to relapse and overdose (OSG 2016). Studies show that methadone and buprenorphine can be successfully used for years at a time and other studies also indicate that long-term treatment is more effective than guick tapering with buprenorphine (VA/DoD 2015).

Behavioral therapies. The second component of MAT is the use of behavioral therapies to help patients develop healthier and more productive coping mechanisms and recognize how their behaviors affect their ability to support long-term recovery. In 2015, 24 states covered some type of psychotherapy, and 39 states and the District of Columbia covered some other type of therapy under their state plan (MACPAC 2016b).

Several types of therapy are effective in treating substance use disorders across different genders, ages, and racial and ethnic groups. Generally, these therapies can be delivered in any treatment setting and include the following:

- cognitive-behavioral therapy (CBT)—teaches coping skills and techniques to identify and modify dysfunctional thinking, usually involves 12–24 weekly individual sessions;
- contingency management—gives material rewards to individuals who are demonstrating



positive behavior changes (e.g., participating in treatment activities or testing drug-free in urine screens);

- motivational enhancement therapy—uses motivational interviewing techniques to help individuals resolve any ambivalence about stopping substance use;
- the Matrix model—a 16-week structured program that includes relapse prevention, family therapy, group therapy, drug education, and self-help;
- family therapy—conducted with partners, children, and others to support an individual's behavior change; and
- 12-step facilitation—therapy designed to prepare individuals to engage in programs such as Alcoholics Anonymous or Narcotics Anonymous (OSG 2016).

Treatment settings. Opioid use disorder treatment can occur in a variety of settings depending on the severity of an individual's disorder and treatment goals (Table 2-4). Many states use the criteria developed by the American Society of Addiction Medicine (ASAM), called the ASAM Criteria, which uses a multidimensional assessment to create a comprehensive and individualized treatment plan, including a determination of the most appropriate setting for care (ASAM 2017).

Recovery support services. Due to the chronic nature of substance use disorders, individuals often require ongoing management and monitoring to support long-term recovery, especially after treatment has ended. Recovery support services can provide emotional and practical support to maintain remission. Individuals who participate in treatment and utilize support services typically have better long-term outcomes than individuals receiving either alone. These services 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). In 2015, 14 states covered some form of peer support for substance use disorders and 9 states and the District of Columbia covered some version of supported employment under state plan authority (MACPAC 2016b).

Medicaid innovations in delivery of care for opioid use disorder

State Medicaid programs are using a variety of legal authorities to organize delivery systems to combat the opioid epidemic. These include:

- Section 1115 waivers;
- Section 2703 health homes option;
- the state plan rehabilitation option; and
- Section 1915(i) state plan option for homeand community-based services.

Below, we describe four state initiatives that are using different authorities to improve access to treatment and improve outcomes.

Vermont: Care Alliance for Opioid Addiction. In Vermont, the Care Alliance for Opioid Addiction, also known as the Hub and Spoke Initiative, is expanding MAT access statewide to Medicaid enrollees with opioid use disorder. The initiative builds on the existing substance use disorder infrastructure and seeks to increase treatment capacity and integration with other types of medical care to provide comprehensive, coordinated, high-quality services. Operating under the Section 2703 health homes option, Vermont receives a temporary enhanced federal match for the services to coordinate care across the continuum of care.

The hubs in the Vermont model are seven (as of January 2017) regional opioid treatment program (OTP) facilities, which coordinate care and support services for clinically complex patients with opioid



use disorder and co-occurring substance use disorders or mental health conditions. Depending on the patient's needs, support services can include mental health treatment, pain management, family supports, life skills, job development, and recovery supports. Methadone dispensing is restricted by federal law to these specially licensed OTP facilities, but buprenorphine may also be available in an OTP. The hubs receive a monthly bundled payment for Medicaid health home enrollees' care (Cimaglio 2017, VTDH 2017, Moses and Klebonis 2015).

The spokes in the Vermont model are patient-centered medical homes; for instance, a primary care practice or a federally qualified health

TABLE 2-4. Medicaid Covered Benefits in Substance Use Disorder Care Settings, 2	2015
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Setting	Medicaid covered benefits		
Medically monitored or managed inpatient hospital care			
For individuals who require withdrawal management, primary medical and nursing care, or both.	Thirty-one states and the District of Columbia covered some form of inpatient detoxification.		
Residential services in 24-hour non-hospital setting			
Provide intensive support, structure, and evidence- based clinical services for individuals who are not stabilized enough to receive care on an outpatient basis.	Twenty-six states and the District of Columbia covered some type of non-detoxification related inpatient care, which may include treatment in residential facilities.		
Partial hospitalization or intensive outpatient services			
Provide a range of services such as counseling, education, and clinically intensive programming. This care is appropriate for individuals who live in a stable environment conducive to recovery but nevertheless require rigorous structure to avoid relapse.	Seventeen states covered some form of partial hospitalization and 21 states and the District of Columbia covered some type of intensive outpatient services.		
Outpatient settings			
Outpatient treatment includes treatment provided in primary and specialty physician practices, community mental health centers, and specialized substance use disorder treatment programs that provide individual and group behavioral interventions or medications. Care in this setting is appropriate for individuals with mild to moderate substance use disorders or as step-down from more intensive treatment.	State coverage of services delivered in these settings varies according to the type of service.		

Note: Estimates of the number of states covering services in these settings is based on an analysis of coverage under 2015 Medicaid state plan authorities.

Sources: MACPAC 2016b, OSG 2016, ASAM 2015.



center (FQHC), that provide opioid use disorder treatment to patients with less complex needs. Patients being treated with buprenorphine can receive treatment in a spoke. The hubs and spokes have reciprocal clinical relationships, and addiction nurses and licensed addiction and mental health counselors are embedded in the spokes to support the buprenorphine-prescribing providers and deliver the continuum of MAT care. In addition to payment for MAT services, spokes also receive a monthly capacity payment for spoke nurses and clinician case managers (VTBH 2017, Moses and Klebonis 2015).

Previously, the state's treatment network had limited capacity for Medicaid beneficiaries, with some areas having long wait lists for OTPs or no access at all. There were also not enough physicians authorized to prescribe buprenorphine. The siloed nature of the delivery system made management of comorbidities difficult. Enrollees with an opioid use disorder were at risk of overdose and their incurred costs were on average three times higher than other beneficiaries (Cimaglio 2015).

Since implementation in July 2013, the number of enrollees receiving MAT has almost tripled to over 6,000 beneficiaries, and the number of physicians in non-specialty settings offering MAT has also increased significantly. Those receiving MAT have lower inpatient, emergency department, and general pharmacy expenditures than other beneficiaries with opioid use disorder who are receiving treatment without use of methadone and buprenorphine (Mohlman et al. 2016).

Virginia: Medicaid Addiction and Recovery Treatment Services. The opioid epidemic in Virginia has been costly in both human and financial terms. In 2013, prescription opioids and heroin were implicated in 80 percent of drug overdose deaths in Virginia. In 2014, Virginia spent \$44 million on Medicaid beneficiaries with a primary or secondary diagnosis of substance use disorder and who were admitted to hospitals or emergency departments. In 2015, there were 216,555 Medicaid enrollees who had at least one claim that included a substance use disorder diagnosis (VDMAS 2016a).

In response, a bipartisan task force formed by the governor recommended that Virginia expand the scope of MAT benefits in Medicaid and expand coverage to all its Medicaid enrollees. With subsequent approval from the legislature and the governor, the state Medicaid agency worked with the Virginia Department of Behavioral Health and Developmental Services to design the Medicaid Addiction and Recovery Treatment Services (ARTS) benefit. This comprehensive set of covered services, modeled after the ASAM criteria, went into effect on April 1, 2017 (Neuhausen 2017).

Through an amendment to an existing Section 1115 demonstration waiver, Virginia expanded benefits to all Medicaid enrollees to include the following:

- inpatient detoxification and inpatient substance use disorder treatment for up to 15 days (previously only available to children);
- residential detoxification and residential substance use disorder treatment (previously delivered using outdated, state-defined program rules); and
- peer supports for individuals with substance use disorders or mental health conditions to provide intensive short-term and long-term recovery coaching.

In addition, to improve provider participation and access to treatment, the agency increased payment for substance use disorder case management by 50 percent and quadrupled payment for substance use disorder partial hospitalization, intensive outpatient services, and the counseling component of MAT. Rates are now on par with, and exceed in some cases, those of commercial insurers. To promote integration with medical and mental health care, the benefit was carved in to standard



managed care contracts. To reduce clinician burden, the state mandated that managed care plans adopt a uniform preauthorization protocol for medication. Using separately appropriated non-Medicaid state funds, Virginia is also conducting a series of provider education and training sessions (Neuhausen 2017, VDMAS 2016b).

Ohio: Maternal Opiate Medical Support (MOMS)

project. In 2013, Ohio Medicaid, in conjunction with the Office of Health Transformation and the Ohio Department of Mental Health and Addiction Services, initiated a two-year pilot project to improve maternal and fetal health outcomes, improve family stability, and reduce the costs associated with neonatal abstinence syndrome. Although pregnant women with opioid use disorder had been receiving treatment as a priority population, they were still at significant risk for overdoses and other related adverse effects. Infants born to these mothers also faced poor health outcomes soon after delivery-19.6 percent were low birth weight compared to 10.0 percent of all Ohio infants; 21.0 percent had respiratory problems compared to 9.5 percent of all Ohio infants; 16.6 percent had feeding difficulties compared to 5.4 percent of all Ohio infants; and 0.8 percent suffered seizures and convulsions compared to 0.2 percent of all Ohio infants (ODH 2017). In 2014, Medicaid paid for nearly 91 percent of hospitalizations for neonatal abstinence syndrome. Treatment costs for these infants came to \$105 million and accounted for nearly 26,000 hospital days (Applegate and Hurst 2016).

The MOMS project piloted a maternal care home model across four sites. This team-based delivery model emphasized care coordination and wraparound services, engaging pregnant women in a combination of MAT and case management. In addition to clinical services, the project's \$4.2 million budget also covered recovery support and non-clinical services such as housing vouchers, transportation, and child care. The care team was led by care coordinators who ensured communication between the client and all program partners and among the program partners themselves-obstetrician-gynecologists, behavioral health providers, MAT providers, social service workers, insurer case managers, and other service providers involved in supporting client recovery (Massatti et al. 2016, ODM and OhioMHAS 2016). This also included collaboration with Medicaid managed care plans. Four out of the five plans covering women enrolled in MOMS integrated their own staff into the MOMS care team meetings. All plans eliminated prior authorization requirements for prescribing of MAT medications and three out of five plans provided transportation to 12-step meetings. Some plans also provided transportation for other purposes, including transportation to court for custody hearings or other type of court proceedings, or to probation appointments (Massatti 2017).

The state is now in the process of evaluating the findings of this study. Preliminary results indicate women enrolled in the project had better treatment retention rates before and after delivery, and infants experienced shorter stays in the neonatal intensive care unit than the matched Medicaid cohort (Massatti 2017). The state also recently received federal funding through the 21st Century Cures Act of 2016 (P.L. 114-255) and is planning to contract with six OTPs per year for two years to develop maternal care homes to integrate obstetric care and MAT. Covered start-up costs may include hiring of clinical care coordinators and business contracting with obstetriciangynecologist practices. All funded sites will be expected to collaborate with Medicaid managed care plans, comprehensive primary care centers, and accountable care organizations for care collaboration and to sustain system changes (OhioMHAS 2017).

Texas: Rehabilitation option. In response to the prevalence of substance use disorders in the Medicaid population and the potential for cost savings, the Texas legislature in 2009 passed legislation enabling Medicaid to offer a comprehensive substance use disorder treatment benefit to all enrollees. Previously, comprehensive treatment had only been available to enrollees



under 21; adults were limited to prescription drugs and in-patient hospital detoxification. Utilizing the state plan rehabilitation option, Texas Medicaid implemented a comprehensive benefits package for substance use disorder treatment, including for opioid use disorder. By January 2011, all Medicaid enrollees in both fee for service and managed care were able to access services such as clinical assessment to evaluate severity of the disorder and identify treatment options, outpatient detoxification, individual and group counseling, MAT, and residential detoxification and treatment (THHS 2017, 2015; TLBB 2015, 2009).

Initial uptake of the treatment benefit was low, however. In fiscal years 2011 and 2012, only 2.2 percent of adult enrollees with a substance use disorder diagnosis on a claim or encounter received substance use disorder treatment through Medicaid. Over time, uptake increased and the total number of unique beneficiaries receiving services grew by 53.6 percent from 2011 to 2014 and use of MAT doubled; this is in contrast to an increase of only 5.7 percent in total Medicaid enrollment in the state (THHS 2015, TLBB 2015).

To help identify and address possible reasons for the disconnect between treatment need and receipt of care, the state is participating in a high-intensity learning collaborative under the auspices of the CMS Medicaid Innovation Accelerator Program (CMS 2016b). As a result, Texas Medicaid is engaging with plans, providers, consumers, and other stakeholders to overcome identified barriers such as:

- variations in plan prior authorization processes, creating confusion and burden for providers;
- lack of coordination in the effort to identify enrollees with treatment needs between plans providing acute care and those that only provide behavioral health services;
- low payment rates; and

• lack of familiarity among providers with substance use disorders and treatment modalities (THHS 2015).

In 2016, the state also added a screening, brief intervention, and referral to treatment (SBIRT) benefit for all adults, and in community-based settings, which can assist in identifying individuals in need of care. Previously, only adolescents presenting in emergency departments for reasons related to substance use could receive an SBIRT intervention (THHS 2016).

Programs to reduce use of prescription opioids

State Medicaid programs are also responding to the rise in opioid misuse and opioid use disorder with policies to regulate and reduce prescription opioid use and misuse, while still allowing their appropriate use for pain management. These policies focus on identifying high-volume users, prescribers, and dispensers; using clinical protocols and guidelines to limit both the duration and dosage of prescriptions; and restricting the types of opioids available. Some states are also promoting use of non-opioid and non-pharmacologic options for management of chronic pain. Some of these efforts are specific to Medicaid; others are broader.

Many states and their Medicaid programs have implemented programs to reduce opioid prescribing, as described below. It is important to note, however, that high opioid prescribing rates are not necessarily correlated with high overdose death rates. In 2012, Alabama, Kentucky, Oklahoma, Tennessee, and West Virginia had the highest opioid prescribing rates (128 to 148 prescriptions per 100 residents). Other states with rates above the national average include Mississippi, Louisiana, Arkansas, Indiana, and Michigan, but not all of these states are in the top tier of opioid death rates (Rudd et al. 2016, CDC 2014).



Prescription drug monitoring programs. All

states but Missouri now have prescription drug monitoring programs (PDMPs) to track dispensing of controlled substances, including opioids. Such programs are most commonly operated by state boards of pharmacy, not Medicaid. In fact, as of December 2014, only 31 state Medicaid programs had access to their state's PDMP (MACPAC 2016c). PDMPs collect data from pharmacies and other dispensers to help physicians and pharmacists avoid potentially fatal drug interactions, to identify providers with inappropriate prescribing patterns, and to help clinicians identify patients who may be at risk for opioid misuse. Possible indicators of misuse include patients receiving overlapping prescriptions from multiple providers (doctor shopping) or filling prescriptions at multiple pharmacies. Individuals found to be at risk may be enrolled in patient review and restriction programs (see below), or referred for substance use disorder treatment (Alexander et al. 2015). A recent study found that between 2011 and 2014, the introduction of state mandates for prescribers to register with or use their state's PDMP was associated with a 9-10 percent reduction in the number of Schedule II opioid prescriptions Medicaid enrollees received as well as Medicaid spending on these prescriptions (Wen et al. 2017a).8

Patient review and restriction programs. Many Medicaid programs use patient review and restriction (PRR) programs, also referred to as lockin programs, to prevent so-called pharmacy and doctor shopping. These programs assign patients considered at risk for misuse and substance use disorders to predesignated pharmacies and prescribers to obtain and fill prescriptions. At-risk patients are identified based on a combination of criteria, unique to each Medicaid PRR, which often include the number of prescriptions and pharmacies a patient has visited to obtain controlled substance prescriptions (Pew 2016).

As of November 2015, Medicaid programs in 48 states and the District of Columbia utilized PRR: 27 states and the District of Columbia in both fee

for service and managed care, 18 states in fee for service only, and 3 states in managed care only. Two states did not operate a PRR program. Most states review patient enrollment in the PRR quarterly, annually, or within a certain number of months before a patient is scheduled to be released from the PRR (Pew 2016).

Drug utilization review. State Medicaid agencies use drug utilization review (DUR) to identify prescribing practices that may contribute to opioid misuse (CMS 2016a). When inappropriate practices are identified, pharmacists, prescribers, and other members of the health team modify and improve drug therapy practices (AMCP 2009). DUR can be conducted prospectively, concurrently, or retrospectively. In the case of prospective review, the Medicaid program would screen prescription drug claims to help pharmacists identify potential problems ahead of dispensingsuch as therapeutic duplication, contraindications, incorrect dosage or duration, drug allergies, or clinical misuse. Forty-five states contract with an outside vendor to run the prospective DUR. Federal law also requires pharmacists to offer patient counseling on proper use of medications and determine if there are specific needs. In 43 states, the board of pharmacy monitors compliance with this requirement (CMS 2016c).

Under concurrent review, prescription drug use is evaluated while the patient is undergoing therapy to identify any potential risk factors that could lead to adverse outcomes. If any concerns are found, they are communicated to the prescribing physicians and dispensing pharmacists. Similarly, in a retrospective review, claims data are reviewed at least quarterly to identify possible patterns of drug misuse; if problems are found, the prescribing clinicians are contacted. Primary responsibility for conducting the review is held by a contractor in 37 states and by an academic organization in 11 states (CMS 2016c).

Utilization management. State Medicaid agencies and managed care plans utilize preferred drug lists (PDLs) to incentivize the prescribing and use of



certain medications over others. All state Medicaid programs operate a PDL; many plans operate their own PDL within the parameters defined by the state. Drugs that are on the PDL often do not require the prescriber or dispenser to receive a prior authorization from the state Medicaid agency or plan. Recently, states began removing methadone for purposes of pain management from PDLs because a large proportion of prescription opioidrelated overdose deaths were associated with methadone when prescribed as a pain reliever (Jones et al. 2016, Reilly 2015). A recent study of three states found an association between Medicaid PDLs requiring prior authorization for methadone and lower rates of methadone overdose among Medicaid enrollees (Faul et al. 2017).

For certain drugs such as opioids where overutilization is a concern, states use clinical protocols to regulate their use, even if the drug is on the state's PDL. A state may impose quantity limits, step therapy controls, or prior authorization on certain drugs. As of June 2016, all but five Medicaid programs had some type of quantity limit on opioids in their PDL (MACPAC 2016c). Step therapies, also known as fail-first policies, require a beneficiary to try one preferred drug and to document side effects, treatment failure, and other criteria before receiving a specific opioid; these are commonly used before prescribing opioids that could be misused. Prior authorization requirements can also be used to identify and address opioid overprescribing by requiring prescribers to seek pre-approval before prescribing a particular drug. Based on a set of clinical criteria, prescribers must demonstrate the clinical need and therapeutic rationale for the selected medication. The goal is to ensure that the drug is a safe and effective choice in treating the patient's condition (CMS 2016a).

Alternatives to opioid treatment. A 2016 survey of Medicaid programs found that 12 states had implemented specific programs and policies to encourage or require the use of nonopioid pain management therapies, including other medications (e.g., non-steroidal antiinflammatories, corticosteroids, anticonvulsants, and antidepressants), cognitive-behavioral therapy, and exercise therapy (Dorr and Townley 2016, Dowell et al. 2016).

Challenges for Medicaid in Addressing the Opioid Epidemic

Many Medicaid enrollees with an opioid use disorder are not receiving treatment, some due to barriers to care common in Medicaid and others due to circumstances unique to substance use disorders. Barriers common in Medicaid include lack of providers, difficulty securing timely appointments, and lack of enabling services such as transportation and translation or interpretation services. As noted above, many states do not cover needed services. Barriers specific to substance use disorders include the stigma of having a substance use disorder (particularly if the substance is illicit or illegal), difficulty understanding why treatment is needed, and physical and mental side effects of treatment that affect adherence and outcomes (Livingston et al. 2012, Mittal et al. 2012). Systems of care for substance use disorder treatment are frequently fragmented and poorly funded, which can create poor coordination among providers and gaps in the continuum of care. These are briefly discussed below.

A fragmented delivery system

As MACPAC noted in its prior work on behavioral health, mental health conditions and substance use disorders have long been considered different from other health needs, with care for these conditions traditionally financed and delivered separately from other medical care. As a result, specialty substance use disorder treatment providers and programs often interact on a limited basis with other parts of the health care system, including Medicaid. Additionally, when states cover few optional services, beneficiaries may need to rely on these non-Medicaid providers and funding



sources, which results in beneficiaries experiencing greater fragmentation in their care or not getting services at all (MACPAC 2016d).

Historically, addiction has been seen as a moral failing, and treatment, if available, was delivered in asylums and so-called narcotic farms run by prisons (OSG 2016). It was not until the 1960s that government and medical authorities began to recognize alcoholism, and later other addictions, as potentially treatable illnesses (Mignon 2015, OSG 2016). Then, despite growing recognition of substance use disorder as a chronic disease, the health care system's lack of experience in caring for individuals with substance use disorders and the continued stigma resulted in treatment programs being run and financed separately from other medical care for many years (OSG 2016). Currently, there are about 14,000 specialized treatment facilities delivering the bulk of care, 62 percent of which reported accepting Medicaid (SAMHSA 2017a).

The origins of widespread prescriptions opioid use can be traced back to the 1990s with the medical profession's introduction of pain as the so-called fifth vital sign (Kolodny et al. 2015). The concept was widely adopted by both health care providers and accrediting bodies such as The Joint Commission. But it also coincided with substantial marketing efforts to prescribers by pharmaceutical manufacturers of opioids. Over time, overzealous prescription of pain relievers was linked to a significant increase in opioid-related morbidity and mortality, including opioid use disorder (Baker 2017, Alexander et al. 2015, Kolodny et al. 2015).

Among insurers, Medicaid is the largest payer of substance use disorder treatment, financing 21 percent of all treatment in 2014. But 41 percent of funding comes from a mix of other non-Medicare and non-Medicaid federal, state, and local government funds (Mark et al. 2016). The Substance Abuse and Mental Health Services Administration (SAMHSA) Substance Abuse Prevention and Treatment (SAPT) block grant to states makes up nearly half of all federal non-Medicaid and non-Medicare spending on substance use disorder treatment.9 Other federal sources include the Veterans Administration, the Department of Defense, the Indian Health Service, the Health Resources and Services Administration, and the Department of Justice (HRSA 2017, OJP 2016, SAMHSA 2013b). Single state agencies for substance abuse, which receive the SAPT block grant funds, and other agencies related to child protective services, corrections, and the courts manage state and local treatment funds (Pew and MacArthur 2015). To expand state ability to address the opioid epidemic, the 21st Century Cures Act of 2016 provided an additional \$1 billion over two years for grants to single state agencies to establish new prevention and treatment programs related to opioids and to expand existing programs.

State substance abuse agency dollars typically fund care for uninsured and underinsured individuals, as well as those who may be Medicaideligible but not enrolled (e.g., the homeless). Because of the variability in Medicaid benefits, state substance abuse agencies may fund treatment services for Medicaid beneficiaries, such as case management and peer support, other recovery support services such as vocational counseling, parenting support and education, and services such as residential treatment and certain housing supports that Medicaid is prohibited from financing. In some states, single state agencies administer the funds allocated by a Medicaid agency's substance use disorder treatment benefit (Pew and MacArthur 2015, Woodward 2015, NASADAD 2010).

Substance use disorder treatment often is not well coordinated or integrated with other mental health or physical treatment. Linkages between addiction and primary care and specialty providers are often suboptimal, affecting diagnosis and treatment of addiction and related comorbidities (Saitz et al. 2008). Despite the prevalence of dual diagnoses, in 2015, only about half of specialty substance use disorder treatment facilities offered comprehensive mental health assessments or diagnoses; fewer



provided testing for common comorbid conditions such as tuberculosis, HIV, hepatitis B and C, and sexually transmitted diseases (SAMHSA 2017a). Specialty substance use disorder treatment providers also are subject to strict confidentiality requirements related to patient medical records, which may hinder their ability to consult with outside treatment providers. A 2012 study also found that 63 percent of specialty addiction treatment providers did not have a fully functioning electronic health record, impeding care coordination (Andrews et al. 2015).

Given the complexity of the substance use disorder delivery system, there are some efforts to align eligibility, financing, services, and oversight across agencies. These efforts include co-locating physical and behavioral health providers, sharing data and information, blending funding streams, and consolidating Medicaid and state behavioral health and substance abuse agencies. Some states are also developing stronger or more formalized relationships between Medicaid and other agencies. For example, Medicaid agencies may work with criminal justice agencies to help transition individuals with an opioid use disorder in and out of prison or jail, as a way to help them continue treatment. To do so, Medicaid programs may decide to suspend rather than terminate Medicaid benefits while these individuals are incarcerated (MACPAC 2016d, Cuellar and Cheema 2012).

The previously mentioned initiatives in Vermont and Virginia are two examples of how states are seeking to mitigate the fragmentation in care. CMS is also working to streamline the substance use disorder treatment system and has promoted a Section 1115 waiver opportunity that would allow some inpatient treatment in a substance use disorder facility to be covered that otherwise would be subject to the institution for mental diseases (IMD) exclusion (described in greater detail below). The waiver opportunity also calls for use of ASAM criteria to ensure a comprehensive continuum of care, including withdrawal management, short-term residential treatment, intensive outpatient treatment, medication assisted treatment, and aftercare supports for long-term recovery such as transportation, employment, housing, and community and peer support services (CMS 2015a). Through the Medicaid Innovation Accelerator Program and its High Intensity Learning Collaborative and other targeted learning opportunities, CMS is also providing technical assistance and education to states to support adoption and evaluation of payment methodologies, care delivery models, and benefit strategies that better identify individuals in need of treatment, expand coverage and access to treatment, and promote improved care and better coordination between addiction and other health care providers (CMS 2016b, CMS 2015c).

Adequate supply of providers

The supply of substance use disorder treatment services available to Medicaid enrollees is affected by several factors including their geographic location; state scope of practice laws, such as ones permitting certain clinicians who are not physicians to prescribe medications; willingness of providers to serve Medicaid beneficiaries; and the number of providers with special federal approval to prescribe and dispense methadone and buprenorphine.

Federal regulations govern the provision of methadone and buprenorphine as part of MAT.¹⁰ Methadone use for treatment of opioid use disorder can be provided only in specially designated OTPs certified and regulated by SAMHSA's Center for Substance Abuse Treatment. Buprenorphine can be prescribed in a general medical office, but physicians must undergo a special eighthour training and receive a DATA-2000 waiver from SAMHSA and the Drug Enforcement Administration, as mandated by the Drug Addiction Treatment Act of 2000 (DATA-2000, P.L.106-310). Depending on the waiver, a physician is limited to prescribing to up to 30, 100, or 275 patients (SAMHSA 2017b).

As of March 2017, 37,526 physicians had obtained a DATA-2000 waiver to prescribe buprenorphine



(SAMHSA 2017c). Even so, most U.S. counties had no physicians with such waivers, meaning that more than 30 million people were living in counties without access to office-based treatment. Additionally, only 3 percent of primary care physicians had received waivers as of July 2012 (Rosenblatt et al. 2015). Another recent study showed nearly all states had opioid use disorder rates higher than their buprenorphine treatment capacity rates; 19 states had a gap of at least 5 per 1,000 people (Jones et al. 2015b).

Trends in the provision of MAT by specialty substance use disorder treatment facilities provide a mixed picture. There has been an increase in the number of facilities providing buprenorphine, but in 2015, they still represented only one-quarter of all facilities. Only about 17 percent offer injectable naltrexone. The number of OTPs providing buprenorphine in addition to methadone, as a percentage of all OTPs, increased from 26 percent to 45 percent between 2005 and 2009 but fell to 35 percent in 2015 (SAMHSA 2017a). Moreover, 38 states also reported at least 75 percent of methadone-dispensing OTPs were operating at 80 percent capacity or more (Jones et al. 2015b).

In addition, OTPs are mostly located in urban areas and often require patients to visit daily for onsite administration of methadone. This limits the ability of rural patients to access such treatment (Dick et al. 2015). One study of specialty treatment provider distribution in 2009 found that counties with a higher percentage of black, rural, and/or uninsured residents were less likely to have at least one outpatient facility that accepted Medicaid (Cummings et al. 2014).

Because of concerns about access to treatment, the Comprehensive Addiction and Recovery Act of 2016 (CARA, P.L. 114-198) included a provision to allow advanced practice nurses and physician assistants to qualify for a waiver for up to 30 patients from 2016 through 2021, so long as their state license includes prescribing authority for Schedule III, IV, or V medications for the treatment of pain. In 2016, SAMHSA also increased the total number of patients a certified physician can request to treat to 275 patients (HHS 2016).

Several states with rural and other underserved areas are also exploring how telemedicine can be used to increase access to care. This may involve utilizing the ECHO model, in which specialist physicians in academic hubs provide case consultations and reviews to primary care physicians in the community to inform and support them in delivering evidence-based substance use disorder care. States are using a variety of sources to fund this model, including Medicaid medical assistance and administrative funds, general state funds, federal grant dollars, and funding from insurance companies (Project ECHO 2017, Tewarson 2016). As of September 2015, Medicaid in 30 states and the District of Columbia covered some type of telehealth services relevant to substance use disorder treatment, such as individual psychotherapy (MACPAC 2016a).

Although there is no comprehensive source of data on the supply of professionals available to treat individuals with substance use disorders, multiple sources suggest there is a shortage of trained providers overall at least in some areas (OSG 2016). A variety of professionals provide substance use disorder treatment services, including addiction and mental health counselors, psychiatrists, addiction medicine physicians, other physicians, psychologists, social workers, advanced practice nurses, case managers, peer support specialists, and recovery coaches (SAMHSA 2015). In surveys conducted by various regional Addiction Technology Transfer Centers, program directors indicated problems recruiting adequately prepared staff, often citing at least one or more unfilled full-time equivalent positions. Recruiting difficulties include insufficient numbers of applicants who meet minimum qualifications, a small applicant pool in specific geographic areas, and a lack of interest due to salary and limited funding (SAMHSA 2013c).

Research on acceptance of Medicaid by physicians has identified several reasons physicians do not



accept Medicaid. Low payment rates relative to those offered by private insurance and Medicare are frequently cited, although the relationship between payment rates and provider participation is not straightforward (MACPAC 2015). Finally, providers note that patients covered by Medicaid tend to require more time and attention than the average patient (ASPE 2015).

Several studies found that a lack of support for existing and potential prescribers of medications for use in MAT can deter physician participation. Physicians may be reluctant to provide MAT if there are not sufficient mental health and substance use disorder treatment services and supportive services to which patients can be referred. There are also concerns about insufficient access to expert consultation (Quest et al. 2012, Netherland et al. 2009). Physicians also identified preauthorization and documentation requirements to secure payment as a barrier to participation, because these requirements are viewed as cumbersome and confusing (SAMHSA-HRSA 2014, Netherland et al. 2009).

Specialty addiction providers may have additional barriers, such as inconsistent credentialing or licensure requirements across payers and state agencies in order for facilities and counseling staff to be paid (ASPE 2015, Ryan et al. 2012). A 2012 survey also found that many specialty addiction treatment providers did not have sufficient information technology systems needed to bill insurers, posing a challenge to providing care to individuals newly covered by health insurance under the Patient Protection and Affordable Care Act (ACA, P.L. 111-148, as amended) (Andrews et al. 2015).

Privacy regulations

In designing effective treatment models, Medicaid officials and clinicians frequently raise concerns about federal regulations at 42 CFR Part 2, often referred to simply as Part 2, which are designed to protect patient privacy but may make it difficult to share information among providers. These regulations govern the confidentiality of substance use disorder records and originate in legislation from the 1970s that sought to address the stigma of substance use disorders and concerns that the people seeking treatment could be subject to criminal prosecution and other serious consequences such as loss of employment, housing, or child custody. The restrictions upon the disclosure and use of substance use disorder patient records currently apply to any federally funded individual or entity, other than a general medical facility, that, "holds itself out as providing, and provides, substance use disorder diagnosis, treatment, or referral for treatment." It also applies to any identified unit within a general medical facility that holds itself out in the same way, as well as, "[m]edical personnel or other staff in a general medical facility whose primary function is the provision of substance use disorder diagnosis, treatment, or referral for treatment and who are identified as such providers" (42 CFR 2.11).

Until recently, Part 2 required written consent to include the name or title of every individual or the name of every organization to which the substance use disorder treatment record is provided. Some stakeholders reported that this requirement makes it difficult for treatment providers subject to Part 2 restrictions to be included in health information exchanges, medical homes, accountable care organizations, and coordinated care organizations. Generally, these latter entities only need to follow the Health Insurance Portability and Accountability Act of 1996 (HIPAA, P.L. 104-191) privacy rules and thus do not have the needed additional consent management capabilities to be compliant with Part 2 requirements. Many entities as a result simply do not include substance use disorder treatment information in their systems. OTPs and most DATA-2000 waivered providers are also prohibited from reporting methadone and buprenorphine prescribing to a state's prescription drug monitoring program (SAMHSA 2016b, 2011).

To assist in sharing data in integrated data systems, SAMHSA updated Part 2 regulations in January 2017 to allow, under certain conditions,



a substance use disorder patient to consent to disclosing their patient identifying information using a general designation to one or more individuals or entities (e.g., "my treating providers"). The revised regulations also make research using patient data easier (HHS 2017).¹¹ But for the most part, the rule covers the same providers and patient consent for all providers accessing their data still apply. It is unclear how providers will respond or if they will be more willing to share data on patients receiving substance use disorder treatment. Numerous stakeholders, including health care providers, health plans, and some patient advocacy groups, called for further harmonization with HIPAA rules, to allow for additional data sharing for purposes of treatment and care coordination and integration. These groups believe that such a move would not sacrifice patient confidentiality, but others-in particular, other patient advocatesbelieve that such changes would undermine Part 2's protections (HHS 2017).

Institution for mental diseases exclusion

The Medicaid IMD exclusion acts a barrier for individuals with an opioid use disorder to receive residential treatment, which, depending on an individual's treatment plan, may be the most appropriate setting for care. The IMD exclusion prohibits states from receiving federal payment for inpatient care provided to individuals over the age of 21 and under the age of 65 who are patients in an IMD. This includes patients in residential substance use disorder treatment facilities, and therefore the exclusion has been cited as a barrier to treatment for beneficiaries with an opioid use disorder (CMS 2015a). The Medicaid IMD exclusion is one of the few instances in the Medicaid program where federal financial participation cannot be used for medically necessary and otherwise covered services for a specific Medicaid enrollee population receiving treatment in a specific setting.

Recognizing the barriers to treatment imposed by the IMD exclusion, CMS, in July 2015, issued guidance to states noting that the agency is willing to grant Section 1115 demonstration waivers that include the ability to receive federal financial participation for substance use disorder treatment services administered at IMDs under certain circumstances (CMS 2015a). California and Virginia both received an 1115 waiver allowing federal matching payments for treatment in substance use disorder residential care facilities (CMS 2016d, 2015b).

Medicaid managed care regulations finalized in 2016 may also affect access to IMD services by clarifying that plans contracting with state Medicaid agencies may provide care in an IMD to beneficiaries in lieu of services or settings covered under the state plan. States can receive the federal match and make a capitation payment on behalf of an enrollee that spends part of the month as a patient in an IMD if a number of conditions are met. including that the length of stay cannot exceed 15 days during a given month. Services for opioid and other substance use disorder treatment provided in IMDs may therefore be covered under these conditions (CMS 2016e). There are no national data on how Medicaid managed care plans use IMDs as in lieu of services, although CMS estimates that in 2010, 17 states used this provision to cover some IMD care (CMS 2016e). It is also possible that the newly enumerated 15-day limit may be more restrictive than what some managed care plans may have provided previously as an in lieu service (AHCCCS 2017).

Restrictive coverage policies

State Medicaid programs, like other payers, use various tools to design their Medicaid benefit packages and control utilization to promote clinically and cost-effective care. As discussed above, state Medicaid programs vary considerably in the specific services that they cover (MACPAC 2016b). Certain policies may be inhibiting access to MAT. For example, all Medicaid programs do



not cover all three medications approved for use in MAT. In addition, Medicaid policies that are identified as potential barriers to timely treatment access include the following:

- limits on prescription dosages (such as annual or lifetime medication limits);
- prior authorization and reauthorization requirements;
- fail-first criteria, also known as step therapy, requiring that other therapies be tried first; and
- insufficient coverage of related counseling or behavioral therapy (OSG 2016, SAMHSA-HRSA 2014, Netherland et al. 2009, Rinaldo and Rinaldo 2013, Quest et al. 2012).

Stigma

Opioid use disorder, although increasingly recognized as a medical illness, has historically been seen as a moral weakness or willful choice (Olsen and Sharfstein 2014, White 2009). Within the substance use disorder treatment community, many still believe that recovery should not involve the use of medications such as methadone or buprenorphine, and that treatment with these medications is simply substituting one addiction for another. As a result, providers of residential treatment may force patients receiving methadone or buprenorphine to taper off the medication as a condition of treatment. Even the language associated with drug treatment ("clean" or "dirty" urine samples, "clean" status associated with lack of using drugs) perpetuates the stigma associated with substance use disorder (Olsen and Sharfstein 2014). Heroin use disorder, because of its illegality, has particularly high stigma attached to it.

This stigma, including that associated with legally obtained prescription opioids, may cause those with the condition to internalize negative stereotypes. High levels of internalized stigma are associated with social isolation, and low levels of self-esteem, self-efficacy, and quality of life. Internalized stigma may undermine adherence to treatment, decrease help-seeking behaviors, and interfere with recovery goals, such as pursuing employment and independent living (Mittal et al. 2012). High levels of stigma and discrimination may also discourage people from self-identifying and dampen advocacy efforts. The opioid epidemic has now become so prevalent that recognition that addiction is a medical illness is increasing, but more education of both providers and the public is needed to encourage people to seek treatment.

Opioid use disorder treatment and Medicaid expansion

In states that opted to expand eligibility to the new adult group, these new enrollees now have coverage for opioid use disorder treatment services. As noted above, states are required to provide Medicaid expansion enrollees with alternative benefit plans that cover 10 essential health benefits, including mental health and substance use disorder treatment services. Legislation passed by the U.S. House of Representatives in May 2017 would change the ACA's Medicaid expansion and sunset Medicaid's obligation to cover the 10 essential health benefits at the end of 2019 (AHCA 2017). Beneficiary advocates, providers, and some governors raised concerns about the potential impact on the availability of opioid use disorder treatment for these individuals (AP 2017, Jacobs 2017, O'Donnell and DeMio 2017).

National estimates of how many individuals covered under the Medicaid expansion are able to receive opioid use disorder treatment are not yet available, but there is evidence from several expansion states that an increasing number of individuals are receiving care (Vestal 2017). One recently published study found that expansion states in 2014 experienced a 70 percent increase in Medicaid-covered buprenorphine prescriptions and a 50 percent increase in buprenorphine spending over non-expansion states, indicating improved access to treatment (Wen et al. 2017b). Another study found that in 2014, Medicaid payments for



medications used to treat alcohol and opioid use disorder (excluding methadone) in outpatient settings increased by 33 percent in expansion states relative to non-expansion states. The same study, however, found no evidence that admissions to specialty treatment facilities differed between expansion and non-expansion states, although it did not account for individuals receiving treatment from primary care or other physicians in private practice or other general medical settings (Maclean and Saloner 2017). In Kentucky, an expansion state, Medicaid payment for substance use disorder treatment services for expansion enrollees increased by 700 percent between the first quarter in 2014 and the second guarter of 2016. Earlier research suggests that many of these enrollees were previously uninsured and had limited access to care before 2014 (FHK 2016).

Endnotes

¹ In 2010, Medicaid covered about half of all births (MACPAC 2014).

² Prior to 2015, the source of this data—the National Survey on Drug Use and Health (NSDUH)—used the term non-medical use of prescription drugs to identify individuals who used a drug that was not prescribed to them or used a drug solely for the experience of feeling high. The definition, however, did not specifically include the criterion of overuse of a prescription medication, which is especially important for assessing prescription pain reliever misuse. Therefore, beginning with the 2015 NSDUH, the survey replaced questions used to identify non-medical use of prescription drugs with questions to identify misuse of prescription drugs (Hughes et al. 2016).

³ This may include individuals dually eligible for Medicare and Medicaid; in these cases, the enrollee receives prescription drug coverage through Medicare Part D, rather than Medicaid. ⁴ Natural opioids include morphine and codeine, which come largely from plants. Semisynthetic opioids include drugs that are derived from naturally occurring opiates and opium alkaloids and include oxycodone, hydrocodone, hydromorphone, and oxymorphone. Synthetic opioid drugs include methadone, tramadol, and fentanyl.

⁵ Prescription drug coverage is also an optional benefit, but all states currently offer it.

⁶ There are several validated screening tools for use by providers who are not addiction specialists to help identify individuals who have a substance use disorder or may be at risk of developing one. In cases where misuse is identified, brief interventions can address substance misuse; these can range from informal counseling to more structured methods (e.g., cognitive-behavioral therapy or motivational interviewing) and can be conducted over the course of several sessions lasting anywhere from 5 to 60 minutes (Townley and Dorr 2017, OSG 2016, Adkins et al. 2014). When conducting the intervention, the clinician informs the patient about safe consumption limits, offers advice about change, assesses the patient's readiness, and tries to resolve any ambivalence the patient may have about modifying his or her problematic use. The intervention can also be used to encourage follow-through on a referral to specialty treatment in cases where the provider makes a substance use disorder diagnosis.

⁷ Methadone is an opioid agonist that binds to and activates the brain's opioid receptors. It is used in detoxification therapy to suppress withdrawal symptoms and in maintenance therapy to control opioid cravings. Research shows that long-term methadone maintenance treatment is more effective than short-term withdrawal management. There is a risk for misuse and it is provided only in SAMHSA-certified and U.S. Drug Enforcement Administration (DEA)-registered programs, called opioid treatment programs (OTPs).

Buprenorphine is a partial opioid agonist that binds to the brain's opioid receptors and activates them, but not as much as methadone. When used with naloxone, there is less risk for misuse. Buprenorphine comes in a sublingual tablet and a sublingual or buccal film and can be used for both detoxification and maintenance therapy. In 2016, the FDA approved an implantable version of buprenorphine, which releases a continuous low dose of the medication



into the bloodstream for six months and is geared toward individuals who are already stable on a moderate to low dose of buprenorphine. OTPs can dispense buprenorphine, and physicians can prescribe it in an office-based practice if they hold a DATA-2000 waiver, which is granted by SAMHSA and the DEA after prescribers meet certain conditions and clinical training.

Naltrexone is an opioid antagonist that binds to opioid receptors but does not activate them. Instead, it prevents opioid agonists from binding to and activating opioid receptors. Naltrexone is used for relapse prevention, because an individual on naltrexone who uses opioids will not experience their effects. The oral formulation is recommended for highly motivated individuals in whom adherence can be monitored and enforced, whereas the extended-release injectable formulation may be more suitable for patients who had trouble adhering to their treatment plan. Because naltrexone carries no known risk for misuse, prescribers do not need a special license (OSG 2016, ASAM 2015, Bagalman 2015, VA/DoD 2015).

⁸ Schedule II controlled opioids have a high potential for misuse and development of a substance use disorder. They include hydromorphone, oxycodone, morphine, and fentanyl (DEA 2017).

⁹ A minimum of 20 percent of the block grant is set aside for prevention activities.

¹⁰ Naltrexone, the third medication that can be used as part of MAT, is not a controlled substance, and any provider with prescribing authority can prescribe it.

¹¹ SAMHSA allows any lawful holder of patient identifying information to disclose Part 2 patient identifying information to qualified personnel for purposes of conducting scientific research, if the researcher meets certain regulatory requirements. SAMHSA also permits data linkages to enable researchers to link to data sets from data repositories holding Part 2 data if certain regulatory requirements are met.

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