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# Addressing opioid use disorder: The role in pharmacotherapy barriers

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**Abstract--Background:** The opioid epidemic in the United States has escalated significantly since the early 2000s, leading to a dramatic increase in opioid-related fatalities and the spread of infectious diseases among users. Despite the availability of three FDA-approved medications for opioid use disorder (OUD), access remains severely limited due to various barriers. **Aim:** This paper aims to analyze the pharmacotherapy barriers affecting the treatment of OUD and propose strategies for addressing these challenges to enhance access to care. **Methods:** A comprehensive review of recent peer-reviewed literature was conducted to identify financial, regulatory, geographic, and attitudinal barriers influencing the delivery of pharmacotherapy for OUD. The analysis involved examining Medicaid coverage, the impact of federal regulations, and the distribution of treatment programs across urban and rural settings. **Results:** Findings indicate significant financial obstacles, including inadequate Medicaid coverage and pre-authorization requirements, which hinder access to treatment. Regulatory constraints, such as limits on prescribing waivers for buprenorphine, further exacerbate these issues. Geographic disparities were also noted, with rural areas lacking sufficient treatment options and healthcare providers. The study emphasizes the urgent need for policy reforms to reduce these barriers and improve treatment accessibility. **Conclusion:** Expanding access to pharmacotherapy for OUD is critical in combating the opioid crisis. Addressing financial, regulatory, and geographic barriers through comprehensive policy changes can enhance the efficacy of treatment programs and ultimately reduce the incidence of opioid-related harm.

**Keywords---**opioid use disorder, pharmacotherapy barriers, medicaid coverage, regulatory constraints, geographic disparities.

## Introduction

Since the early 2000s, the prevalence of heroin use and the non-medical consumption of prescription opioids in the USA has risen, particularly among predominantly non-urban, white populations [1, 2]. This growing epidemic has contributed to a 200% increase in opioid overdose fatalities between 2000 and 2014, culminating in 28,647 deaths in 2014 alone [3]. The rise in opioid injection practices has also heightened concerns regarding the transmission of HIV and HCV infections [4].

Currently, three FDA-approved medications are available for the treatment of individuals diagnosed with opioid use disorder (OUD) [5]. Methadone, an opioid agonist, is administered exclusively through specially regulated Opioid Treatment Programs (OTPs). It has been extensively studied and proven in clinical trials to be more effective than non-pharmacological treatments in maintaining patients in therapy and reducing heroin use [6]. Buprenorphine, a partial opioid agonist, is accessible through both OTPs and physicians who have completed an 8-hour approved training or hold a specialized addiction board certification and have obtained a federal "waiver" [7]. Clinical trials indicate that buprenorphine outperforms placebos in retaining patients in treatment and reducing illicit opioid use [8]. Evidence suggests that both agonist medications are linked to a decreased risk of overdose from illicit opioids [9–14]. Additionally, naltrexone, an opioid antagonist available in oral and extended-release injectable forms (XR-NTX), has a duration of effect lasting approximately 30 days. A clinical trial conducted in Russia demonstrated that XR-NTX was more effective than placebo injections in reducing illicit heroin use [15], while an open-label trial in the USA found it superior to standard treatment (without medication) for reducing illicit opioid use among adults involved with the criminal justice system [16]. Unlike methadone and buprenorphine, naltrexone is not subject to specific regulatory restrictions.

Increasing access to pharmacotherapy for OUD is a crucial component of the broader effort currently underway in the USA to combat the opioid crisis [17]. There remains a significant gap between the number of individuals requiring OUD treatment and the availability of agonist medications [18]. In fact, the majority of OTPs in the nation are operating at 80% or more of their capacity, and even if all buprenorphine-waivered physicians in the USA were at full capacity, more than one million individuals would still be left without access to treatment [18]. As of 2014, among the 14,152 treatment facilities in operation in the USA, only 9% were OTPs, 23% provided buprenorphine, and 14% offered XR-NTX [19]. Although not all individuals with OUD will seek treatment or opt for medication-based therapies, there are waiting lists at some OTPs [20]. There is an urgent need to expand access to pharmacotherapy, but several barriers, including financial, regulatory, geographic, attitudinal, and logistical factors, hinder treatment expansion. This paper aims to present an updated analysis of these barriers based on recent peer-reviewed research.

## **Financial Barriers**

In the United States, treating opioid use disorder (OUD) with medications is primarily available through a robust fee-for-service delivery system dominated by the private, for-profit sector. Approximately half of the nation's Opioid Treatment Programs (OTPs) operate as for-profit organizations [21]. Access to treatment in these programs is generally feasible if they are within commuting distance and if the patient can either pay out-of-pocket or has insurance accepted by the program. For individuals unable to pay out-of-pocket, government-subsidized grants and insurance programs may be available, though the extent of coverage varies significantly across different states. Financial barriers to providing pharmacotherapy for OUD persist [22, 23] and affect both opioid agonist and antagonist treatments.

Medicaid, a federal health insurance program for low-income individuals and those with disabilities, plays a critical role in funding OUD treatment [24–26]. However, states have considerable discretion in determining eligibility for Medicaid, the substance use treatments it will cover, and the specific medications included, along with the rates and restrictions applicable to those treatments. In 2006, four years after the approval of buprenorphine for OUD treatment, state Medicaid program coverage of the medication was significantly linked to its use in outpatient programs [22]. Between 2004 and 2013, the number of states covering both methadone and buprenorphine under Medicaid increased from 21 to 32. However, as of 2013, five states did not cover either medication, or eight did not include methadone in their Medicaid programs [27].

The absence of Medicaid coverage for opioid agonist treatment can render this therapy inaccessible for low-income individuals unless supported by the federal Substance Abuse Prevention and Treatment (SAPT) block grant [28, 29] or local funding sources [23]. A study by Saloner and colleagues [30] examined how Medicaid and SAPT block grant funding for methadone influenced treatment utilization among Medicaid recipients. After adjusting for demographic and substance use history variables, it was found that 17% of OUD-diagnosed Medicaid patients received methadone treatment in states without block grant or Medicaid coverage, 30% in states with block grant coverage, and 45% in states where Medicaid covered the treatment. These findings highlight the critical need to address barriers to treatment, especially in states severely affected by the opioid crisis that have not expanded Medicaid under the Affordable Care Act, or in those that expanded Medicaid but excluded methadone from coverage [30].

Although Medicaid expansion and OUD pharmacotherapy coverage reduce access barriers, they are insufficient. Policies of Medicaid managed care companies can still impede access. For instance, Burns et al. [27] reported a threefold increase in the requirement for pre-authorization for buprenorphine treatment, along with other changes such as the implementation of copayments and the requirement for counseling beyond what is provided by the physician. Pre-authorization requirements can deter physicians from offering treatment due to delays and administrative complexities. Copayments can place treatment out of reach for some patients, while mandatory additional counseling increases the burden on patients, who may not desire or have access to these services. Notably, a study by

Hutchinson and colleagues [31] of family practitioners in rural Washington State found that the most commonly cited barrier to providing buprenorphine was the lack of available counseling, which the state's Medicaid program required as part of the treatment. Importantly, research has not consistently demonstrated clinical benefits from adding counseling to buprenorphine treatment beyond the medical management provided by the prescribing physician [32–34].

In the context of an intervention to promote the use of opioid treatment medications within health plans and associated treatment programs in three Mid-Atlantic states, Alanis-Hirsh and colleagues [35] collected qualitative data from key personnel at treatment centers, health plan managers, employees of the manufacturer of extended-release injectable naltrexone (XR-NTX), and their technical assistance contractors. Similar to the findings for buprenorphine, this study identified several payer policy barriers to XR-NTX treatment. Some payers required prior authorization for XR-NTX, while others mandated that patients "fail" non-medication treatments before approving the medication. Additionally, some insured patients faced prohibitive costs due to high copayments or deductibles, with the retail cost of XR-NTX around \$1,200 per monthly dose (excluding provider fees), making it inaccessible for uninsured patients. Unexpectedly, providing XR-NTX can also be financially challenging for providers when health plans require them to purchase the medication for a specific patient before administration. These plans permit providers to invoice the health plan only after administering the medication. This arrangement exposes providers to financial risk if the medication goes unused or if the health plan refuses reimbursement.

### **Regulatory Restrictions**

In the U.S., physicians who wish to treat opioid use disorder (OUD) with buprenorphine (but not for pain management) face several regulatory requirements. Physicians must either hold an addiction specialty board certification or complete an 8-hour training course on OUD treatment to be eligible to apply for a waiver to prescribe buprenorphine. Nurse practitioners and physician assistants are also allowed to prescribe the medication after completing a more extensive course. However, even after receiving the waiver, prescribers face limitations on the number of patients they can treat. During the first year of obtaining the waiver, physicians are restricted to treating only 30 patients, and after that period, they may treat up to 100 patients. This restriction differs significantly from other countries, such as France, where any licensed physician can prescribe buprenorphine without specific training requirements, leading to a significant increase in treatment availability and a reduction in overdose deaths [9]. Molfenter and colleagues [23] identified this federal cap on patient numbers as a barrier to expanding treatment access in Ohio. At the time of their study, waived physicians were limited to 30 buprenorphine patients in their first year and up to 100 patients afterward [7]. However, a 2016 rule change now allows waived physicians, under certain conditions, to treat up to 275 patients, which may help address capacity challenges in some regions [36].

Opioid treatment programs (OTPs) in the U.S. are also subject to strict federal and state regulations, along with local zoning laws. Zoning restrictions, influenced by

political and community attitudes, can limit the establishment of new treatment programs or restrict the number of patients a program can serve. Some of these zoning laws have been found to be discriminatory under the Americans with Disabilities Act (ADA) [37]. Moreover, federal and state regulations require counseling to accompany opioid agonist treatments like methadone, which can create waiting lists if there is a shortage of available counselors. However, federal regulations do permit interim methadone treatment, allowing patients to receive methadone without counseling while they wait for more comprehensive treatment. Research has shown that this approach is more effective than waiting lists alone in terms of treatment entry and reducing illicit opioid use [38, 39].

Innovative approaches are also being tested to overcome regulatory barriers. For instance, Sigmon and colleagues [20] piloted a program using interim buprenorphine, administered through a computerized device that released one dose daily for self-administration at home. Patients only needed to visit the clinic bi-weekly, and they reported daily using an interactive voice response system. The pilot showed high adherence rates, acceptability, and a high number of negative urine drug screenings. Further research is underway to explore the potential of such strategies.

### **Geographical Barriers**

Geographic barriers significantly affect access to opioid treatment programs (OTPs) and buprenorphine-waivered physicians in the U.S. Recent studies have explored the relationship between geographic location and the availability of these physicians, revealing disparities in access across different regions [40]. Knudsen [41] conducted a nationwide study to assess the supply of buprenorphine-waivered physicians based on state macro environments, healthcare resources, and the demand for opioid use disorder (OUD) treatment. By the end of 2013, 23,629 U.S. physicians had waivers to prescribe buprenorphine, with 29% authorized to treat up to 100 patients. There was an average of 8.0 waived physicians per 100,000 people, with higher concentrations in the Northeast compared to other regions. Multivariate regression analysis indicated that states with better Medicaid coverage and more OTPs or drug treatment programs had higher rates of waived physicians. States with higher rates of opioid overdose deaths also had more waived physicians, suggesting that the medical community may be responding to local public health needs, though other factors like financing might also play a role.

Stein and colleagues [43] used data from SAMHSA and the U.S. Census between 2008 and 2011 to examine the number of waived physicians by county. While the mean number of physicians per county increased from 4.8 in 2008 to 7.0 in 2011, this growth was unevenly distributed. In 2008, over half of U.S. counties had no waived physicians, although this percentage declined to 43.4% by 2011. Furthermore, the distribution of waived physicians remained uneven, indicating that many counties still have limited access to OUD treatment. This study also found that counties in states with Medicaid or other state funding for buprenorphine treatment had the highest rates of waived physicians, underscoring the importance of financial support for expanding access to treatment.

### **Geographic Barriers Cited by Physicians in Rural Areas**

Physicians in rural areas face multiple challenges in prescribing buprenorphine, which limits access to treatment for opioid use disorder (OUD). Key barriers include a lack of institutional support, concerns about patient load, and affordability issues for patients [44, 45]. This is particularly significant due to the uneven distribution of buprenorphine-waivered physicians and the scarcity of opioid treatment programs (OTPs) in rural regions. Understanding these barriers is crucial for expanding OUD treatment in less populated areas. Hutchinson and colleagues [31] conducted a study in rural Washington State, finding that family physicians who either did not apply for the waiver or did not prescribe buprenorphine after training reported barriers such as insufficient office support, time constraints, low confidence in treating OUD, and resistance from colleagues. Another study by DeFlavio et al. [46] surveyed 108 family physicians in New Hampshire and Vermont, where the majority (97) were not prescribing buprenorphine. The top barriers cited were inadequate staff training (88%), lack of time (80%), and insufficient reimbursement (52%).

### **Attitudinal Barriers**

Negative attitudes toward pharmacotherapy, particularly opioid agonist treatment, further impede the use of buprenorphine. These attitudes are prevalent among various groups, including physicians, criminal justice professionals, individuals with OUD, and even treatment providers [35, 47–53]. In a qualitative study conducted in Ohio, county board leaders and addiction treatment providers who expressed negative views about opioid agonist treatment were found to prescribe buprenorphine less frequently than those with more favorable attitudes, even when additional funding was available [23]. Similarly, philosophical opposition to extended-release naltrexone (XR-NTX) in some substance abuse treatment programs in Washington State was identified as a barrier to its use [35].

### **Attitudinal Barriers**

Many individuals with opioid use disorder (OUD) find themselves within the criminal justice system, yet pharmacotherapy remains underutilized in this context [54] [47]. A particularly troubling practice in U.S. jails involves discontinuing opioid agonist treatment, such as methadone, for individuals who are receiving such therapy at the time of their arrest. This interruption poses a significant risk, as it increases the likelihood of relapse and overdose following release [55]. In fact, a randomized trial demonstrated that individuals whose methadone treatment was maintained during detention were more likely to return to treatment upon release compared to those whose treatment was interrupted [55]. This fear of treatment disruption has even been cited by opioid-addicted individuals as a reason to avoid entering treatment in the first place [56] [57].

Drug courts have grown in influence across the U.S., with 2,734 operational courts by 2012 [58]. These courts, which aim to offer a therapeutic alternative to incarceration, are in a unique position to facilitate treatment, but the reality is more complex. A representative survey of drug court coordinators and

administrators revealed significant barriers to opioid agonist treatment within these systems. Half of the respondents indicated that opioid agonist medications, such as buprenorphine and methadone, were not available under any circumstances, and only 40% allowed participants already receiving such treatment to continue it [59].

The barriers to buprenorphine use cited by drug courts included cost (43%), clients being withdrawn from illicit opioids before entering the court (42%), a lack of providers (41%), and court policies (40%). Similarly, methadone treatment faced obstacles due to court policies (52%), provider recommendations (49%), and concerns about potential diversion (36%) [59]. These barriers are particularly surprising given that drug courts were designed as therapeutic interventions. The restrictions likely reflect broader attitudinal issues within the criminal justice and treatment systems, where some providers or court staff may lack knowledge or support for the use of FDA-approved, evidence-based medications [6] [8]. A survey by Matusow et al. found that over 40% of non-physician drug court staff acknowledged that buprenorphine and methadone reduce relapse, but an equally large percentage expressed uncertainty [59]. This suggests a substantial opportunity for educating drug court personnel on the effectiveness of these medications in treating OUD.

### **Logistical Barriers**

Logistical barriers to receiving pharmacotherapy often arise from a combination of regulatory restrictions, financial limitations, lack of awareness about treatment options, and issues related to medication formulation, particularly extended-release naltrexone (XR-NTX). For intravenous heroin users, a population that could benefit significantly from treatment, logistical barriers are especially concerning. Previous studies have explored ways to engage needle exchange participants in methadone treatment [60–62]. Fox et al. [63] interviewed 93 participants in New York who had heard of buprenorphine to identify perceived barriers. Of those, 51% reported not knowing where they could access treatment, while other obstacles included lack of money (33%) and transportation issues (28%). Notably, individuals who had used illicit buprenorphine were significantly more likely to not know where to seek treatment, though 83% of this group expressed a strong willingness to enter buprenorphine treatment if offered through the needle exchange program.

While buprenorphine faces logistical barriers, XR-NTX encounters even more significant hurdles, despite not having regulatory constraints. According to Alanis-Hirsh et al. [35•], treatment staff, health plan managers, and others highlighted several challenges with XR-NTX, including its need to be stored and shipped under refrigerated conditions. Additionally, the medication requires a complex preparation process that involves warming, mixing, and injecting the dose in a limited timeframe, which sometimes leads to patients leaving before receiving the treatment. Another significant obstacle is the required 7–10 days of opioid abstinence prior to administering XR-NTX to avoid precipitated withdrawal, a difficult requirement to meet, especially on an outpatient basis. Insurance companies are often hesitant to approve extended residential stays to facilitate this abstinence period.

Newer approaches have been tested to address these logistical barriers, such as rapid induction processes for XR-NTX. One promising method by Sullivan and colleagues involved giving a single dose of buprenorphine, followed by gradual daily doses of oral naltrexone, leading to successful initiation of XR-NTX 7 days sooner than traditional methods [64, 65]. This rapid induction process could help specialty providers overcome a critical logistical barrier to the use of XR-NTX.

## **Conclusion**

The current opioid epidemic in the USA underscores the critical need to reduce the regulatory, geographical, attitudinal, and logistical barriers that hinder prompt access to effective pharmacotherapies such as methadone, buprenorphine, and naltrexone. Addressing a single barrier is often insufficient to improve access; for example, providing block grant funding may not overcome geographic barriers if the number of potential patients is too small to support an opioid treatment program (OTP) economically.

Access to pharmacotherapies varies by state, particularly for low-income populations. States that did not expand Medicaid under the Affordable Care Act or do not cover methadone treatment through Medicaid or block grants restrict care for these groups [30••]. Private for-profit OTPs tend to serve those who can afford care, leaving behind indigent populations [66]. Even in states with Medicaid coverage, restrictive managed care policies, such as preauthorization and copayments, can still limit access to pharmacotherapy [27••]. Financial barriers could be addressed by expanding Medicaid, covering all three medications for opioid use disorder (OUD), reducing administrative hurdles by managed care organizations, and using federal block grants to fill funding gaps. Methadone and buprenorphine face unique regulatory barriers. Unlike naltrexone, which can be prescribed by any licensed medical practitioner, methadone treatment for OUD is only provided through licensed OTPs, which must also offer counseling, urine testing, and direct methadone administration. The scarcity of OTP counselors often results in waiting lists, although interim methadone treatment could help manage the wait [38]. Rural access to OTPs is further limited by travel challenges and high costs. In contrast, many countries allow primary care physicians to prescribe methadone, with medication dispensed through pharmacies [67]. The USA permits similar models through "medication units" attached to OTPs, which could improve access in rural areas [68].

Buprenorphine has fewer regulatory constraints, but federal training requirements and patient caps on physicians who prescribe it remain barriers. Unlike prescribing more lethal opioids for pain, buprenorphine is subject to patient limits, although recent expansions and the inclusion of nurse practitioners and physician assistants may alleviate some barriers. New formulations, such as implantable buprenorphine, may also help overcome logistical challenges, especially in rural areas. Physicians in rural regions often report a lack of confidence in treating OUD, despite training [31], but mentorship programs such as those provided by the American Academy of Addiction Psychiatrists might help address this concern [69]. Negative attitudes toward OUD medications are another barrier, particularly among proponents of 12-step



recovery programs, which often advocate for abstinence-based approaches. Misconceptions about the effectiveness of medications can be addressed through education and training, which is particularly important in the criminal justice system, where many individuals with OUDs receive supervision. Ultimately, overcoming these barriers is crucial to addressing the opioid epidemic. Expanding access to the three FDA-approved medications—methadone, buprenorphine, and naltrexone—can reduce the epidemic's adverse impact on public health.

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## معالجة اضطراب تعاطي الأفيون: الدور في عقبات العلاج الدوائي

### الملخص:

**الخلفية:** تفاقم وباء الأفيون في الولايات المتحدة بشكل كبير منذ أوائل العقد الأول من القرن الحادي والعشرين، مما أدى إلى زيادة كبيرة في حالات الوفاة المتعلقة بالأفيون وانتشار الأمراض المعدية بين المستخدمين. على الرغم من توفر ثلاثة أدوية معتمدة من إدارة الغذاء والدواء لعلاج اضطراب تعاطي الأفيون (OUD) ، إلا أن الوصول إليها لا يزال محدودًا بشدة بسبب عقبات متعددة. **الهدف:** يهدف هذا البحث إلى تحليل العقبات المتعلقة بالعلاج الدوائي التي تؤثر على علاج اضطراب تعاطي الأفيون واقتراح استراتيجيات لمعالجة هذه التحديات لتعزيز الوصول إلى الرعاية.

**الطرق:** تم إجراء مراجعة شاملة للأدبيات الحديثة التي تمت مراجعتها من قبل الأقران لتحديد العقبات المالية والتنظيمية والجغرافية والسلوكية التي تؤثر على تقديم العلاج الدوائي لعلاج اضطراب تعاطي الأفيون. شملت التحليل فحص تغطية Medicaid ، وتأثير اللوائح الفيدرالية، وتوزيع برامج العلاج عبر المناطق الحضرية والريفية.

**النتائج:** تشير النتائج إلى وجود عقبات مالية كبيرة، بما في ذلك عدم كفاية تغطية Medicaid ومتطلبات الموافقة المسبقة، مما يعيق الوصول إلى العلاج. كما أن القيود التنظيمية، مثل الحدود المفروضة على تصاريح وصف البوبرينورفين، تزيد من تفاقم هذه المشكلات. لوحظت أيضًا التفاوتات الجغرافية، حيث تفتقر المناطق الريفية إلى خيارات علاج كافية ومقدمي الرعاية الصحية. تؤكد الدراسة على الحاجة الملحة إلى إصلاحات سياسية لتقليل هذه العقبات وتحسين إمكانية الوصول إلى العلاج.

**الختاتمة:** إن توسيع الوصول إلى العلاج الدوائي لعلاج اضطراب تعاطي الأفيون أمر حاسم في مكافحة أزمة الأفيون. يمكن أن يعزز معالجة العقبات المالية والتنظيمية والجغرافية من خلال تغييرات سياسية شاملة فعالية برامج العلاج ويقلل في نهاية المطاف من حدوث الأضرار المتعلقة بالأفيون.

**الكلمات الرئيسية:** اضطراب تعاطي الأفيون، عقبات العلاج الدوائي، تغطية Medicaid ، القيود التنظيمية، التفاوتات الجغرافية.