Utilizing Medication-Assisted Treatment for Opioid Disorders in Rural Settings
1. Introduction

In recent years, the abuse of opioids such as prescription pain medications and heroin has become a growing epidemic in many States and communities. Opioid abuse has become a dangerous threat to the Nation's public health, and the number of opioid overdoses has increased at a shocking pace. On average, more than 90 people died each day from opioid overdose in 2015.¹

The U.S. Department of Health and Human Services (HHS) has recognized opioid use disorder (OUD) as a national crisis. In response, HHS has created an initiative that targets three areas:

1. Opioid prescribing practices;
2. Expanded use and distribution of naloxone to treat overdose; and
3. Increased access to medication-assisted treatment (MAT for OUD).²

Several HHS agencies have each identified policy steps, aligning with their respective missions and mandates, to help address these problems: Centers for Disease Control and Prevention (CDC), National Institute on Drug Abuse (NIDA), Agency for Healthcare Research and Quality (AHRQ), Health Resources and Services Administration (HRSA), and Substance Abuse and Mental Health Services Administration (SAMHSA).

In 2016, AHRQ commissioned the development of a technical brief in which a literature review and interviews with key informants were used to gather information on MAT models for use in primary care settings. That report, Medication-Assisted Treatment Models of Care for Opioid Use Disorder in Primary Care Settings, described the evidence base for promising and innovative MAT models and noted barriers to the implementation of MAT, including those in rural and other underserved settings.

The purpose of this environmental scan is to build on AHRQ's previous work related to OUD, by further exploring the unique factors of implementing MAT in rural primary care settings, as well as the evidence and availability of tools needed to implement MAT.

1.1 Opioid Use Disorder

As defined by the Diagnostic and Statistical Manual of Mental Disorders, 5th edition (DSM-5), OUD is "a problematic pattern of opioid use leading to clinically significant impairment or distress."³ In 2015, 2
million people had a prescription opioid use disorder and nearly 600,000 people had a heroin use disorder.\(^4\) AHRQ reported that between 2005 and 2014, opioid-related inpatient hospitalizations increased by 64 percent and emergency department visits rose by 99 percent.\(^5\)

For some with OUD, the addiction may be fatal. According to CDC, in 2015, more than 52,000 people in the United States died from a drug overdose, and approximately 33,000 of these deaths (63%) involved an opioid.\(^1\)

Contributing to these high rates of opioid-related deaths is the prevalent use of prescription opioids such as hydrocodone and oxycodone. Each year, an estimated 289 million opioid prescriptions are dispensed in the United States, making opioid analgesic pain relievers the most frequently prescribed class of medications.\(^6\) One study found that, on average, more than half of these prescriptions were dispensed to individuals who had already filled another opioid prescription within the past month.\(^7\) Primary care providers (PCPs) are the main prescribers of opioid analgesics, with approximately 29 percent of prescriptions coming from these physicians.\(^7\)

Increased access and availability to prescription opioids brings a greater risk of misuse and abuse. In 2015, the National Survey on Drug Use and Health found that 12.5 million people misused pain relievers in the past year. Most of these individuals (54%) obtained the pain reliever from a friend or family member, while about one-third (36%) received pain relievers through a prescription by a health care provider. Young adults and males were both more likely to misuse prescription pain relievers than other age groups and females, respectively. In the survey, the most commonly cited reason for misusing pain relievers was to ease physical pain (63%), while other reasons included to feel good or get high (12%) and to relax (11%).\(^8\)

Misuse and abuse of prescription opioid pain relievers may lead to OUD, which not only poses a threat to public health but also represents a significant economic burden to society. One study estimated that, in 2013, prescription opioid overdose and OUD cost $78.5 billion. These costs from health care services, substance use treatment, and criminal justice weigh heavily on the public sector.\(^9\)

Another significant concern is that misuse of prescription opioids may lead to initiation of heroin use, as it is cheaper and, in some cases, easier to access.\(^10\) Heroin overdoses, in particular, have seen a sharp rise in the past decade. The number of heroin overdose deaths in 2015 was more than quadruple the number in 2010.\(^11\) Moreover, between 2014 and 2015 alone, there was a 21 percent increase in heroin-related deaths.\(^1\)
The demographics associated with heroin use have also shifted in recent years. Cicero, et al., found that early users of heroin in the 1960s and 1970s were predominantly young men, many of whom were minorities. In contrast, more recent users of heroin tended to be slightly older white men and women who live outside of urban areas.  

1.2 Medication-Assisted Treatment

In the face of the alarming trends of the opioid epidemic, attention to MAT has risen. SAMHSA defines MAT as "the use of medications, in combination with counseling and behavioral therapies, to provide a 'whole-patient' approach to the treatment of substance use disorders" (SUDs). For OUD specifically, MAT uses medications to prevent the euphoric effects of opioids, lessen cravings for opioids, and decrease withdrawal symptoms by acting as opioid agonists, partial agonists, or antagonists.

A full agonist is a chemical that binds to receptors in the brain, in this case opioid receptors, and triggers a biologic response such as pain relief, euphoria, or respiratory depression. Agonists include opioids such as heroin and prescription pain medications. A partial agonist also activates these receptors; however, the effect is more limited than a full agonist because it does not completely bind to the receptors. On the other hand, an antagonist is a chemical that binds to a receptor and blocks the effects of any opioids present.

Currently, three main medications are approved by the Food and Drug Administration (FDA) for OUD: methadone, buprenorphine, and naltrexone. These different types of MAT are summarized in Table 1.

Methadone is an opioid agonist that is frequently used to minimize withdrawal symptoms and block the euphoric effects of other opioids. Because of the potential risk for abuse or overdose associated with methadone, only opioid treatment programs (OTPs) certified by SAMHSA and registered with the U.S. Drug Enforcement Administration (DEA) may dispense methadone for the treatment of OUD. OTPs exist in a variety of settings, such as outpatient, residential, and hospital-based programs, and may administer buprenorphine or naltrexone as well.
Table 1. Comparison of medications for the treatment of OUD

<table>
<thead>
<tr>
<th>Name</th>
<th>Mechanism of Action</th>
<th>Forms</th>
<th>Uses</th>
<th>Restrictions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methadone</td>
<td>Agonist</td>
<td>Oral tablet or liquid</td>
<td>Withdrawal and treatment</td>
<td>Dispensed in certified opioid treatment programs</td>
</tr>
<tr>
<td>Buprenorphine</td>
<td>Partial agonist</td>
<td>Oral tablet, buccal film, or extended-release implant</td>
<td>Withdrawal and treatment</td>
<td>Prescribed with appropriate waiver</td>
</tr>
<tr>
<td>Buprenorphine/naloxone</td>
<td>Combination</td>
<td>Oral tablet or buccal film</td>
<td>Withdrawal and treatment</td>
<td>Prescribed with appropriate waiver</td>
</tr>
<tr>
<td>Naltrexone</td>
<td>Antagonist</td>
<td>Oral tablet or extended-release injectable</td>
<td>Treatment</td>
<td>None noted</td>
</tr>
</tbody>
</table>

Buprenorphine is taken in the form of a tablet (e.g., Subutex), buccal film (e.g., Belbuca), or extended-release implant (e.g., Probuphine). As a partial opioid agonist, buprenorphine activates opioid receptors but generates a limited effect in terms of euphoria, pain relief, or respiratory depression compared with that caused by a full agonist such as heroin, methadone, or prescription pain medications. However, except for the buprenorphine implant, the use of buprenorphine for maintenance treatment involves some risk of misuse or overdose.

To minimize the risks, a combination medication that includes naloxone, an opioid antagonist not well absorbed through the oral mucosa or gastrointestinal tract, may be used instead. These combination products, such as Suboxone, Zubsolv, and Bunavail, were designed to discourage intravenous abuse of buprenorphine, because, when injected, they can induce withdrawal symptoms.

Under the Drug Addiction Treatment Act of 2000 (DATA 2000), physicians are allowed to obtain a waiver to prescribe buprenorphine for the treatment of OUD. To become waived, providers must be trained in the use of buprenorphine for MAT and acknowledge they have access to counseling services.

Until recently, waived physicians could initially provide buprenorphine treatment for up to 30 individuals for the first year, after which they could treat up to 100 patients. However, as part of an effort to increase access to this medication, regulations were changed in 2016 to allow waived providers to request approval to treat up to 275 patients. Also in 2016, the Comprehensive Addiction and Recovery Act (CARA) extended the ability to prescribe buprenorphine to trained and waived nurse practitioner and physician assistants.
Unlike buprenorphine and methadone, naltrexone is an opioid antagonist that blocks opioid receptors to prevent any of the effects of opioids if they are used. Therefore, it is recommended for relapse prevention rather than management of withdrawal symptoms. Naltrexone does not carry a risk for abuse or overdose like buprenorphine or methadone, so no restrictions are in place on which health care providers may prescribe it. Naltrexone is available in both oral tablets and extended-release injectable formulations, commonly known as Revia and Vivitrol, respectively.

In addition, MAT is a multimodal and comprehensive treatment approach that must include a psychosocial component, such as cognitive behavioral therapy, motivational enhancement therapy, or peer-delivered recovery support services. The psychosocial treatment component aims to modify underlying behaviors that may affect substance abuse, by increasing knowledge and motivation to change.

Two opioid substitution therapies, buprenorphine and methadone, appear in the World Health Organization Model Lists of Essential Medicines. MAT with buprenorphine or methadone reduces the risk of premature mortality associated with opioid dependence. Research has demonstrated that MAT can be a highly effective treatment option in terms of retaining people in treatment and reducing opioid abuse and overdose deaths. In addition, research has demonstrated that MAT can be beneficial to society beyond decreasing drug abuse, as it is a cost-effective intervention that has been shown to reduce illicit drug use and the transmission of HIV and hepatitis C. Thus, MAT can also lead to significant reductions in criminal activity.

While the body of evidence supports the use of MAT in general, conclusions vary regarding the optimal length of participation for treatment to be effective. For example, one study found patients who receive MAT for less than 90 days do not have significantly improved outcomes. Research also suggests the likelihood of relapse decreases significantly for those who are in treatment for at least 3 years.

1.3 Rural Context

Communities in rural areas continue to be among the hardest hit by the opioid epidemic. States with large rural populations have some of the highest increases in morbidity and mortality related to prescription opioid misuse. For example, CDC has estimated that people in rural counties are approximately twice as likely as those in urban areas to overdose on prescription painkillers.
Rossen, et al., found that from 1999 to 2009, mortality rates due to drug poisoning rose more rapidly among rural areas than large metropolitan counties, growing by 394 percent within the decade. The rate of opioid-related inpatient hospitalizations increased across the Nation between 2009 and 2014; however, the sharpest increases were in States with large rural populations, such as Georgia, North Carolina, Oregon, Washington, and South Dakota.

To explain these discrepancies between urban and rural areas, Keyes, et al., hypothesized that several factors may have increased prescription opioid misuse in rural areas. First, there is increased availability of opioids in States with large rural populations because of high prescription rates. In part, this finding may be due to strategic and aggressive marketing in rural regions such as Appalachia when OxyContin was released. The large kinship networks unique to rural areas may contribute to the spread of prescription opioids as friends and family with prescriptions are often a main source of access to these drugs. Also, individuals living in rural areas may be more likely to suffer injuries in labor occupations that lead to higher rates of chronic pain and prescription opioid abuse.

Moreover, age demographics of rural populations may contribute to the increased use of opioids. In the last few decades, rural areas have experienced an outmigration of many young adults and have been hard hit by economic downturns. For those who remain in these communities, the stress of their economic struggles and high levels of unemployment predisposes them to increased risk of drug abuse. For example, key informants in Appalachian counties in Kentucky explained individuals' misuse of prescription drugs as an "escape from 'hopelessness' and the 'lack of opportunity.'"

In his book *Dreamland: The True Tale of America's Opioid Epidemic*, Sam Quinones offers a detailed description of how the opioid epidemic arose in rural areas. He paints a vivid picture of how a number of complex factors actually drove the opioid problem in the United States. When the great industries in America restructured and declined due to globalization and outsourcing, the gap between poverty and affluence widened.

At the same time, practices were changing in the medical and pharmaceutical institutions. Pill mills thrived in rural areas such as Portsmouth, Ohio, where synthetic opioids and other drugs were dispensed more freely than in other regions in the country. Quinones notes that the heroin problem developed gradually, as increased restrictions on pill mills made access to prescription opioids more
difficult. Mexican drug cartels targeted rural areas and provided reliable home delivery of heroin to those who could no longer access the prescription drugs they had become addicted to.

Appalachia has been particularly hard hit by the opioid crisis, and Quinones describes it as "the canary in our societal coal mine" for opioids. As long as the crisis was hitting only the nameless poor in rural America, it received little notice in the press and elsewhere. When it began to become more widespread across the country, affecting rich as well as poor, attention to the problem grew. The issue became more visible as celebrities died from opioid overdoses.

Despite the critical need, individuals with OUD in rural counties often lack access to MAT. For example, although primary care physicians are important providers of health care in rural areas, one study found that only 3 percent of primary care physicians had obtained a waiver to prescribe buprenorphine. Due to this lack of waivered physicians, approximately 21 million people were living in rural counties with no local access to physicians authorized to provide buprenorphine treatment. These challenges associated with access to care will be explored in greater detail later in this report.

1.4 Methodology

This environmental scan reflects two literature reviews. The purpose of the first literature review was to find peer-reviewed articles and grey literature on MAT for OUD, with special interest in MAT for OUD implementation in rural primary care. Professional librarians conducted a comprehensive literature search of MAT for OUD. Searches were conducted in PubMed, PsycInfo, CINAHL (Combined Index in Nursing and Allied Health Literature), ASSIA (Applied Social Sciences Index and Abstracts), PILOTS (Published International Literature on Traumatic Stress), Sociological Abstracts, Social Services Abstracts, ERIC (Education Resources Information Center), and WorldCat. A grey literature search was also conducted. Results were limited to the English language and date limits were 2006 to 2016.

The second literature review was for MAT tools. This search was also conducted by professional librarians, and searches were conducted in PubMed, PsycINFO, PILOTS, and HAPI (Health and Psychosocial Instruments). Grey literature was also searched for MAT tools. Results were limited to the English language and date limits were 2006 to 2017.
We used the AHRQ publication *Medication-Assisted Treatment Models of Care for Opioid Use Disorder in Primary Care Settings, Technical Brief #28,* published in December 2016, as a point of departure. In addition, we conducted searches of the reference lists of key studies and of relevant websites. The significant impact of the opioid epidemic in the United States is resulting in a proliferation of published and grey literature. Particularly with regard to MAT tools, and to the challenges and strategies for delivering MAT in rural primary care settings, significant focused searches were required.

### 2. Delivering MAT in Rural Primary Care Settings

Using primary care to deliver MAT services is an effective way to treat patients with OUD, especially in rural areas. Primary care physicians are "on the front lines of the health care system and of the opioid epidemic. They provide first-line therapies for chronic pain, and account for 50 percent of all opioids dispensed."27

"Addiction" is a term used for the most severe, chronic stage of a substance use disorder. In the DSM-5, the term "addiction" is synonymous with the classification of a severe substance use disorder.28 A short definition of addiction is provided in a policy statement by the American Society of Addiction Medicine (ASAM):

> Addiction is a primary, chronic disease of brain reward, motivation, memory and related circuitry. Dysfunction in these circuits leads to characteristic biological, psychological, social and spiritual manifestations. This is reflected in an individual pathologically pursuing reward and/or relief by substance use and other behaviors.29

The ASAM fact sheet *Treating Opioid Use Disorder as a Chronic Disease* provides an excellent comparison of the treatment of opioid addiction with that of other chronic diseases. Citing the work of McClellan, et al.30 ASAM notes the remarkable similarities in relapse rates between addiction and these other chronic diseases.

Like other chronic diseases, opioid addiction cannot be cured but can be effectively treated and managed. "When addiction is viewed as a chronic disease, the goal of treatment moves from 'quick cure' to 'long-term management' and ultimately strives to produce a system in which the patient is able to manage his or her own disease and reduce or eliminate symptoms."31
As with other chronic disorders, medications are available for all phases of treatment of opioid disorders. ASAM points out that, despite evidence that addiction is a chronic disease, addiction treatment is still largely set off from mainstream health care and "is built on infrastructure and financing models that continue to treat addiction under an acute care model, rather than within the framework of chronic disease management." Insurer-imposed limits on patient access to drug therapies further reduces the availability of medications across the full continuum of care. Restrictions on dosage and duration of treatment, prior authorization requirements, and "fail first" or step therapy requirements are also typical.

In general, the integration of behavioral health and primary care promotes comprehensive, whole-person, patient-centered care. In 2016, *Facing Addiction in America: The Surgeon General's Report on Alcohol, Drugs, and Health* concluded that integrated care is "a logical and necessary shift that our society must make to prevent substance misuse and its consequences and meet the needs of individuals with substance use disorders." Integration allows providers to simultaneously manage complex comorbid medical conditions, mental health, and SUDs. For example, individuals with OUD who started misusing opioid analgesics prescribed for chronic pain conditions could strongly benefit from treatment by a provider who understands both the physical and behavioral elements of their treatment needs. In the AHRQ Technical Brief *Medication-Assisted Treatment Models of Care for Opioid Use Disorder in Primary Care Settings*, key informants commented that the "most promising models of care are those that emphasize the integration of management of OUD with primary care and other medical and psychological needs." Fewer physicians and other health care providers decide to practice in rural areas, so these counties often lack availability of specialty medical services such as those for mental health and substance use treatment. It is estimated that 17 percent of noncore rural counties (i.e., counties not part of metropolitan or micropolitan areas) have no behavioral health providers, including:

- Counties without psychiatrists, 80 percent;
- Counties without psychologists, 61 percent;
- Counties without social workers, 35 percent;
- Counties without psychiatric nurse practitioners, 91 percent; and
- Counties without counselors, 24 percent.\textsuperscript{34}

Therefore, PCPs are frequently encountering patients with OUD. This situation is especially common in rural areas with few, if any, behavioral health specialists. Incorporating MAT into primary care would give these physicians the tools they need to meet a wider range of their patients' needs. In addition, individuals with OUD may prefer to receive substance use treatment from their PCP because of the stigma often associated with behavioral health specialty services. In one study, researchers found that people with SUDs were more willing to receive treatment in primary care settings than in a specialty drug treatment center.\textsuperscript{36}

In rural areas, primary care may be practiced in a variety of settings and facilities, depending on what is locally available. Many rural residents will receive primary care from family practitioners or internal medicine physicians at private practices. Also, federally qualified health centers (FQHCs) are critical in providing health care to rural residents and qualify for reimbursement under Medicare and Medicaid as safety net providers.

Similarly, rural health clinics (RHCs) are public or private facilities that aim to increase access to care in rural, medically underserved areas, and they are federally certified to receive special Medicare and Medicaid payments. Another option available to rural members of federally recognized Tribes is the Indian Health Service (IHS). This agency provides health care to American Indians and Alaska Natives through Federal and Tribal facilities.

\section*{2.1 Challenges and Strategies for Overcoming Them}

In the issue brief \textit{Primary Care: On the Front Lines of Addiction}, Bachhuber, et al., point out that:

\begin{quote}
\ldots despite the increasingly effective treatments, only about 10 percent-20 percent [of Americans with substance use disorder] receive any treatment, a shortfall that reflects patient, health system, financial, and regulatory barriers. But an overarching reason for the continuing failure to address this outsize need is the longstanding separation between care for substance use disorders and the rest of the health care system.\textsuperscript{27}
\end{quote}

While this problem exists nationwide, it has a particular impact in rural areas where specialty treatment services for substance use and other behavioral health problems are in short supply.
While there is a "growing consensus about the need to address illicit drug use disorders in primary care, few PCPs do so today." Patients, providers, and their communities face many barriers in accessing or delivering MAT in primary care settings in rural areas.

Individuals living in rural counties may experience health inequities, which are shaped by broader social determinants of health. For instance, rural residents are often more likely to live in poverty and have lower levels of education than those in metropolitan areas. Education directly affects employment opportunities and income, which in turn have been identified as predictive risk factors for substance use.

Similarly, rural residents may have lower levels of health literacy, which can affect overall health status because they may experience challenges managing chronic illness, adhering to instructions for medications, or communicating effectively with their providers. Also, people living in rural areas may have unique concerns related to environmental health, as many work in rural industries such as mining and farming that pose additional health risks.

2.1.1 Workforce and Training

Often, rural communities have limited health services available, and a lack of access to treatment is one of the primary barriers to receiving MAT for OUD. Among PCPs who practice in rural communities, very few have obtained waivers that make them eligible to prescribe buprenorphine as part of MAT. An analysis of the geographic distribution of waivered providers found that approximately 90 percent of physicians with waivers were in metropolitan areas and only 1.3 percent were in small and remote rural counties.

This lack of waivered providers is one of the most significant barriers to receiving MAT for OUD in rural areas, and efforts are greatly needed to increase the number of providers eligible to prescribe buprenorphine. As previously noted, CARA allows nurse practitioners (NPs) and physician assistants (PAs) to become trained on buprenorphine maintenance treatment and waivered to prescribe the medication. NPs and PAs who have completed the required training and seek to become DATA waivered for up to 30 patients can apply as of early 2017.

Rural communities with a lower density of PCPs can take advantage of these new regulations and encourage NPs and PAs to obtain waivers since they often outnumber physicians. If NPs and PAs
can prescribe buprenorphine, the capacity for a clinic or private practice to offer MAT will increase greatly.

To obtain a waiver, physicians must participate in an 8-hour training to qualify to prescribe and dispense buprenorphine. PAs and NPs must obtain no fewer than 24 hours of initial training, and they may take the same 8-hour DATA-waiver course for OUD treatment, designed by national experts, that physicians take.

The DATA-waiver course is offered for free by SAMHSA through the Providers' Clinical Support System for Medication-Assisted Treatment (PCSS-MAT). This training must address each of the topics in 21 USC 823(g)(2)(G)(ii)(IV), and it must be provided by one of the following organizations:

- American Society of Addiction Medicine,
- American Academy of Addiction Psychiatry,
- American Medical Association,
- American Osteopathic Association,
- American Nurses Credentialing Center,
- American Psychiatric Association,
- American Association of Nurse Practitioners,
- American Academy of Physician Assistants, or
- Any other organization that the Secretary of Health and Human Services determines is appropriate.

SAMHSA will also offer the additional 16 hours of training for free through the PCSS-MAT once it has been developed.

Many of these trainings are offered in distance learning environments, which may be more convenient for rural providers as they can be completed without travel and, in some cases, on the provider's schedule.
SAMHSA-supported continuing medical education (CME) training courses include:

- "Buprenorphine Waiver Training" from the American Academy of Addiction Psychiatry,
- "Buprenorphine Course for Office-Based Treatment of Opioid Use Disorders" from the American Society of Addiction Medicine, and
- "Providers Clinical Support System for Medication Assisted Treatment Self Study" from the American Osteopathic Academy of Addiction Medicine.

These courses may require registration and a fee to participate.

Not only is training a challenge for rural providers offering MAT, but there is often a lack of education and preparedness among other staff as well. The larger medical team and office staff can be properly trained on how to implement new clinical protocols and interact with patients. Education can emphasize the brain chemistry of addiction, signs and symptoms of OUD, neonatal abstinence syndrome, and effectiveness of MAT.

It is also important that staff be taught to use tools such as urine drug screens to implement new policies and procedures associated with MAT services. To address these concerns, resources such as the Addiction Technology Transfer Center Network, created by NIDA and SAMHSA, offer training modules about MAT for nonphysician professionals.

2.1.2 Provider Knowledge, Attitudes, and Beliefs

Even if waivered providers are available, they often are not actively prescribing or offering MAT services. In one study, Hutchinson, et al., found that only 28 percent of waivered physicians reported actively prescribing buprenorphine and that fewer than half of those listed their name on the SAMHSA Physician and Treatment Locator site. Similarly, another analysis of pharmacy claims data found that most buprenorphine providers were treating a small number of patients, with almost one-third of providers having a single patient and almost half of providers treating five or fewer patients. A provider's willingness to become waivered and to offer MAT services may be strongly influenced by their knowledge, attitudes, and beliefs about the treatment.

Issues such as stigma and the above-noted historical segregation of patients with SUD from mainstream medicine are key reasons for lack of access to treatment. For example, some providers
have cited unease in engaging in substance use treatment services in primary care settings because they lack confidence in their knowledge about addiction medicine and their ability to treat these patients.39

Treatment of SUDs is not a core component of medical education, represented by the fact that few medical schools require a course on addiction medicine.644 ASAM notes that a critical component of the overhaul and reform of addiction treatment is "improved training of the medical workforce, specifically those working in primary care environments."31 Primary care physicians are trained to treat chronic medical conditions such as asthma, diabetes, and hypertension, all of which have complex behavioral aspects to them. Treating addiction is really not so different than treating other chronic conditions.

In the face of the opioid epidemic, educators and students alike believe that awareness of opioid addiction risks needs to begin in medical school, with additional opportunities in residency to develop competency in treating addictions in primary care. The Association of American Medical Colleges (AAMC) joined the Federal Government and other partners in October 2015 when they agreed to implement new efforts to address the substance abuse epidemic.45

Institutions are adding innovative programs in response to the growing needs they are seeing in their communities. It has been suggested that learning to provide MAT in their practice should be part of the Accreditation Council for Graduate Medical Education milestones for primary care and psychiatry residencies.

A wide variety of resources are also available to providers to obtain CMEs in addiction medicine. Although rural providers may not have local access to these resources, virtual learning and consultations can be used. For example, web-based learning networks such as Project ECHO (Extension for Community Healthcare Outcomes) use video conferencing and clinical management tools to help PCPs build knowledge and confidence to provide substance use treatment. This innovative model uses specialists with addiction expertise to mentor and engage community providers in case-based learning to provide specialized care to patients in underserved areas, such as rural communities.46

Even if they have learned the basics of treating SUDs, providers may not have access to addiction expertise for complex patients whom they would feel otherwise overwhelmed in treating. To overcome this challenge, providers or practices may want to adopt different treatment strategies for MAT. For example, patients with more complex needs may be referred to regional OTPs. When
specialty treatment centers are not available or convenient, providers could also use a telemedicine model in which patients receive patient care from experts in addiction medicine. Telephone-based services for substance use treatment are both simple to use and cost-efficient. Also, live video conferencing for direct patient care with a specialist has shown promising results in both treatment outcomes and patient satisfaction.47

Providing substance use treatment services can be stressful, and providers need to have emotional support and practice self-care to avoid burnout. Early adopters of buprenorphine treatment for OUD expressed a need for a better support system and connections with other providers delivering MAT with whom they can share experiences.48 To address these needs, providers could join networks such as PCSS-MAT, which has a mentoring program that supports clinicians by improving their confidence in their ability to treat OUD.49 Institutional support, or lack thereof, also plays a key role in a provider's willingness to offer MAT services.42,50 Some providers cite resistance from practice partners.42

Providers and other office staff may also have biases against patients seeking MAT.32 In interviews with physicians, one study found that 75 percent of participants noted that negative attitudes toward people with SUD discourage providers from prescribing buprenorphine.50 For example, many providers view abstinence as a "better" treatment than MAT because they consider using opioid maintenance therapy as replacing one addicting drug with another.3,39

In part, these negative perceptions of patients seeking MAT services may be due to concerns about diversion (the illegal distribution and use of drugs that deviates from their original medical purpose) and misuse of buprenorphine.39,51 The provider can use buprenorphine combined with naloxone to minimize the risk of abuse or diversion.

Other strategies for dealing with the concern about diversion include increasing frequency of clinic or counseling visits, requiring supervised medication ingestion, or providing smaller amounts of unsupervised medication.51 In addition, providers can do pill counts to make sure patients have the appropriate amount of medication based on how many days they have used the prescription. When pill counts are part of the regular visit, they are easy to do. Since MAT may be highly stigmatized, it is important for providers to become properly educated about the effectiveness of MAT and to acknowledge that addiction is a chronic disease often affecting those who are genetically predisposed to it and that it requires ongoing support.52
2.1.3 Community Support

The stigma surrounding addiction and OUD often pervades rural communities and poses a significant barrier as it discourages patients from seeking treatment. Individuals with SUDs have reported they do not seek treatment out of fear it would jeopardize their employment or compromise their social relationships with friends and neighbors. Societal values strongly influence this stigma, which may stem from a lack of health literacy about addiction and MAT in particular. One study found more than half of respondents believed treatment options for drug disorders were not effective, and almost one-third thought recovery from drug addiction was not possible. To combat misperceptions and to achieve buy-in, communities need to be educated about the evidence on the effectiveness of MAT.

Further, providers need to set the right example with their language choice when discussing SUDs to reinforce that addiction is a chronic brain disorder. Per guidance from the White House Office of National Drug Control Policy, providers should use clinical, nonstigmatizing, and person-first language when speaking about SUDs and avoid terms that imply moral judgments or fault. Regarding MAT specifically, use of the terms "replacement" or "substitutions" should be avoided as they reinforce the notion that one drug is simply being exchanged for another.

Local providers and organizations could be advocates in their communities to change the larger conversation about substance use by engaging key stakeholders. For example, community correctional agents in particular may hold stigmatizing beliefs toward MAT, describing it as a "crutch" or "cheap fix." These attitudes may in turn translate into supervisory behaviors that impede or interfere with treatment. These agents play an important role in providing treatment referrals, and they need to build knowledge regarding addiction and the effectiveness of MAT in order to better serve people with OUD.

One strategy to build support for MAT in the local community is to create an awareness campaign. For example, Advancing Recovery West Virginia used local media to share editorials featuring success stories of individuals who were treated with MAT for OUD. Focus groups can also be conducted to identify the perceptions and needs of the local community in order to better determine how best to engage the public.

Communities also play a significant role in the delivery of MAT because many providers rely on community resources for the psychosocial component of treatment. Many providers cite the need for more behavioral health services as an obstacle in delivering MAT. In one survey, waivered
providers noted that in some cases, local mental health agencies were "unwilling or reluctant" to provide therapy to patients receiving buprenorphine treatment, because they favored an abstinence-based 12-step approach. Therefore, West Virginia's and Maine's Advancing Recovery partnerships addressed this need by creating 12-step groups that welcomed individuals receiving MAT.

When providers lack referral options for counseling, they can take several steps to optimize psychosocial support during office visits. A survey of patients' experiences revealed they want physicians who are knowledgeable, trustworthy, and understanding, qualities that are not unique to substance use treatment providers. Further, providers should engage in patient-centered care by learning about motivational interviewing techniques and shared decision making. Some practices use prompts in the electronic health record to help novices move through motivational interviewing techniques.

In addition, other innovative telehealth technologies may be available to replace face-to-face therapy, such as a computer-based version of cognitive behavioral therapy for substance dependence. For example, through the Tele-Behavioral Health Center of Excellence, the IHS offers tribally operated facilities and programs virtual direct care services, including psychiatry and therapy.

Recovery supports offered by local groups and organizations also have a significant impact on the success of MAT, because treatment retention and adherence are difficult to achieve without social support, housing, employment, child care, or transportation. These nonclinical services help individuals achieve their recovery goals and include peer supports, spiritual and faith-based support, parenting education, and more.

Many rural communities do not have an organized continuum of care between treatment services and recovery supports, making it difficult to fulfill a patient's basic needs such as health care, housing, and transportation. Therefore, it is very important for providers delivering MAT services to coordinate care with other providers and agencies whenever possible to connect patients with the services needed to aid in their recovery. Some innovative suboxone programs also are offering "higher level care," such as daily, witnessed dosing and daily therapeutic groups for those who require more intensive supports.
2.1.4 Logistical Barriers

Even if an adequate number of providers are trained and willing to offer MAT, logistical barriers may impede providers from delivering MAT services and patients from receiving them. First and foremost, there may be not be a sufficient number of patients to justify the startup costs, including time and resources, associated with implementing a MAT program. While the initial investment may present a challenge to interested providers, a number of financing opportunities associated with MAT will be discussed further later in this paper.

Telehealth initiatives can be a more cost-efficient means of providing training, consultations and expert support, and direct patient care. For example, Project ECHO only requires use of basic teleconferencing platforms. Because there is no direct doctor-patient relationship, it does not require pricey telemedicine technology that is compliant with the Health Insurance Portability and Accountability Act (HIPAA).

Another challenge for PCPs implementing MAT in their offices is a lack of time and office space to see these patients. Many physicians feel their practices are already overburdened and they do not have the capacity to attend to patients these physicians perceive to be "high needs." To address some of these challenges, providers may benefit by implementing a care model that uses nonphysician providers, such as full-time nurses, to perform key tasks and care coordination.

Alternatively, rural providers could adopt an approach in which the labor-intensive induction process is handled by an addiction specialist and then the patient is referred to a general practitioner for maintenance. Many providers do home inductions in which they give the patient enough suboxone for the first 7 days and instruct them on how to use it. At West Virginia University's Comprehensive Opioid Addiction Treatment clinic, providers found group appointments for patients receiving MAT to be the most efficient use of their time, and clients also reported positive feedback about receiving care in a group setting.

Cumbersome regulations, including periodic DEA audits of patient records, also deter physicians from offering MAT services. Some providers have noted that they found DEA's approach "threatening" and providers with buprenorphine waivers were unfairly subjected to greater scrutiny than those prescribing opioids for pain.

Even if services are available, it may still be difficult for patients to seek regular treatment. For example, travel to clinics poses a significant challenge to people living in rural areas. These areas
tend to lack public transportation options, and those that are offered are often underused and inconvenient. Because rural residents often live in poverty, the expenses of gas and vehicle maintenance may present a real economic burden.\textsuperscript{37}

One survey of patients receiving MAT revealed it took, on average, one hour to travel to the clinic, often daily, and that these visits cost patients almost 50 dollars per week in transportation-related expenses.\textsuperscript{64} Further, these long travel times may jeopardize a patient's employment status, which can, in turn, reduce the number of followup visits and adherence to treatment.\textsuperscript{3}

To address these barriers, providers could consider prescribing forms of MAT that can be administered unsupervised at home or over longer periods of time. For example, extended-release forms of naltrexone and buprenorphine could decrease the frequency of visits to providers and thus reduce the travel burden, particularly once the patient has progressed through the initial stages of recovery, when more frequent contact is needed.\textsuperscript{3} Providers may also want to use innovative telehealth solutions to communicate with patients virtually, connect patients with other telemedicine care options, or provide computer-based counseling.

\subsection{2.1.5 Health Information Technology and Telehealth}

Technology can play a key role in rural health care, as it connects providers and their patients with resources and services that may otherwise be unavailable. In this emerging field, there are primarily two different ways health-related technology can improve access to and quality of health care: health information technology (health IT) and telehealth. Because these innovative technologies are relatively new, consensus is lacking on how to strictly define these terms.

For the purposes of this paper, health IT is the storage and exchange of health data, including systems for electronic health records, electronic prescribing, clinical decision support tools, and other functions. Rural primary care practices can and do benefit from the use of health IT, because it allows efficient and secure information exchange in a coordinated care environment.\textsuperscript{65} Because patients receiving MAT may be seen by multiple providers and practices, these technologies can play an important role in delivering effective care.

The National Telehealth Resource Centers define telehealth as "a collection of means or methods for enhancing health care, public health, and health education delivery and support using telecommunications technologies."\textsuperscript{66} The main types of telehealth include: live video (synchronous),
store-and-forward (asynchronous) videos and digital images, remote patient monitoring, and web-based and mobile health applications. Telehealth may serve as an innovative way to obtain training and medical education and to connect providers and patients with experts in addiction medicine. For the delivery of MAT services in rural areas, primary forms of telehealth technologies that would likely be most useful are video conferencing and web-based or mobile applications.

While health IT and telehealth may represent two different types of technologies that can be very beneficial for rural primary care, they both present many similar challenges. First and foremost, there are a number of financial barriers to the implementation of health IT and telehealth solutions. Adoption by rural providers has been slow because it requires significant investment in time and resources to acquire, implement, and manage a new system.

While economic costs pose distinct obstacles for rural providers to implement and use health IT and telehealth, many grant and loan programs may be available to assist with these efforts. For example, the U.S. Department of Agriculture's (USDA's) Rural Development agency has provided grant funding through its Distance Learning and Telemedicine Grants and Rural Economic Development Loans and Grants. Because health IT and telehealth can play a critical role in health care quality and access, grant opportunities from AHRQ, HRSA, and the Federal Office of Rural Health Policy may also be able to support these technology initiatives.

The electronic exchange of patient health information must be done in compliance with HIPAA standards and other laws and regulations intended to protect patient confidentiality. Depending on the nature of the provider organization, they may also be subject to the Federal Confidentiality of Substance Use Disorder Patient Records regulations (42 Code of Federal Regulations [CFR] Part 2). SAMHSA provides complete information on these regulations and their applicability to providers. In most cases, 42 CFR Part 2 does not apply to primary care clinics providing MAT. In addition, many States have other laws or regulations intended to ensure the privacy of health information, although they can sometimes create challenges to the implementation and use of these technologies.

Each system and care mechanism must be carefully evaluated for compliance with privacy regulations. Health IT systems or telehealth platforms can be infiltrated if information is passed over unsecured connections, so it is important to create high levels of security to maintain patient privacy. When providers are selecting new software or applications to implement, they need to carefully consider these privacy issues and ensure they meet the necessary standards.
Rural primary care facilities may also experience challenges implementing health IT or telehealth solutions due to a lack of broadband access. Broadband availability is incredibly important for both providers and patients to use these innovative systems and platforms. According to the Federal Communications Commission’s (FCC’s) 2016 Broadband Progress Report, 23 million rural Americans lack access to broadband at benchmark speeds. Moreover, individuals and practices in rural areas who do have access to broadband may end up paying three times more for these services than their urban counterparts.

While limitations on access to broadband currently exist, a number of programs are in place to assist in the expansion of broadband service to rural communities. These include:

- FCC’s Rural Health Care Program;
- Universal Service Administrative Company’s Rural Health Care Program;
- USDA Community Connect Grants;
- USDA Rural Broadband Access Loan and Loan Guarantee Program; and
- USDA Telecom Infrastructure Loans and Loan Guarantees.

Another barrier to the use of health IT is that it requires additional staff with the expertise to set up and maintain the systems; however, rural practices often find it difficult to recruit and retain these workers. To address workforce issues, current clinical staff may need to be trained in health IT so they can fulfill some of these functions. Rural providers may also choose to participate in a rural health IT network to help manage the implementation of health IT. In these networks, organizations may share trained staff, receive deals on volume-based purchasing of software and training, and participate in health information exchanges.

The Office of the National Coordinator for Health Information Technology also serves as a valuable resource that aims to help providers implement health IT and the electronic exchange of health information. Both the Health IT Workforce Development Program and the Community College Consortia to Educate Health Information Technology Professionals help train skilled professionals in health IT.

Telehealth, specifically, presents a unique set of challenges to its use. Because telemedicine is, by definition, care delivered by providers at a different site than where patients are, it is possible for these services to cross jurisdictional lines. Nearly four out of five States require clinicians providing
telemedicine to be licensed in the State in which the patient is located, so complying with each State's individual licensure laws poses a significant burden. The Federation of State Medical Boards is working to create an Interstate Medical Licensure Compact, which will be a new pathway to obtain expedited licensure in multiple States. If States adopt this program, it will help facilitate some of the licensing challenges associated with telemedicine.

While prescribing buprenorphine via telemedicine could significantly increase access to these medications for rural areas that lack waivered providers, there are a number of obstacles to this practice. The Ryan Haight Online Pharmacy Consumer Protection Act of 2008 provides a definition for the "practice of telemedicine," which allows prescribing to take place even if there is no physical encounter as long as certain conditions are met. The practice of telemedicine is defined as the practice of medicine by a practitioner who is at a location remote from the patient and is communicating with the patient or health professional treating the patient via a telecommunication system so long as the patient "is being treated by, and physically located in, a hospital or clinic" or "while the patient is being treated by, and in the physical presence of, a practitioner." However, States can set additional restrictions on Internet prescribing, such as requiring a patient-provider relationship to be established in an in-person encounter, or prohibit it all together. It is wise for providers to carefully examine State and Federal regulations to understand what is allowable regarding prescribing in the jurisdiction in which they operate.

Variability in reimbursement for telehealth services may also discourage providers from adopting these solutions when delivering MAT services. Since the payment environment is still rapidly changing, telemedicine providers should check with each insurance company or payer to determine the specific rules around payment for services. However, as the industry increasingly adopts these new technologies, there may be more parity between reimbursement for telehealth services and in-person patient care visits. For instance, Medicaid programs do cover some level of telehealth services in nearly every State, and more than two-thirds of employee-sponsored insurance plans of large companies planned to cover telemedicine consultations by 2017.

2.1.6 Payment and Reimbursement

Sustainable financing is essential to ensuring the availability and use of MAT services. Individuals with SUDs, including OUD, often have low incomes and so rely on public insurance programs such as Medicaid. Medicaid is the largest single source of coverage for SUD treatment and other
behavioral health services.\textsuperscript{77} Although some individuals have private insurance, rural workers are more likely to be employed in industries that do not offer employee health insurance.\textsuperscript{78}

**Health Insurance Coverage.** Due to the rapidly changing health policy environment, insurance coverage of rural populations has changed substantially in recent years and may well change again. Before the implementation of the Affordable Care Act (ACA), rural residents were more likely to be uninsured than their urban counterparts.\textsuperscript{33} In 2014, about three-quarters of uninsured rural individuals were eligible for assistance in obtaining health coverage under the ACA, either through Medicaid expansion or premium tax credits for private insurance; however, nearly two-thirds of uninsured individuals lived in a State that opted not to expand Medicaid coverage under the law. Therefore, about 15 percent of uninsured rural individuals fell in the coverage gap.\textsuperscript{78}

**Behavioral Health Parity.** One effect of the ACA was the prohibition of coverage denial on the basis of preexisting conditions. This meant that individuals with SUDs could no longer be denied insurance on the basis of the preexisting SUD.\textsuperscript{18} The Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) required health insurers to administer health benefits in a manner that applied no greater limitations on mental health or substance use services than those for medical care.\textsuperscript{35} These MHPAEA requirements were applied more broadly through provisions of the ACA.

In 2016, the Centers for Medicare & Medicaid Services (CMS) clarified that these parity protections apply to Medicaid managed care, the Children's Health Insurance Program, and Medicaid alternative benefit plans. This ruling may improve access to OUD treatment through Medicaid.\textsuperscript{35} The ACA also established minimum essential coverage requirements for 10 services, including treatment for mental illness and SUDs.

**Low Payment Rates.** Despite the parity requirements, SUD treatment providers still cite low payment rates as an obstacle to offering MAT services. Many providers choose not to implement MAT because their primary funders would not substantially reimburse the costs of medications, laboratory tests such as urine drug screens, and physician time associated with office visits.\textsuperscript{44,79}

Since Medicaid is such a large payer for SUD treatment, each State's Medicaid benefit package has a strong influence on whether and how providers decide to offer certain services.\textsuperscript{80} This finding is demonstrated by the fact that States with public funding for office-based MAT, including Medicaid and other sources, such as SAMHSA's Substance Abuse Prevention and Treatment Block Grants, have higher numbers of buprenorphine-waivered physicians.\textsuperscript{81}
Medication Formularies. With the growth of the opioid crisis nationally, MAT has become more commonly used, and coverage of these medications has significantly increased. By 2014, all 50 States and the District of Columbia (DC) offered Medicaid coverage for buprenorphine, and 31 States and DC offered coverage of buprenorphine, methadone, and at least one form of naltrexone. However, coverage may be limited by the use of medication formularies that designate preferred medications.

For example, extended-release naltrexone (e.g., Vivitrol) is less likely to be reimbursed across private insurance plans and Medicaid because of its relatively high monthly cost. While this extended release formula could be useful in rural areas because it decreases the burden of frequent health care visits, it is not listed on many health plans' preferred drug lists. Providers may also have the option of purchasing this medication from a distributor in bulk and then billing the health plan after the patient receives the medication; however, this approach carries the risk that the payer will reject the claim and the provider will be left storing expensive medication that may expire.

Utilization Management Policies. Despite increased coverage of medications for OUD, some payers, including some State Medicaid programs and their managed care organizations, have put in place utilization management policies that limit access to MAT and discourage providers from offering these services. For example, an analysis of State-level disparities in Medicaid coverage of OUD treatment found that utilization management policies were imposed on buprenorphine in all but one State.

Utilization management policies vary widely but may include burdensome prior authorization requirements, restrictions on treatment duration or doses, and step therapy that requires the medication to be offered only after less costly alternatives have failed. Prior authorization means a prescriber must receive permission from a benefit plan to prescribe a medication in order for that drug to be covered. State Medicaid programs frequently require prior authorization for medications to treat OUD to constrain costs and discourage misuse or diversion. In recent years, some insurance companies have moved away from these preauthorization measures.

In some cases, payers may also require the provider to refer the patient to behavioral therapy in order to receive coverage of the medication. However, in rural areas, it may be a challenge to link patients to behavioral health services quickly. If there is a requirement that counseling start at the same time as the medication, the patient may be lost to treatment before counseling can begin. Also, concurrent counseling requirements may discourage patients from seeking MAT in rural areas if they are concerned about the stigma associated with therapy in a specialty behavioral health organization.
Other techniques to manage costs include quantity limits, which may restrict the number of doses of medication covered by a single prescription or copayment. While these restrictions vary depending on the plan, they present payment challenges for patients and providers alike.

If payers will not cover the cost of MAT services, providers may be able to find other programs that will help pay for these medications. Some States provide low-cost drug programs for individuals who are ineligible for Medicaid but still fall below a designated income threshold. Also, some pharmaceutical companies may offer patient assistance programs that facilitate the distribution of free or low-cost medication to low-income patients.

**Deductibles and Copayments.** In general, SUD treatment services covered by Medicaid do not require copayments and deductibles. However, a number of State Medicaid programs have implemented cost-sharing measures for medications and services associated with MAT, which may pose a significant economic burden for these patients.

**Same-Day Billing Restrictions.** While there is no Federal restriction on same-day billing for medical and behavioral health services, 30 percent of States still prohibit same-day billing. Such provisions can jeopardize physicians' ability to get reimbursed if they are trying to provide integrated care and minimize the number of patient visits. Payment and reimbursement challenges such as these ultimately make it more difficult for rural providers to set up a sustainable MAT program.

**New Medicaid Demonstration Waivers.** CMS recently made an important policy change that could make it easier to support substance use treatment, including MAT, through the Medicaid program. In 2015, CMS gave States the opportunity to apply for Section 1115 demonstration waivers that allow States to transform their SUD treatment delivery systems and create a continuum of care.

A number of States have already applied for these new waivers. For example, New Hampshire, which has been deeply affected by the opioid epidemic, is planning a 5-year $150 million program that will create a series of regionally based integrated delivery networks to increase care capacity for behavioral health services and promote integrated care. Ultimately, these Section 1115 waivers must be cost neutral, but CMS and the States believe the reductions in emergency department visits and hospital admissions will likely offset the cost of the expanded SUD treatment services provided.
**Federal Grant Programs.** While financing remains an obstacle to extending MAT services, a number of Federal grant funding opportunities have become available to States due to the threat the opioid crisis poses to the Nation's public health. In addition to allowing NPs and PAs to obtain a waiver to prescribe buprenorphine, CARA included authorization for $25 million in funding to expand access to MAT for OUD in areas of high opioid use.\(^{18}\)

The 21st Century Cures Act provides an additional $1 billion to fight the opioid epidemic.\(^{18}\) These funds will be distributed to States for prevention and treatment programs for OUD beginning in fiscal year 2017 through State Targeted Response to the Opioid Crisis grants administered by SAMHSA. The grants will "help address the opioid crisis by providing support to states for increasing access to treatment, reducing unmet treatment need, and reducing opioid-related overdose deaths."\(^{87}\)

SAMHSA plays a critical role in providing funding for treatment and recovery services through the Substance Abuse Prevention and Treatment Block Grant, which can be used for prevention, treatment, and recovery services.\(^{35}\) In 2016, SAMHSA announced a funding opportunity for service grants, known as Targeted Capacity Expansion: Medication-Assisted Treatment Prescription Drug and Opioid Addiction grants. These grants administer funds to 28 States that experienced significant increases in treatment admissions for OUD between 2007 and 2013. SAMHSA will extend up to $1 million to no more than 11 grantees over a period of 3 years.\(^{88}\)

In addition, in 2016, the Bureau of Primary Health Care within HRSA provided $94 million in funding to more than 270 health centers to expand the health care workforce in underserved populations. The 2016 ACA Substance Abuse Service Expansion Supplement emphasized using these funds in part to expand access to MAT for OUD.\(^{89}\)

### 2.1.7 Policy

The influence of Federal, State, and local policies plays a critical role in the delivery of MAT. Each level of government has a distinct impact on laws and regulations related to several areas, including workforce, operations, patient care, and supports to address the opioid crisis. ASAM states that in order to treat OUD, it is:

…necessary to eliminate the arbitrary barriers that discourage appropriate, high quality, cost-effective care. Inappropriate prescribing limits that are not based on the quality of care delivered should be assessed regarding
whether such policies actually serve a legitimate, realistic purpose given the current opioid climate.\textsuperscript{31}

ASAM further notes that both public and private insurance should "offer accessibility to the full range of appropriate clinical services for the treatment of opioid use disorders, including medications, psychosocial therapy, and recovery support services."\textsuperscript{31}

**Qualifications To Provide MAT.** As previously discussed in the "Workforce and Training" section, Federal and State policy regulates what professional certifications and competencies are required to be qualified to provide MAT. Federal laws such as DATA 2000 and CARA determine who is authorized to prescribe buprenorphine and stipulate limitations on these privileges through patient caps.\textsuperscript{35,90} SAMHSA is responsible for administering these laws and ensuring compliance. State medical boards may also identify needs for targeted education and training and then use their authority to require providers to participate in CME on these topics. Through these professional development mechanisms, States can "improve substance use disorder treatment, improve prescribing practices, and reduce stigma."\textsuperscript{91}

States may provide more detailed guidance regarding the use of buprenorphine, such as clinical guidelines, which can lead to an increase in the number of waivered physicians in that area.\textsuperscript{81} State policies regulate licensing and prescribing privileges for health care professionals, which may affect the ability of rural facilities leveraging telehealth solutions to increase access to MAT for OUD.\textsuperscript{67,76} The challenges these policies pose and their implications for telehealth platforms are further discussed in "Health Information Technology and Telehealth."

**Practice Operations.** In addition, regulations affect the operations of a practice providing MAT in many ways. For example, regulations set standards for aspects of everyday processes in the office, including safety codes, standards for laboratory testing, and requirements for storing and dispensing medications.\textsuperscript{40} Practices must ensure compliance with applicable provisions of Federal privacy laws and regulations such as HIPAA in order to ensure the privacy of patients receiving substance abuse treatment.\textsuperscript{47}

In particular, privacy provisions under 42 CFR Part 2—intended to encourage individuals with SUDs to seek treatment—are very challenging to implement and sometimes limit sharing of information that can be critical for patient safety and treatment effectiveness.\textsuperscript{92} However, as noted previously, 42 CFR Part 2 may not apply to primary care clinics (see SAMHSA web page cited previously to clarify\textsuperscript{71}). As noted in the earlier section "Health Information Technology and
Telehealth," privacy laws, while extremely important, may complicate the implementation of innovative technologies that help facilitate access to care in rural areas.

**Payment.** As explained in greater detail in the "Payment and Reimbursement" section, Federal and State policies that control reimbursement, including those that regulate Medicaid coverage and payment rates, have a significant impact on a provider's ability to offer MAT services for OUD. While States must ensure their Medicaid programs meet all Federal requirements, they can tailor their benefits package to improve OUD treatment. For example, they can increase payment rates for substance use treatment, eliminate or loosen preauthorization requirements for MAT, and remove limitations that are not clinically indicated on duration or quantity of MAT drugs. In recent years, States such as New York and Massachusetts enacted legislation that either restricted or entirely eliminated the ability of public and private insurers to require prior authorization for some SUD treatment services.

**Patient Care.** Federal and State policy also may set forth regulations that influence a number of activities related to patient care. There may be standards for patient rights and responsibilities, informed consent, and clinical documentation. Guidelines might also include recommendations for practice related to prescribing, substance use treatment, or coordination of care. For example, a number of voluntary prescribing guidelines have been developed by State departments of health, professional associations, and CDC.

State policy can be leveraged in several ways to prevent OUD. Several States have now enacted legislation that sets limits on opioid prescribing practices, such as restricting the length of first-time opioid prescriptions for the treatment of acute pain. Similarly, 49 States, DC, and Guam all have prescription drug monitoring programs (PDMPs), which are electronic databases that collect information on prescribing of controlled substances such as opioids. A number of States have recently begun to mandate provider use of the PDMP to prescribe an opioid. State Medicaid plan authorities have the flexibility to adopt coverage of alternative pain management services, such as acupuncture, massage therapy, and cognitive behavioral therapy.

Thoughtfully designed State and local policies and programs can help equip and support community-based services that prevent substance abuse and provide a continuum of care and recovery supports. OUD is a chronic, recurring condition that requires both behavioral health and medical care. State and local governments can enact policies that promote integrated or coordinated care that will in turn strengthen both primary care and behavioral health services. For instance, policies can encourage the use of screening for substance use in primary care, such as using the
Screening, Brief Intervention, and Referral to Treatment (SBIRT) model. Another strategy to promote collaborative care between these systems includes enacting policies that strengthen partnerships between FQHCs and community mental health centers.

**Pregnant Women and Infants.** Policy solutions are also needed to facilitate care for women who use opioids and become pregnant, as well as for their infants who may experience neonatal abstinence syndrome (NAS), which represents a pattern of withdrawal after opioid exposure. The increasing number of NAS cases has become a serious public health problem as the condition may cause complications, including fever, weight loss, and seizures, that jeopardize the infant's long-term developmental outcomes.

A number of stakeholders may be involved in the care of these women and their children, including those from the medical and behavioral health systems, child welfare agencies, and education systems. Each system has its own set of policies that may help or hinder successful outcomes for maternal and child health. To align the goals of all parties involved, communities could take a collaborative approach that emphasizes training and implementation of best practices. One model that could be adopted is the Substance-Exposed Infants framework, which emphasizes the need for cross-system coordination and highlights five different timeframes in the life of an infant in which policy intervention could have an impact.

Similarly, policies can strengthen coordination between different local systems, using a model such as Screening and Assessment for Family Engagement, Retention and Recovery. This model promotes collaboration among child welfare professionals, substance abuse treatment providers, and family court representatives. States and localities can also implement child welfare policies that incorporate screenings for SUDs to better serve these children and their families.

**Incarcerated Individuals.** Approximately 65 percent of currently incarcerated individuals have a SUD, but few receive the behavioral health services they need. To address this issue, many communities have shifted their focus from criminalizing those with SUDs to emphasizing the need for treatment. Local governments can work with law enforcement to prioritize diverting people with OUD to treatment programs and services as opposed to incarcerating these individuals. Also, drug courts provide an opportunity to increase referrals to MAT, although some of these courts have adopted a short-sighted blanket prohibition against opioid maintenance therapy.

Some States have adopted policies that increase availability of MAT services within the criminal justice system at intake, during incarceration, and after discharge. After reentry into the
Implementing MAT for OUD in Rural Primary Care: Environmental Scan (V1)

Community, some people with SUDs may find their probation or parole agencies prohibit them from receiving MAT. Policymakers can change these policies to enhance access to this treatment without fear of violating probation or alternative sentencing programs.

**Harm Reduction.** Given the barriers and unique challenges of substance abuse treatment in rural areas, some primary care practices may not be ready to provide MAT services. However, these providers and their communities can still support patients and reduce the health consequences of drug abuse through harm reduction interventions. PCPs can help educate patients and families about the risk of overdose from opioids and about the use of naloxone. They can also facilitate access to naloxone and sterile needles for individuals using intravenous drugs.

Overdose reversal drugs such as naloxone (e.g., Narcan) play an important role in combating the opioid epidemic. In rural areas, policies that expand access to naloxone are vital, because first responders may be slower to reach individuals experiencing an overdose and may have to travel longer distances to reach a medical facility. Because of these challenges, States are implementing policies to widen the scope of practice of emergency medical responders and emergency medical technicians to include the training and authority to administer naloxone.

Local and State laws have been passed that permit pharmacists to dispense naloxone without a "direct, individual prescription from a medical provider" to increase access to this drug for other key members of the community, such as family members of individuals with OUD, law enforcement, and emergency responders. Some States have passed legislation that even allows nonmedical entities, including schools and homeless shelters, to dispense naloxone or have the drugs onsite. In addition, Good Samaritan laws encourage individuals who observe an overdose to offer naloxone by shielding them against lawsuits. As of January 2017, the National Conference of State Legislatures reports that 37 States and DC have enacted a version of this legislation.

Local leaders play a unique role in the community support systems that are confronting the opioid epidemic. County officials can advocate on behalf of their communities and work with their State and Federal partners to promote the implementation of policies that will best address their needs in fighting the opioid crisis. For example, some local communities permit or provide needle exchanges or safe injection sites, two practices that show promise for reducing morbidity and mortality associated with OUD.

Law enforcement officers have often proven to be among the most effective advocates for treatment, especially in their own communities. Other first responders are also playing an important
role in the effort to deal with opioids in communities. Many first responders are now equipped with naloxone for treating overdoses. Relevant public laws and policies are often intertwined throughout the local, State, and Federal levels, and it is essential to have coordination and cooperation to deliver the most effective and efficient services possible. Those who hope to make MAT more widely available and take other steps to address the opioid crisis must be aware of applicable Federal, State, and local laws and regulations and, perhaps, work to ensure that they support effective strategies to improve public health.

2.2 Promising Models for Use In Rural Settings

AHRQ Technical Brief #28 provided an analysis of a number of innovative models of care that offer MAT services. The technical brief also outlined a number of characteristics their expert informants suggested were applicable to all the effective models. Those characteristics include:

- **A care coordinator** who "is designated with providing care integration and coordination for treatment of OUD and coordinating primary medical care and mental health needs. The care coordinator may also serve as the main point of contact for patients, allowing for less extensive physician-patient contact."\(^3\)

- **Primary care clinicians** (waivered physicians, physician assistants, or nurse practitioners) who "primarily prescribe buprenorphine, have less frequent face-to-face visits with the patient, and provide consultation as needed."\(^3\)

- **Psychosocial services**, which are "essential to successful MAT models of care." In addition, "provision of counseling is required to meet requirements for office-based MAT as specified in DATA 2000."\(^3\)

The technical brief also makes clear the importance of consulting resources to support office-based provision of MAT in primary care settings. Across various models and cases, these consulting resources may come from OTPs, other SUD specialty treatment clinics, and university-based tertiary care medical facilities. They also may include web-based resources, such as PCSS-MAT, which provides linkages to a national network of trained physician mentors. The consultation may be in person, by telephone, or through web-based video linkages.

This section briefly presents three models of care for the delivery of MAT for OUD that appear promising for use in rural primary care settings. The descriptions below are brief and we refer the reader to the technical brief for a more detailed description of the features of the models. Where
available, we also provide links to websites that may provide relevant resources and additional description.

**The Hub and Spoke Model.** This model was developed in Vermont and functions well in rural areas because it increases access to treatment in a cost-effective manner. As the number of individuals with OUD rose in Vermont, the substance use treatment system became overburdened and wait times to receive treatment rose dramatically, as high as 1.5 to 2 years in 2011. While it was necessary to implement MAT in primary care practices to increase treatment capacity across the State, this model was successful because these practices were supported by the specialty expertise at regional and embedded support staff. Further, the implementation of MAT in the primary care facilities balanced costs to expand access to MAT with reduced burden on medical expenditures. In Vermont, Medicaid beneficiaries receiving MAT had lower health care expenses and utilization of inpatient hospital and outpatient emergency department services than those receiving substance abuse treatment without medication.

The Hub and Spoke Model includes two levels of care: regional OTPs that serve as the "hubs" and community clinics that function as the "spokes." The OTPs that serve as the hubs also provide methadone and typically have extensive experience in OUD treatment. Characteristics of the community clinics vary more, but they include waivered providers who can prescribe (typically buprenorphine/naloxone), care coordinators, and some level of counseling and psychosocial services.

The model emphasizes care coordination and features a "care connector" such as a registered nurse or clinician case manager at spoke clinics. In this model, patients are screened for their level of complexity and treatment needs and managed accordingly. Patients with more complex needs may be referred to the hub, while more routine cases are treated in a spoke. Hub staff serve as consultants to the spoke clinic team, and responsibility for patient care may shift back and forth between hub and spoke as needed. For example, initial treatment induction might be conducted by the hub OTP, and then the patient could be transferred to the spoke clinic for ongoing management. Less clinically complex patients may receive care only in office-based clinic settings.

**The Project ECHO Model.** The Project Extension for Community Healthcare Outcomes (ECHO) was developed in the very rural State of New Mexico and was designed to leverage the knowledge and skills of the university-based health care system to expand treatment capacity
throughout the State. Over the past 12 years, this model has been widely adopted to treat a range of chronic health conditions throughout the United States and around the globe.

In 2016, the U.S. Senate passed the ECHO Act, which directs HHS to further study the impact and opportunities for the Project ECHO model in rural health care. Using inexpensive web-based televideo capabilities, teleECHO clinics use "grand rounds" style, case-based presentations to build providers' knowledge and skills related to addiction medicine. The rural providers present the cases and remain the clinicians of record. The role of the university-based experts is solely to educate, consult, and mentor rural providers on treatment approach—patient identifiers are not disclosed.

The Integrated Addictions & Psychiatry (IAP) TeleECHO Clinic was created to expand access to high-quality and effective medical and behavioral treatment for addiction and mental illness in communities throughout New Mexico. Through this initiative, originally funded by the GE Foundation, family nurse practitioners (FNPs) worked in eight community health centers recruited by Project Echo to receive additional training and experience in behavioral health treatment.

The FNPs were paired with community health workers (CHWs) who also received specialized training and focused practice experience. The FNPs learned to screen for, diagnose, and treat unipolar and bipolar depression, anxiety disorders, posttraumatic stress disorder, psychotic disorders, and addiction to alcohol, opioids, and tobacco. The CHWs assisted with such things as screening, brief interventions to improve treatment adherence, basic case management, and health education.

The Project Echo model of linking academic medical centers to medically underserved areas has been widely replicated throughout the country and internationally and has been applied to a growing variety of medical conditions. For example, the State of Washington has essentially replicated the program, the University of Washington Psychiatry and Addiction Care Conference, or UW-PACC. The goals of this program are similar and it focuses on providing support to both primary care and mental health care providers across the State. "Similar efforts in other rural areas have shown high rates of provider satisfaction."
The Opioid Addiction Treatment ECHO includes three different types of teleECHO clinics focused on the following groups:105

- Providers and primary care team members,
- CHWs and medical assistants, and
- Counselors, social workers, and psychologists.

In this way, Project ECHO provides training and support to staff members who can address each critical element of a sound MAT program. In addition to building workforce capabilities, participation in the Opioid Addiction Treatment ECHO community can decrease feelings of professional isolation, which often plague rural providers.46 Also, as the opioid epidemic sweeps the Nation, there has been an influx of new opioid-related resources, tools, and practices. The teleECHO clinic is very useful for the rapid dissemination of information relevant to clinical practice for these providers offering MAT services.46

**The Office-Based Opioid Treatment with Buprenorphine (OBOT-B) Collaborative Care Model.** The OBOT-B Collaborative Care model, also known as the Massachusetts Model, was created at Boston Medical Center in 2003. Then, in 2007, this model was expanded into community health centers (CHCs) across the State to improve access to buprenorphine treatment, primarily among underserved and marginalized communities.106

Nurse care managers (NCMs) play a key role by providing support to and acting as a liaison between patients and waivered physicians. A training program for medical professionals delivers education on MAT best practices and encourages more PCPs to start prescribing buprenorphine.3 Within this model are four treatment stages in which the NCM (or physician, as needed):106

1. Conducts an initial screening and assessment of the patient's appropriateness for OBOT-B,
2. Supervises medication induction,
3. Monitors stabilization and provides support to the patient with frequent visits or telephone communication, and
4. Holds followup visits with the patient, as appropriate, for maintenance.

Often, physicians may be deterred from providing OBOT-B because they have competing priorities at their busy primary care practices and lack adequate support to manage these patients. However,
with the OBOT-B Collaborative Care Model, NCMs take on the responsibilities of complex care management while communicating with the physician primarily through documentation in the electronic medical record. This approach benefits patients as well because NCMs are more accessible than physicians, so they can quickly address patient issues and concerns.

By implementing the OBOT-B Collaborative Care Model across the CHCs in the State, Massachusetts created a network that allows patients to transition easily between physicians if a provider stops prescribing buprenorphine. Because these patients may be at high risk for relapse, continuity of treatment is incredibly important. However, one disadvantage of this model is that the availability of onsite psychosocial services may vary depending on the CHC.

Overall, the OBOT-B Collaborative Care Model successfully increased access to MAT for OUD in CHCs. Three years after the program started, retention rates in treatment were very impressive, with 65 percent of patients remaining in treatment for 1 year or more. There were significant increases in the number of waivered physicians as well as the number of annual patient admissions for buprenorphine treatment at the participating CHCs. Also, this model proved to be financially sustainable because CHCs that were FQHCs were reimbursed for nursing visits at a rate comparable to those of other clinical providers.

AHRQ's Technical Brief #28 provides extensive descriptions of these and several other models. A careful reading of that document would be worthwhile for those aiming to introduce MAT for OUD into rural primary care. As noted above, it may be necessary to combine components of various models to develop an accessible and effective approach that is workable in your local environment.

In the spirit of the phrase that "all health care is local," those who want to develop primary care-based MAT in rural areas should feel free to develop unique local solutions so long as they include the elements described above—care coordination, waivered providers with prescription authority, psychosocial services, and consulting resources. These elements may be provided in person, via telehealth, or through referral, keeping in mind local laws and regulations as well as rules related to reimbursement for services. Monitoring of patient outcomes and a commitment to continuous quality improvement can help ensure that problems are identified and addressed in an ongoing fashion.
A variety of tools and resources are available for providers and patients who offer or use MAT services. As part of this environmental scan, a list of tools has been assembled for use in the implementation of MAT. Although the tools were not all created specifically for rural primary care practices, they are potentially useful in those and other settings.

The tools and resources found by this environmental scan are listed and described in the tables in Volume 2 of this report. They come from a variety of public and private sources. For example, many government entities, such as the Office of the Surgeon General, CDC, SAMHSA, NIDA, Department of Veterans Affairs, IHS, and Office of Disease Prevention and Health Promotion, have created a number of useful tools related to OUD and MAT. Tools included in the tables were identified through methodical searches of the published and grey literature and through individual searches for specific kinds of tools (see Methodology section).

Among the resources are the NIDA-funded BupPractice, which provides many tools for both providers and patients. BupPractice offers buprenorphine waiver training for physicians, nurse practitioners, and physician assistants. In addition, the PCSS-MAT is a collaborative effort led by the American Academy of Addiction Psychiatry (AAAP) in partnership with the American Osteopathic Academy of Addiction Medicine (AOAAM) and a broad network of other addiction-related organizations. This effort provides training and a mentoring project that helps providers implement MAT for OUD in a variety of settings, including primary care.

Professional societies also provide a wealth of resources for their members and the public that can be used in implementing MAT for OUD. These include but are not limited to the ASAM, AAAP, AOAAM, American Psychiatric Association, American Medical Association, and California Society of Addiction Medicine. Other materials have been developed by institutions of higher education and medical professionals for use in their practices. Many of these organizations and others are also partners in the PCSS-MAT initiative.

In the tables, the tools have been categorized by topic, although there are many different types and formats. For example, there are materials that can be used for provider, patient, and community education, such as guidelines, toolkits, training materials, and fact sheets. Further, some of these tools, such as screening and assessment instruments, consent forms, patient agreements and
contracts, implementation materials and checklists, protocols, and web- or mobile-based applications, can be used in practice.

- **Table 1** includes resources related to OUD prevention. Given the challenge of providing sufficient MAT capacity, it certainly makes sense to work to prevent more people from developing SUDs. This section includes tools for assessing and managing pain, prescribing opioids, and promoting awareness and education about OUD.

- **Table 2** focuses on MAT training opportunities and educational materials for providers, medical teams, patients, and families.

- **Table 3** provides tools that may be useful in the implementation of MAT in office-based settings. These tools cover the entire MAT process, including conducting initial screenings, assessing withdrawal, terminating opioid therapy, implementing SBIRT interventions, setting up MAT services in your practice, and incorporating psychosocial therapy.

- **Table 4** includes tools related to both the prevention of and response to overdose, as any patients receiving MAT are at risk of overdose if they relapse.

It is important to note that the tools detailed in these tables do not represent everything that has been developed. In the face of this opioid crisis, constant streams of new tools are being created. For example, a new mobile application that helps combat opioid overdose is in development as a result of the 2016 Naloxone App Competition sponsored by FDA. Further, this environmental scan does not address whether the tools have been validated or how widely they are used.

While many of the tools are in the public domain, some may require purchase or permission to use. For the purposes of this report, each tool is categorized by access and terms of use, as follows:

1. **Public domain**: tools are available for public use without current copyright or licensing restrictions, primarily published by the government.

2. **Copyrighted, freely available**: tools are accessible without purchase but may be subject to restrictions for use and distribution.

3. **Access may require fee or membership**: tools are exclusively owned or rights are held by an individual or organization and may require purchase, membership, or an account to access.

The inclusion of any of these tools does not imply endorsement by AHRQ, HHS, or the U.S. Government.
4. Conclusion

Ultimately, implementing MAT services in primary care settings is a new challenge for many PCPs, and those in rural areas experience a significant number of unique challenges. These barriers are found at the patient, provider, community, and system levels. Despite these obstacles, a number of strategies can be undertaken to deliver high-quality, cost-efficient MAT in rural primary care.

To fight the opioid epidemic, it is critical to:

- Build the workforce of available providers who offer MAT services in rural areas;
- Decrease stigma surrounding SUDs and treatment; and
- Implement policies that support the work of these providers and the community-based programs that provide services and supports to those in recovery.

At this time, the available literature provides a modest number of evidence-based models for implementing MAT services specifically in rural primary care settings. It is essential that there be a major focus on increasing access to this treatment in rural communities. Future research should evaluate what strategies are being successfully used in rural areas and how they can be disseminated in other communities for broader adoption. In support of this goal, AHRQ invested in a 2016 grant initiative, Increasing Access to Medication-Assisted Treatment of Opioid Abuse in Rural Primary Care Practices to help support rural primary care practices in delivering MAT.

AHRQ created the grant program to learn more about effective strategies for facilitating the implementation of MAT for OUD in rural primary care practices and is investing more than $12 million over 3 years in this initiative. Five grants were awarded to:

- **University of Colorado, Denver** – "Implementing Technology and Medication-Assisted Team Training and Treatment in Rural Colorado (IT MATTTRs Colorado)."
- **University of North Carolina at Chapel Hill** – "UNC Extension for Community Healthcare Outcomes for Rural Primary Care Medication-Assisted Treatment (UNC ECHO for MAT)."
- **American Institutes for Research in partnership with the State of Oklahoma** – "MAT Expansion in Rural Oklahoma."
Pennsylvania State Department of Human Services in partnership with the Pennsylvania Office of Mental Health and Substance Abuse Services and the University of Pittsburgh – "Enhancing the Access and Quality of MAT for Individuals With Opioid Use Disorder (OUD) in Rural Pennsylvania's Medicaid Primary Care Practices."

University of New Mexico – "ECHO-F Model to Expand Medication Assisted Treatment in Rural Primary Care"

These grantees aim to improve access to MAT in rural areas by increasing the number of waivered PCPs delivering MAT and using innovative means, such as patient-controlled smart phone apps and virtual training and consultations with Project ECHO. As a result, care will be provided to more than 20,000 individuals with OUD. Using the lessons learned from these projects, AHRQ, together with the grantees, will develop and disseminate a blueprint for how other communities and primary care teams can address the challenges of providing MAT and ensuring access to care across America's rural communities.

While a number of challenges remain, a wealth of tools and resources are available to providers working to implement MAT for OUD in rural primary care settings. Many of these tools are not specific to rural communities or primary care, but they can still be used in these settings. AHRQ will make the collection of tools identified through this environmental scan publicly available. In addition, there may be some benefit to developing tools in the future that are specifically adapted or designed for the unique obstacles rural providers and practices face.

As communities across America are fighting the opioid crisis, new tools and resources are rapidly emerging. The results of this environmental scan represent the available published and grey literature to date, although they will likely be superseded by additional resources in the near future.
"This course was developed from the public domain document: Moran GE, Snyder CM, Noftsinger RF, et al. Implementing medication-assisted treatment for opioid use disorder in rural primary care: environmental scan, volume 1. (Prepared by Westat under Contract Number HHSP 233201500026I, Task Order No. HHSP23337003T). Rockville, MD: Agency for Healthcare Research and Quality; October 2017. Publication No. 17(18)-0050-EF."