

Delivering Medications for Opioid Use Disorder in Primary Care:

Environmental Scan



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Delivering Medications for Opioid Use Disorder in Primary Care: Environmental Scan

Prepared for

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I. Background

The Medications for Opioid Use Disorder (MOUD) Playbook, first published in 2019 on the AHRQ Academy website, serves as an interactive guide for implementing MOUD in primary and other ambulatory care settings, with a focus on rural and underserved communities. In the five years since publication of the Playbook, there has been a dramatic shift in the understanding and treatment of opioid addiction. Opioid Use Disorder diagnoses, opioid-related overdoses, synthetic opioids, and polysubstance use are rising. Access to treatment is also expanding, with promising federal and state policy changes. Furthermore, there is an increased understanding of barriers to MOUD treatment and corresponding efforts to reduce stigma and change primary care processes to address these barriers.

Given these trends and the dynamic environment of OUD treatment, Westat conducted an environmental scan, consisting of a **literature review** and **key informant interviews** to inform **a synthesis and recommendations** for content updates to the Playbook and identify new tools and resources. Five specific research questions guided the approach to the environmental scan, as summarized in Exhibit 1 below. The research questions examined the impact of **policy and regulatory changes; secular changes in treating patients with OUD**; and **new models, tools, and resources**.

Research Questions Guiding the Environmental Scan

Policy and regulatory changes

- 1. How have changes in policy and regulation impacted the availability of medication (largely buprenorphine) to treat people with OUD in different settings and with different populations (e.g., elimination of the X-waiver requirement for prescribers; changes in funding or payments, etc.)?
- Secular changes in treating patients with OUD using medications
- 2. How has the environment of opioid use or MOUD changed (e.g., polysubstance use; emerging drugs of concern, like Xylazine and similar substances; barriers to treatment; etc.)?
- **3.** How has the approach to using medication to treat people with OUD changed (e.g., growth in telemedicine; whole person care; new drug formulations, such as extended-release buprenorphine; evidence about different treatment medications; etc.)?

New Models, Tools, and Resources

- 4. What are the models (e.g., medication first model, low-barrier care, harm reduction, etc.) being employed to treat people with OUD using medication?
- 5. What are the evidence-based tools and resources to facilitate using medications to treat people with OUD?

This document provides a description of the methodology used to conduct the environmental scan, key findings from the literature review and key informant interviews, as well as a synthesis and associated recommendations for updates to the Playbook based on the environmental scan findings.



II. Methodology

Westat completed each of the three components of the environmental scan—**literature review**, **key informant interviews**, and **synthesis**—sequentially, with each step informing the next. This section briefly describes Westat's methodology for conducting the literature review and key informant interviews and producing the synthesis and recommendations. An in-depth description of our methodology appears in Appendix 1.

Literature Review

The literature review encompassed a search of peer reviewed literature and grey literature, as described below.

Peer Reviewed Search Strategy. The literature review identified and mapped the breadth of peerreviewed and grey literature published between 2017 (just after the current Playbook was published) and 8/31/2024. The published literature search strategy was driven by the research questions and designed to yield peer-reviewed and other indexed literature. Westat librarians developed and tested the search strategy with feedback from project staff, select National Integration Academy Council (NIAC) members—the panel of experts who guide the work of the AHRQ Academy, and other affiliated subject matter experts. Searches were performed in PubMed/MEDLINE; CINAHL (Cumulative Index to Nursing and Allied Health Literature); APA PsycINFO®; Applied Social Sciences Index & Abstracts (ASSIA); Cochrane Central Register of Controlled Trials (CENTRAL). The searches yielded 8,534 articles for review. The team reviewed the full sample and identified 450 literature items for analysis based on inclusion and exclusion criteria listed in Exhibit 2 of Appendix 1. The team then analyzed the sample further and assigned topic tags to each article. A senior team member and the Principal Investigator analyzed the results and extracted the overall themes that responded to the research questions.

Grey Literature Search Strategy. The above search terms were used to identify web-based resources from federal agencies and non-federal organizations. The top 50-results were reviewed from federal agencies and the top 25-results reviewed from non-federal organizations. The federal organizations were a selection of agencies and offices within the U.S. Department of Health and Human Services and the non-federal organizations represented non-governmental organizations and other non-profits doing significant work related to behavioral health integration (as determined by a pre-screen of search results). The review team then conducted the same analysis as the peer reviewed literature.

Tools and Resources. There were 173 tools and resources identified in the literature review, which staff compiled into a results table. Staff reviewed each resource to determine if it was already in the Academy's Substance Use (SU) or Unhealthy Alcohol Use (UAU) Tools and Resources Collections. After the team verified resources already in those collections, they created a list of

the remaining resources. The new resources were then uploaded to the website. The types of resources added to the collection included screeners, training materials, guides for clinicians on different facets of MOUD, and regulatory documentation.

Key Informant Interviews

We conducted nine virtual, semi-structured interviews with subject matter experts (SMEs) to supplement the literature review. The purpose of these interviews was to (1) provide context to areas in the current Playbook identified as deficient by the project staff, and (2) provide context to gaps in the literature. We gathered a diverse range of perspectives from primary care providers with extensive experience implementing MOUD into primary care, researchers, and policy experts. An interview guide was prepared specifically for each interviewee with a focus on their area of expertise and how it could inform the Playbook, with a flexible agenda to allow for a dynamic conversation driven by interviewee responses. The Principal Investigator or a senior team member conducted the interviews via videoconference. The senior team member reviewed each transcript, wrote a summary memo for each interview, and identified common themes and unique insights. Simultaneously with the key informant interviews, we collected written and oral feedback from members of the Technical Expert Panel (TEP), a carefully curated panel of experts appointed to guide this work, who individually reviewed the Playbook in its entirety, provided individual written feedback, and met as a group to discuss their thoughts.

Synthesis and Recommendations

The synthesis and recommendations component incorporates findings from both the literature review and key informant interviews and highlights several key areas and themes to guide content updates of the MOUD Playbook to ensure it remains a valuable and practical resource for primary care providers. The recommendations focus on simplifying the Playbook to make it more accessible, updating content to reflect changes in the opioid landscape, promoting a low-threshold approach to prescribing MOUD, addressing stigma as a barrier to implementing MOUD, enhancing training and education resources, and incorporating recent policy changes. By implementing these updates, the Playbook will better support providers in delivering effective and compassionate care to patients with OUD.

III. Findings: Literature Review

The first part of the environmental scan for the MOUD Playbook content update was a comprehensive review of peer reviewed and grey literature, which uncovered notable changes in policy, regulation, and the landscape related to the treatment of substance use, as well as new treatment models, tools, and resources. This section discusses findings from the literature review regarding these key topics.

A. Policy and Regulatory Changes

Related Research Question

1. How have changes in policy and regulation impacted the availability of medication (largely buprenorphine) to treat people with OUD in different settings and with different populations (e.g., elimination of the X-waiver requirement for prescribers; changes in funding or payments, etc.)?

The literature review found significant policy changes and regulatory issues affecting the availability of MOUD including: 1) the elimination of the X-waiver requirements for providers; 2) new policies to support the expansion and use of telehealth; 3) the passing of the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act; and 4) changes in cost, payment, and reimbursement.

X-waiver Requirements

As of 2023, providers are no longer required to obtain a DATA-2000 waiver (commonly known as the X-waiver), to prescribe buprenorphine for OUD.¹ Previously, providers needed to obtain the X-waiver by participating in specialized training and submitting a letter of intent to SAMHSA. The time and administrative burden associated with these steps prevented some providers from obtaining the waiver. The current requirement for providers is a valid Drug Enforcement Agency (DEA) registration that includes Schedule III authority, provided they comply with applicable state law. There is a training requirement, but providers can start prescribing immediately and complete training before the renewal of their DEA registration, which occurs every three years.

The training requirements can be met through one of three ways:

1. A total of eight hours of training on opioid or other substance use disorders for practitioners renewing or newly applying for a registration from the DEA to prescribe any Schedule II-V controlled medications. This training can be obtained through various programs, such as those offered by SAMHSA and other accredited organizations. Training covers essential topics, including the foundations of opioid use disorder, safe opioid prescribing practices, complex patient care, and opioid stewardship for risk reduction.

- 2. Board certification in addiction medicine or addiction psychiatry from the American Board of Medical Specialties, American Board of Addiction Medicine, or the American Osteopathic Association.
- **3.** Graduation within five years and status in good standing from medical, advanced practice nursing, or physician assistant school in the United States that includes successful completion of an opioid or other substance use disorder curriculum of at least eight hours.

Though the elimination of the X-waiver was designed to make buprenorphine more accessible, recent research suggests limited impact of this policy change on actual provider rates of prescribing buprenorphine, indicating that barriers to buprenorphine prescribing persist.^{2–4}

Addressing the Challenge: Further training Opportunities

While no other training is required, some providers have reported a general lack of training and education as contributing to their hesitancy to treat patients.⁵⁻¹¹ While time may be another challenge, the American Society of Addiction Medicine (ASAM) offers a comprehensive range of CME programs, including live courses, webinars, and on-demand content focused on various aspects of addiction medicine. Additionally, the American Medical Association (AMA) collaborates with ASAM to offer specialized CME courses in addiction care. Other forums, such as web-based learning networks through 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.¹²

Telehealth Policies

Telehealth broadly includes a variety of healthcare services delivered remotely over the internet. Such services may include healthcare providers meeting with patients via videoconferencing and patient portals that enable patients to access medical information such as test results and to send and receive messages from their provider. In recent years, telehealth has become an integral aspect of healthcare delivery. The COVID-19 pandemic significantly accelerated the adoption and integration of telehealth, highlighting its critical role in ensuring resilient and adaptable healthcare systems.¹³⁻¹⁶ Telehealth is considered effective, efficient, and feasible, with comparable clinical outcomes to in-person treatment in behavioral health,^{17,18} and telehealth implementation has helped address some of the challenges of the opioid crisis by expanding geographical reach to patients in rural areas with few providers.^{19,20}

Policy changes stemming from the COVID-19 pandemic have supported ongoing use of telehealth for MOUD. Prior to the COVID-19 pandemic, new OUD patients were required to have an in-person evaluation by a MOUD physician before being prescribed controlled substances (Ryan Haight Act of 2008).²¹ During the COVID-19 pandemic, the U.S. Department of Justice, Drug Enforcement Administration (DEA) issued a temporary relaxation of provisions within the Ryan Haight Act of 2008.²² As a result, SAMHSA allowed authorized practitioners to admit and treat new patients with

OUD during the pandemic and prescribe buprenorphine to new and existing patients with OUD via telephone, which expanded access to OUD treatment, especially among vulnerable patients who did not have access to in-person providers or videoconferencing capabilities. This temporary relaxation was well received. It increased access and retention in care without increasing buprenorphine-related overdoses and also helped to mitigate workforce shortages.¹³ On November 19, 2024, the DEA and SAMHSA issued a third temporary extension of COVID-19 telemedicine flexibilities for prescription of controlled medications, effective January 1, 2025, through December 31, 2025.²³ This facilitates the continued availability of telemedicine for controlled medication prescriptions that patients and practitioners have come to rely on, though the future status of these flexibilities after December 31, 2025 is uncertain.

While these policy changes have provided some flexibility in the treatment of OUD, there are various legal requirements and licensing issues associated with telehealth that can be complex and vary by region. Previously, some states required clinicians providing telemedicine to be licensed in the state in which the patient was located, potentially limiting patient care or posing a significant burden of needing to be licensed in more than one state. Currently, forty states, the District of Columbia, and the Territory of Guam have all joined the Interstate Medical Licensure Compact to simplify the licensing process for physicians who want to practice in multiple states.²⁴ The Compact offers a faster path to licensure for physicians who qualify.²⁵ Other states are currently drafting legislation to join the Compact.²⁵ Moreover, the exchange of patient health information must follow HIPAA standards and other laws to protect patient confidentiality, and some organizations must also comply with the Federal Confidentiality of Substance Use Disorder Patient Records regulations (42 CFR Part 2).²⁶

Best Practices for Telehealth Privacy and Security

The American Health Information Management Association (AHIMA) offers the following best practices for telehealth privacy and security:

- **Patients' Telehealth Privacy.** Being aware of patients' location prior to initiating the telehealth visit and being mindful of the patient's privacy needs.
- Secured Information Online. Using appropriate measures to protect patient information when sharing information online.
- **Privacy and Security Standards.** Incorporating telehealth services into privacy and security policies, procedures, and workflows; integrating telemedicine into the Notice of Privacy Practices.
- **Reimbursement for Telehealth Services.** Reviewing insurers' coverage determinations for telehealth services before scheduling visits and confirming that billing codes meet payor requirements.

Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act

In late 2018, Congress passed and the President signed the SUPPORT Act (Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act).²⁷ This sweeping legislation included 25 separate provisions, most related to addressing the opioid epidemic. Among the most important provisions was the requirement that all state Medicaid programs "cover medication-assisted treatment (MAT), including all FDA-approved drugs, counseling services, and behavioral therapy."²⁸ The Medicare program also began covering methadone provided at Opioid Treatment Programs (OTPs) in 2020, which resulted in much broader accessibility to methadone treatment for Medicare recipients.²⁹

One of the most impactful provisions of the SUPPORT Act was to allow state Medicaid programs to reimburse for treatment of substance use disorders in residential treatment facilities with more than 16 beds (so called Institutions for Mental Disease or IMDs). Some states had already incorporated residential treatment in IMD settings through Medicaid 1115 Research and Demonstration Waivers, but the new SUPPORT Act provision resulted in much broader expansion of the practice. Medicaid waivers specific to the treatment of SUD have now been approved in 35 states, and a recent analysis found that most Section 1115 waivers' special terms and conditions purport to ensure that Medicaid beneficiaries with SUD have access to the whole continuum of care for SUD treatment, using the ASAM continuum of care to inform expansion of services.³⁰

States have used a combination of 1115 waivers and amendments to their Medicaid state plans to achieve the desired expansion of SUD treatment services. Some states chose the 1115 waiver option because of the greater flexibility such waivers provide, while others decided to incorporate most service expansions into their state plans so they would be permanent and not subject to the 5-year limit of the 1115 waivers.³¹ By 2021, these service expansions resulted in every state covering buprenorphine, oral naltrexone, and injectable naltrexone, and 85% covering methadone maintenance. Use of quantity limits, prior authorizations, and other utilization management methods also declined from 2017 to 2021.³²

Cost, Payment, and Reimbursement

Policies related to cost, payment, and reimbursement can have a major impact on the availability and accessibility of MOUD. Lack of insurance,³³ insurance with high co-payments or cost sharing, or insurance that excludes the MOUD medications they would prefer to use (i.e. long-acting buprenorphine), all pose barriers that can make it less likely that a person will start and/or be retained in treatment for an adequate time.



Insurance Status and Care Affordability and Coverage. OUD affects people from all socioeconomic backgrounds, but it is more prevalent among individuals with lower incomes who disproportionately rely on public insurance for healthcare coverage or may lack health insurance altogether. Approximately 84% of people with OUD in 2019 had health coverage through Medicare, Medicaid, or private insurance.³⁴ Medicaid is the largest payer for MOUD treatment, insuring 40 percent of all adults under 65 receiving MOUD.^{35,36} In 2021, approximately 1.5 million people enrolled in Medicaid had OUD, representing nearly 2 percent of the total Medicaid population that year.³⁵ Two-thirds (more than 1 million) of these enrollees received MOUD that year through Medicaid or, for some dually eligible enrollees, Medicare.³⁵ In 2018, 2.8% of the Medicare fee-for-service population, representing about 591,000 individuals, had OUD.³⁷

Many patients with insurance coverage still face barriers to accessing MOUD due to benefit limits and out-of-pocket costs,^{38,39} and approximately 1 out of 6 non-elderly uninsured individuals with OUD face even greater obstacles in obtaining treatment.³⁴ In fact, in 2022, among the 4% of U.S. adults who needed OUD treatment, only 25% received recommended medications.⁴⁰ Provider reimbursement rates for those with private insurance are higher than for Medicare or Medicaid, but out-of-pocket costs and other cost-related barriers may also be higher.³⁴ Uninsured patients may face high out-of-pocket costs for MOUD. The capacity of community health centers, free clinics, patient assistance programs, drug discount cards, and other resources is insufficient to meet demand.³⁴ Receipt of services at an Opioid Treatment Program falls under the Medicare Part B deductible, which was \$240. Office-based MOUD, which is often applicable to primary care settings, falls under the Part D deductible, which ranges from \$0 to \$545 depending on the plan.⁴¹

Medicaid programs in all states and the District of Columbia cover some form of buprenorphine and naltrexone to treat OUD, though injectable and implantable buprenorphine formulations are not yet covered by all state Medicaid programs.⁴² Additionally, states have the option to charge premiums and to establish out of pocket (cost-sharing) requirements for Medicaid enrollees.⁴¹ While the maximum Medicaid co-payment for non-preferred drugs is only \$8.00 for those below the federal poverty level (FPL), states can impose higher charges for targeted groups of somewhat higher income.⁴¹ Even the nominal costs for those below the FPL can serve as a barrier in some cases.

Certain vulnerable groups, such as children and pregnant women, are <u>exempt from most out of</u> <u>pocket costs</u> and copayments, and coinsurance cannot be charged for certain services, including emergency services, family planning services, pregnancy-related services, or preventive services for children.⁴³ To encourage the use of lower-cost drugs, states may establish different copayments for generic versus brand-name drugs or for drugs included on a preferred drug list or formulary. Additionally, some people choose to pay out of pocket rather than let it be known that they are living with OUD due to stigma.³⁴

Provider Reimbursement Rates. On the provider side, one key barrier is inadequate reimbursement levels that fail to cover the cost of treatment services, let alone provide an incentive to begin offering these services. Recent analysis finds that 75 to 90 percent of people with OUD who could benefit from the approved treatment medications do not receive them.^{39,44} Low reimbursement rates and high administrative burdens are a disincentive for providers to offer office-based MOUD to Medicaid and Medicare patients.³⁹ As a result, access to an already limited number of providers makes it even more challenging for those who are publicly insured. A report from the Department of Health and Human Services Office of the Inspector General showed many U.S. counties do not have MOUD services available through providers and treatment programs, and even in counties that do, Medicare and Medicaid beneficiaries often do not have access.⁴⁵ Almost one-third of counties did not have a provider treating Medicare or Medicaid enrollees.⁴⁵

Payment levels for those on Medicaid are particularly salient. These payment levels are highly variable across states, and nearly always very low compared to already low Medicare payment levels. An analysis from 2022 found that Medicaid fees for services related to OUD treatment varied up to 5-fold across states and were lower relative to Medicare for almost all state services examined. The Medicaid-to-Medicare fee index was 64 percent of Medicare fees in 2021, ranging from 52 percent for evaluation & management to 76 percent for toxicology testing.⁴⁶

One recent study concluded that national initiatives to increase the supply of buprenorphine providers in primary care will not work unless accompanied by payor reimbursement policies that create incentives and reduce administrative burdens. This same study also noted the effect that low reimbursement can have on the quality of care when providers must choose what wrap-around care they can afford to provide.³⁹ Low payment levels may help to explain why more than 80 percent of new buprenorphine prescribers ceased prescribing within one year of starting and only 10 percent of prescribers served 10 or more patients for a full six-year period.⁴⁷ Other provider payment-related barriers include administrative burdens associated with requirements for prior authorization or other regulatory requirements, inability to bill for some services that may be required, and the logistical and payment issues associated with the long-acting injectable forms of MOUD.³⁹

Changes to Medicare and Medicaid Billing. Changes to Medicare and Medicaid have expanded treatment options. In 2017, Medicare introduced Behavioral Health Integration (BHI) Services codes to enhance the integration of behavioral health care into primary care settings. The BHI codes allow healthcare providers to bill for services that involve a collaborative care model, where primary care providers work closely with behavioral health specialists to manage patients' mental health needs.⁴⁸ Primary care providers can use these codes to bill for services that involve managing and treating SUDs as part of a comprehensive behavioral health care plan. Additional changes in 2024 included expanding the types of providers eligible to bill for behavioral health services and the types of services for which they can bill. As of 2025, nearly half of the states have included BHI codes in their Medicaid coverage.⁴⁹ Medicare also recently changed policy to cover Intensive Outpatient services, closing a significant gap in Medicare coverage of mental health and SUD services.⁵⁰



In most states and localities, payment for MOUD provision is through a fee-for-service model. As noted above, the fees are often inadequate to cover the costs associated with service provision.⁵¹ Fee-for-service pays providers for each service provided and has been criticized for rewarding providers for the volume of services they offer rather than the value or quality of care provided.⁵² By contrast, alternative payment models (APM), including value-based payment (VBP) models consider the quality and cost-efficiency of care in determining payments to clinicians.⁵² Value-based models provide an incentive payment for the provision of higher quality care.

While several states and other payers have begun to implement some alternative and value-based payment models, those initiatives remain at an early stage of implementation. Some states are using Medicaid 1115 waivers to require Medicaid managed care providers to set value-based performance targets. Other states and managed care organizations are implementing APMs and VBPs to tie quality and outcome measures to payment. In 2021, the Centers for Medicare and Medicaid services announced a target of having every Medicare beneficiary and most Medicaid beneficiaries in a value-based care relationship by 2030 for which care providers would have accountability for quality and total cost of care.⁵³ However, analysis by SAMHSA in 2023 found that only 8 states had well-developed and ongoing VBP initiatives for SUD treatment and recovery services. Twenty-four states did have SUD quality payment incentives in their Medicaid programs, while no evidence of the use of VBP was found in 20 states.⁵² In summary, a transition to a more promising and sustainable payment model may have begun, but the current reality in much of the nation remains problematic.

Prior Authorization Policies. Prior authorization requirements for primary care providers prescribing MOUD can vary by state and insurer. Across all insurers, the prevalence of prior authorization requirements for MOUD has declined in recent years.⁵⁴ However, many still require prior authorization, which can delay care for patients who urgently need treatment. In 2023, the American Medical Association found that 94 percent of physicians reported care delays due to prior authorizations and 80 percent reported that it could sometimes lead to treatment abandonment.⁵⁵ Indeed, patients who are in the office and want immediate treatment may not return to the office once prior authorization is received. Insurers may also have dosage and quantity restrictions,⁵⁶ requiring the patient to have their prescription filled more frequently. While these policies are intended to balance effective treatment with the goal of preventing misuse and ensuring cost-effective care, they can also create barriers to timely access to MOUD.

Behavioral Health Parity. In 2024, the Mental Health Parity and Addiction Equity Act (MHPAEA) saw significant updates aimed at strengthening parity between mental health/substance use disorder (MH/SUD) benefits and medical/surgical (M/S) benefits.^{57,58}

These included:

- Equal Treatment: The law now clearly states that mental health and addiction treatment must be covered equally to other medical treatments.
- Fair Rules: Insurance companies cannot have stricter rules for mental health and addiction treatment than they do for other medical treatments. This includes things like needing approval before getting treatment.
- **Data Monitoring:** Insurance companies must collect and review data to make sure people have equal access to mental health and addiction treatment. If the data shows problems, they need to fix them.
- **Regular Checks:** Insurance companies must regularly check and compare how they handle mental health and addiction treatment versus other medical treatments to ensure fairness.

Historically, despite the policy, mental health and SUD treatment have not been covered at equivalent rates. It remains to be seen how new regulations will improve this.

B. Secular Changes in Treating Patients MOUD

Related Research Questions

- 2. How has the environment of opioid use or MOUD changed (e.g., polysubstance use; emerging drugs of concern, like Xylazine and similar substances; barriers to treatment; etc.)?
- **3.** How has the approach to using medication to treat people with OUD changed (e.g., growth in telemedicine; whole person care; new drug formulations, such as extended-release buprenorphine; evidence about different treatment medications; etc.)?

The literature review found important shifts in the environment of opioid use and updated evidence regarding medications to treat people with OUD, the effectiveness of MOUD, initiation of MOUD in additional care settings, ongoing challenges with stigma, population-specific considerations for MOUD, use of telehealth, and barriers to integrating MOUD into health care settings.

Environmental Changes and Factors

After two decades of continuous rise between 2003-2023, drug overdose death rates in the U.S. have taken a promising downturn. Provisional data from the Centers for Disease Control for 2023-2024 shows a nearly 24% decline in opioid overdose deaths from the previous year. The data shows about 87,000 drug overdose deaths from October 2023 to September 2024, down from around 114,000 during 2022-2023.⁵⁹ This is the fewest overdose deaths in any 12-month period since June 2020. Data also show smaller decreases in emergency department visits for overdose and a continued decrease in self-reported youth substance abuse.⁵⁹ Increased use of MOUD is one of the factors contributing to this welcome shift, though future trends in overdose death rates following the COVID-19 pandemic remain to be seen.



While this national decline is encouraging news, overdose remains a leading cause of death for Americans aged 18-44.⁶⁰ Also, recent research shows overdose death rates continue to rise among Black and Native American/Alaskan Native populations and in certain parts of the nation.⁶¹⁻⁶⁵ Since the publication of the first Playbook, overdose deaths skyrocketed, due to several factors. These include:

Increase in Synthetic Opioid Overdoses. Synthetic opioids, particularly fentanyl and its analogs, have driven an increase in overdose deaths in recent years. The rate of overdose deaths involving synthetic opioids other than methadone increased by 289% from 2011 to 2021.⁶⁶ Fentanyl is extremely potent, estimated to be up to 50 times stronger than heroin and 100 times stronger than morphine, and it has become dominant in some parts of the US and Canada.⁶⁷ It is generally cheaper than other street opioids like heroin and is often mixed with other drugs. As such, in some markets, fentanyl is replacing — not just adulterating or supplementing — heroin. Moreover, people using street drugs may not know they are using fentanyl, or how much, putting themselves at unknown risk.⁶⁸

Polysubstance Use and Adulteration. Nearly 63% of opioid overdose deaths involve one or more additional substances, such as cocaine, methamphetamine, or benzodiazepines.⁶⁹ Synthetic substances, such as Xylazine,⁷⁰⁻⁷³ a tranquilizer not approved for human use, are particularly dangerous when combined with opioids like fentanyl.

Urbanization of Opioid Use. The opioid crisis has increasingly affected urban areas, with significant rises in overdose deaths in large metropolitan regions.⁶⁰ However, rural areas continue to experience high rates of OUD, often with limited access to treatment services.⁶⁰

Impact of the COVID-19 Pandemic. The pandemic exacerbated the opioid crisis by disrupting access to treatment and increasing social isolation.^{74,75} Lockdowns and social distancing measures led to the closure or limited operation of treatment facilities, making it harder for individuals with OUD to receive necessary care.^{76,77} The pandemic also heightened anxiety, depression, and other mental health issues, which can exacerbate SUDs. However, government agencies' efforts to reduce barriers to treatment during this time led to changes in regulations that proved successful during the pandemic, as discussed in the previous section on Policy and Regulatory Changes.⁷⁷

Recent Developments in Medications

The Food and Drug Administration has approved three medications to treat opioid use disorder: buprenorphine, methadone, and naltrexone. Changes in their use and formulations are described below. For more information about these medications, including a list of brand names, as relevant, see Appendix 2. **Decreased Use of Naltrexone.** There has been a shift away from using Naltrexone as MOUD, with preference instead for buprenorphine and methadone. Naltrexone is an opioid antagonist that blocks opioid receptors without activating them. Consequently, patients must be completely opioid-free before starting treatment. This can take up to 10 days and requires patients to go through withdrawal. Another concern is that since naltrexone eliminates any tolerance for opioids, there is an enhanced risk of overdose if there is a recurrence of use. While naltrexone and buprenorphine are similar in effectiveness, the challenges starting naltrexone and the greater risk of overdose if the medication is stopped have led to reduced use of naltrexone.⁷⁸

Increased Use of Naloxone. Naloxone is a life-saving rescue medication, and persons with OUD, those using opioids to manage chronic pain, and others who spend time with people from these groups are encouraged to carry naloxone for safety as it can reverse an overdose. Indeed, access to naloxone is associated with a 14% reduction in opioid overdose deaths.⁷⁹ Recent widespread public health initiatives have increased awareness, availability, and use of naloxone, and in 2023, the Food and Drug Administration (FDA) approved over-the-counter Naloxone nasal spray.⁸⁰ It is available without a prescription in all 50 states and the District of Columbia, and can be ordered online. While this FDA approval increased access, barriers to obtaining over-the-counter Naloxone persist, as not all pharmacies carry it ^{81,82} and it currently costs about \$40 per twin-pack to purchase.⁸³ Over-the-counter naloxone has a higher out-of-pocket cost than insurance-paid naloxone prescriptions,^{84,85} indicating the continued importance of prescribed naloxone and naloxone access in community-based settings.

State and local governments have taken action to expand policies and fund public health initiatives to educate, promote, and provide naloxone. People can obtain Naloxone free-of-charge from some public spaces such as libraries, community health centers, and social service agencies. Moreover, some initiatives include harm reduction vending machines, home delivery, and street outreach. Additionally, in 2024, the California Department of Health Care Access and Information announced an agreement with a pharmaceutical manufacturer to produce a generic formulation for \$24 per twin-pack.⁸⁶

New Formulation of Buprenorphine. In 2017, the FDA approved a long-acting formulation of buprenorphine, administered as a subcutaneous injection by healthcare providers on a weekly or monthly basis. The primary benefits of this long-acting formulation include improved adherence to treatment because patients do not need to take oral medication daily, and better management of withdrawal symptoms and cravings because of the steady, ongoing release of the medication. However, barriers include pharmacy regulations for managing medication supply (pharmacy regs); administrative hurdles including registration in the long acting injectable (LAI) buprenorphine Risk Evaluation and Mitigation Strategy; and prior authorization, particularly for Medicaid coverage.⁸⁷

Take-Home Doses of Methadone. In February 2024, the U.S. Department of Health and Human Services (HHS), through the Substance Abuse and Mental Health Services Administration (SAMHSA) released the 42 CFR Part 8 Final Rule, which updated criteria for consideration of take-home doses of methadone and allowed patients to receive take-home doses from the first week of treatment under certain conditions. The rule made permanent the COVID-19 flexibilities which demonstrated that wider access to methadone improves outcomes, without increasing rates of diversion, when paired with individualized clinical judgment, safeguards, and patient education.⁸⁸ To the extent that these changes make receiving methadone from OTPs more accessible and less stigmatizing, this may provide another treatment alternative for some people with OUD.

Effectiveness of MOUD

Recent research has also brought to light the importance of longer treatment durations to improve the effectiveness of MOUD. Studies suggest that treatment lasting at least 90 days is associated with significantly better outcomes, including reduced return to use rates and improved overall health.⁸⁹ In one study, receipt of MOUD over 1-year was associated with a lower mortality rate compared to retention for 1 year or less.⁹⁰ Another study found improvements in outcomes after 18 months of MOUD relative to baseline, with estimates suggesting that rates of abstinence increased (55% to 77%), while rates of opioid-related overdoses (7% to 2%), emergency department visits (9% to 4%) and arrests (15% to 7%) decreased.⁹¹ Similarly, research also suggests the likelihood of return to use decreases significantly for those who are in treatment for at least 3 years.⁹²

From a provider perspective, one of the primary challenges to sustaining care is the potential difficulty in maintaining consistent and meaningful contact with patients taking MOUD. Retention rates vary across clinics, with some studies showing up to 50% of patients discontinuing treatment within the first year.⁹³⁻⁹⁶ Early discontinuation is particularly common, with about half of those who discontinue doing so within the first 30 days of starting treatment.^{97,98} Factors contributing to early discontinuation include acute medical and psychosocial needs, lack of trust and support from care team members, and clinic-level factors such as appointment scheduling and care coordination.⁹⁹ Many patients with OUD may have unstable living situations, lack reliable transportation, or face other socio-economic barriers that make it hard for them to attend regular appointments.^{100,101} This inconsistency can lead to gaps in treatment and reduced effectiveness of MOUD programs. High patient volumes, productivity goals, and limited appointment times can also restrict the ability of providers to spend the necessary time with each patient to build rapport and address their concerns comprehensively.¹⁰² Finally, research has found that patients who received higher doses of initiating buprenorphine treatment remained in treatment longer than those prescribed lower doses,^{103,104} and that buprenorphine dosing limits may need to be extended in light of established research and the profound harms from fentanyl.¹⁰⁵

MOUD Initiation in Acute Care Settings

Currently, few hospitals provide MOUD to admitted patients with OUD, but growing evidence shows that hospitalizations represent important opportunities to engage individuals with SUD in long-term MOUD treatment. Several studies demonstrated positive outcomes following discharge from the hospital. In one study, patients who were given buprenorphine or methadone had significantly fewer unplanned readmissions. MOUD initiation during inpatient withdrawal management for Medicaid adults with OUD was associated with a higher likelihood of short-term MOUD, reductions in short-term service utilization, and opioid overdose after discharge.¹⁰⁶ There are, however, numerous barriers to initiating MOUD in inpatient settings. Hospital-based clinicians often lack sufficient knowledge and comfort with MOUD initiation, which can hinder effective treatment.¹⁰⁷ Structural issues such as limited availability of outpatient buprenorphine prescribers to refer to, siloed addiction treatment systems, and long wait times for outpatient care can discourage hospital providers from initiating MOUD.¹⁰⁸

Similarly, emergency department (ED) visits represent a promising but still underutilized opportunity to initiate MOUD. The rate of emergency department visits with a primary diagnosis of SUD among adults in the U.S. during 2020-2021 was 103.8 per 10,000 population, representing a significant increase from the year before (74.4 per 10,000 population during 2018–2019).¹⁰⁹ Each visit represents a potential opportunity to provide MOUD. Yet, a large study of cross.sectional data including encounter records found that MOUD and other medications for opioid overdose are infrequently used in the ED setting.¹¹⁰ This finding varied by race and geographic region, with Hispanic race and Western region being associated with increased odds of receiving MOUD; by mode of arrival, with arrival by ambulance being associated with decreased odds of receiving MOUD; and by practitioner, with evaluation by an advanced care practitioner increasing the likelihood of MOUD treatment. This variation underscores the need for further study of the root causes of these differences.

Barriers to widespread adoption of MOUD initiation in the ED are similar to those in inpatient settings. Still, research indicates the feasibility of and opportunity for initiating MOUD in the emergency department. For example, a California Bridge program with 52 hospitals implemented low-threshold ED buprenorphine treatment, with a harm reduction approach and active navigation to outpatient addiction treatment. The program was successful in achieving buprenorphine treatment for opioid use disorder in diverse California communities.¹¹¹ A similar New Mexico Bridge program successfully implemented ED-based MOUD programs across six diverse hospitals, in a highly rural state, leading to an increase in buprenorphine prescriptions and expanded staff hiring and training.¹¹²

Whether from inpatient or emergency care, a direct transition from these settings to primary care could engage patients without risking an interruption in their MOUD treatment. These transitions may be supported by social workers, case managers, or peers. This is not yet common practice, however. Tailored support during post-discharge transitions to longitudinal care settings, including

primary care, may improve MOUD retention and treatment outcomes. Additional research related to optimal approaches to support these transitions is needed, as a review of transition strategies found they were varied and often not well described. The most common strategy was scheduling an appointment with a community-based treatment provider prior to discharge.¹¹³

Stigma and Stigma Reduction

Stigma continues to be a significant and enduring barrier to treating SUDs. The stigma surrounding addiction and SUD pervades communities and frequently discourages patients from seeking treatment.¹¹⁴⁻¹¹⁶ Although substance use is a complex chronic health issue, many people hold entrenched views of drug use as a moral failing or a lack of willpower.¹¹⁷ Likewise, the criminalization of drugs and drug use, further reinforces negative perceptions, as users are often seen as criminals.¹¹⁷ People who use drugs may belong to other stigmatized groups, such as those based on race, socioeconomic status, or mental health conditions, compounding the stigma they face.¹¹⁸ Individuals with SUDs have reported they do not seek treatment out of fear it would jeopardize their employment or compromise their social relationships.¹¹⁹

Stigma is also pervasive among healthcare providers, creating a barrier for patients in seeking treatment and receiving adequate treatment from a supportive provider.^{120,121} Clinical guidelines have defined substance use as a chronic disease for a decade, yet some providers hold onto negative and judgmental stereotypes. Misconceptions about the use and effectiveness of MOUD make some providers reluctant to prescribe it.¹²² One survey of primary care physicians found that one-third did not perceive MOUD to be more effective than non-medication treatments or safe for long-term use.¹²³ Some providers view MOUD as a replacement of one addiction with another.¹²⁴

Provider stigma can have a negative effect on patient care and outcomes. For example, a survey of attitudes among primary care providers showed that greater stigma was associated with lower likelihood of prescribing MOUD or supporting policies to increase access to MOUD; specifically, every unit increase in stigma was associated with an 11-percentage point lower likelihood of prescribing OUD medication.¹²⁰ Additionally, there may be concerns about the potential for diversion and misuse of buprenorphine, which can make providers cautious about prescribing it without comprehensive resources and support.¹²⁵

Additionally, recent research highlights the significant impact that provider use of stigmatizing language about or toward individuals with SUD has on treatment seeking. Terms like "drug abuse" and "addict" can trigger explicit and implicit biases among healthcare providers, leading to suboptimal care and reduced treatment engagement.¹²⁶ Stigmatizing language fosters discrimination and dehumanization, which can deter individuals from seeking help and negatively affect their treatment outcomes.¹²⁷ In contrast, using person-first language, such as "person with OUD," is associated with better treatment adherence and more favorable health outcomes.¹²⁶ Table 2 provides recommendations for non-stigmatizing language to replace language that stigmatizes people with SUD.

Recommendations for non-stigmatizing language about substance use disorder (adapted from Shatterproof.org resources)

Recommended language	Stigmatizing language
 Substance use disorder, addiction (if clinically accurate) Use (for illicit substances); misuse, used other than prescribed (for prescription medications) Harmful, hazardous, problematic, or risky use 	Abuse, Drug problem, Habit/ Drug habit, Dependence
Person with opioid/alcohol use disorder	Abuser, Addict, Druggie, User, Junkie
Has a [X] use disorder	Addicted to [X]
Substance-free; related: no longer using [X substance]	Clean
Adherent	Compliant
Withdrawal management	Detox
Person who tests positive for substance use	Dirty
Baby with neonatal opioid withdrawal/neonatal abstinence syndrome; related: newborn exposed to substance	Drug addicted infant, addicted baby, born addicted
Use of X substance	Drug of choice or abuse
Person arrested for drug violation; related: person with criminal legal involvement	Drug offender
Person in recovery or person in long-term recovery	Ex-addict, former/ reformed addict
Medication for Opioid Use Disorder (MOUD)	Opioid replacement/ substitution/ maintenance therapy, medication assisted treatment
Resumed or experienced a recurrence of substance use or substance use disorder symptoms	Relapse, lapse, slip
Recovery management	Relapse prevention
Well, healthy, in recovery	Sober
Maintained recovery	Stayed clean
Person who is using [X substance]	Untreated addict

Addressing Stigma in Healthcare. Stigma reduction trainings for healthcare providers can contribute to improving the quality of care for patients with SUDs. These trainings often include educational components that address the root causes of stigma, such as misconceptions about addiction and biases against people who use substances.¹²⁸ Interactive elements, such as role-playing and direct interactions with individuals who have lived experience of substance use, are also effective in reducing stigma.¹²⁹ Additionally, incorporating motivational interviewing techniques helps providers develop more empathetic communication skills.¹²⁹ Multi-component interventions that combine education, training, and structural changes within healthcare settings have shown to be particularly effective.¹³⁰ Other interventions that combined education, training, and in-person contact with people in recovery have been shown to have enhanced provider-client interaction at 9-month follow-up and reduced negative attitudes at 12-month follow-up.¹³¹

These trainings not only improve provider attitudes but also enhance patient outcomes by fostering a more supportive and non-judgmental healthcare environment.¹³¹

Needs of Specific High-Risk Populations

Supporting Pregnant and Postpartum Women with OUD. Pregnant women with OUD are at elevated risk for pregnancy complications and maternal death, and their babies are at higher risk of adverse outcomes such as neonatal opioid withdrawal syndrome (NOWS), poor fetal growth, preterm delivery, or stillbirth.¹³² Therefore, it is important for providers to be aware that substance use treatment recommendations are different for pregnant women.^{133–135} For example, clinicians should carefully weigh both the benefits and risks of continuing opioid medications and the benefits and risks of tapering opioids, and consult with other expert medical providers.^{136,137}

Providing non-punitive, non-stigmatizing care is important. Historically, people who use substances during pregnancy have been highly stigmatized, and even penalized, for their addiction.¹³⁸ According to advocates, as recently as 2024, prenatal substance use was considered child abuse in 25 states and a crime in 7 states.¹³⁹ The rate of child protection system involvement attributed to perinatal or parental substance use has doubled in recent years.¹⁴⁰ As a result of a punitive approach, people who use substances while pregnant may be deterred or delayed from seeking care because of fear of detection, prosecution, and punishment.¹⁴¹ However, supportive, rather than punitive approaches, can lead to better health outcomes for both mother and child. Keeping babies with their mothers helps with bonding and attachment, and promotes a healthier start for the child. Breastfeeding has been shown to reduce the severity and duration of NOWS, and methadone and buprenorphine are compatible with breastfeeding.¹³⁸ Furthermore, keeping mothers and babies together can provide a sense of stability and support for the mother, which is critical during the postpartum period. This support can help mothers stay engaged in their treatment and reduce the risk of return to use.¹⁴²

Caring for pregnant and postpartum women also provides an opportunity to implement traumainformed and family-friendly care practices, given the high rates of trauma and intimate partner violence among women with OUD.¹⁴³ Harm reduction strategies, such as providing access to naloxone, syringe services, and safe breastfeeding practices, can help reduce poor obstetrical outcomes and parental mortality.¹⁴⁴ Increasing training for health care providers in both obstetric and addiction medicine is necessary to equip them with the skills to care for pregnant women with OUD and manage co-occurring conditions.¹⁴⁴ Expanding access to support services like doula care, home-visiting programs, and childcare services can improve maternal health equity, reduce stigma, and support treatment engagement.¹³⁸ **People Leaving Incarceration.** A significant overlap between substance use and incarceration underscores the need for effective treatment programs within the criminal justice system and following release. Approximately 65% of people in prison have an active SUD.¹⁴⁵ Additionally, another 20% of inmates, while not meeting the official criteria for an SUD, were under the influence of drugs or alcohol at the time of their crime.¹⁴⁵ The highest risk of overdose for individuals with OUD occurs within the first two weeks following their release from incarceration.¹⁴⁶ During this period, the risk of opioid overdose is significantly elevated, with former inmates being up to 40 times more likely to die of an opioid overdose compared to the general population.¹⁴⁶ This heightened risk is due to several factors, including reduced tolerance to opioids after a period of abstinence during incarceration and the challenges of reintegrating into society without adequate support.^{145,147}

MOUD treatment significantly reduces the risk of post-release mortality and supports long-term recovery, even in comparison to other substance use treatments. Despite evidence of efficacy, few carceral settings provide MOUD to prisoners. One carceral system that incorporated MOUD has shown that administering buprenorphine and other types of MOUD in a jail setting has reduced deaths immediately following release and led to relatively high retention for people to fill their first prescription of buprenorphine outside the jail.¹⁴⁸

Effective pre-release planning can bridge the gap between incarceration and community reintegration,¹⁴⁹ reducing the likelihood of return to use and recidivism. Beginning in 2023, some Medicaid 1115 waivers allow Medicaid to cover treatment for individuals with OUD during the last 30 days before their discharge from incarceration. These waivers aim to improve care transitions, increase continuity of health coverage, and reduce disruptions in care, improving health outcomes and reducing recidivism rates.¹⁵⁰ By leveraging 1115 waivers, states can create more integrated and effective systems of care for individuals with SUD, ultimately improving health outcomes and reducing the burden of substance use on the healthcare system.¹⁵¹

Telehealth delivery

Telehealth has shown promise for improving MOUD retention and lower odds of medically treated overdose.^{152,153} As discussed in the Policy and Regulatory Changes section, the COVID-19 pandemic led to rapid expansion of telehealth and associated policies and regulations that supported the use of telehealth as a model of care. SAMHSA made permanent other provisions that were introduced during the COVID-19 public health emergency, including allowing for the initiation and continuation of MOUD, including buprenorphine, through telehealth, which can be conducted via audio-visual or audio-only platforms.⁷⁷

Beyond creating a policy and regulatory environment conducive to increasing uptake of telehealth in primary care settings, the pandemic also created an emerging market for commercial telehealth vendors. Some partner directly with medical practices and others, such as Bright Heart Health, offer direct substance use care to patients, and can provide MOUD or psychosocial



interventions, such as contingency management or cognitive behavioral therapy (CBT), or collect and track patient-reported outcomes (PROMs). Additionally, there are various electronic health applications (apps) now on the market, such as Affect Therapeutics, CHESS Health, and WEConnect Recovery, that provide digital health platforms and solutions to support individuals in their recovery from SUDs. Some include features that allow people to track recovery progress, view motivational content, learn cognitive behavioral therapy techniques to support recovery, access educational material, and locate local support groups. These are tools providers could recommend to patients.

Barriers to Integrating MOUD into Health Care Settings

Too Few Primary Care Providers Prescribing MOUD. Primary care providers are well positioned to screen patients for OUD and engage these individuals in treatment. However, a lack of providers who prescribe MOUD creates a significant barrier to treatment with MOUD.^{154–156} According to a report by the U.S. Department of Health and Human Services' Office of Inspector General, in 2022, 19% of U.S. counties did not have an MOUD provider, despite many of these counties having a high need for such services.⁴⁵ Primary care providers often serve as the first point of contact for patients, including those experiencing persistent or chronic pain symptoms.¹⁵⁷ In a 2019 analysis, the most common specialties prescribing high volumes of opioids were family medicine (32%) and internal medicine (23%), with significant variations between geographic regions.¹⁵⁸

The Centers for Disease Control, the National Institute on Drug Abuse, American Society for Addiction Medicine, and the Food and Drug Administration all emphasize that treating patients using MOUD does not require specialization.¹⁵⁹ Studies have shown that primary care providers can effectively manage MOUD with outcomes comparable to those in specialty settings.^{99,160} However, a significant gap remains between those who can prescribe MOUD and those who actually do. Beginning in 2021 with the relaxation of the X-waiver requirements, 5,830 new providers were certified to treat MOUD. However, it did not result in a marked increase in the number of patients with OUD filling buprenorphine prescriptions.¹⁶¹ Even without the X-waiver and with an increase in assistive tools like telehealth, progress toward increasing the number of primary care providers offering MOUD has been slow, particularly in rural areas.¹⁶²

Behavioral Health Workforce Shortages. According to HRSA, the US is experiencing a mental health crisis with increased levels of unmet behavioral health needs among people of all ages.¹⁶³ Substantial shortages of addiction counselors, therapists, psychologists, psychiatrists, and school counselors are projected in 2037.¹⁶³ As of August 2024, more than one third of the U.S. population lives in a Mental Health Professional Shortage Area. Rural counties are more likely than urban counties to lack behavioral health providers.¹⁶³ Residents of rural counties are also more likely to receive behavioral health services from primary care providers.¹⁶³ The lack of uniformity in behavioral health providers' scope of practice, reimbursement challenges, and increased burnout hinder the accessibility of the behavioral health workforce.¹⁶³



While MOUD is a stand-alone treatment, the absence of a sufficient behavioral health workforce can significantly impact the effectiveness of offering MOUD in primary care settings. Behavioral health specialists, such as counselors and social workers, play a crucial role in providing the comprehensive care needed for patients with OUD. Without adequate behavioral health support, patients may not receive the necessary counseling and psychosocial interventions that complement MOUD, potentially leading to poorer treatment outcomes.⁹⁹ Moreover, a shortage of behavioral health workforce may also increase the likelihood of early discontinuation of MOUD. Patients with OUD often have complex needs that require coordinated care and continuous support, especially during the initial stages of treatment. Without behavioral health services, patients may struggle to stay engaged in treatment, increasing the risk of return to use and overdose.⁹⁹

Inadequate Pharmacy Supplies. Despite the critical role of buprenorphine in treating OUD, some retail pharmacies do not stock this life-saving medication.¹⁶⁴ A study published in May 2023 revealed that fewer than 60% of retail pharmacies carry buprenorphine, with independent stores being less likely to stock it compared to chain pharmacies.¹⁶⁴ This lack of availability creates significant barriers for patients seeking treatment, forcing them to visit multiple pharmacies to fill their prescriptions.¹⁶⁴ The American College of Emergency Physicians (ACEP) highlights this issue in their 2023 report, emphasizing the need for increased pharmacy participation to improve access to OUD treatment.¹⁶²

Moreover, national companies that faced lawsuits related to the opioid crisis are hesitant to stock or produce buprenorphine in large quantities.^{164,165} These companies, including major pharmacy chains and opioid manufacturers, are concerned about the potential legal and reputational repercussions of being associated with high levels of buprenorphine prescriptions.^{164,166} The ACEP report underscores that while the removal of the X-waiver requirement has expanded the number of eligible prescribers, the reluctance of pharmacies and healthcare providers to fully embrace buprenorphine remains a significant hurdle in the fight against the opioid epidemic.¹⁶²

Prescribing Limits. State policies have been enacted to curtail prescribing prescription opioids. Currently, 46 states have mandatory Prescription Drug Monitoring Programs (PDMP) that require dispensers to report prescription information for controlled substances. The specifics of these mandates can vary by state, such as the frequency of reporting and the types of substances that must be reported.¹⁶⁷ In addition, many states have enacted legislation that sets limits on opioid prescribing practices, such as restricting the length of first-time opioid prescriptions¹⁶⁸ or upper limit doses for buprenorphine.¹⁰⁵ A study of a West Virginia cohort of Medicaid patients concluded that a state level policy was too broad and that policies that were more tailored to the patient were more effective at reducing the length of opioid prescriptions.¹⁶⁸ Moreover, buprenorphine, as a partial agonist, was initially included in the Suspicious Order Reporting System (SORS) as a typical opioid rather than a treatment medication for OUD.



Access to Treatment Barriers. Access to treatment remains inadequate for many Americans. In 2021, an estimated 2.5 million people aged 18 years or older in the U.S. had opioid use disorder in the past year, yet only 1 in 5 of them (22%) received medications to treat it.¹⁶⁹ Some groups were substantially less likely to receive medication for opioid use disorder, including Black adults, women, those who were unemployed, and those in nonmetropolitan areas.¹⁶⁹ Other barriers include a lack of MOUD providers in their area and having to travel long distances to get access to medications; health-related social needs, including transportation to get to appointments; and access to related care, such as psychosocial services.¹⁰⁰ Access to free or affordable treatment is limited for those without insurance³⁴ and those with public insurance may have few options for providers who will accept it.³⁴ Stigma, a fear of withdrawal symptoms, or disinterest in pursuing or maintaining treatment are some of the personal barriers to MOUD. Many are not aware that treatment is effective or that it is available. In addition to providing medical treatment, providers need to be educators and advocates to promote retention and recovery for their patients.

C. New Models, Tools, and Resources

Related Research Questions

- 4. What are the models being employed to treat people with OUD using medication? (e.g., medication first model, low-barrier care, harm reduction, etc.)
- 5. What are the evidence-based tools and resources to facilitate using medications to treat people with OUD?

The literature review indicated the low-threshold care model as the prevailing evidence-based care model to treat MOUD and highlighted trends in the use of psychosocial services and peer recovery specialists. As noted, the literature review also identified 173 tools and resources to facilitate treatment with MOUD, which are currently under review for inclusion within the AHRQ Academy's Substance Use (SU) or Unhealthy Alcohol Use (UAU) Tools and Resources Collections.

Low-Threshold Care Model

Low-threshold care has emerged as the evidence-based care model most accessible for people with OUD and feasible for primary care providers. Low-threshold care for providing MOUD is based on harm reduction principles. The model emphasizes removing the barriers common to conventional OUD treatment, such as lengthy intake prior to initiating medication, and ensuring equitable access to care and treatment. Low-threshold approaches prioritize a "medication first" approach to buprenorphine; individualized psychosocial support; and caring, long-term clinical relationships. Benefits of low-threshold programs for patients with OUD, include greater access, improved retention, and reduced overdose rate, and are supported by substantial scientific evidence.^{170–175}

Putting this into practice, key components of low-threshold treatment programs for patients with OUD include:

- Prompt (same day) initiation of buprenorphine prior to lengthy assessments or treatment planning sessions.
- Maintenance buprenorphine delivery without arbitrary tapering or time limits.
- Offering—but never requiring—individualized psychosocial services.
- Buprenorphine continuation based solely on the patient's clinical circumstances; positive tests for illicit substances should not result in discontinuation of buprenorphine.
- Flexibility in dosing, protocols, policies, and workflows for initiating and maintaining buprenorphine therapy.
- Availability in settings that best meet patient needs, such as primary and ambulatory care, mobile treatment sites, syringe exchange programs, and telehealth.

More detailed guidance and information about implementing low-threshold care can be found in this AHRQ Academy Issue Brief: <u>The Role of Low-Threshold Treatment for Patients with OUD in</u> <u>Primary Care</u>.

Use of Psychosocial Services

Analysis of data from between 2015 and 2017 found that over 60 percent of people with OUD had a mental illness in the previous year.¹⁷⁶ People with OUD are also more likely to die by suicide: a global systematic review found that people with OUD died by suicide at nearly eight times the expected rate.¹⁷⁷ Common mental health disorders include depression, anxiety, post-traumatic stress disorder, and attention-deficit/hyperactivity disorder (ADHD).¹⁷⁸ Many people with OUD also experience health related social needs, such as unstable housing, food insecurity, living in unsafe places, or financial stress.¹⁷⁹

Given the current emphasis on medication as a front-line approach, there are differing perspectives on the importance of psychosocial approaches in MOUD treatment. A number of studies have found no significant difference between MOUD-only and MOUD with psychosocial support services in treatment retention.¹⁸⁰ However, psychosocial services play a key role in many peoples' recovery. The best available evidence suggests there is a valuable role for psychosocial supports in conjunction with MOUD, but the studies and reviews to date do not establish which models of psychosocial treatment are most likely to prove effective, in which type of setting, or with which populations.¹⁸¹ Most important, care that is person-centered will inform what a person in recovery needs to support them.

Use of Peer Recovery Specialists

There has been growing use of peer recovery specialists, who can play a crucial role in MOUD treatment by providing support and guidance based on their own lived experiences with recovery. They offer emotional support and mentorship, serving as positive role models and sharing their recovery journeys to inspire hope and demonstrate that recovery is possible.¹⁸² Additionally, they educate individuals about MOUD, dispelling myths and misconceptions, and advocate for patients' needs within the healthcare system.¹⁸³ While there is a need for additional research on the impact peer recovery specialists have on MOUD retention or remission, incorporating peer support services into treatment, either in primary practice or adjacent, is an accessible and increasingly utilized way to engage and retain patients in recovery support.^{184,185}

Tools and Resources

Tools and Resources identified in the literature review fall under five categories:

- 1. OUD Awareness and Education
- 2. OUD Prevention
- 3. Training and Education for MOUD
- 4. MOUD Implementation
- 5. Preventing Overdose

Materials included fact sheets and brochures, clinical guidelines, instruments and protocols, patient forms, reports, issue briefs, toolkits, training and educational materials, webinars and videos, and websites. Many of the tools and resources came from government agencies, such as AHRQ, SAMHSA, National Institute on Drug Abuse, the Department of Veterans Affairs, state health departments, and others. Other sources included professional organizations such as the American Society of Addiction Medicine.

The materials largely focus on provider knowledge and cover topics such as understanding OUD, addiction, and MOUD and include guidelines for prescribing, dosing and tapering, and pain management. The materials also include hands on tools such as checklists, assessments, screeners, patient agreements, and materials to share with patients with low health literacy. While the tools and resources are mostly geared toward primary care providers, they may also be of interest to pharmacists. In addition, public-facing educational materials and toolkits are for local health departments, hospitals and health systems, rural communities, and others to use to engage the public in learning about and working to address the ongoing opioid crisis.

As noted, these tools and resources were reconciled with the existing materials available in the Academy's collections and new items added to the <u>Substance Use (SU)</u> or <u>Unhealthy Alcohol Use (UAU)</u> Tools and Resources Collections, as appropriate.



D. Literature Review Summary and Conclusion

Since the first Playbook was published, the opioid crisis has continued and the landscape of drug use has changed dramatically, reaching alarming levels. This urgent problem has called for an equally urgent response—first and foremost, to keep people alive.

This literature review uncovered new developments in MOUD policy and regulation, substance use trends and approaches, and models to improve MOUD integration into primary care. Numerous challenges to implementing MOUD treatment into primary care remain and a multifaceted approach is necessary to increase care delivery. While removal of the X-waiver requirement did not result in a major increase in prescribing, it revealed the potential to meet the need for MOUD. Telehealth is now an established part of healthcare practice that improves access to MOUD care. Buprenorphine is a much needed, under-utilized medication and integrating it into accessible primary health care has the potential to increase access and save lives.

Stigma toward people with SUDs by health care providers is an enduring barrier to optimal patient care and outcomes. Other structural and logistical challenges also require time and resources, but there is growing evidence of success in implementation and better outcomes. Low-threshold care holds promise as an accessible model for primary care providers to adopt in the larger effort of saving lives.

These findings highlight recent trends and research that influences MOUD in primary care settings and areas for additional and refined Playbook content.



IV. Findings: Key Informant Interviews

The second part of the Environmental Scan for the MOUD Playbook content update gathered the perspectives of subject matter experts to learn about significant developments in MOUD since the original Playbook was published. This work resulted in the identification of several key themes, including 1) addressing stigma as a barrier and developing support for MOUD provision at all levels of the practice organization; 2) challenges to implementation, including provider workload, low reimbursement levels, education and training needs, and the impact of the X-waiver elimination; and 3) facilitators to implementation, including low-threshold care, practice facilitators, and reimbursement policies. This section discusses these findings in more detail.

Addressing Stigma and Gaining Support for MOUD Integration

All key informants identified stigma as the greatest barrier to providers' willingness to offer MOUD treatment and for building institutional support. However, without support from other providers, staff, or practice leadership, an MOUD program will struggle to "get off the ground" or be sustained over time. According to several key informants, a multi-faceted approach is required, providing medical information, public health data, and other relevant fact-based information, as well as demonstrating the human, compassionate side of providing substance use care.

"You have to hit them in the head and the heart."

Three of the key informants were long-time rural primary care providers who had spent decades training and mentoring other providers to integrate MOUD treatment in their practices. They described a framework of tenets for implementing MOUD, which included garnering the support of all involved, engaging everyone in training, and mentoring staff until they were established and comfortable operating on their own. It is a process that can take months or years to complete and requires strong institutional support. While many primary care practices may not have access to this level of resources, the guidance for the Playbook provided by the key informants can inform an incremental approach to tailoring training and building support.

Key informants described successful strategies for addressing stigma and misinformation providers and staff may have about substance use disorders. Some of their recommendations include:

- Encouraging sharing of all questions and concerns from the care team and leadership, no matter how implausible or extreme they may seem. As one key informant emphasized, it is crucial to address any preconceptions that might deter someone from treating a patient with OUD.
- Providing data to counter misconceptions and inaccurate beliefs. For example, present and explain data that indicates people with OUD are unlikely to seek opioids at the ED, where there are often long wait times.

Delivering Medications for Opioid Use Disorder in Primary Care: Environmental Scan

- Understanding that some stigma is rooted in concerns for personal safety or safety of others, such as what to do if a patient becomes violent. Clearing up misconceptions about how people with OUD generally behave (not violently) can remove unwarranted concerns.
- Sharing stories about patients who have been successful in recovery and regained control of their lives, and emphasizing the unique and powerful role providers play in preventing overdose through the prescribing of buprenorphine.

"I have stories from working, seeing patients and having lives change. Having people get kids back out of the foster care system. People that are pregnant and using fentanyl and stabilizing and having a delivery and having that dyad stay together, people going back to work."

Several key informants highlighted the importance of "normalizing" opioid use disorder (OUD) by comparing it to other chronic illnesses, such as diabetes, which are routinely managed by primary care providers. They also emphasized that providers might already have patients with OUD who do not fit the typical stereotype of a person who uses drugs. For instance, a patient might be taking high doses of opioid prescription medication for pain without being recognized as having OUD. One key informant shared an experience of working with practice staff in a small community. When the staff realized how many personal connections they had to individuals who had died from overdoses, they began to view patients with OUD as neighbors rather than "others."

However, it is important to understand there is no "one-size-fits-all-approach;" depending on the characteristics of a practice, experiences in addressing stigma and reaching patients with OUD may be different. The key informants who practiced in rural areas work in a context where primary care practices are central hubs for health care and approaches can be adapted for local needs. Treating patients with OUD may not be successful in other primary care locations or with different populations. What works in a rural practice may be a world away from what is feasible in an urban hospital.

Implementation Challenges

Provider Workload. Key informants emphasized a discouraging lack of interest by primary care providers to offer MOUD. Among other reasons, these providers already manage a wide range of services within tight schedules, making them hesitant to take on patients with substance use disorders, who are perceived as requiring more complex and time-consuming care. As one key informant noted, primary care providers are asked to do more and more but with the same resources. Asking them to add an additional service without adding resources or reducing current obligations increases their already heavy workload. With a national shortage of primary care providers, an already overburdened system may have limited capacity to expand services to meet the current needs of OUD patients in some communities.

Reimbursement Levels. Treatment services for substance use disorder are reimbursed at lower rates than for physical health conditions, despite parity laws that aim to close this gap. Low reimbursement rates may be a challenge to primary care practices who operate on tight budgets. Several key informants recommended that higher reimbursement could both incentivize and enable health care providers to offer MOUD.

Education and Training. Findings from the literature review emphasized that training and knowledge about treating OUD is a crucial component for providers to feel confident in their skills and abilities. One key informant, a policy expert, felt that inadequate training explained low rates of retaining prescribers to provide MOUD. A study he conducted found as many as 80 percent of buprenorphine prescribers were no longer prescribing one year later.

Key informants noted a dearth of medical education or residency programs that incorporate training on addictions and their treatment, limiting the potential for a more prepared workforce of newly trained providers. However, one key informant who trains medical residents in addiction treatment said residents who receive this training and move on to other hospitals sometimes pressure their new institutions to expand treatment services.

"Every medical school [in the state] is now training the medical students on substance use disorders...then they show up at residency, and they're like, why are we not doing this?

While training during formal medical education may be limited, there are ample resources for continuing medical education, training, or technical assistance, including online classes, hub and spoke models, ECHO case presentation sessions, on-site or virtual practice facilitation, mentoring, consultation lines, or other strategies. However, it can be challenging to engage primary care providers in training. One key informant described the significant effort a colleague put into creating original content targeted toward rural primary care providers and substantial outreach efforts, which resulted in disappointingly low participation.

The Impact of Eliminating the X-waiver. When the X-waiver requirement was paused, and later eliminated in 2023, the number of potential buprenorphine prescribers increased exponentially to an estimated 1.8 million healthcare providers. However, there has not been a significant rise in the number of prescribers, indicating other factors remain significant obstacles. Several key informants explained the X-waiver had not been a major barrier in the first place, and it would be unrealistic to expect a flood of providers to begin prescribing MOUD with its elimination. The change in policy, however, demonstrates the volume of potential providers and reduces the barriers to prescribing buprenorphine for OUD. One key informant, a policy expert, suggested that a greater impact may be achieved from supporting fewer providers to become "high-volume" prescribers, rather than casting a broader net to try to capture more providers who are less likely to begin prescribing and more likely to stop prescribing.

Implementation Facilitators

Low-Threshold Care. Key informants and TEP members felt strongly that primary care settings should provide low-threshold care for buprenorphine treatment and are equipped to do so. Because this model emphasizes rapid access to buprenorphine without requiring extensive assessments or mandatory counseling sessions, providers do not need to devote limited time and resources to engaging a client in care before getting them started on medication. Some TEP members pointed out that some low-resource practices may not have the capacity to do more, but the most important step for saving a person's life, prescribing medication, is within reach.

Practice Facilitators. Several key informants described practice facilitation as vital in helping healthcare practices implement and enhance their MOUD programs, if this resource is available to them. Facilitators provide essential training and support to healthcare teams, ensuring they are well-equipped to treat patients and integrate MOUD into the practice's workflow. They also offer ongoing guidance and troubleshooting to help practices overcome challenges and continuously improve their services. Furthermore, they aid in data collection and evaluation to assess the effectiveness of the MOUD program and identify areas for improvement. This role is crucial in expanding access to effective treatment for opioid use disorder and ensuring healthcare providers have the confidence and resources to support their patients.

Reimbursement Policies. While reimbursement remains a challenge, there have been important changes related to payment for substance use treatment and related care in recent years. Many states have applied for Medicaid waivers to bolster their efforts to address the opioid epidemic through paying for additional services, raising reimbursement rates, deploying alternate payment methods, supporting additional provider types, and other means. Some private insurers have also become more innovative in efforts to support more and better treatment of OUD, and several philanthropic organizations have also supported treatment initiation and innovation. The applicability of these changes is highly localized to each clinic, depending on their state, payer mix, and other factors. Consultation with peer organizations and experts on payment methodology may be very helpful in developing a financially sustainable approach to MOUD treatment.

Some of these changes have also reduced the charges to patients with OUD. For example:

- In one key informant's state, co-payments and the cost of the medication had been prohibitive in the past but are now fully covered for patients.
- This key informant emphasized the importance of making treatment affordable, preferably free, for patients. In rural populations with low incomes and high rates of uninsured people, the cost of care can determine an individual's ability to pursue treatment.
- Another key informant in a rural state mentioned Medicaid expansion during the COVID-19 pandemic resulted in coverage of 75% of buprenorphine prescriptions. Medicaid also began paying for methadone and telehealth, which increased access for patients with transportation difficulties.

Key Informant Interviews Summary and Conclusion

The integration of MOUD into primary care settings is a complex but essential endeavor to effectively address the opioid crisis. These key informant interviews highlight several critical themes and challenges in this integration process.

Support from healthcare administration, commitment from champions, and reducing stigma are foundational to successful MOUD integration. Education and ongoing implementation support are necessary to build the knowledge and confidence of primary care providers. Additionally, the challenges and facilitators to implementation are multifaceted. Primary care providers face significant workload pressures and may lack the resources to treat patients with OUD effectively. Increasing and retaining prescribers is vital, as is addressing the low levels of reimbursement for providers. The low-threshold care approach has gained traction, emphasizing the importance of rapid access to medication without upfront burden.

The insights of these key informants underscore the importance of a multi-pronged approach to overcoming stigma, enhancing provider education, and ensuring sustainable integration of MOUD into primary care. As one provider stated, "I can write a prescription. I can save lives. How dare I not?"



V. Synthesis & Recommendations

This synthesis incorporates findings from the environmental scan (comprehensive literature review and key informant interviews), as well as written feedback gathered from the Technical Expert Panel (TEP) on the full Playbook and discussed in a virtual meeting on January 6, 2025. Although other topics emerged during this analysis, these are the most relevant areas to address to ensure the Playbook content is accurate and serves as a practical resource for primary care providers. The topics presented are not in order of priority.

Present the Playbook as an Easy-to-Understand, Non-Intimidating Resource

Key informants and TEP members stressed the importance of simplifying information in the Playbook, especially for new prescribers. Providing too much information, especially for providers who have not yet started providing MOUD, could be overwhelming and may discourage clinicians from treating patients with OUD. Recommendations for modifying Playbook information to make it more accessible are as follows:

- Create a "Quick Start" guide that only includes the essential steps for a provider to get started providing MOUD immediately. Items would include assessing the need for treatment, educating the patient, managing withdrawal, creating a care plan, and other necessary early steps for initiating and engaging a patient in care. The Quick Start guide should be featured prominently at the beginning of the Playbook and linked throughout. The Guide should make it clear that while the remainder of the Playbook contains helpful and actionable information for improving and expanding MOUD treatment and services, using the Quick Start Guide does not create an expectation that providers will go beyond its contents prescribing the medication is the most essential component of treatment and saves lives.
- Significantly reduce the length of the Self-Assessment Checklist and develop it in a manner that indicates to the user where in the Playbook they should begin based on their results. Work with the creators of the <u>IMAT</u> tool, a measure of organizational capability to provide MOUD, to create an adapted version to be used in the Playbook as the Self-Assessment Checklist; this would ensure this tool is populated with previously studied and validated questions to assess readiness.
- Generally, edit and regroup content to be more user-friendly. Currently, many sections of the Playbook are lengthy and dense with text. While the information is valuable, providers should be able to scan it quickly to find what they need. Reducing sections with lengthy paragraphs of text by editing out extraneous information and "chunking" information using bullets, call-out boxes, tables, and infographics is recommended.

Update Treatment Strategies to Reflect the Evolving Opioid Crisis

Major changes have occurred in the landscape of MOUD treatment since publication of the original Playbook; the Environmental Scan elucidated many of these changes and key updates will be made throughout the Playbook, as appropriate. Recommendations include:

- Update substance use trends that have impacted treatment approaches. Notably, the shift from prescription opioids to synthetic opioids, use of stimulants, and polysubstance use has prompted the need for rapid, comprehensive care. The model best suited for implementation in primary care is low-threshold care. The Playbook should emphasize and provide guidance and resources on this evidence-based approach.
- Update terminology and concepts (i.e., MAT to MOUD, clinical terms); clinical information (i.e., new formulations such as injectable forms of buprenorphine, changes in frequency of dosing, etc.); and outdated informational and instructional content.
- Ensure the Playbook content is current, which is critical to its usefulness as a resource. However, trends in substance use disorders and clinical implications are evolving rapidly. As these initial content updates are made it should be considered how best to provide the information to ensure future content updates can be made quickly and easily. For example, when addressing topics where clinical guidelines are changing especially frequently, such as medication formulations and dosing, it may make sense to embed resources that link to the latest guidance rather than build out the information in the Playbook.

Refocus the Playbook to Promote Low-Threshold Care

Low-threshold care as a model for treating patients with OUD in primary care settings has grown in emphasis substantially since publication of the original Playbook. It is celebrated for its patientcentered approach, reducing as many barriers as possible to accessing care, and its emphasis on the urgency of prescribing buprenorphine. In the original Playbook, low-threshold care was only briefly mentioned as a guiding principle in the *Implement MAT for OUD* section, with several sections of the Playbook preceding it. The Playbook content and structure should strongly promote a low-threshold care approach and recommendations for doing so are as follows:

- Emphasize a low-threshold care approach to MOUD as a core message of the Playbook. It is important that we clearly convey that minimizing the demands placed on clients and making services readily available and easily accessible save lives and is not unduly burdensome for providers. Additionally, emphasize that there are external partners available that can provide services beyond the scope or capacity of primary care providers.
- Use the Quick Start Guide to convey that prescribing buprenorphine comes first and is most important. Subsequent sections of the Playbook, through their content and organization, should make it clear that their contents are for improving and expanding MOUD treatment

and services *after* prescribing begins. The contents should proceed from the most basic required elements (Quick Start Guide) to more advanced material (for example, providing whole person care). The recent AHRQ Academy <u>Topic Brief</u> on The Role of Low-Threshold Treatment for Patients with OUD in Primary Care outlines a stepwise approach to MOUD treatment that could serve as a useful model for reorganizing Playbook content from beginner to advanced levels of care.

• Reframe the role of counseling and other psychosocial services as important but not *required* to start treating patients using MOUD. Psychosocial services are a valuable component of OUD treatment; however, the Playbook's priority focus should be to help primary care providers offer buprenorphine to patients. Primary care providers may not have the capacity to address other behavioral health needs. For those interested in expanding their approach beyond medications, the Playbook will contain quality, updated information about the options for integrating other behavioral health treatments into MOUD care, which users can easily access.

Address Stigma as a Barrier to Care

Stigma is one of the greatest barriers to treating patients with OUD, yet the current Playbook includes brief and decentralized information on the topic. Providers need guidance on reducing stigma to implement MOUD care. Recommendations for updating the current Playbook include:

- Feature information in the "Quick Start Guide" about the impact of stigma on MOUD care and how to address it. Integrate information about stigma and links to resources throughout the Playbook.
- Provide training resources for easy, off-the-shelf use. Training is the cornerstone to addressing stigma and foundational topics such as countering misinformation, using non-stigmatizing language, and providing compassionate care can be used broadly within healthcare settings.
- Provide assessment tools clinicians can use to measure stigma. These assessments can be incorporated to evaluate the impact of initiatives or programs designed to reduce stigma, measure the level of stigma in an organization as part of a needs assessment, as an educational and awareness building tool, or as part of a continuous quality improvement program.
- First-hand accounts from clinicians providing MOUD and patients receiving MOUD were noted by key informants as especially powerful in reducing stigma:
- Feature brief case studies from providers committed to this work, including what led them to begin offering MOUD and how they have been personally enriched by the experience of helping people with OUD turn their lives around.
- Feature brief case studies of lived experiences of people with OUD who are in recovery and received help from MOUD.

Design the Playbook as a Hub for Training and Education

Results from the Environmental Scan emphasized the importance of training and education for building knowledge, competence, and confidence, as well as reducing stigma. The TEP made suggestions on enhancing training resources in the Playbook including:

- Provide easy to use materials. Several members of the TEP suggested that providers prefer a limited number (those best supported by evidence) of straightforward tools and resources, including templates with examples, checklists, and reference documents.
- Describe and provide links to validated resources from credible organizations, such as ASAM, SAMHSA, PCSS, etc. at the national-level, and state and local resources, such as those from the ECHO program, technical assistance, and mentoring programs, etc.
- Offer webinars to introduce the Playbook and explain its features.

Describe the Impact of Recent Policy Changes

The most significant policy changes impacting MOUD delivery since the first Playbook was published are the elimination of the X-waiver; changes in telehealth delivery; and the availability of naloxone. Playbook content updates should include updated information on these policy changes as follows:

X-Waiver

- Healthcare providers with a Drug Enforcement Agency (DEA) license can prescribe buprenorphine for OUD and no longer require a special waiver. Current Playbook content on this topic is out-of-date and needs to be updated to reflect current regulations.
- Continuing education training requirements are eight hours of training on opioid or other substance use disorders. Providers do not need to have this training before they begin prescribing but will need to receive it before renewal of their three-year DEA registration.
 Recommended resources to add to the Playbook include <u>SAMHSA's guidance on specific</u> training requirements and links to approved training courses.

Telehealth

• Telehealth provides tremendous potential for primary care providers to treat patients with OUD. Providers can initiate MOUD treatment and prescribe buprenorphine via telehealth, rather than in-person only, making low-threshold care easier to implement. It can reduce patient stigma and is low-burden for providers who may be facing workforce shortages. It improves access to treatment in provider deserts and rural areas; addresses logistical barriers to care (i.e., childcare, transportation); allows patients to be seen confidentially; and

increases efficiency for the provider. A section with information on the evidence supporting telehealth programs for MOUD and integrated care, as well as best practices for establishing a telehealth program, should be added to the Operations and Workflow section of the Playbook.

Naloxone

- Increasing the availability of naloxone in recent years has reduced overdose deaths. Broader public health efforts to distribute it for free or reduced cost have helped improve access. As of 2023, naloxone can be bought over the counter. The current Playbook should update the Introduction to MAT section to include naloxone and include it in the discussion about harm reduction.
- The Playbook should include resources for providers to locate naloxone distribution in their communities and share with their patients, such as the National Harm Reduction Coalition.

Provide Guidance on the Unique Care Needs for Pregnant and Postpartum Women with OUD

The number of pregnant and postpartum women with OUD has significantly increased in recent years and it is important for primary care providers to be knowledgeable of unique treatment recommendations and care needs for this subpopulation. The Playbook includes some information about the special considerations for this subpopulation in the Treatment Approaches section; however, this content requires updating. Recommendations for improving content include:

- Update informational content in the Treatment Approaches section of the Playbook outlining the current recommended guidelines for treating pregnant women with OUD. Providers should be aware that pregnant women with OUD have treatment needs that differ from non-pregnant women, including the risks of withdrawal, risks of opioid exposure to fetuses/infants, and the importance of prenatal and postpartum care.
- Highlight opportunities to encourage recovery. According to a key informant, women with OUD are often more motivated to recover when they are pregnant. Comprehensive care that includes prenatal care, addiction treatment, mental health services, and postpartum support improves outcomes for both mothers and their babies.
- Provide information and resources to help clinicians understand their state's policies on mandated reporting to child protective agencies. Clinicians need to balance providing compassionate care to women who may be distrustful of health care providers and fearful of state agency involvement, and their legal responsibilities.

VI. Conclusion

The environmental scan and feedback from the TEP have highlighted several key areas for updating the MOUD Playbook to ensure it remains a valuable and practical resource for primary care providers. The recommendations focus on simplifying the Playbook to make it more accessible, updating content to reflect changes in the opioid landscape, promoting a low-threshold approach to prescribing MOUD, addressing stigma, enhancing training and education resources, and incorporating recent policy changes. Additionally, special considerations for treating pregnant and postpartum women with OUD have been emphasized. As in the previous version of the playbook, there will also be discussion of other high-risk populations, including those without housing, adolescents, and some minorities. By implementing these updates, the Playbook will better support providers in delivering effective and compassionate care to patients with OUD.



Appendix 1. Methodology for Literature Review and Key Informant Interviews

The environmental scan provided an understanding of how the context of MOUD has changed since the original Playbook was produced and informed the updated content of the Playbook. The revised Playbook will serve as a stand-alone implementation support tool for delivery of MOUD treatment in primary care.

The environmental scan consisted of three components:

- I. Literature Review
- II. Key Informant Interviews
- III. Synthesis and Recommendations

Literature Review Methods

The published literature search strategy was driven by the research questions (provided in the Methodology section) and designed to yield peer-reviewed and other indexed literature, as well as gray literature from Federal and non-Federal sources. Westat librarians developed the search strategy through iterative testing of subject headings and keywords in select databases to identify relevant terms, with feedback from project staff, select NIAC members, and other subject matter experts affiliated with the Academy.

The search strategy was centered on the concepts of interest using an array of search terms related to substances, medication and psychosocial treatment, and care systems and venues, including telehealth. To answer the research questions, the concepts incorporated into the search were focal populations, equity, barriers and facilitators, and models, tools, and resources.

Librarians conducted a comprehensive search for literature published from 1/1/2017-8/31/2024 in PubMed/MEDLINE, CINAHL (Cumulative Index in Nursing and Allied Health Literature), APA PsycINFO®, ASSIA (Applied Social Sciences Index and Abstracts), and Cochrane Central Register of Controlled Trials (CENTRAL).

Search strategy – Grey literature

The grey literature search was informed by the published literature strategy but strategically focused on web-based resources from the federal government, nonprofit organizations, and academia, as well as on MOUD tools. Search results were limited to 2019-2024.



Screening and Data Extraction – Published Literature

The literature search yielded 8,534 peer-reviewed sources. Screening of search results occurred in two rounds of review: (1) title and abstract and (2) full text.

Project staff used the software program Covidence to screen article titles and abstracts for inclusion or exclusion based on pre-determined criteria (Exhibit 1). The sample was narrowed to 450 articles for further analysis. Staff developed a set of keywords based on themes they observed as they screened the large sample of literature (Exhibit 2). They then assigned the keywords to the abstracts as appropriate to group together literature with similar topics and themes. Once sorted, the Project Director extracted the articles from Covidence for the next phase of analysis. Using Microsoft Co-Pilot, an internet-based Artificial Intelligence program, project staff generated brief summaries of individual abstracts categorized by each keyword. Finally, staff reviewed results in keyword groups to identify common themes.

Exhibit 1: Inclusion and Exclusion Criteria

Inclusion Criteria

- Literature within the specified search timeframe.
- Literature focusing on healthcare delivery or workers, or patients within the United States (note: articles that discuss the US as part of a larger analysis that also examines other countries would be in scope).
- Literature that is a peer-reviewed journal article (excluding study protocols), or a reputable grey source: full-text presentations, technical reports, white papers, issue-briefs, or other government-related documents.
- Literature focusing on care related to patients with OUD (excludes surgery, oncology, ophthalmology, etc.) and within primary and other ambulatory care settings (for research questions 3, 4, and 5).
- Literature within scope of the primary research questions: (1) addresses changes in MOUD policy, (2) characterizes changes in the OUD or MOUD environment, (3) addresses changes in approach to MOUD treatment, or (4) describes a model (a framework based on a theory or observation that prescribes a set of tenets or practices), tool (an instrument used to carry out a specific function), or resource (materials used to instruct or guide on a topic) in use to treat people with OUD using medications.

Exclusion Criteria

- Literature outside the specified timeframe.
- Literature focused on industries, workers, or consumers outside of health care.
- Literature focused on countries other than the United States.
- Literature that is a study protocol, not a peer-reviewed journal article, or a reputable grey source: editorials, commentaries, blog posts, letters, and book reviews; conference abstracts/posters with no full-text; proprietary documents; etc.
- Literature focused on care not related to patients with OUD or in care delivery settings other than primary and other ambulatory care settings (for research questions 3, 4, and 5).
- Literature outside of the scope of the primary research questions.

Exhibit 2: Keywords

- Background: articles characterizing the epidemic/problem rates of OUD or overdose, etc.; contributing factors polysubstance abuse, etc.; how things have changed as a result of COVID-19, etc.
- Barriers to treatment: stigma, access (geographical/distance), available providers, childcare, employment, etc.
- Community partners: settings outside primary care emergency department, jails, recovery centers, mobile clinics, etc.
- Workforce/care team: adding new roles recovery coach, peer navigators, pharmacists, etc.; adding new responsibilities to existing roles, etc.
- Special populations: women, maternal health, adolescents, justice involved, LGBTQ+, elderly, specific ethnic groups
- Telehealth: distance appointments with providers
- Medications: different medications and how they are delivered naltrexone, methadone, buprenorphine
- Rural: articles addressing rural populations (should specific rurality in text)
- Digital health: apps, online courses, etc.
- Tool/resource: toolkits, guides, screeners, etc.
- Models/clinical approaches: cognitive behavioral therapy, motivation interviewing, contingency management, group appointments, medication first model, low-barrier care, harm reduction, etc.
- Finance/payment: cost effectiveness, how to pay for MOUD services, etc.

Screening and Data Extraction – Grey Literature

Project staff and the Principal Investigator reviewed the results of the grey literature results, which consisted of federal grey literature, non-federal grey literature, and tools and resources, following the inclusion and exclusion criteria used for the published literature review (Exhibit 1). Project staff organized the included sources into a spreadsheet, reviewed each one, wrote a brief description for each, and assigned relevant keywords from the same list used for the published literature (Exhibit 2).

Inclusion and Exclusion Criteria – Tools and Resources

Tools and resources that were identified during the literature review and included in the tracking sheet were compared to the existing Academy Substance Use (SU) and Unhealthy Alcohol Use (UAU) Tools & Resources Collections to note if the item already exists in those collections. The list was reviewed and discussed by the larger MOUD Playbook research team and decisions made about what to include in each collection. Decisions about what to include were made according to the Inclusion and Exclusion Criteria detailed in Exhibit 3.



Exhibit 3: Inclusion and Exclusion Criteria – Tools & Resources

Inclusion Criteria

- Identified tools and resources from credible sources. Credible sources are the established, trusted, respected authors and organizations in the field.
- Identified tools and resources that are not already included in the Substance Use or Unhealthy Alcohol Use Tools and Resources collections.
- **Note:** The best-supported tools and resources on a topic, as determined by the research team and subject matter experts (utilizing TEP members and outside consultants, as appropriate) will be highlighted in the updated Playbook; this applies to new resources identified in the environmental scan, as well as existing resources in the Substance Use Tools and Resources collection.

Exclusion Criteria

- Identified tools and resources that are not from credible sources.
- Identified tools and resources that are already available in the Substance Use or Unhealthy Alcohol Use Tools and Resources Collections.

Tools and Resources.

There were 173 tools and resources identified in the literature review, which staff compiled into a results table. Staff reviewed each resource to determine if it was already in the Academy's Substance Use (SU) or Unhealthy Alcohol Use (UAU) Tools and Resources Collections. After the team verified resources already in those collections, they created a list of the remaining resources. The new resources were then uploaded to the website. The types of resources added to the collection included screeners, training materials, guides for clinicians on different facets of MOUD, and regulatory documentation.

Key Informant Interview Methods

We conducted nine virtual, semistructured interviews with subject matter experts (SMEs). This supplementation had two objectives: (1) providing context to areas in the current Playbook identified as deficient by the project staff, and (2) providing context to understudied areas of the literature. After reviewing the MOUD literature and noting its major themes and limitations, the project team reviewed the current Playbook and identified what would benefit from expert feedback and reached out to potential interviewees, accordingly. Many of the areas that emerged as major themes in the literature review were found to be missing from or underdeveloped in the Playbook. To supplement the available evidence, key informants offered their perspectives as frontline subject matter experts. We aimed for diverse perspectives on the most important themes relevant to integrating MOUD into primary care practice.

Identification and Recruitment of Key Informants

Key informants included primary healthcare providers, experts in integrated behavioral health implementation, researchers, and policy experts. We identified and recruited key informants

through professional networks, including individuals with pre-existing relationships with AHRQ, the AHRQ Academy, Technical Expert Panel (TEP) members, and the National Integration Academy Council.

Key Informant Interviews

Interview questions for each key informant were drafted by the Principal Investigator and project staff, as well as tailored to the interviewee's background and provided before the meeting. A flexible set of questions allowed for a dynamic conversation driven by participant responses. Interviews were conducted using Microsoft Teams by the Principal Investigator and project staff. All key informants agreed to be recorded and were assured their responses would remain anonymous in the Environmental Scan Report, and any subsequent deliverables to reduce social desirability bias and protect their confidentiality. Interviews lasted approximately an hour and both the recordings, and the transcripts produced by Microsoft Teams, were stored on Westat's secure server.

Analysis and Summary of Key Informant Responses

Transcripts for each interview were reviewed for errors and corrected. A senior researcher who helped conduct interviews analyzed each interview transcript. Analysis was a multi-step process. After an initial read, the researcher reviewed the transcript again, highlighting passages relevant to themes and questions posed by the research questions, as well as unique responses to questions that drew from the informant's area of expertise. The researcher then transferred the text to a new document, organizing it according to themes, making annotations, and summarizing the main findings. The senior researcher discussed the main themes with the Principal Investigator and Project Director and continued to share and discuss findings throughout the co-writing of the report.

Inclusion of Technical Expert Panel Feedback

Simultaneously with the key informant interviews, the Technical Expert Panel (TEP) individually reviewed the Playbook in its entirety, provided individual written feedback on strengths and weaknesses, gaps, and recommendations, and met as a group to discuss their thoughts. Written feedback and notes from the meeting transcript were consolidated and summarized into main themes by research staff.

Synthesis and Recommendations

The research team reviewed results from the literature review, key informant interviews, and TEP feedback all together to develop recommendations for Playbook updates and additions. The group met several times to review the main findings from all stages of the environmental scan and re-reviewed sections of the current Playbook to further refine our recommendations before writing a summary report.

Appendix 2. Medications for Opioid Use Disorders

The Food and Drug Administration has approved three medications to treat opioid use disorder: buprenorphine, methadone, and naltrexone. In addition, naloxone is an emergency antidote for opioid overdose, which is available without a prescription.

Buprenorphine is a Schedule III opioid medication that can be prescribed by any provider with a DEA license. Those who do not have a DEA license can apply for one without any special training.

Buprenorphine is a partial opioid agonist, so it does not fully activate the opioid receptors. Therefore, it results in less euphoria or breathing problems. Buprenorphine still involves some risk of misuse or lethal overdose when combined with other substances. To lessen the risks of misuse or diversion, providers often prescribe a medication that combines buprenorphine with naloxone, an antagonist that blocks opioid receptors when injected intravenously. If these buprenorphinenaloxone combination products are taken properly as an oral tablet or as a film placed under the tongue (sublingual) or inside the cheek (buccal), the naloxone is not absorbed through the lining inside the mouth or digestive tract. However, if someone tries to inject or snort the medication, the naloxone will become bioavailable (i.e., activated) and they will go into withdrawal.

Different modes of administration provide flexibility to tailor treatment to the individual patient's needs. For example, long-acting buprenorphine injections can allow treatment to be delivered weekly, monthly, or every eight weeks (for low-dose maintenance), which can improve adherence. These injections can be beneficial to all persons with OUD but may be particularly ideal for individuals being released from an emergency room or from jail.

Naltrexone is an antagonist that blocks opioid receptors. This medication prevents the rewarding effects and euphoria from any opioids in the brain. Unlike methadone and buprenorphine, naltrexone cannot be used to manage symptoms of opioid withdrawal, but it can help with craving. Because it is an opioid antagonist, starting this medication requires abstinence from all opioids to prevent triggering a severe opioid withdrawal episode. If given before resolution of withdrawal, it may worsen withdrawal symptoms. There are no restrictions on the setting or qualifications to prescribe naltrexone as it does not carry a risk for misuse or overdose.

Methadone is an agonist medication. It is important to understand the benefits of methadone as you may need to refer patients to this treatment modality based on the complexity of their OUD. Methadone for treatment of OUD can only be prescribed in certified opioid treatment programs (OTPs). To find an OTP near you, see <u>State Opioid Treatment Authorities (SOTA) | SAMHSA</u>

The table below compares the different pharmacotherapy options for MOUD.

Name	Mechanism of Action	Forms	Uses	Typical Dosage	Restrictions
Methadone	Agonist	Oral tablet, Liquid	Withdrawal & treatment	Daily (60-120mg) for tablet or liquid	Dispensed in opioid treatment programs
Buprenorphine (e.g., Subutex, Sublocade, Brixadi)	Partial agonist	Sublingual tablet, Buccal/ sublingual film, Injection (extended-release)	Withdrawal & treatment	Daily tablet (<6-24mg) or film, Injection: Weekly (8- 32mg) Monthly (64-300mg)	DEA licensed provider
Buprenorphine/ naloxone (e.g., Suboxone, Zubsolv, Bunavail)	Partial agonist	Sublingual tablet, Buccal/ sublingual film	Withdrawal & treatment	Daily Dosage differs by brand buprenorphine/ naloxone)	DEA licensed provider
Naltrexone (e.g., ReVia, Vivitrol, Depade)	Antagonist	Oral tablet, Injection (IM)	Treatment	Monthly injection (380mg)	None

Naloxone is a life-saving medication that can be used in an emergency to reverse an overdose. It is available over the counter and online without a prescription. Persons with OUD, those using opioids to manage chronic pain, and others who spend time with people from these populations are encouraged to carry naloxone for safety.

Name	Mechanism of Action	Forms	Uses	Typical Dosage	Restrictions
Naloxone (e.g., Narcan,	Antagonist	Nasal spray, Injection (IM, SQ)	Reverse opioid overdose	As needed Nasal spray (4-10mg),	None
Rezenopy, Evzio, Kloxxado, RiVive,				Injection (5mg/0.5ml, can give multiple)	
LifEMS Naloxone,					
Zimhi)					



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