



ASAM American Society *of*
Addiction Medicine



ASAM, founded in 1954, is a professional medical society representing over 7,000 physicians, clinicians and associated professionals in the field of addiction medicine. ASAM is dedicated to increasing access and improving the quality of addiction treatment, educating physicians and the public, supporting research and prevention, and promoting the appropriate role of physicians in the care of patients with addiction.



Regulation of the Treatment of Opioid Use Disorder with Methadone

Adoption Date: October 23, 2021



AGENDA

01 – **Background**

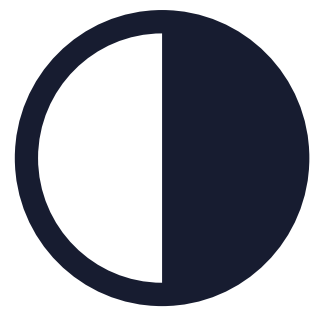
02 – Highlighted
Recommendations



Background



- Strong evidence exists **associating methadone treatment for opioid use disorder (OUD) with decreased all-cause mortality by over 50%** and shows it has multiple other positive individual and public health outcomes.



- Yet, in 2020, **just over half of U.S. specialty substance use disorder (SUD) facilities offered any of the FDA-approved medications for OUD.**



- Only **2% of specialty addiction residential treatment settings offer methadone.**

Federal Methadone Regulation

1974

Congress granted the DEA additional jurisdiction over methadone

New Regulations

- Both the FDA and SAMHSA replaced the usual practice of physician autonomy with strict rules governing the provision of methadone for OUD treatment that does not apply when it is prescribed for pain.
- These regulations specified criteria on:
 - Eligibility
 - Initial methadone dosages
 - Required counseling services
 - Supervised dosing
 - Restricted methadone treatment provision within a closed system of regulated clinics

Impact of Regulations

- Detailed regulations may have led to an orientation toward regulatory compliance to the detriment of individualized patient care and a misunderstanding of abstinence that is defined as cessation of methadone pharmacotherapy.
- 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.
- Yet, the core regulations governing methadone treatment of OUD have remained largely unchanged since 1974.



Regulation Has Limited the Reach of OTPs



Overview

- As access to methadone has been restricted to regulated OTPs, it has limited the potential for expansion of this treatment modality.
- The number of OTPs in the U.S. has not increased as quickly as the growth of the prevalence of OUD; most U.S. counties have no OTPs.

Burdensome Local & State Regulations

Inadequate public funding and unfavorable local and state zoning regulations have historically resulted in waitlists at some OTPs.

1

OTPs have established only a **limited number of “mobile components” (medication vans)** 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.

2

In addition, **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.

3

Psychosocial Counseling is Beneficial, But Not a Prerequisite for Treatment



Overview

- 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.

Stakeholder Views

SAMHSA

- 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

- Other organizations, such as NASEM and the WHO, highlight that psychosocial treatment should be available, but not be a condition of receiving medication.



Former Patients

- Interviews with former patients have indicated that a common reason for leaving OTPs is difficulty with program rules.



Regulatory Barriers and ‘Interim Maintenance Treatment’

A Model of Medication-Based, Low-Threshold Treatment at OTPs

- In response to historic waiting lists of more than two weeks for comprehensive services in OTPs, ‘interim maintenance treatment,’ which provides medication without counseling services, was developed. It has been found to reduce illicit opioid use, reduce criminal activity, increase engagement in comprehensive services, and reduce arrests, compared to those on wait lists.

Regulatory Barriers Exist to Broader Adoption



- 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
- Is limited to 120 days in any 12-month period, which may be insufficient if waiting lists stretch beyond that timeframe.

Frequency of OTP Attendance for Dosing is a Barrier to Treatment

Supervising Requirements

- Another oft-cited regulatory barrier to methadone access and utilization is the requirement for frequent supervised medication dosing.
- Federal OTP regulations mandate frequent attendance—typically close to daily—for the first 9 months of treatment, resulting in high travel burdens and costs affecting treatment retention and quality of life.
- People who use opioids and specialist providers have rated ‘restricted takeaways’ as one of the top perceived barriers to treatment.

Impacts

- Reducing daily supervised dosing improves:
 - Quality of life,
 - Employment,
 - Access to treatment,
 - Retention in treatment,
 - Cost-effectiveness of treatment,
 - Participation with family; and,
 - Decreases stigmatization.
- Daily supervised dosing is particularly an issue for pregnant and peripartum people who may need twice daily doses due to the pharmacological properties of methadone.



Unsupervised Dosing During COVID-19

- During the COVID-19 pandemic, OTP regulations on unsupervised dosing were relaxed, and there have been calls for continued expanded access to unsupervised dosing beyond the national health emergency.

Greater Clinical Discretion in Methadone Treatment Can Benefit Patients

Balanced Approaches

- Benefits of reducing daily attendance must be balanced with potential harms in terms of increased methadone overdose among the opioid naïve.

OTP Regulations



- In 1995 the Institute of Medicine (IOM) noted 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.



- Although the IOM 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.

Rise in Methadone-Associated Mortality in 2000s Was Largely Linked to Methadone for Pain

SAMHSA Analysis

- In 2003 SAMHSA's "National Assessment on Methadone-Associated Mortality" analysis reported that a significant rise in methadone-associated mortality in the US. Was best explained by the parallel increase in methadone prescribed for pain rather than methadone used to treat OUD.

Methadone Doses



- 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, especially if treatment personnel overestimate a patient's degree of opioid tolerance.



- Therefore, gradual dose increases with frequent reassessment during induction is recommended.



- Outside the U.S., unsupervised dose practices are recommended in practice in several national guidelines rather than mandated through regulation.

Medical Care Integration

Separation of Methadone Treatment from General Medical Care is a Barrier to Treatment

- 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.
- 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 than in the U.S., with few adverse impacts.



Interpretation of Regulation Risks Unnecessary Delays in Patients' Transfers from Hospitals to SNFs

- When patients enter a skilled nursing facility (SNF), they need to be enrolled in an OTP to have their methadone dose ordered and delivered.
- In some areas of the country, the interpretation of 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.
- Relying on OTPs for methadone delivery to SNFs for patients being transferred from acute care hospital settings risks unnecessary delays and disrupted medication continuity.



Regulatory Challenges to Optimizing Quality of Care

Overview

- Stringent regulations impact not only access but also pose challenges to optimizing quality of care in OTPs.
- Retention in treatment is an accepted measure of OTP and other OUD treatment effectiveness and **12-month OTP treatment retention rates often range between 34% and 54% in the U.S. compared to rates of 80% internationally.**

Accreditation Processes are Not Focused on Optimizing Individualized Care

- To operate, OTPs must maintain accreditation through a SAMHSA-approved accrediting body and is largely through the Joint Commission or CARF; only two state departments of health have been approved as accrediting bodies.
- For OTPs, existing systems of accreditation do not identify or prioritize standards of greater or lesser importance (of the over 700 guideline elements based on SAMHSA's 2015 Federal Guideline Standards for OTPs) and this causes confusion and an exaggerated focus on regulatory compliance rather than the most appropriate individualized care.
- An audit of SAMHSA's oversight of OTP accreditation bodies conducted by the HHS OIG found that SAMHSA did not take actions to address accreditation bodies' noncompliance with survey requirements, nor determine whether OTPs complied with the federal regulations.



Limited Innovation in OTP's EHR Systems Prevents Optimal EHR Use

- 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 substance use disorders.
- 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.



AGENDA

01 – Background

02 – **Highlighted
Recommendations**



Highlighted Recommendations for Reducing Regulatory Barriers to Broader Access (1/2)

1

States should align their OTP regulations with federal regulations and current medical best practices to promote access to and retention in treatment.

2

SAMSHA 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.

3

SAMHSA regulations should reduce barriers to the use of Interim Maintenance Treatment when it is needed.

4

SAMHSA should issue guidance clarifying that methadone split dosing for pregnant and peripartum patients should not be regulated as take-home doses.

5

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.



Highlighted Recommendations for Reducing Regulatory Barriers to Broader Access (2/2)

6

SAMHSA and DEA regulations should be clarified to explicitly allow for initiation and titration of methadone for OUD in hospitalized patients by hospital clinicians.

7

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.

8

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.

9

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.

Highlighted Recommendations to Reduce Regulatory Barriers to Optimizing the Quality of Care

10

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.

11

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.