



ASAM American Society of
Addiction Medicine

Public Policy Statement on the Regulation of the Treatment of Opioid Use Disorder with Methadone

PURPOSE

The treatment of opioid use disorder (OUD) with methadone has a long history and robust scientific evidence supporting its effectiveness. Currently, U.S. federal law limits its availability to certified, accredited, and heavily regulated opioid treatment programs (OTPs), a structure that has implications for access to, and quality of, care. This policy statement outlines existing regulatory barriers that prevent broader access to methadone treatment for OUD and summarizes current challenges to optimizing the quality of care offered by OTPs. Recommendations address ways to improve both access to, and the quality of, methadone treatment for OUD by making such treatment more patient-centered and integrated with other medical care. Such improvements are expected to reduce overdose deaths and improve health outcomes.

BACKGROUND

Drug overdose deaths are the leading cause of accidental death in the U.S., and most are opioid-involved¹ despite the existence of highly effective Food and Drug Administration (FDA)-approved medications for the treatment of OUD. There is strong evidence that methadone treatment for OUD is associated with decreased all-cause mortality by over 50%^{2,3} and has multiple other positive individual and public health outcomes. Methadone has been considered the “gold standard” of OUD treatments,⁴ and is listed by the World Health Organization (WHO) as an essential medicine.⁵ Initially known as “methadone treatment programs,” OTPs are accredited treatment facilities with Substance Abuse and Mental Health Services Administration (SAMHSA) certification, Drug Enforcement Administration (DEA) registration to administer and dispense opioid agonist medications that are approved by the FDA to treat OUD,⁶ and are typically licensed by state departments of health. OTPs can dispense or administer methadone and trans-mucosal buprenorphine, administer injectable naltrexone or injectable buprenorphine, and directly observe self-administration of other medications. In 2020, just over half of U.S. specialty substance use disorder (SUD) facilities offered any of the FDA-approved medications for OUD.⁷ Only 2% of specialty addiction residential treatment settings offer methadone.⁸ While multiple barriers to OUD treatment with methadone exist, including insufficient workforce, inadequate professional education, stigma, and generally fragmented systems of care delivery and financing, overly stringent, non-evidence based regulatory and legal policies are significant contributors to underutilization of this therapeutic modality.^{9,10}

Regulatory Barriers to Broader Access

The regulatory framework for OUD treatment with methadone dates back over 45 years. Methadone was first used for OUD treatment in the 1960s under Investigational New Drug applications issued by the FDA at a time when providing opioids for OUD remained illegal otherwise.¹¹ In 1972, the FDA determined that methadone was safe and effective for this indication.¹² At the same time, erroneous beliefs that methadone replaced one addiction for another, reports of methadone-related deaths and diversion,¹¹ and concerns over increasing crime rates¹³ created a climate of skepticism and hostility toward methadone-based OUD care. In 1974, Congress granted additional jurisdiction over methadone by the DEA.¹¹ Both FDA and subsequently SAMHSA replaced the usual practice of physician autonomy with strict rules governing the provision of methadone for OUD treatment that do not apply when it is prescribed for pain.

These regulations specified criteria on eligibility, initial methadone dosages, required counseling services, supervised dosing, and restricted methadone treatment provision within a closed system of regulated clinics.¹¹ Some note that such detailed regulations surrounding a specific medical practice led into an orientation toward regulatory compliance to the detriment of individualized patient care and carried along with it a misguided conception of abstinence defined as cessation of methadone pharmacotherapy.¹⁴ Others have observed that the highly regulated system of methadone-specific clinics in the U.S. may reflect racism and contribute to health disparities among different people with OUD.¹⁵ With a few exceptions, the core regulations governing methadone treatment of OUD have remained unchanged since 1974.

With access to methadone restricted to regulated OTPs, the potential for expansion of this treatment modality has been limited. The number of OTPs in the U.S., 1,754 in 2020, increased by about 42% over the prior 11 years, much more slowly than the growth of the prevalence of OUD.⁷ Most U.S. counties have no OTPs.¹⁶ Inadequate public funding and unfavorable local and state zoning regulations have historically resulted in waitlists at some OTPs.^{17, 18, 19, 20, 21} OTPs have established only a limited number of “mobile components” (medication vans)²² and a limited number of satellite medication units in locations such as free-standing dispensaries, pharmacies, jails, prisons, federally qualified health centers (FQHCs), and residential treatment facilities, resulting in limited geographic reach.²³

States and localities often add requirements that are not based on best practices and are more restrictive than federal regulations regarding unsupervised medication doses, counseling frequency, dose limitations, caps on the number of OTPs, and other restrictions.^{24, 25} These include requirements that medication be administered and/or dispensed by pharmacists, specified patient-to-staff ratios, or strict requirements in siting OTPs.

Psychosocial treatment and other services are an important component of quality care beneficial to many people with OUD. However, requiring that these services be provided to all patients, especially early in care, can present a barrier to accessing OTP services for some patients. In addition, a close read of federal regulations finds that the requirement for counseling services rests at the OTP level and does not tie the provision of medication to a requirement for counseling attendance. In fact, SAMHSA’s 2015 Federal Guidelines for Opioid Treatment Programs notes that “Maintaining a patient on medication, even when psychosocial treatment or other clinic services may not be yielding optimum results, is beneficial to both the individual patient and the public health.” Other organizations, including National Academies of Sciences, Engineering, and Medicine (NASEM),⁹ the WHO,²⁶ and the SAMHSA Treatment Improvement Protocol 63,²⁷ along with the updated 2020 ASAM National Practice Guideline on

Medications for the Treatment of Opioid Use Disorder,²⁸ highlight that psychosocial treatment should be available for the treatment of OUD, but not be a condition of receiving medication.

This medication-first model with methadone is not without precedent. In response to historic waiting lists of more than two weeks for comprehensive services in OTPs, 'interim maintenance treatment,' a model of providing medication without counseling services, was developed. This model of medication-based, low-threshold treatment in OTPs has been found in randomized controlled trials to reduce illicit opioid use, reduce criminal activity, increase engagement in comprehensive services²⁹ and reduce arrests³⁰ compared to wait list control groups. Regulatory barriers exist to broader adoption of this model at this point, including that it requires permission from state and federal authorities and individual patient-level detailed reporting requirements; can only be used when no non-profit or governmental comprehensive OTP is available within a reasonable geographic area; disallows any unsupervised dosing of medication; is not permitted for use by for-profit OTPs; and is limited to 120 days in any 12-month period which may be insufficient if waiting lists stretch beyond that timeframe.

In fact, interviews with former patients have indicated that a common reason for leaving OTPs is difficulty with program rules.³¹ Low-threshold approaches to treatment not only prioritize reducing barriers to entry, but also focus on retention in treatment without requiring abstinence from drug use, and typically accommodate individuals who do not necessarily have abstinence as a treatment goal.^{32,33} Compared to no treatment, low-threshold treatment, sometimes co-located with syringe service programs, has been associated with significant reductions in total mortality, overdose mortality, and HIV risk behaviors,^{32,34,35,36} and may be associated with increased participation in treatment. In Amsterdam, where low threshold methadone treatment is available, an estimated 60–70% of people with OUD are in treatment.³⁴ In Ontario, Canada, greater discretion of clinicians in methadone dosing, consequences of positive drug screens, counseling expectations, and unsupervised dosing decisions were followed by "dramatic" increases in treatment participation.³²

Another oft-cited regulatory barrier to methadone access and utilization is the requirement for frequent supervised medication dosing. According to a 2019 NASEM report, "rigid and time-consuming requirements [of daily observed methadone dosing] can impede patients' ability to maintain employment and relationships . . ."⁹ Federal OTP regulations mandate frequent attendance – typically close to daily - for the first nine months of treatment, resulting in high travel burdens and cost affecting treatment retention and quality of life.^{37,38} OTP physicians may petition their State Opioid Treatment Authority (SOTA), the entity that oversees all OTPs operating in a particular state, and the federal Division of Pharmacologic Therapies, for exceptions to the attendance requirements for an individual patient but at times, the application of the regulations appear to go beyond their stated intent. For example, OTP physicians anecdotally report that SOTAs often reject exception requests for unsupervised dosing based on positive drug test results, in spite of the fact that, according to federal regulations, "Absence of recent abuse of drugs" . . . is only one of the criteria that "the medical director shall *consider* (emphasis added)."³⁹ People who use opioids and specialist providers have rated 'restricted takeaways' as one of the top perceived barriers to treatment.⁴⁰ Reducing the need for daily attendance for supervised dosing improves quality of life, employment, access to treatment, retention in treatment, cost-effectiveness of treatment, participation with family, and reduced stigmatization.^{41,42,43,44,45,46} This is particularly an issue for pregnant and peripartum people who, due to pharmacological properties of methadone, may need twice daily doses for optimal OUD treatment.^{47,48} Technically, under current regulations, this would require that pregnant and peripartum patients meet all the federal requirements for unsupervised dosing, which may not be clinically realistic. OTP regulations on unsupervised dosing have been relaxed during the COVID-19 pandemic, and there have been calls for continued expanded

access to unsupervised dosing beyond the national health emergency.^{49,50,51,52, 53, 54} One analysis suggests that SAMHSA may have the legal authority to make permanent the methadone dispensing flexibilities associated with the COVID-19 Public Health Emergency without additional authorization from Congress.⁵⁵ While the potential benefits for patients of more relaxed regulations are clear, the full impacts are not known.

The benefit of reducing the frequency of attendance for methadone administration must be balanced with its potential harm in terms of increased methadone overdose among those who are not regularly using opioids. Methadone-related deaths have been attributed to methadone diverted from OTPs.^{56,57} However, some of these findings have been questioned in view of challenges in attributing cause of death to a particular opioid.^{12,41,58} A 1995 Institute of Medicine (IOM) Committee noted that medical examiners' interpretation of methadone-related deaths, which formed the basis of the 1972 regulatory framework for OTPs, may have been spurious due to difficulty in interpreting toxic methadone blood levels.¹² More recently, in January 2021 the Clinical Trials Network Methadone Access Research Task Force Report recommended additional research to assess the impact of expanded access to methadone on methadone diversion, non-fatal and fatal overdoses involving methadone, and initiation of opioids via methadone.

Although the aforementioned IOM committee recommended continued OTP regulations, it concluded that there is no compelling medical reason for methadone to be regulated differently than other FDA-approved medications, including other opioids, and that the benefits from authorizing greater clinical discretion in methadone treatment far outweigh the risks from diversion.^{12,59} A 2017 Cochrane review including two randomized controlled trials could not ascertain differences in the rate of diversion between supervised versus unsupervised dosing policies due to a lack of robust research.⁶⁰ Based on several lines of evidence, SAMHSA's "National Assessment on Methadone-Associated Mortality" analysis reported in 2003 that a significant rise in methadone-associated mortality in the U.S. was best explained by the parallel increase in methadone prescribed for pain rather than methadone used to treat OUD.⁶¹ Methadone is unusual among opioid agonists in that the slow accumulation of serum levels during initial dose adjustment may contribute to the risk of fatal methadone overdose,⁶² especially if treatment personnel overestimate a patient's degree of opioid tolerance.⁶¹ Therefore, gradual dose increases with frequent re-assessment during induction is recommended.⁶³ In a number of national guidelines outside the U.S., unsupervised dose practices are recommended in practice guidelines rather than mandated through regulation.^{64,65}

In 2019, NASEM reported that fragmentation resulting from OUD treatment settings being separated from other medical care creates significant access barriers and is not supported by evidence.⁹ While they exist in the U.S., models of integrated treatment of OUD with methadone with primary and other medical care are much more common internationally, with few adverse impacts. A 2017 international meta-analysis showed a significant reduction in all-cause mortality among people treated with methadone for OUD, both by general practitioners and specialty clinics.^{2,66} Randomized controlled trials have demonstrated that methadone treatment of stable patients in primary care can be safe and effective.^{67,68} Safety has also been shown in multiple non-randomized studies, some with 9 to 15 years of follow-up.^{69,70,71} Methadone has been available by prescription in Australia since 1970, and in Great Britain since 1968.⁶⁶ In Canada, marked increases in the number of individuals with access to methadone treatment occurred following the 1996 implementation of office-based prescribing and pharmacy dispensing, from 2,800 patients in 1996 to 13,000 in 2012 in British Columbia, and from 700 to nearly 30,000 patients in Ontario.⁷² The recent pandemic-related expansion in the use of telehealth has reduced barriers to health services that disproportionately have impacted people of color and may serve

as another way of connecting medical staff with satellite medication units or rural OTPs where daily on-site medical coverage is limited.

The closed system of regulated clinics also poses barriers to treatment of patients with OUD who are admitted to hospitals and subacute or skilled nursing facilities. Many hospitals refrain from initiating or adjusting opioid agonist therapy for inpatients with OUD⁷³ due to the lack of understanding at best, and lack of clarity at worst, of 21 C.F.R. §1306.07 ('Administering or Dispensing of Narcotic Drugs'). This rule prohibits the provision of an opioid for OUD outside of an OTP but also specifies that "this section is not intended to impose any limitations on a physician or authorized hospital staff to administer or dispense narcotic drugs in a hospital to *maintain or detoxify* a person as an incidental adjunct to medical or surgical treatment of conditions other than addiction . . ." (emphasis added).^{74, 75} According to staff at some hospitals who have consulted with representatives of DEA and the Center for Substance Abuse Treatment (CSAT), hospitals may initiate and adjust opioid agonists for the treatment of OUD in hospitalized patients in certain circumstances.⁷⁵ This approach with methadone and buprenorphine has been shown to be feasible^{76, 77} and effective.⁷⁸

However, when patients enter a skilled nursing facility (SNF), they need to be enrolled in an OTP to have their methadone dose ordered and delivered. Federal regulations (Federal Opioid Treatment Standards, 42 C.F.R. §8.12) require that an initial OTP physical evaluation be conducted by a program physician, a primary care physician, or a healthcare professional under the supervision of a program physician. The regulations further state that the OTP must provide "adequate" medical and other assessment and treatment services at the primary OTP facility except where formal, documented agreements for these services are in place with other practitioners, institutions, organizations, or private and public agencies. In some areas of the country, the interpretation of this regulation has prevented patients who have been initiated on methadone while hospitalized from being directly transferred to a skilled nursing facility if they are unable to visit an OTP en route for this purpose. In other areas, as part of pilot projects, some hospitals accomplish OTP admission by having the OTP physician review a physical evaluation performed by an addiction medicine consult physician seeing patients in the hospital. The narrow scope of these regulations and their variable interpretations contribute to confusion in the field about what is and is not permissible in terms of hospitalized patients with OUD who could benefit from treatment with methadone. The regulations also impose an undue burden on OTPs to deliver methadone to SNFs for mutual patients. This is an expectation without precedent elsewhere in medicine as SNFs are themselves responsible for procuring all other medications patients need. In fact, health care providers, in general, are required by federal law, including the Americans with Disabilities Act, the Fair Housing Act, and/or the Rehabilitation Act of 1973, to make reasonable accommodations to support ongoing access to methadone therapy for OUD without discrimination or exclusion. Relying on OTPs for methadone delivery to SNFs for patients being transferred from acute care hospital settings risks unnecessary delays and disrupted medication continuity.⁷³

Regulatory Challenges to Optimizing Quality of Care

Stringent regulations impact not only access but also pose challenges to optimizing quality of care in OTPs.^{37, 38} Retention in treatment is an accepted measure of OTP and other OUD treatment effectiveness.^{12, 79, 80} Duration of treatment is associated with reductions in heroin use and related clinical and social problems according to large-scale observational studies,^{81, 82} as well as with improved quality of life and substantial reductions in all-cause and overdose mortality.^{2, 83} In the U.S., 12-month OTP retention rates often range between 34-54%^{31, 81, 84, 85} although individual OTPs not reported in the literature may have higher rates. However, some international 12-month retention rates among

individuals with OUD who are treated with methadone have been found to be as high as 80%.^{86, 87} While not completely clear, these differences may be related to the highly regulated system in the U.S.

Two specific areas having to do with accreditation and electronic health records directly related to quality of care deserve mention.

To operate, OTPs must maintain accreditation through a SAMHSA-approved accrediting body. Most OTPs in the U.S. rely on accreditation by The Joint Commission (TJC) or the Commission on Accreditation of Rehabilitation Facilities (CARF). Each of these entities has developed approximately 2,000 accreditation standards and elements of standards, while SAMHSA's 2015 Federal Guidelines for Opioid Treatment Programs⁶ outline approximately 700 guideline elements based on the federal OTP regulations in Federal Opioid Treatment Standards, 42 C.F.R. §8.12. SAMHSA has approved only two state departments of health, in Missouri and Washington, as accrediting bodies. Both states base their accreditation of OTPs on federal regulations alone and any additional applicable state regulations. For OTPs, existing systems of accreditation do not identify or prioritize standards of greater or lesser importance, and this causes confusion and an exaggerated focus on regulatory compliance rather than the most appropriate individualized care. It is also unclear to what extent accredited OTPs comply with federal regulations. An audit of SAMHSA's oversight of OTP accreditation bodies conducted by the HHS Office of Inspector General found that SAMHSA did not take actions to address accreditation bodies' noncompliance with survey requirements, nor determine whether OTPs complied with the federal regulations.⁸⁸

Measurement-based care is recognized as an essential component of health care quality improvement and is one of the WHO's international standards for the treatment of drug use disorders.⁸⁹ The Medicare and Medicaid Promoting Interoperability Program has provided incentives to health practitioners to promote adoption of meaningful use of electronic health records (EHRs) to enhance measurement-based care.⁹⁰ However, SUD providers were not included in the program, and measurement of outcomes through EHRs used in OTPs remains challenging. For optimal use, electronic health records in OTPs need to not only serve the usual functions an electronic medical record, meet meaningful use standards, but also have medication dispensing capacity and provide the detailed inventory and dispensing records required by the DEA for controlled medications. Lack of specific incentives for upgrading existing OTP-aligned EHR systems has limited innovation in this niche market, particularly in comparison to the rest of healthcare.

More recently there have been calls for updated regulations to reduce barriers to a more humane and potentially more effective system of OUD treatment with methadone that promotes therapeutic alliances and an individualized recovery orientation in treatment.¹⁴ Based on the experience and evidence to date on the impact of the current regulatory structure in the U.S. specific to methadone treatment for OUD, ASAM makes the following recommendations.

RECOMMENDATIONS

Recommendations for Reducing Regulatory Barriers to Broader Access

1. SAMHSA should revise regulations regarding patient admission criteria for inclusion of current OUD of any duration or a history of OUD, warranting medication treatment for OUD.
2. SAMHSA and DEA should promote the use of satellite medication units and mobile components (medication vans) affiliated with OTPs.
3. States should align their OTP regulations with federal regulations and current medical best practices to promote access to and retention in treatment.
4. SAMHSA should issue guidance clarifying that counseling and ancillary services should be fully and reasonably available but should not be a condition of receiving methadone treatment for OUD.
5. SAMHSA regulations should reduce barriers to the use of Interim Maintenance Treatment when it is needed.
6. SAMHSA should specify time in treatment requirements for unsupervised dosing in practice guidelines rather than in federal regulations.
7. SAMHSA should issue guidance clarifying that absence of substance use, or a substance use disorder, is not a strict requirement for unsupervised dosing, but is a factor to be considered.
8. SAMHSA should issue guidance clarifying that methadone split dosing for pregnant and peripartum patients should not be regulated as take-home doses.
9. SAMHSA should make permanent the methadone unsupervised dosing and OTP-related telehealth flexibilities implemented during the COVID-19 Public Health Emergency with continued study of the impact of these flexibilities.
10. SAMHSA and DEA regulations should allow pharmacy dispensing and/or administration of methadone that has been prescribed for patients who meet certain criteria by a legally authorized prescriber of controlled medications who is affiliated with an OTP, is an addiction specialist physician, or is a physician who has met specific qualifications.
11. The Department of Health and Human Services (HHS) should promote payment and information systems that support innovation and integration of services, such as specialty addiction treatment center (OTP) medical home models, hub and spoke models, and Certified Community Behavioral Health Centers.
12. SAMHSA and DEA regulations should allow the initial medical evaluation for treatment of OUD with methadone by audio-video telemedicine when deemed by the OTP medical director as necessary and appropriate.

13. SAMHSA and DEA regulations should be clarified to explicitly allow for initiation and titration of methadone for OUD in hospitalized patients by hospital clinicians.
14. SAMHSA regulations should issue guidance clarifying that an initial medical evaluation performed by hospital staff and reviewed by an OTP clinician may be used for admission by the OTP for facilitating the direct transfer of a hospitalized patient, who was initiated on methadone for OUD, to a skilled nursing facility (SNF) or other inpatient rehabilitation facility (e.g., acute inpatient rehab, long-term acute care hospital).
15. The federal government should monitor and ensure enforcement of federal laws that protect patients who are treated with methadone for OUD so that they have access to all SNFs.
16. SAMHSA and DEA regulations should allow pharmacies affiliated with a SNF, other rehabilitation facility, or residential treatment facility to have authority for dispensing methadone that has been prescribed by a legally authorized prescriber of controlled medications who is affiliated with an OTP or is an addiction specialist physician for patients in these facilities for OUD treatment.
17. The federal government should make legislative or regulatory changes to create a special registration exemption for jails, prisons, and their authorized personnel to prescribe and otherwise dispense controlled medications for initiation, maintenance, or withdrawal management of OUD that is significantly less burdensome than the applicable registration requirements in the Controlled Substances Act and related regulations. The special registration should not limit the number of detained or incarcerated persons who can be treated with such medications by a qualified practitioner.⁹¹

Recommendations to Reduce Regulatory Challenges to Optimizing Quality of Care

18. SAMHSA should ensure that OTP accreditation standards are simplified by establishing them directly, or by re-evaluating standards established by accrediting bodies.
19. SAMHSA should ensure that OTP accreditation standards prioritize collection and use of subjective and objective patient-centered outcome and process measures relevant to OUD, such as retention in treatment, reduction in substance use, and quality of life.
20. SAMHSA should partner with relevant agencies to promote population-level collection and use of patient-centered outcomes data.
21. The Centers for Medicare and Medicaid Services (CMS) should develop incentive programs specifically for OTP-focused electronic health records to spur the development and adoption of meaningful use aligned, interoperable systems that facilitate the collection and use of outcome measures.

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