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Issues in Access to Opioid Treatment Medication

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Issues in Access to Opioid Treatment Medication

Introduction

The “Opioid Crisis” is a bit of a misnomer. That there was a single peak in opioid abuse in American History is false; in fact, abuse of opioids has had many faces ranging from types of opiate drugs to opioid replacement medications, the dependency upon which has ebbed and flowed in ongoing waves that the American government, medical professionals, and insurance companies combat to this day. A more apt description of this social phenomenon is perhaps the opioid epidemic. The terminology surrounding opioid dependency is always bound by some temporal limit, however, opioid dependency remains an ongoing problem that has not seen any significant resolution to date.

Real social cognizance of opioids as a problem to acknowledge and target emerged in the early 1970’s, with the adoption of the Controlled Substances Act, which classified types of opioids and regulated them according to their classification.¹ However, large-scale addiction to opioids dates back to the civil war era, when soldiers became dependent on the morphine their pain was treated with.² This highlights a key aspect of the phenomenon that is the opioid epidemic: much of addiction historically and continually buds from medicinal uses of opioids, and an ongoing effort to market new forms of opioids (from morphine, to heroin, to oxycodone) as “safer” to use for temporary medicinal purposes.³ As a result, we are met in the modern day with a conundrum. If opioid

¹ <https://www.georgetownbehavioral.com/node/2013>

² <https://www.georgetownbehavioral.com/node/2013>

³ <https://www.georgetownbehavioral.com/node/2013>

replacement medications are a provenly effective means to combat opioid addiction, how must they be regulated so as to not advance the cycle of treatment and dependency on treatment? This conundrum is in turn met with the social and economic realities of modern American society; access to healthcare and treatment can be inherently classist, and with a large percentage of opioid users being of the lower working class, opioid treatment in the form of replacement therapy is at an apparent road block. Road blocks preventing access to opioid treatment medications come in many forms, some through marketing schemes, others present in legislation, and most exist in exorbitantly long application processes required by insurance providers and medical professionals, which by their nature isolate certain communities of whom are the largest percentage of opioid users.

A Look into the Past and Present of Opioid Addiction and Treatment

After morphine was introduced in the 1860's as a means to treat wounded civil war soldiers, dependency quickly became a problem, spiraling into mass addiction. According to Journal of the Civil War Era, "*Opium Habit*, published in 1868, Horace B. Day estimated that 80,000 to 100,000 Americans were addicted to opium."⁴ This was the largest and first real drug epidemic to strike America.⁵ "Maimed and shattered survivors from a hundred battle-fields," Horace B. Day wrote, "diseased and disabled soldiers released from hostile prisons, anguished and hopeless wives and mothers, made so by the slaughter of those who were dearest to them, have found, many of them, temporary relief

⁴ <https://www.journalofthecivilwarera.org/2016/11/civil-war-veterans-opiate-addiction-gilded-age/>

⁵ <https://www.journalofthecivilwarera.org/2016/11/civil-war-veterans-opiate-addiction-gilded-age/>

from their sufferings in opium.”⁶ The addiction wasn’t contained to the soldiers and quickly spread to society at large. At the bud of opiate addiction, the majority of consumers and abusers proved to be mostly Southern, white individuals.⁷

In 1898, Bayer Company, now a pharmaceutical giant, introduced heroin into mainstream commerce where it was largely marketed and regarded as a “wonder drug.”⁸ With its commercial accessibility, heroin became widely abused, especially when people realized its effects were maximized by injection.⁹ This incited a federal response that came in the form of The Harrison Narcotics Act which taxed the importing, producing, distributing, and dispensing of narcotics.¹⁰ This marked a developing social awareness to the addictive nature of narcotics and opiates, and so developed the stigma against users as doctors refused to treat those addicted to narcotics.¹¹ In 1924, heroin was finally outlawed.¹²

The 70’s were notorious for drug consumption, with cultural markers like Woodstock and a later punk and early grunge era glamorizing the use of many drugs, ranging from psychedelics to narcotics. The 70’s was the start of a major opioid epidemic, which morphed into a crack epidemic in the 80’s and reared its head once again in the 90’s when Purdue Pharma began testing and finally released OxyContin in 1996.¹³

⁶ Horace B. Day, *The Opium Habit* (New York: Harper & Brothers, 1868), 6-7

⁷ Id.

⁸ <https://www.cnn.com/2016/05/12/health/opioid-addiction-history/index.html>

⁹ Id.

¹⁰ https://www.journalofthecivilwarera.org/2016/11/civil-war-veterans-opiate-addiction-gilded-age/#_ftn5

¹¹ Ibid.

¹² Id.

¹³ <https://www.cnn.com/2016/05/12/health/opioid-addiction-history/index.html>

Marcia L. Meldrum, PhD, writes on Purdue Pharm's OxyContin that "Purdue's aggressive marketing of its controlled-release opioid Oxycontin as safe for chronic pain intersected with the trafficking of cheap, very pure heroin in smaller cities across the West, Midwest, and Appalachia. Purdue advertised OxyContin as nonaddictive because the drug was released within the body over 12 hours; recreational users quickly learned to get high by crushing or dissolving the pills, or simply taking very high doses."¹⁴ Existing evidence shows that individuals at greatest risk for prescription opioid overdose include:

- White and American Indian/Alaska Native people
- Men (although overdose among women is on the rise)
- People living in rural areas (clusters in the Southeast—especially in the Appalachian region)
- Adults aged 45-54 years
- People who obtain multiple controlled substance prescriptions (especially the combination of opioid analgesics and benzodiazepines) from multiple providers
- People who take high daily dosages of opioid pain relievers¹⁵

The National Capital Poison Center and Poison Control reports of the 90's that "during this time, pharmaceutical companies also began to promote the use of opioids in patients with non-cancer related pain even though there was a lack of data regarding the risks and benefits in these patients. By 1999, 86% of patients using opioids were using them for non-cancer pain. Communities where opioids were readily available and prescribed liberally were the first places to experience increased opioid abuse and diversion (the transfer of opioids from the individual for whom they were prescribed, to

¹⁴ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4940677/>

¹⁵ https://aspe.hhs.gov/system/files/pdf/107956/ib_OpioidInitiative.pdf

others, which is illegal)”¹⁶ This eventually led to a slew of public and legal backlash against the Sackler family, who control Purdue Pharma and were blamed for much of the addiction and death resulting from OxyContin marketing.

The New York Times writes of “lawsuits filed by the attorneys general of Massachusetts and New York,” cases which “lay out the extensive involvement of a family that has largely escaped personal legal consequences for Purdue Pharma’s role in an epidemic that has led to hundreds of thousands of overdose deaths in the past two decades,” after years of investigation.¹⁷ The Sackler family involvement in profiting from addiction took a sickening form in the mid-2000’s, a new business endeavor called “Project Tango.” Details of Project Tango emerged from the Massachusetts and New York attorneys general lawsuits. “Pain treatment and addiction are naturally linked,” one Project Tango document, included in the New York complaint (*The People v. Purdue Pharma*, linked herein), said. It depicted a big blue funnel. The fat end was labeled “pain treatment”; the narrow end was labeled “opioid addiction treatment.” The company, the document said, could make money at both ends of the funnel as an “end-to-end pain provider.”¹⁸

The prospect that the Sackler family, with an estimated 13 billion dollars in personal fortune, could profit off replacement medications that address the addiction and mortality risk they’ve allegedly caused is chilling.¹⁹ The New York Times reports that

¹⁶ <https://www.poison.org/articles/opioid-epidemic-history-and-prescribing-patterns-182>

¹⁷ <https://www.nytimes.com/2019/04/01/health/sacklers-oxycontin-lawsuits.html?section=Health>

¹⁸ *Id.* (quoting, *The People of the State of New York v. Purdue Pharma* at https://ag.ny.gov/sites/default/files/oag_opioid_lawsuit.pdf)

¹⁹ *Id.*

“Since OxyContin came on the market, more than 200,000 Americans have died of overdoses related to prescription opioids.” A 2001 email included in the documents in the Massachusetts case catches Richard Sackler stating “we have to hammer on abusers in every way possible... they are the culprits and the problem. They are reckless criminals.”²⁰

The stigmatization of users and abusers as criminal or untreatable echoes the 20’s rhetoric when doctors refused to treat narcotics users. There is a sort of cycle where opioids are marketed and distributed by providers and companies, but users are then criminalized for problems developed from misuse of those very products. The vacuum between them is a major social issue, and the gaslighting of American society and opioid-addicted individuals themselves to reframe their victimhood as controlled criminal actions serves as a barrier to treatment. This is not to say that there are no treatment options available for users and abusers of opioids. In fact, there are a number of methods ranging from rehabilitation programs to replacement drugs meant to wean individuals off of the drugs. However, access to such treatment proves to be complex, between economic barriers, system guideline barriers, and a low morale amongst users.

Treatment Options and Replacement Medications

Attempts to curb the epidemic and prevent opioid-related deaths took on many structural forms. Adoption of Prescription Drug Monitoring Programs (“PDMP”), allowed for healthcare providers to closely monitor their patients’ use of prescribed opioids, including tracking other providers’ prescriptions to their patients. Because

²⁰ <https://www.nytimes.com/2019/04/01/health/sacklers-oxycotin-lawsuits.html?section=Health>

PDMPs are computer programs, they are highly efficient, relatively affordable, and can allow interstate monitoring of patients.²¹ Interstate monitoring can not only allow protection of individuals but helps in preventing cross-state trafficking of prescription opioids.²² This method, however, only helps to identify high risk individuals.²³ The introduction of opioid-specific guidelines for individuals with chronic pain also helps medical providers by establishing dosage requirements and caps. Although little research is available as to the benefit of these guidelines, it reflects a systemic effort to combat opioid abuse.²⁴

One of the most provenly effective methods to combatting the opioid epidemic is Medication-assisted Treatment, or MAT. Mat includes the use of medications to slowly decrease opioid and other substance intake amounts and rates with the goal of both reducing overdose and death and slowly rehabilitating addicts.²⁵ MAT is often combined with other rehabilitative measures like counseling and therapy and is more a process for recovery assisted by medication than a simple replacement, as is often assumed. “Studies have shown that the most effective treatments for opioid use disorders are those that include a set of comprehensive medical, social, psychological and rehabilitation services that address all the needs of the individual.” The medications most commonly used in MAT are buprenorphine, methadone, and extended-release naltrexone (which, in its non-extended-release form, is also used to reverse the effects of opioid overdose).²⁶ These

²¹ https://aspe.hhs.gov/system/files/pdf/107956/ib_OpioidInitiative.pdf (“What Works”)

²² Id.

²³ Id.

²⁴ Id.

²⁵ Id.

²⁶ Id.

medications work by precipitating withdrawal symptoms to avoid relapse. Although many studies indicate that MAT is an effective, if not the most effective, treatment method for opioid users, it is only used by approximately 1 out of 2.5 million Americans who would benefit from it.²⁷ This beckons the question of why more people don't use this method if it's one of the best.

The first reason is the risk of diversion. Because medications like buprenorphine and methadone work to combat withdrawal symptoms, and in fact are used by a majority of users for therapeutic purposes, they are regarded as "replacing" opioid alternatives, the dependence on which is often actually an avoidance of withdrawal symptoms.²⁸ They, therefore, are feared to pose a risk of dependency. The fear is essentially that people who previously misused opioids (misused meaning used outside of prescribed methods and amounts or without prescription) may find themselves leaning heavily on medications like buprenorphine and methadone in ways they would have their opioids.

However, reports show that most patients being treated for opioid addiction do not rank buprenorphine as their "primary drug of misuse."²⁹ There is a minority percentage of individuals (about 8-25%) who misuse buprenorphine, a minority that has been decreasing over time as a result of buprenorphine's dissimilar, less rewarding effects.³⁰

²⁷ Id. at Page 6

²⁸ Bazazi AR, Yokell M, Fu JJ, Rich JD, Zaller ND. Illicit use of buprenorphine/naloxone among injecting and noninjecting opioid users. *J Addict Med.* 2011;5(3):175-180. doi:10.1097/ADM.0b013e3182034e31

²⁹ National Institute on Drug Abuse, quoting Cicero TJ, Surratt HL, Inciardi J. Use and misuse of buprenorphine in the management of opioid addiction. *J Opioid Manag.* 2007;3(6):302-308.

³⁰ Id.

Most fear of diversion has to do with methadone, which has higher rates of overdose. However, these rates correlate directly to the purpose of the prescription: most people who overdose on methadone are being prescribed methadone for pain, *not* as a form of substance abuse treatment.³¹ The individuals who use methadone as part of their MAT plan make up the stark minority of those who overdose or showcase diversion symptoms.³²

Access to Treatment

A. Who's Addicted and How MAT Medications are Classified by Medicaid

According to the National Institute on Drug Abuse, an estimated 2.1 million people in the United States had a substance use disorder related to prescription opioid pain medicines in 2016.³³ However, only about 17.5 percent of people with prescription opioid use disorders received specialty treatment.³⁴ So who are the individuals who currently have substance abuse disorder and are addicted to opioids?

“According to the NSDUH, of the 10 States with the highest reported rates of past year nonmedical pain reliever use within the total population aged 12 or older, 7 out of 10 were in the Western region of the United States (Arizona, Colorado, Idaho, Nevada, New Mexico, Oregon, and Washington). And, of the States with the lowest rates of past year nonmedical pain relievers, 4 were in the Midwest region (Illinois, Iowa, North Dakota, and South Dakota). Within states and regions, illicit use of pain relievers differs

³¹ Centers for Disease Control and Prevention (CDC). Vital signs: risk for overdose from methadone used for pain relief - United States, 1999-2010.

³² *Id.*

³³ <https://www.drugabuse.gov/publications/research-reports/medications-to-treat-opioid-addiction/overview>

³⁴ *Id.*

substantially by the urban/rural characteristics of the population in the state/region. Interestingly, NSDUH respondents in smaller metropolitan areas reported the highest rate of illicit use of pain relievers (5.4%), while rural areas reported the lowest rate of use (3.5%). However, research studies that focus specifically on adolescents have suggested that for this at-risk population group use rates of illicit pain relievers are higher in rural areas.”³⁵

According to the Nation Institute on Drug Abuse,

- Roughly 21 to 29 percent of patients prescribed opioids for chronic pain misuse them.
- Between 8 and 12 percent develop an opioid use disorder.
- An estimated 4 to 6 percent who misuse prescription opioids transition to heroin.
- About 80 percent of people who use heroin first misused prescription opioids.
- Opioid overdoses increased 30 percent from July 2016 through September 2017 in 52 areas in 45 states.
- The Midwestern region saw opioid overdoses increase 70 percent from July 2016 through September 2017.
- Opioid overdoses in large cities increase by 54 percent in 16 states³⁶

Although no one is immune to the addictive quality of opioids, the largest increase in overdose deaths affects relatively young people, particularly men, from their 20s to 40s.³⁷ “Fringe metro and micropolitan areas see the highest rates of addiction and death. The states with highest rates of death fall mostly on the eastern side of the US – New

³⁵ https://www.asam.org/docs/default-source/advocacy/aaam_implications-for-opioid-addiction-treatment_final

³⁶ <https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis>

³⁷ <https://www.rehabspot.com/opioids/opioid-epidemic/>

Hampshire, West Virginia, Massachusetts, and Ohio.”³⁸ The large majority of those impacted by addiction and overdose from opioids are white, working class people, and this is perhaps because white people are more readily prescribed medications for pain.³⁹ “Medicine has a long, unsavory history of expecting people of color to tolerate larger levels of pain,” said Dr. Steven Woolf of Virginia Commonwealth University. Since a large percentage of those addicted to opioids’ addiction began with prescription pain killers, which are often prescribed to individuals with chronic pain, the demographic makes some sense with Dr. Woolf’s comments in mind. Another contributor may be implicit physician biases that white individuals may be less likely to “abuse” drugs or engage in criminal acts, like distributing drugs to others, and a greater willingness to entrust those individuals with more addictive substances.

Although a large percentage of those suffering from substance abuse disorders actually go untreated, those who are treated tend to be covered by Medicaid and Medicare (government affordable care programs) because of their socioeconomic status. Medicaid programs tend to vary by state, however they have historically proven to pose various barriers in access to MAT and other treatments. While most states have chosen to provide some type of addiction treatment under Medicaid, many have taken a long time to (and still do not) reflect modern effective means of treatment, like MAT.⁴⁰

³⁸ <https://www.rehabspot.com/opioids/opioid-epidemic/>

³⁹ Kaiser Health News: <https://khn.org/morning-breakout/how-unconscious-physician-biases-about-race-ethnicity-and-pain-plays-a-role-in-the-opioid-crisis/>

⁴⁰ https://www.asam.org/docs/default-source/advocacy/aaam_implications-for-opioid-addiction-treatment_final

Additionally, regional improper use of opioids, particularly prescription opioids, correlates to the associated geographic need for healthcare in the form of MAT and other forms of substance abuse treatment.⁴¹ “It is also worth noting that even amongst addicted individuals who are employed or have substantial incomes, as opioid dependence progresses, those incomes may cease and subsequently these once-covered or self-pay addicted patients may have to rely on public funding including Medicaid in order to access addiction treatment and health care if they can.”⁴²

Where Medicaid programs may cover forms of treatment and counseling, there are an array of rules and criteria that must be met in order for medication or treatment services to be covered.⁴³ Opioid dependence treatment coverage in particular (especially in the form of MAT) demands a strict criteria be met, including “documented patient compliance with counseling.”⁴⁴

Historically, coverage has been limited to detoxification and short-term rehabilitation of those suffering from substance abuse disorders.⁴⁵ However, some common medications used to treat substance abuse disorders have found their way into the Medicaid market, though in ways that limit their actual availability.⁴⁶ Methadone, for example, though included in many Medicaid plans is often not fully covered.⁴⁷ Additionally, “medicaid coverage of buprenorphine is usually as a pharmacy benefit,

⁴¹ Id.

⁴² Id.

⁴³ Id.

⁴⁴ Id. at page 7.

⁴⁵ Id.

⁴⁶ Id.

⁴⁷ Id.

either under Medicaid FFS or via Medicaid managed care plans contracted with the state Medicaid agency.”⁴⁸

Injectable Naltrexone, on the other hand, is treated as a “medical benefit” not a “pharmacy benefit.” Medical Benefits include physician-administered and/or injectable medications, while pharmaceutical benefits are usually patient-administered. Because of this, many Practitioners are not aware of injectable naltrexone’s existence because it is not listed as a pharmaceutical benefit. This poses a few issues; since injectable Naltrexone is the primary medication used to treat on-spot overdose, it is essential for those who may be verging on opioid addiction. With the rates of addiction to use being so high, it would make sense to have access to the antidote to the poison, so to speak. However, many recipients may not have both types of coverage which limits their access from the already limited selection of the three main medications used in MAT, and further limits ability to treat any potential overdose symptoms.

B. Lock-In Programs; A Barrier or a Tool?

Lock-In programs was established within the last decade or so by the Division of Medical Services as a means to keep individuals from excessive intake of opioid-replacement drugs.⁴⁹ The way it works is a patient is “locked-in” to a particular pharmacy or provider who can monitor their medication consumption and make sure it doesn’t exceed usual amounts. While Lock-In programs at face value seem to be geared towards

⁴⁸ Id.

⁴⁹ Executive Office of Health and Human Services, <http://www.eohhs.ri.gov/ProvidersPartners/ProviderManualsGuidelines/MedicaidProviderManual/Pharmacy/PharmacyLock-InProgram.aspx>

protecting individuals from becoming addicted to the MAT medications, they also serve to curb diversion, or pharmacy-hopping for the purpose of selling the opioid replacements. However, they also serve to identify individuals at risk for abusing MAT medications and restrict their access to those medications.⁵⁰ “For years, states have been establishing and augmenting effective “lock-in” programs that require Medicaid enrollees who are “at-risk” for misusing or abusing opioids to use only one pharmacy and/or get prescriptions from only one medical office. The Comprehensive Addiction and Recovery Act of 2016 (CARA) provides CMS with the authority to allow Medicare Part D plans to implement similar pharmacy and prescriber lock-in programs. For both Medicaid programs and Medicare Part D plans, lock-in programs are an additional tool to promote better coordination between providers and beneficiaries who meet the guidelines for lock-in.”⁵¹ However, the computerized process does not detract from the exorbitant amounts of documentation and criteria that must be met, and the strict rules placed on individuals. The lock-in program can result in denial of medication to beneficiaries, or denial of medications for circumstantial reasons like pregnancy (which may not be negatively impacted by the use of MAT medications, and in fact can have much better results on pregnancy than cold-turkey withdrawal). Regardless of the algorithm for lock-in

⁵⁰ U.S. National Library of Medicine National Institutes of Health, Evaluation of a Medicaid Lock-in Program: Increased Use of Opioid Use Disorder Treatment but No Impact on Opioid Overdose Risk, Naumann RB.

⁵¹ <https://www.hhs.gov/about/agencies/asl/testimony/2018-04/tracking-opioid-and-substance-use-disorders-medicare-medicaid-hhs-programs.html>

programs, there will always be outliers who are misjudged as at-risk, and denied access to much needed medication.

C. Pre-Authorization: The Biggest Barrier

One of the most significant barriers to access to opioid-treatment medications is the Pre-Authorization Process required by many Medicaid programs. Currently, approximately 44 states require pre-authorization for the 3 FDA approved opioid treatment drugs, Buprenorphine, Methadone, and Naltrexone.⁵² Pre-authorization is essentially a process required by Medicaid programs prior to administration of opioid replacement or treatment drugs (MAT medications). The pre-authorization process differs from state to state depending on its Medicaid program, and some Pre-Authorization programs require a counseling program or session prior to issuance of the MAT medication. Issues arise when that same Medicaid program that requires counseling for Pre-authorization or reauthorization would offer minimal counseling coverage.⁵³ The counseling and other Pre-Authorization measures often require extensive detail and document submission.⁵⁴ The process, whether or not counseling is involved, often takes a number of weeks to process, which is time precious to at-risk patients who may suffer relapse, overdose, or even death in that time.⁵⁵

⁵² Id.

⁵³ https://www.asam.org/docs/default-source/advocacy/aaam_implications-for-opioid-addiction-treatment_final

⁵⁴ Id.

⁵⁵ Id.

The American Society of Addiction Medicine writes on injectable Naltrexone, “. . . if the injectable naltrexone is covered as a Medicaid pharmaceutical benefit. . . adjudication and approval of the medication is much more rapid and electronic, often taking 24 hours or less if requirements (edits) are met. However, substantial prior authorization requirements may also be embedded in the electronic approval process. Counseling may be dealt with separately under medical benefits. Documentation of "patient is enrolled in approved substance use disorder therapy" may also be required during preauthorization and repeated in reauthorization in order for the treatment plan and the medication involved to be approved.”⁵⁶ Even in attempts to expedite the approval process for medications such as injectable Naltrexone, the pre-authorization elements remains a time-consuming variable. Furthermore, where Naltrexone may be listed as a medical benefit rather than a pharmaceutical one, access would be subject to a whole separate prior authorization process through the practitioner, medical group, or hospital, since the medication would not be available on a drug list.⁵⁷ “The data available from the survey and from secondary sources indicate that 20 states require prior authorization for injectable naltrexone, 11 states do not appear to require prior authorization and 20 states had no information available on prior authorization requirements for this alcohol and opioid dependence medication as a component of addiction treatment”⁵⁸

The American Society of Addiction Medication, partnered with NIDA (National Institute on Drug Abuse), SAMHA (Center for Substance Abuse treatment of the Substance Abuse and Mental Health Services Administration), ONDCP (Office of

⁵⁶ Id.

⁵⁷ Id.

⁵⁸ Id.

National Drug Control Policy), and OASH (Office of the Assistant Secretary for Health of the US Department of Health and Human Services) write an astute analysis regarding preauthorization as a barrier. In its project, AMSAM includes the following sample pre-authorization form:

“Injectable naltrexone (Vivitrol) may be approved for the prevention of relapse to opioid dependence following detoxification when the individual:

1. Is being treated for opioid dependence; AND
2. Has had an initial response and tolerates oral naltrexone (Revia) but is unable to comply with daily dosing; AND
3. Has successfully completed an opioid detoxification program; AND
4. Has been opioid-free (including buprenorphine and methadone) for at least 7 days prior to initiating treatment with naltrexone (Vivitrol) injection; AND
5. Actively participates in a comprehensive rehabilitation program that includes psychosocial support; AND
6. Patient has none of the following:
 - a. Currently on opioid analgesics for pain management; OR
 - b. Currently in acute opioid withdrawal;
 - c. A positive urine screen for opioids; OR
 - d. A failed naloxone challenge test; OR
 - e. Acute hepatitis;

f. Liver failure; OR

g. Previous hypersensitivity to naltrexone, 75:25 polyactide-co-glycolide (PLG), carboxymethylcellulose or any other component of the diluent.”

Of particular interest here is the utterly equivocal language used. That pre-authorization “may” be approved, should applicant “successfully” meet requirements shows that meeting the elements is discretionary depending on the program, administration method, location, and other subjective variables, and that even should the applicant be deemed “successful,” they “may” nonetheless be denied authorization. This is emphasized when “in describing preauthorization the plan states ‘[p]reauthorization requirements are subject to change at any time and without notice’ and “[i]f preauthorization for a particular service or treatment is denied, you may be held financially responsible for the expense of the test, equipment, service or procedure.”⁵⁹ The very nature of the pre-authorization form denies the reality of the applicant, who is as discussed prior, most likely working-class fringe-metro or otherwise rurally located, may not have the financial or other means to meet these requirements in any real sense. To be specific, issues that may present like lack of transportation to facilities in a more metropolitan area, whether the rehabilitation programs are covered by applicant’s insurance, whether applicant can afford co-pay for these programs, all serve to isolate the typical pre-authorization applicant or one who would need MAT the most.

Access to Buprenorphine seems to be no different. “The results of [the] survey [conducted by ASAM] and information obtained from secondary sources indicate that 21

⁵⁹ Id.

states require a physician to certify that a patient either is attending or plans to attend counseling in order for a prior authorization for buprenorphine to be approved. At least another 9 states require very specific documentation of that counseling to be submitted, sometimes including requirements about who provides the counseling and whether or not that counseling is to be only by state approved counselors.” The extensive documentation process requires multiple doctors’ appointments and follow-ups, and is ultimately up to a physician’s discretion whether or not to certify. The extensive documentation process for counseling, and then transfer of those documents to the physician in charge, takes a lot of time from both the physician and the patient. This is time that is invaluable to the patient, who throughout the process, remains in need of treatment and assistance and can be at risk for relapse, overdose, and even death.

Time proves to be a repeated, overarching issue, regardless of the medication/MAT sought. If the applicant does not meet the criteria for pre-authorization at the time, they are forced to schedule an appointment for rehabilitation or psychological counseling which can take weeks, or wait the seven days without using opioids (a crucial time for relapse that can result in overdose or death). This does not account for the time it will take the form itself to process. The pre-authorization itself is time-sensitive, and there are periods for reauthorization for applicants. This means that many of the steps taken must be repeated each reauthorization period.

However, there is some hope. Many organizations and legislative forces are working to urge Medicaid programs to drop preauthorization altogether, or expedite the process as is more prevalent in commercial insurance programs. The AMA (American Medical Association) has proposed a bill modeled on Pennsylvania’s, where Governor

Tom Wolf removed pre-authorization for MAT and persuaded outside insurers to do the same.⁶⁰ “In addition to removing prior authorization for MAT in Medicaid and the commercial markets, the AMA model bill requires MAT to be on the lowest cost-sharing tier, extends MAT protections to correctional settings and includes provisions to strengthen oversight and enforcement of mental health and substance-use disorder parity laws.”⁶¹ This improvement would serve to reduce time wasted and resources between physicians and patients.

Additionally, “the President’s FY 2019 Budget includes a proposal that would require state Medicaid programs to cover all FDA-approved MAT for OUD, including associated counseling and other costs. These up-front investments in expanded MAT treatment are expected to reduce total Medicaid expenditures over time as more individuals recover from OUD; this provision would result in an estimated \$865 million in savings over ten years.”⁶² Hopefully, with an economic incentive in place as well, we may see a lean towards an adoption of some of AMA’s proposed goals.

Also, “under current law, states are able to implement lock-in requirements for enrollees who have utilized Medicaid services at a frequency or amount that is not medically necessary, according to guidelines established by the state. These limitations may be imposed for “a reasonable period of time.” Almost all Medicaid agencies have a

⁶⁰ <https://www.ama-assn.org/advocacy/patient-advocacy/quick-take-moves-cut-barriers-opioid-use-disorder-treatment>

⁶¹ <https://www.ama-assn.org/advocacy/patient-advocacy/quick-take-moves-cut-barriers-opioid-use-disorder-treatment>

⁶² <https://www.hhs.gov/about/agencies/asl/testimony/2018-04/tracking-opioid-and-substance-use-disorders-medicare-medicaid-hhs-programs.html>

Lock-In or Patient Review and Restriction Program in which the state identifies potential fraud or misuse of controlled drugs by a beneficiary.⁶³ While the lock-in programs don't cut out the documentation barriers, they will most likely save a lot of money as a more efficient, computerized method.

Strategies targeting opioid dependency and previous policy regarding MAT access have been cropping up in the past five years across many sources.

“According to The U.S. Department of Health and Human Services,

In April 2017, HHS outlined its five-point Opioid Strategy, which provides the overarching framework to leverage the expertise and resources of HHS agencies in a strategic and coordinated manner. The comprehensive, evidence-based Opioid Strategy aims to:

- Improve access to prevention, treatment, and recovery support services to prevent the health, social, and economic consequences associated with opioid addiction and to enable individuals to achieve long-term recovery;
- Target the availability and distribution of overdose-reversing medications to ensure the broad provision of these drugs to people likely to experience or respond to an overdose, with a particular focus on targeting high-risk populations;

⁶³ <https://www.hhs.gov/about/agencies/asl/testimony/2018-04/tracking-opioid-and-substance-use-disorders-medicare-medicaid-hhs-programs.html>

- Strengthen public health data reporting and collection to improve the timeliness and specificity of data and to inform a real-time public health response as the epidemic evolves;
- Support cutting-edge research that advances our understanding of pain and addiction, leads to the development of new treatments, and identifies effective public health interventions to reduce opioid-related health harms; and
 - Advance the practice of pain management to enable access to high-quality, evidence-based pain care that reduces the burden of pain for individuals, families, and society while also reducing the inappropriate use of opioids and opioid-related harms.⁶⁴

With these efforts from AMA encouraging doctors to affect legislation and giving them the tools to do so, the presidential budget changes in 2019, and a few states spearheading the change in their Medicaid policies, there seems to be a bit of a turn for the more positive. At the very least, there appears to be a renewed social awareness to the paradoxical nature of preauthorization, and a less stigmatized regard for MAT overall.

⁶⁴ <https://www.hhs.gov/about/agencies/asl/testimony/2018-04/tracking-opioid-and-substance-use-disorders-medicare-medicaid-hhs-programs.html>

Pennsylvania as an Example

Pennsylvania was and remains one of the highest-risk states when it came to opioid addiction, overdose, and fatality. In the past five years alone, Pennsylvania has been ranked one of the top 5 states with the highest opioid-induced fatality rates.⁶⁵ In fact, Pennsylvania declared the opioid crisis a state of emergency only about two years ago which was described as one of the worst crises in the country.⁶⁶ The crisis is ongoing.⁶⁷ However, the state has made and is continuing to make active effort towards changing how opioid addiction is dealt with on a systemic level. “The state has gotten more people into treatment, they said, and lowered a key barrier that has long kept people with addiction from medication-assisted treatment, the “gold standard” of addiction treatment. It’s also begun, slowly, to expand access to those treatments to the state’s inmates, who are particularly vulnerable to substance-use disorder, and relapse and overdose upon their release.”⁶⁸ The state initiated a drug-treatment hotline, which received over 15,000 calls within its first year of operation, and almost half of whose callers were immediately connected with treatment.

One of the more groundbreaking achievements occurred just about a year ago when the state of Pennsylvania eliminated the Pre-authorization process for

⁶⁵ <https://www.philly.com/philly/health/addiction/dea-fatal-ods-rose-37-across-pa-in-2016-20170608.html>

⁶⁶ <https://www.philly.com/health/opioid-crisis-update-progress-pennsylvania-overdoses-addiction-20190107.html>

⁶⁷ Id.

⁶⁸ Id.

MAT medications under Medicaid altogether.⁶⁹ The widespread Medicaid change prompted for-profit insurance companies to do the same, with many dropping prior authorization for MAT medications to be able to compete with Medicaid.⁷⁰

“In addition to removing this unnecessary restriction on treatment, insurers have also committed to including a comprehensive range of medications to treat substance use disorders on the lowest cost-sharing tier of a health plan’s pharmacy benefit as part of this agreement.”⁷¹ Additionally, since then, Pennsylvania has opened almost fifty more treatment facilities specific to opioid users to help coordinate help and treatment.⁷² “Before these “centers of excellence” opened, about 48 percent of such patients were receiving addiction treatment. Now, 70 percent of that population has sought addiction treatment, and 60 percent stayed in treatment past 30 days.”⁷³ This is a significant improvement, and Pennsylvania is now directing its focus to ensuring that those who receive treatment continue on the road to recovery.⁷⁴

Pennsylvania serves as an example of what lifting the prior authorization requirement has done and the effect it can have if adopted nationwide. ““With this requirement lifted for a preferred buprenorphine agent, significantly less administrative time is spent completing forms, attaching chart notes and compiling results to submit to insurance companies, as well as monitoring when prior authorizations need to be

⁶⁹ Id.

⁷⁰ Id.

⁷¹ <https://www.ama-assn.org/press-center/press-releases/pennsylvania-removes-prior-authorization-opioid-treatment>

⁷² Id.

⁷³ Id.

⁷⁴ Id.

renewed,' [David O'Gurek, M.D., of Philadelphia] told *AAFP News*. And time saved translates to lives saved.

'For every delay, every lack of completion of review in the timeframe, every fax that apparently got lost and was never received,' O'Gurek said, 'individuals struggling with opioid-use disorder were at risk for relapse, overdose or death.'"⁷⁵

Prior authorization is one of many barriers in access to one of the most provenly effective treatments of a crisis that has faced America for decades. Dating back to before the civil war, opioids have always been a concern. It is only now that we have the tools to effectively treat those who suffer addiction or dependency. With a little attention to continuing health and recovery in individuals and less time spent on paperwork and authorization, which can isolate those who need the treatment the most, states with high fatality rates may see some change.

⁷⁵ <https://www.aafp.org/news/government-medicine/20181120pennpriorauth.html>