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5 Barriers to Broader Use of Medications to Treat Opioid Use Disorder

Confronting the major barriers to the use of medications to treat opioid use disorder is critical to addressing the opioid crisis.

Despite the strong evidence for the effectiveness of medications in reducing morbidity and mortality, increasing treatment retention, and improving well-being for individuals with opioid use disorder (OUD), numerous barriers prevent broader access to medication-based treatment. According to 2019 estimates, less than 35 percent of adults with OUD had received treatment for opioid use in the past year (Jones and McCance-Katz, 2019), and no national data sources are currently available to precisely estimate the share of those patients who are being treated with one of the three U.S. Food and Drug Administration (FDA)-approved medications. Furthermore, national estimates indicate that there is usually a gap of several years between the onset of OUD and entering treatment. The delay between disease onset and initial treatment receipt has been estimated to be, on average, in the range of 4 to 7 years (Blanco et al., 2013; Wang et al., 2005). The barriers preventing broader access to life-saving medications for OUD include stigma, inadequate professional education and training related to the evidence base for using medication, and challenges in connecting individuals with medication-based treatment due to delivery system fragmentation, regulatory and legal barriers, barriers related to public and private health insurance coverage, and reimbursement and payment policies that do not incentivize the provision of high-value care for OUD. A critical unanswered question is which interventions or policy changes would be most likely to drive real system-level changes to increase access and use of medication-based treatment for people with OUD?

STIGMA

There are high levels of stigma toward individuals with OUD and toward medications to treat OUD both among the general public and among professionals in key sectors that commonly interact with individuals with OUD. This stigma poses significant barriers to the uptake of medication-based treatment. According to Link and Phelan (2001, p. 377), “stigma exists when elements of labeling, stereotyping, separation, status loss and discrimination occur together in a power situation that allows them.” While some definitions of stigma do not include discrimination, in this report, we conceptualize stigma based on Link and Phelan's reasoning that the term stigma cannot hold the meaning we commonly assign to it when the concept of discrimination is not included. According to Link and Phelan (2001, p. 371), people are stigmatized when “the fact that they are labeled, set apart and linked to undesirable characteristics leads them to experience status loss and discrimination,” thereby affecting their life prospects including income, education, housing status, and well-being. National public opinion data indicate that negative attitudes toward individuals with prescription OUD exceed those reported for other medical conditions, including mental illness (Barry et al., 2014). More than three-quarters of respondents in a 2016 national survey reported viewing individuals with OUD as to blame for their substance use, and nearly three-quarters of respondents characterized people with OUD as lacking self-discipline (Kennedy-Hendricks et al., 2017). Two-thirds of

respondents were unwilling to have a person with a drug use disorder marry into their family, and a majority endorsed discriminatory measures, such as allowing employers to deny employment to a person with OUD (Kennedy-Hendricks et al., 2017). Individuals who had personal experience with OUD—for example, having a family member or close friend with OUD—reported equally negative or more negative attitudes toward the disorder than the general public (Kennedy-Hendricks et al., 2017). This is notable because it differs from research on stigma toward people with mental illness (Alexander and Link, 2003; Corrigan et al., 2012; Couture and Penn, 2003; McSween, 2002), which generally finds personal experience with mental illness to be associated with less negative attitudes. Higher levels of stigma were also associated with greater support among the public for more punitive policy responses to the opioid epidemic (e.g., arresting and prosecuting people who obtain multiple prescriptions from different doctors) and lower support for public health-oriented policy responses (e.g., expanding Medicaid insurance benefits to cover OUD treatment) (Kennedy-Hendricks et al., 2016b).

Stigma toward people with OUD and toward people with substance use disorders (SUDs) more broadly is intertwined with persistent stigma (including labeling, stereotyping, status loss, and discrimination) that occurs on the basis of race and social class in the United States. Historically, U.S. drug policies have disproportionately targeted already marginalized groups (Morone, 1997; Singer and Page, 2014). For instance, early restrictions on opium were implemented during a period of heightened xenophobia toward Chinese immigrants (Morone, 1997). Studies have also focused attention on race-based stigma and discrimination directed toward African Americans as a profound legacy of the war on drugs (Capitani and Herek, 1999; Kulesza et al., 2013; Minior et al., 2003; Semple et al., 2005). An analysis of a small sample of news media published between 2001 and 2011 found that white non-urban people with prescription OUDs were represented more sympathetically than non-white urban people with heroin use disorder (Netherland and Hansen, 2016). Substance use is often featured in media representations of economically disadvantaged populations (Bullock et al., 2001; Singer and Page, 2014). By tying populations that are already disenfranchised to substance use, these media representations may contribute to and reinforce negative attitudes among the public toward people with SUDs. Some evidence bears this out; an experimental study found that attitudes toward people with OUD were more positive among people randomized to read a narrative about a woman with OUD of high socioeconomic status compared to those randomized to read about a woman with OUD of low socioeconomic status (Kennedy-Hendricks et al., 2016b).

Furthermore, high rates of stigma have been documented within key professions that interact regularly with individuals with OUD. Stigmatizing attitudes among health professionals have been shown to be widespread, which has detrimental consequences for connecting persons with OUD to treatment (Brondani et al., 2017; DeFlavio et al., 2015; Livingston et al., 2018; van Boekel et al., 2013). One recent large-scale study assessing primary care physicians' views indicated that the rates of stigma—including measures of blame for the condition and a desire for social distance from individuals with prescription OUD—were as high as or higher than stigma rates among the general public (Kennedy-Hendricks et al., 2016a). Stigmatizing attitudes toward people with OUD are also found among professionals working in the public safety and criminal justice settings, the housing sector, and the child welfare system (Rich et al., 2005; Stringer and Baker, 2018; Wittman et al., 2017).

Fewer studies have examined stigma directed specifically toward the medications to treat OUD, particularly the agonist medications methadone and buprenorphine. Stigma toward the opioid agonists appears to be grounded in the misperception that these medications are substituting one drug for another (Volkow et al., 2014). A 2017 national public opinion study revealed low rates of awareness among the public about the evidence base for medications to treat OUD; Blendon

and Benson found that half of U.S. adults reported believing that there is no effective treatment for OUD (Blendon and Benson, 2018). Similarly, attitudinal surveys and qualitative data collected from professional groups indicate high levels both of misinformation and of stigma about agonist medication for OUD among personnel within drug courts (Matusow et al., 2013) and in the prison system (McKenzie et al., 2009; Nunn et al., 2009). Semi-structured interviews with individuals with OUD using methadone confirm that this group experiences high rates of stigma related to their medication use in interactions with the public and with health care professionals (Woo et al., 2017). Some limited evidence suggests that as clinicians gain experience treating patients with OUD with buprenorphine, they gain more positive perceptions about the role of medications in effective treatment (Thomas et al., 2008).

A systematic review of studies examining the consequences of the high rates of stigma experienced by individuals who use drugs found consistent evidence that stigma has a detrimental effect on their psychological well-being (Kulesza et al., 2013). In turn, shame or self-stigma is characterized as the internalization of the social opprobrium from public stigmatization that leads to the association of negative stereotypes with addiction (Matthews et al., 2017). While it makes intuitive sense that self-stigma would reduce treatment seeking (Olsen and Sharfstein, 2014), more research is needed to better understand how self-stigma and negative attitudes toward OUD medications among people with OUD may inhibit an individual from entering treatment.

In the context of stigma, increasing attention has focused on the role of language in reinforcing negative perceptions about OUD (McGinty et al., 2017). Terms such as “substance abuser” have been shown in randomized experiments to increase stigma relative to person-centered terms like “person with a substance use disorder” (Kelly and Westerhoff, 2010). Other research studies based on randomized experiments have confirmed that the use of certain terms can reinforce blame of individuals with OUD and drive up stigma rates (Ashford et al., 2018a,b). Conversely, Ashford and colleagues found that use of the term “pharmacotherapy” produced more positive associations than the term “medication-assisted treatment” (Ashford et al., 2018b). This research has prompted stigma-reduction efforts focused on language (McGinty et al., 2017; Wakeman, 2017). Recent efforts have included the release of a memorandum on terminology from the White House Office of National Drug Control Policy (ONDCP, 2017), *Changing the Language of Addiction*, and a 2017 version of the Associated Press Stylebook recommending more careful attention to language by reporters covering news stories about the opioid epidemic (Aliferis, 2017).

It will be critical to build an evidence base for effectively confronting stigma associated with medications for OUD, particularly opioid agonists. A small but growing body of evidence is being used to identify and test the effectiveness of communications strategies targeting the general public and professionals in key sectors (e.g., health care, law enforcement, corrections) in an effort to reduce stigma and to encourage higher rates of entry into medication-based treatment. There has also been a growing interest in increasing awareness of the benefits of medication for OUD and in decreasing stigma through communications campaigns (McGinty et al., 2017). Approaches highlighting the effectiveness of medication-based treatment in helping patients sustain remission (McGinty et al., 2015) and approaches presenting sympathetic narratives (Bachhuber et al., 2015)—particularly those that illuminate the barriers that people with OUD face in trying to access treatment (Kennedy-Hendricks et al., 2016b)—have been shown to be effective in reducing stigma, but they need to be studied further.

CONCERNS ABOUT DIVERSION OF MEDICATIONS FOR OUD

Concerns about the misuse and diversion of medications for OUD also contribute to the insufficient numbers of providers willing to prescribe them. Evidence suggests that these concerns emanate from stigma and misunderstanding about the motivations for using diverted medication. A fear of patients engaging in the diversion of medication is cited by prescribers as a barrier to treating individuals with OUD (Lin et al., 2018; Netherland et al., 2009). One national survey of buprenorphine prescribers found that one-third of respondents viewed diversion as a significant or very significant concern; half reported that they would no longer be willing to see a patient suspected of diversion (Lin et al., 2018). But education can help. A survey of both buprenorphine-waivered and non-waivered physicians found that 26 percent of non-waivered physicians were concerned about diversion, compared with 10 percent of waivered physicians (Huhn and Dunn, 2017).

Providers' concerns about the diversion of medication are inconsistent with available data, particularly in the context of medications that are formulated with deterrent properties, such as buprenorphine/naloxone. The buprenorphine/naloxone formulation was developed as a deterrent to misuse because it blocks the rewarding effects of opioids and triggers withdrawal if injected. Rates of misuse of the buprenorphine/naloxone formulation are much lower than for the mono-buprenorphine formulation. The Research Abuse, Diversion and Addiction-Related Surveillance System, which tracks the rates of misuse and diversion of medications, found that past-month injection use of mono-buprenorphine was 45 percent, compared with 16 percent for the buprenorphine/naloxone formulation (Lofwall and Walsh, 2014). Due to the higher rates of misuse of the mono-buprenorphine, the combination product is the most commonly prescribed formulation. Of the different formulations of buprenorphine/naloxone, rates of both misuse and diversion are lowest for the buprenorphine/naloxone film (Lavonas et al., 2014). Methadone diversion rates in the United States have been declining by 13 percent each year since 2011 (Jones et al., 2016) and are now slightly lower than the rates for buprenorphine. To put diversion of OUD medications in context, it is worth noting that these rates are lower than the diversion rates for other prescribed medications. For instance, prescribed antibiotics and allergy medications are diverted at rates of 25 and 21 percent, respectively (Caviness et al., 2013; Goldsworthy et al., 2008; Lofwall and Walsh, 2014).

Importantly, the rates of both misuse and diversion decline as buprenorphine availability increases (Cicero et al., 2007; Lofwall and Walsh, 2014). The reasons reported for misuse or diversion include peer pressure, a desire to help a friend or family member or to make money, and a lack of access to buprenorphine treatment (Fox et al., 2015; Lofwall and Walsh, 2014). While some individuals with OUD report misusing buprenorphine to achieve intoxication, more report using it to relieve symptoms of withdrawal (Lavonas et al., 2014).

INADEQUATE PROFESSIONAL EDUCATION AND TRAINING

Another barrier to the availability and use of medications to treat OUD is the lack of appropriate education and training among health care providers and personnel in law enforcement and the judicial system.

Health Workforce Education and Training

A broad range of professions typically provide treatment or related services for addiction in the United States, including physicians, physician assistants (PAs), nurses, and nurse practitioners (NPs); psychologists, social workers, and therapists; pharmacists; and addiction counselors. However,

few among the broad range of providers who may treat patients with addiction are trained in or knowledgeable about evidence-based practices in addiction prevention and treatment. . . . Compounding this problem is that the diversity in education and training among the different types of individuals providing addiction treatment results in inconsistent treatment approaches and care for patients with addiction. (CASA, 2012, p. 178)

Because addiction treatment is typically separate from mainstream health systems (Frank and Glied, 2016), education about OUD is often neither required nor standardized for health care providers in the United States. The American Board of Medical Specialties only recognized addiction medicine as a subspecialty in 2015 (ABMS, 2016), and many schools and training programs have limited access to experts to develop and teach curricula. Consequently, providers often lack the education required to address numerous aspects of OUD assessment and treatment (Merrill, 2002). Even though treating addiction has similarities to treating other chronic conditions, health education curricula do not educate all providers about addiction (Merrill et al., 2002; Moran et al., 2017). Integrating addiction treatment into mainstream health systems could expand treatment capacity and improve providers' education about addiction medicine (Merrill, 2002). It should be noted, however, that the sole reliance on workforce education and training is not an assurance that evidence-based interventions will be implemented into standard care (Patterson Silver Wolf, 2015; Patterson Silver Wolf et al., 2017).

Law Enforcement and Judicial System Education and Training

For patients with OUD, critical treatment decisions often occur in the law enforcement and judicial systems rather than in medical settings. However, no policies are in place to require that the people making these decisions have received any education about evidence-based OUD treatment. Education and training about OUD for court officers could increase the uptake of medications to treat OUD. Probation and parole officers also need to be trained on medications used to treat people with OUD. Many prison medical directors limit treatment to abstinence-only or detoxification-only modalities for people with OUD in their prisons. A survey of prison medical directors across the United States revealed that many were not familiar with the medical and social benefits of providing medications for OUD—particularly buprenorphine—in correctional facilities (Nunn et al., 2009). Implementing methadone treatment in correctional facilities can be logistically complicated and impeded by stigma toward the medication among management and staff; however, those challenges can and should be addressed, given the potential health and social benefits to be gained by providing the medication (McKenzie et al., 2009).

SYSTEM FRAGMENTATION

The delivery and financing of treatment for people with OUD is rarely integrated with care delivered in the broader medical care system. Separate addiction treatment delivery settings and care financing streams are reinforced by regulatory and legal requirements that impose further barriers on accessing medication-based treatment for OUD. The existence of distinct treatment systems and financing mechanisms for SUDs has created sizable barriers to providing integrated services, particularly for people who have OUD and co-occurring medical or mental health conditions. For example, while primary care settings are an important venue for providing care for most chronic medical conditions, these settings have not historically been a prominent locale for addiction treatment.

Similarly, the sources of payment for SUD treatments differ in important respects from the broader medical care system. Compared to the general medical treatment sector, a substantially

larger share of the financing of SUD treatment—including OUD treatment—comes from public sources. In 2014, for example, 69 percent of SUD treatment was paid via public sources, including Medicaid (21 percent), Medicare (6 percent), other federal sources (12 percent), and other state and local sources (29 percent) (SAMHSA, 2016). Only 18 percent of financing for SUD treatment is paid via private insurance: 9 percent paid by consumers out of pocket and 4 percent paid through other private sources (SAMHSA, 2016). A lack of care integration and underfunding are legacies of the historical separation of drug treatment from the mainstream system, with what limited funding exists coming primarily from state and local funding grants rather than through insurance programs (Buck, 2011). Unlike insurance, these funding sources can lead to waitlists if funded slots are insufficient to meet treatment needs within a community.

In the United States, a large share of SUD treatment has been provided through a network of specialty addiction treatment facilities, but only 6.1 percent of these facilities offered all three FDA-approved medications in 2016 (Mojtabai et al., 2019). The share of facilities offering methadone barely changed over the past decade, from 9.4 percent of facilities offering methadone in 2007 to 10.3 percent in 2016. The reasons why some facilities offer medications and others do not is not well understood, although the rates of offering medications for OUD are higher in regions with heightened past-year heroin use and overdose death rates.

The provision of medications for OUD in treatment facilities varies substantially across the country. Among outpatient specialty SUD treatment facilities, the highest rates of offering medications for OUD are found in Rhode Island (76.1 percent), New York (73.7 percent), and Vermont (73.7 percent). The states with the lowest rates of offering medications include Idaho (16.8 percent), Arkansas (14.1 percent), and Hawaii (8.6 percent) (Mojtabai et al., 2019). Recent estimates indicate that only 23 percent of publicly funded facilities in the country offer medication-based treatment for OUD (Knudsen et al., 2010). Among those facilities, the likelihood of medication being adopted and offered was greater in programs endorsing cognitive behavioral therapy than in programs emphasizing 12-step approaches (Knudsen et al., 2010). Publicly funded programs are also less likely to have a physician on staff to prescribe medications for OUD (Abraham et al., 2013).

System fragmentation poses barriers beyond the health care sector that extend to other settings with high prevalence rates of OUD. For example, as was noted in [Chapter 4](#), major barriers to OUD medication uptake and continuation are driven by the high rates of OUD within criminal justice settings, the lack of availability of medication-based treatment during incarceration, and the absence of strong connections with outpatient treatment in community settings offering medications upon release from incarceration (Fox et al., 2015). The implementation of comprehensive medication-based treatment programs for OUD in correctional settings has been shown to be feasible and is associated with significant mortality declines (Green et al., 2018).

To better address this fragmentation, research is needed on system integration models. For example, research could explore how office-based collaborative care approaches used to treat depression in primary care with specialty consultation, care management, and peer support might work in the context of medication-based OUD treatment. Future research could focus on patient-centered care approaches that measure the preferences of individuals with OUD, including their preferred attributes of treatment or settings for receiving treatment. For example, some research suggests a higher willingness to pay for SUD treatment in primary care settings than in specialty addiction treatment settings (Epstein et al., 2015). In a large national sample of individuals who met the diagnostic criteria for SUD but were not currently in treatment, only 24.6 percent reported being willing to enter drug treatment in specialty settings, compared with 37.2 percent for primary care (Barry et al., 2016a). Additionally, little is known about patient preferences for integrated delivery system approaches, such as provider co-location, which allow individuals to

receive addiction care alongside primary care and chronic or infectious disease management for co-occurring conditions. Furthermore, research is needed on how best to integrate care for justice-involved individuals with OUD and other health care needs who are moving into community-based treatment settings.

LEGAL AND REGULATORY BARRIERS

Legal and regulatory barriers prevent broad access to medication-based treatment for OUD within the mainstream of the medical care system. As noted previously, methadone is the most stringently regulated of the three FDA-approved medications. It can be dispensed only by opioid treatment programs (OTPs) that are certified by the Substance Abuse and Mental Health Services Administration (SAMHSA) and registered with the Drug Enforcement Administration (DEA). Buprenorphine can only be prescribed for OUD by providers after they receive training and specialized certification by the DEA. In contrast, extended-release naltrexone can be prescribed by any licensed health care provider.

Legal and Regulatory Barriers for Methadone

In providing methadone, OTPs have limited flexibility in tailoring treatment plans to the individual needs of patients. Regulations with little to no evidence base—which vary by state—often restrict take-home medication privileges, require supervised medication consumption, and mandate the frequency of urine testing and counseling. Patients receiving care through an OTP are mandated to receive counseling as part of their treatment. However, studies of the effectiveness of this counseling have not demonstrated differences in treatment retention or opioid use among patients randomized to receive little or no interaction with clinic drug counselors as compared with those who received the federally mandated level of counseling (Gruber et al., 2008; Schwartz et al., 2006, 2012; Yancovitz et al., 1991). See Chapter 2 for a more detailed discussion of behavioral interventions in conjunction with medication. Most patients receiving methadone are required to visit treatment programs daily to receive their medications. For some patients, these rigid and time-consuming requirements can impede their ability to find and maintain employment and can affect their relationships; these requirements may also discourage providers from opening new treatment programs (Harris and McElrath, 2012). As a strategy to increase access to evidence-based treatment, there has been increased attention on removing regulatory barriers to prescribing methadone in primary care. Methadone may be prescribed in primary care clinics and filled in community pharmacies in Australia, Canada, and Great Britain (Merrill, 2002). Pilot studies examining the use of methadone in primary care suggest that this care delivery model is feasible and can positively affect treatment access and retention (Fiellin et al., 2001; Merrill et al., 2005). For example, a randomized controlled trial comparing office-based care versus OTP care for people who are stabilized on methadone treatment found physician offices to be a feasible and effective setting for maintenance treatment (Fiellin et al., 2001). Calls are increasing to allow methadone to be prescribed for OUD in a wider range of medical settings (Samet et al., 2018).

Legal and Regulatory Barriers for Buprenorphine and Naltrexone

Buprenorphine is less stringently regulated at the federal level than methadone, but federal regulations on certification and state regulations on the scope of practice result in limited provider capacity. The Drug Addiction Treatment Act (DATA) of 2000 allowed physicians who completed an 8-hour course to become waived by the DEA to prescribe buprenorphine in office-based settings. Initially, federal requirements limited waived providers to treating only 30 patients with OUD in their first year of certification and 100 thereafter. The Comprehensive Addiction and Recovery Act (CARA) of 2016¹ increased the maximum number of patients that

waivered physicians could treat concurrently to 275 for physicians who met certain criteria, but the eligibility requirements may be difficult for rural physicians to meet. Federal guidelines also require providers to reduce the risk of diversion and to provide patients with reasonable access to complementary services, such as counseling (CRS, 2018). Fifty-six percent of U.S. counties now have a physician with a DEA waiver, which is an increase from 47 percent in 2012 (Andrilla et al., 2018b). CARA also allowed NPs and PAs who complete 24 hours of training to treat up to 30 patients concurrently in the first year, and 100 patients in subsequent years, for a 5-year time period. In 2018 the Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act permanently allowed NPs and PAs to prescribe buprenorphine. The bill further aims to increase access to medications for OUD by allowing nurse anesthetists, nurse midwives, and clinical nurse specialists to prescribe buprenorphine for the next 5 years.² Twenty-eight states prohibit NPs from prescribing buprenorphine without oversight by a waivered M.D. Three states (Oklahoma, Tennessee, and Wyoming) prohibit any prescribing of buprenorphine by NPs, and Kentucky prohibits prescribing by PAs.

The inclusion of NPs and PAs in the workforce that can prescribe medication-based treatment has modestly increased the provider supply across the country. Among urban counties, 45.9 percent have a waivered NP and 24.5 percent have a waivered PA. Among rural counties, 13.8 percent have a waivered NP and 4.6 percent have a waivered PA (Andrilla et al., 2018b). The increase in the number of waivered providers is also reflected in the changes in the provider-to-population ratios since 2012. In urban counties, the number of waivered physicians per 100,000 population increased from 6.3 to 11.0; furthermore, adding NPs and PAs to this provider workforce raised the current urban provider-to-population ratio to 12.4 (Andrilla et al., 2018a,b).

Despite this progress, most providers who are waivered to prescribe buprenorphine maintain patient panels well below the regulated patient limits. According to one estimate, fewer than 30 percent of buprenorphine-waivered physicians were actually prescribing the medication, and less than 50 percent of waivered physicians had elected to be listed on SAMHSA's physician and treatment locator site (Moran et al., 2017). Most waivered providers treat a small number of patients: half of providers treat five or fewer patients with buprenorphine and one-third treat just a single patient (Moran et al., 2017). Even if all waivered providers were prescribing at capacity, the treatment coverage would still be inadequate to meet the need for treatment for OUD. Estimates suggest that just half of all people with OUD would receive treatment if all waivered providers were prescribing at capacity (Huhn and Dunn, 2017; Jones et al., 2015; Murphy et al., 2014; Rosenblatt et al., 2015).

Reasons cited by waivered physicians for not prescribing buprenorphine at capacity include a lack of time for new patients, concern about diversion, and reimbursement concerns (Huhn and Dunn, 2017; Molfenter et al., 2015). Another survey reported that diversion concerns were common, especially among rural physicians (Andrilla et al., 2017). Waivered physicians tend to have partners who are also waivered (Hutchinson et al., 2014). Additional barriers to buprenorphine prescription reported by waivered primary care physicians include a lack of institutional support, mental health support, and psychosocial support (Hutchinson et al., 2014). Waivered providers have also reported that the DEA's approach can be “threatening,” and some buprenorphine-waivered providers feel that they are unfairly scrutinized by the DEA (Moran et al., 2017). More recent aggressive enforcement strategies by the DEA and several state attorneys general—including increases in raiding, auditing, and launching criminal investigations of waivered providers—perpetuate the fear of such surveillance that has been articulated by waivered and non-waivered providers (Mendoza et al., 2016).

When asked about their willingness to prescribe buprenorphine, non-waivered providers report that they are concerned about attracting people who use drugs to their practices as well as about

encountering resistance from clinical practice partners (Andrilla et al., 2017). Other reasons for not prescribing cited by non-waivered providers include concerns about managing the volume of patient requests for buprenorphine and concerns about buprenorphine diversion (Huhn and Dunn, 2017). In a survey of non-waivered providers, respondents indicated a number of factors that could increase their willingness to begin prescribing buprenorphine, including being provided with information about local counseling resources, having access to an experienced prescriber for consultation, and receiving continuing medical education about OUD (Huhn and Dunn, 2017). In another survey of family physicians, the barriers to adopting buprenorphine treatment included the lack of adequately trained office staff, a lack of time, inadequate office space, regulatory requirements, a mistrust of people with addiction, the perception of people with addiction as a difficult population, and poor perceived efficacy of buprenorphine treatment (DeFlavio et al., 2015).

In contrast to the literature examining why providers do or do not obtain and use the DATA waiver to treat OUD, no evidence base supports the waiver process itself. Buprenorphine management is less risky and complicated than many other treatments that do not require special certification (Wakeman and Barnett, 2018). To expand access to buprenorphine treatment, there have been calls to eliminate prescribing limits on the grounds that there is no evidence base for limiting access to this medication (Fiscella et al., 2018). Another concern that has been raised involves the need to develop best practices to enhance the certification processes for prescribing clinicians and to better ensure high-quality prescribing practices (Blum et al., 2016).

Relative to methadone and buprenorphine, the legal barriers to accessing naltrexone are low. Naltrexone can be provided in an office setting with few regulatory requirements. The most common barrier to wider access identified by providers of naltrexone is related to its high cost, about \$1,200 per monthly dose (Alanis-Hirsch et al., 2016).

Privacy Regulations

Privacy regulations, particularly 42 Code of Federal Regulations (CFR) part 2 regulations, present a gap in knowledge in terms of policy impact on individual behavior, as it is unclear whether they act to promote or discourage treatment initiation and retention. The 42 CFR part 2 regulations stipulate that a program that receives any federal funding—including funding through the Medicaid or Medicare programs—and “holds itself out as providing . . . treatment” of SUDs may not disclose that its patients have a SUD or are in treatment without explicit patient consent or a court order (SAMHSA, 2018). Given the history of stigma and discrimination, this regulation protects the privacy of patients with SUDs, similar to statutes protecting sensitive health conditions like HIV. The regulation creates a high bar for disclosure of treatment status to individuals or organizations, which have the power to sanction patients for engaging in evidence-based medical treatment, such as the criminal justice system, governmental agencies such as Child Protective Services, and housing corporations. In this way, privacy protections may encourage patients to seek treatment at specialized centers. At the same time, the special privacy protection contributes to the traditional separation of addiction treatment from the rest of medical care. Consequently, a patient's primary care, inpatient, mental health, and SUD treatment provider may not be aware of the patient's status in treatment for OUD, unless the patient chooses to disclose that status; this can complicate the patient's overall medical treatment regimen and discourage continuity of treatment for OUD when a patient transitions from one care location to another.

Another knowledge gap concerns differences in medical and pharmacy records and how this impacts patient treatment selection. Extended-release naltrexone is generally covered under a medical benefit and administered in a provider's office, so the level of privacy depends on

whether the provider is subject to 42 CFR part 2. On the other hand, state and regional Prescription Drug Monitoring Programs (PDMPs) track records of controlled substances, so the vast majority of patients who are maintained on buprenorphine have their treatment status disclosed without their consent—whether or not their provider's medical record is subject to the 42 CFR part 2 regulations. Because methadone for OUD is provided only at licensed specialty programs, 42 CFR part 2 regulations prohibit disclosure of dispensed medication to the PDMP.

PUBLIC AND PRIVATE INSURANCE BARRIERS

Regulations that govern public and private insurance coverage pose substantial barriers to patients' ability to access medication-based treatment for OUD. Adjusting policies related to coverage and reimbursement has the potential to expand access to life-saving medications across the country and to make headway against the opioid epidemic.

Medicaid

Medicaid is the single most important source of insurance coverage for individuals with OUD. It is the largest health insurance program in the United States, covering more than 62 million Americans, including millions of the nation's lowest-income individuals and families. Medicaid covers an estimated 4 in 10 non-elderly adults with OUD (Zur and Tolbert, 2018), and more than \$9 billion was paid by Medicaid for the treatment of OUD in 2016 alone (Niederee and Lawless, 2018). Research suggests that Medicaid coverage can help individuals access medication-based treatment for OUD and facilitate treatment retention. States that expanded access to Medicaid under the Patient Protection and Affordable Care Act (ACA) have experienced increased use of buprenorphine treatment (Saloner et al., 2018; Sharp et al., 2018; Wen et al., 2017). One analysis found that Medicaid expansion states were associated with a 70 percent increase in buprenorphine prescriptions covered by Medicaid and a 50 percent increase in buprenorphine spending (Wen et al., 2017). Having stable Medicaid eligibility is also associated with higher rates of retention on medication for OUD (Deck et al., 2009). One study found a 50 percent lower risk of return to use among Medicaid enrollees treated with medication relative to other treatments, and longer treatment duration among Medicaid enrollees was associated with lower return to use rates (Clark et al., 2011). Among publicly funded addiction treatment organizations, reliance on Medicaid reimbursement has been positively associated with offering medications for OUD (Knudsen et al., 2010). Under one state's Medicaid program, enrollees treated with OUD medication had lower overall health care expenditures; coupled with reduced medical care costs, this offset the cost of medication-based treatment for OUD (Mohlman et al., 2016). Conversely, the elimination of Medicaid coverage for active methadone patients under one state's Medicaid program led to negative outcomes for patients with OUD, including an increased inability to afford treatment, increased property crimes, greater frequency of medical care visits, and employment-related challenges (Fuller et al., 2006).

Important gaps remain in Medicaid coverage for medications to treat OUD. One survey identified five states that excluded both buprenorphine and methadone from their Medicaid coverage policies (Burns et al., 2016); 14 states lack any facility that offers medication-based treatment and also accepts Medicaid coverage for OUD (Jones et al., 2018). Use management policies under Medicaid serve as additional barriers to medication access, including prior-authorization requirements, formulary restrictions, and restrictions on treatment duration and doses (Moran et al., 2017). In addition, new approaches being instituted in some state Medicaid programs through section 1115 waivers including work requirements, increased cost-sharing and deductibles, and other consumer-oriented approaches such as health savings accounts that put enrollee coverage at risk for failure to make payments could pose barriers to access and continuation on medication for OUD (Somers et al., 2018).

Medicaid and Incarceration

Importantly, Medicaid expansion under the ACA has created unprecedented opportunities for addressing the low rates of insurance coverage among individuals with OUD who are returning to the community following incarceration. Medicaid expansion meaningfully affects justice-involved individuals, which is a group that consists disproportionately of low-income men who have historically been excluded from Medicaid coverage (Cuellar and Cheema, 2012). Birnbaum and colleagues report that nearly all criminal justice-involved individuals are eligible for Medicaid in expansion states upon release (Birnbaum et al., 2014). By federal regulation, however, Medicaid dollars cannot be used to cover health care provided while a person is incarcerated (Somers et al., 2014). Medicaid coverage must be terminated or suspended during periods of incarceration (Gates et al., 2014; Rosen et al., 2014). Typically, people on medication-based treatment for OUD who become incarcerated are rapidly tapered off medication, and people with OUD are rarely initiated on medication-based treatment while incarcerated. For people who are discontinued when incarcerated, being disconnected from care contributes to lost opportunities to more cost-effectively and humanely treat chronic diseases; it also perpetuates extremely high overdose mortality risk upon release. For an inmate leaving incarceration in states that terminate Medicaid benefits, re-enrolling in coverage can cause months-long delays that contribute to disruptions in the receipt of care. Such disruption has negative clinical impacts for patients with OUD. Some states are instituting policies to lower the barriers to Medicaid coverage for justice-involved individuals, including those with OUD (Bandara et al., 2015). Those policies include suspending rather than terminating Medicaid benefits during incarceration, allowing enrollment in Medicaid during incarceration, and presumptive eligibility policy options.

Private Insurance

Private insurance also offers important opportunities for expanding access to medications for OUD. Evidence suggests an association between gaining private health insurance and accessing medication-based treatment for OUD. One study of individuals injecting drugs found that when participants acquired private insurance, the likelihood that they would report a buprenorphine prescription and a regular source of medical care increased (Feder et al., 2018). However, until recently, private coverage for SUD treatment required higher cost sharing and special annual service caps relative to the insurance benefits for other medical conditions (Barry and Sindelar, 2007; Gabel et al., 2007).

A number of recent policy changes have lowered barriers to receiving medication-based treatment for OUD paid for via insurance. The Mental Health Parity Act of 1996 (MHPA) mandated that large-group health plans cannot impose annual or lifetime dollar limits on mental health benefits that are less favorable than any such limits imposed on medical and surgical benefits. The Mental Health Parity and Addiction Equity Act of 2008 preserves the MHPA protections and adds significant new protections, such as extending the parity requirements to SUDs. Evidence suggests that as a result of this law, the treatment rate for SUDs increased by 9 percent in all specialty treatment facilities and by 15 percent in facilities accepting private insurance (Wen et al., 2013). Federal parity also increased inpatient SUD admissions. Some evidence also suggests that the parity ensured by this law led to a decrease in the financial burden on families of paying for addiction treatment via commercial insurance (Azzone et al., 2011). Importantly, parity requirements and other insurance market changes extend private health insurance to more individuals with OUD. These include the “dependent care” provision, which allows children to be kept on their parents’ insurance until the age of 26 years, as well as the ACA ban of the once common insurance industry practice of refusing to sell insurance policies to individuals with pre-existing disorders (Barry et al., 2016b; Humphreys and Frank, 2014).

Nonetheless, barriers continue to prevent access to medication for OUD under private insurance. For example, a recent study of benefits in 2017 marketplace plans found that 14 percent of health plans did not cover any formulations of buprenorphine/naloxone. Despite the new patient protections, plans were more likely to require prior authorization for covered office-based buprenorphine or naltrexone treatment than for short-acting opioid pain medications. Only 10.6 percent of plans covered implantable buprenorphine, while 26.1 percent covered injectable naltrexone (Huskamp et al., 2018).

Reimbursement and Payment System Barriers

Research indicates that altering reimbursement and payment incentives could lower the barriers to accessing medications for OUD. Reimbursement concerns—some of which are specific to Medicaid (Quest et al., 2012)—are a commonly cited barrier to buprenorphine prescribing, particularly among waived physicians (Barry et al., 2009). The predominant fee-for-service model of reimbursement for providers rewards quantity rather than care quality (Fodeman, 2017). Efforts are under way to address this by shifting to value-based payment systems through accountable care and payment reforms (e.g., global payment, bundled payment). Payment changes that drive health systems to provide high-value care could be instrumental in increasing OUD medication-based treatment rates. However, some evidence suggests that the addiction treatment sector is not keeping pace with the rest of the health care field in adopting new value-based payment systems (McDowell et al., 2018; Stuart et al., 2017).

A 2006 Institute of Medicine report made sweeping recommendations to improve the quality of SUD care in the United States, but few of those recommendations have been implemented (IOM, 2006). The lack of performance metrics for measuring the uptake of OUD medication poses additional barriers to progress (Thomas et al., 2011). An important area in which SUD care is lagging behind the rest of the medical care sector is the development, evaluation, and implementation of health quality measures aimed at increasing patients' access to medications and their continuation in evidence-based treatment for OUD; these measures include metrics that can be used in value-based payment systems (Pincus et al., 2016). For example, a performance metric for OUD medication could track and reward providers who are able to maintain a sizable share of their patient populations in longer-term, medication-based treatment. Other types of payment incentives might also be considered—for example, requiring that substance use treatment facilities receiving federal block grant funding provide medications for OUD as a condition of participation.

Conclusion 7: Confronting the major barriers to the use of medications to treat opioid use disorder is critical to addressing the opioid crisis.

The major barriers to the use of medications for OUD include

- High levels of misunderstanding and stigma toward drug addiction, individuals with OUD, and the medications to treat it.
- Inadequate education of the professionals responsible for working with people with OUD, including treatment providers and law enforcement and other criminal justice personnel.
- Current regulations around methadone and buprenorphine, such as waiver policies, patient limits, restrictions on settings where medications are available, and other policies that are not supported by evidence or employed for other medical disorders.

- The fragmented system of care for people with OUD and current financing and payment policies.

Footnotes

- 1 Public Law 114-198.
- 2 See House amendment to Senate amendment to House of Representatives bill H.R. 6. <https://www.congress.gov/115/bills/hr6/BILLS-115hr6eah.pdf> (accessed February 12, 2019).

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