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Medication-Assisted Treatment (MAT) Regulation in the United States

Introduction

The United States is facing an almost unprecedented public health crisis: an epidemic of overdose deaths related to opioid use disorder (OUD).[i] OUD is a chronic brain disease that is associated with a 20-fold greater risk of early death by infectious disease, trauma, overdose, and suicide.[ii] According to the U.S. Department of Health and Human Services, approximately 2 million Americans have an OUD.[iii] An alarming 47,800 people died from an opioid overdose in 2019 in the United States.[iv] This equates to more than 130 opioid-related deaths each day.[v]

Modern medicine has developed a set of effective tools to address the opioid epidemic: medication-assisted treatment (MAT), a treatment method that combines behavioral therapy and medication to treat substance use disorders.[vi] While these medications save lives, MAT is severely underused throughout the nation, as the majority of people with OUD in the United States receive no treatment. This is due to a number of factors, including a series of intensive regulations and policies, such as waiver requirements, patient limits, and restrictions on settings. These stringent regulations and policies are not supported by evidence or employed for other medical disorders.[vii] Withholding or failing to provide MAT in any care or criminal justice setting is denying appropriate medical treatment.[viii]

MAT Regulatory Overview

There are three medications commonly used to treat opioid addiction: methadone, buprenorphine, and naltrexone, each of which are described in more detail in Appendix A. Under federal law, methadone (with limited exceptions) can only be used in opioid treatment programs (OTPs) certified by the Substance Abuse and Mental Health Services Administration (SAMHSA).[ix] MAT for opioid addiction is subject to federal law, most notably 42 CFR 8.[x] The regulations preserve states' authority to regulate OTPs.[xi] Although most states do not stray far from the federal requirements and baselines, almost every state has enacted legislation regulating the operation of OTPs.[xii] For example, federal law does not set a mandatory patient to counselor ratio within OTPs, but some states do require such a ratio, with most states requiring one counselor for every fifty patients.[xiii] Further, a growing number of states require a central registry of OTP patients, something that is not required by federal law.[xiv] Additionally, many states, and some cities, regulate the location of OTPs through zoning restrictions and proximity provisions.[xv]

The Drug Addiction Treatment Act (DATA) of 2008 (Public Law 106-310) amends 21 USC 823(g) and permits physicians who meet certain qualifications to treat opioid dependence with FDA-approved narcotics in treatment settings other than OTPs.[xvi] This law effectively provides a waiver from the registration requirements of the Narcotic Addiction Treatment Act.[xvii] Specifically, a practitioner may obtain a waiver to dispense narcotic drugs in Schedule III, IV, or V in an office-based setting, if the practitioner meets the conditions enumerated in the law.[xviii] These conditions include board certifications, eight hours of approved training in the treatment of opioid addiction, a capacity to provide the patient with the FDA-approved medications and appropriate counseling, and a 30-patient limit during the first year of the waiver.[xix] This law has paved the way for buprenorphine, a Schedule III drug, to be prescribed by physicians both in OTPs and in office-based settings for physicians who go through the regulatory steps to obtain the waiver.[xx] The Comprehensive Addiction and Recovery Act of 2016

further authorizes qualifying nurse practitioners and physician assistants to prescribe buprenorphine for the treatment of opioid dependency if they complete at least 24 hours of additional specified training and are licensed to prescribe Schedule III medications with the appropriate state-required supervision from a qualified physician.[xxi]

MAT in Correctional Facilities

In 2004, 13.1% of state prisoners and 9.2% of federal prisoners reported regularly using heroin or other opiates prior to incarceration, compared to less than 1% of the general population.[xxii] Incarcerated individuals also have a significantly higher risk of death from drug overdose post-release and a higher risk of recidivism, among other problems. Despite these high opioid addiction rates and risks, the majority of these addicted prisoners receive very limited treatment or are not treated at all while incarcerated.[xxiii]

Despite being the most common MAT, only approximately half of all United States prisons offer methadone, and most of these prisons only offer methadone treatment to a very small number of inmates under limited circumstances (i.e. many prisons that offer methadone only offer it to pregnant women).[xxiv] A literature review of the results from methadone maintenance treatment studies indicates that methadone treatment while incarcerated has the potential to increase substance use treatment engagement post-release and decrease illicit opioid use post-release and has the potential to reduce some health risk behaviors such as intravenous drug use and syringe sharing.[xxv]

MAT and COVID-19: Federal Response

In response to COVID-19, the federal government has implemented changes to their MAT regulation. SAMHSA issued guidance allowing OTPs to increase access to 28-day, take-home supplies of methadone for all stable OTP patients, not just those meeting the previous requirements. Additionally, OTPs may now allow access to a 14-day, take-home supply for less stable patients if it is determined to be safe – an allowance that required a year of treatment prior to the COVID-19 guidance.[xxvi] Additional guidance outlines the process for methadone receipt for OTP patients who are quarantined or in isolation through surrogate take-home pick-up or "doorstep delivery."[xxvii]

Further, the Office of Civil Rights announced that it would waive potential HIPAA violations against health care providers for using non-HIPAA compliant communication technologies during the pandemic. However, patients who are just entering methadone treatment are still required to appear for in-person visits during COVID-19 as take-home medication is still not permitted for patients in short-term or interim treatment.[xxviii] Already existing patients, and those initiating buprenorphine treatment, are allowed to have OTP visits over telemedicine, including phone appointments.[xxix]

Conclusion

Regulatory and legal barriers prevent broad access to MAT for individuals with OUDs.[xxx] Methadone is the most stringently regulated of the FDA-approved medications, while buprenorphine and extended-release naltrexone are also highly regulated. Confronting and changing these barriers is required to properly confront the opioid crisis ravaging communities across the nation.

Appendix A

MAT Medications

Methadone is an opioid agonist that is administered orally and is the most common MAT medication in both community and correctional settings. Methadone maintenance treatment has been shown to reduce opioid withdrawal symptoms and cravings, increase substance use treatment engagement and retention, reduce illicit opioid use, reduce criminality and recidivism, and reduce both fatal and nonfatal opioid overdoses.[xxxi] Under federal law, methadone (with limited exceptions) can only be dispensed at a SAMHSA-certified OTPs, which are regulated by the Drug Enforcement Agency (DEA).[xxxii] Patients must receive the medication under the supervision of a physician, and following a period of stability, patients may be allowed to take methadone at home between program visits. These rules require two years of OTP enrollment to receive a month's worth of take-home medication.[xxxiii]

Buprenorphine is a Schedule III synthetic opioid treatment medication.[xxxiv] Through DATA 2000, qualified physicians can offer buprenorphine prescriptions to treat opioid dependency in various settings, including OTPs, community hospitals, health departments, correctional facilities, and physician offices.[xxxv] The Comprehensive Addiction and Recovery Act of 2016 further amended 21 USC 823(g) by authorizing qualifying nurse practitioners and physician assistants to prescribe buprenorphine for the treatment of opioid dependency.[xxxvi] To qualify, nurse practitioners and physician assistants must (1) be licensed under state law to prescribe Schedule III, IV, or V medications for the treatment of pain; (2) complete at least 24 hours of specified training; and (3) if required by state law, be supervised by or work in collaboration with a physician who is qualified to prescribe buprenorphine.[xxxvii]

Naltrexone is an unscheduled medication and non-narcotic opioid treatment used in MAT to treat both opioid and alcohol use disorders.[xxxviii] It has no abuse or diversion potential, so it can be prescribed in all settings by any practitioner with prescribing authority.[xxxix] Detoxification from opioids must be completed at least one week before the extended-release injectable (most commonly, Vivitrol) can be used to treat opioid dependency.[xl] It is often not recommended for use as an opioid dependence treatment, however, due to issues with patient compliance.[xli]

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[vi] *Medication-Assisted Treatment*, SAMHSA, available at https://www.samhsa.gov/medication-assisted-treatment. Medication-assisted treatment is also referred to as medications for opioid use disorder (MOUD).
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[xvi] 21 U.S.C. § 823(g).
[xvii] *Id.*
[xviii] *Id.*
[xix] The number of patients can be extended to 100 after the first year if need and intent are shown. *Id.*; In August 2017, the Department of Health and Human Services promulgated a new regulation which increases the patient limit to 275 for the prescribing of buprenorphine in treating opioid addiction if the practitioner meets the enumerated requirements. Content expert Gail Groves Scott, MPH, Health Policy Network, LLC, explained that this limit has been interpreted to not necessarily be 30 patients per physician, but 30 patients per practice health system due to the single tax ID number for the practice/health system. This interpretation therefore decreases the level of access.
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