



MASSACHUSETTS  
GENERAL HOSPITAL

PSYCHIATRY ACADEMY

# Regulatory and Advocacy Updates

Laura G. Kehoe, MD, MPH, FASAM

Assistant Professor of Medicine

Harvard Medical School

# Disclosures



MASSACHUSETTS  
GENERAL HOSPITAL

PSYCHIATRY ACADEMY

I have the following relevant financial relationship with a commercial interest to disclose:

## Consultant

MCSTAP Massachusetts Consultation Service for the Treatment of  
Addiction and Pain (funded by Massachusetts government)  
Baycove Health and Human Services and Gavin Foundation

Advisory board, non-branded speaker  
Indivior

Medical Director  
Health Care Resources Center OTP



# American Society of Addiction Medicine

## 2025-26 Priorities

Advocacy efforts and changes in clinical practice related to addiction have focused on **shifting from criminalization to health-based approaches**, expanding access to evidence-based treatments, and addressing structural racism and health disparities

- **Telehealth expansion**
- **Integration of addiction treatment into primary care**
- **Trauma-informed and structurally competent care**
- **Non-abstinence-based approaches**
- **Addressing medication stigma**
- **Screening and intervention practices**
  - overdose education and naloxone distribution now recommended for all patients with opioid use disorder and those on chronic opioid therapy.
- **Centering lived experience** in policy development, ensuring people in recovery and families inform solutions.

*“We support policies that foster innovative approaches to addiction medicine research and development, treatment delivery, and protection of community health.”*

[ASAM Advocacy](#)

## ASAM Advocacy

ASAM is dedicated to improving access to evidence-based addiction treatment through our national advocacy efforts.

[SUBSCRIBE TO UPDATES →](#)

[POLICY STATEMENTS →](#)

## National Advocacy Principles

ASAM envisions a future when addiction prevention, treatment, remission, and recovery are readily available to everyone, profoundly improving the wellbeing of all people. The following principles shape ASAM's advocacy at all levels:

- **Promote Science, Not Stigma.** Addiction is a treatable, chronic medical disease, not a moral weakness. Addiction policy should reflect the latest science and best practices and reject outdated constructs.
- **Build an Infrastructure That Lasts.** Addiction policy solutions must be proactive, strategic, and multifaceted to build an addiction care infrastructure that can comprehensively address public health needs, threats, and crises.
- **Make Addiction Care a Right.** Everyone with addiction deserves compassionate, evidence-based addiction care – no matter who they are or where they live.
- **Center Lived Experience.** Addiction policy and advocacy should respect, integrate, and elevate the perspectives of people with addiction and their loved ones.



# 2025-6 National Advocacy Agenda — Core Priorities

3 major strategic pillars that guide national policy goals to advance addiction prevention, treatment, remission, and recovery:

1. Innovation
2. Individualized Pathways
3. Strong Continuum of Care for All



# 1. INNOVATION

- Boost integration of technologies and expanded electronic health records (with privacy protections).
- Support evidence-based psychosocial treatments and smarter prescription drug monitoring that serves public health.
- Promote smart drug policy reform, such as contingency management incentives and better coordination between primary and behavioral health providers.
- Increase federal research and development on addiction treatments.
- Support public health-oriented policy actions on substances (e.g., federal alcohol excise taxes, rescheduling marijuana to Schedule III, and eliminating flavored tobacco products).



## 2. INDIVIDUALIZED PATHWAYS

- Make Methadone Treatment Accessible
- Optimize Telemedicine for Addiction Care
- Improve Treatment Engagement and Retention for Non-abstinent Patients
- Eliminate Pharmacy Access Barriers
- Promote Access to Quality Recovery Residences



## 3. STRONG CONTINUUM OF CARE FOR ALL

- Close Residential Addiction Treatment Gaps in Medicare and Medicaid
- Promote Addiction Care Continuity for Individuals in the Criminal Legal System
- Ensure Addiction Care for All in Need
- Grow the Addiction Workforce



# Ongoing National Advocacy priorities

ASAM's advocacy engagements at the national level have included efforts around legislation such as:

- *Modernizing Opioid Treatment Access Act (MOTAA)* — expanding methadone access outside highly regulated OTP settings.
- *Residential Recovery for Seniors Act* — creating Medicare coverage for residential addiction treatment levels.



# Evolution of OTP Care 42 CFR Part 8 Final Rule First Update since 2001

## Past

- Highly regulated
- Highly punitive
- High barrier
- Devoid of evidence base
- Devoid of patient autonomy
- Devoid of individuality
- Abstinence based
- Outdated

## Present

- Person-centered
- Lower barrier
- Evidence based
- Incorporates patient voice and goals
- Individualized
- Addresses natural history of SUD
- Harm reduction
- Acknowledges a changing drug supply

# The Modernizing Opioid Treatment Access Act: M-OTAA



MASSACHUSETTS  
GENERAL HOSPITAL

PSYCHIATRY ACADEMY

Amid Overdose Crisis, Leadership Shifts, and a Renewed Focus on Empowering Physicians and Patients, Stakeholders Urge Congress to Pass the Modernizing Opioid Treatment Access Act (S. 644/H.R. 1359)

Nov 12, 2024

Download



More than 125 organizations submitted a joint letter to Congressional leaders today urging them to address the demand-side of America's overdose crisis by prioritizing the bipartisan legislation in any year-end legislative package

- bipartisan bill, sponsored by Sen Ed Markey
- Would permit OTP providers AND addiction specialist physicians working outside of OTPs to prescribe methadone for OUD and have it dispensed to patients from community pharmacies, [which is permitted in other countries](#).
- The bill has received broad support from national organizations



## Top Government Researcher Calls For Easier Access To Drug That Treats OUD: "No Reason Why Not"

The top addiction researcher in the U.S. government has called for the broad deregulation of methadone in a major departure from how it is currently made available. Dr. Nora Volkow, who is director of the National Institute on Drug Abuse (NIDA), made her comments, as reported by STAT News, at a recent Stat Summit.

Dr. Volkow was clear in her comments about her desire for methadone to be available by prescription. "There's absolutely no reason why not [to allow prescription of methadone]," Volkow told the summit.

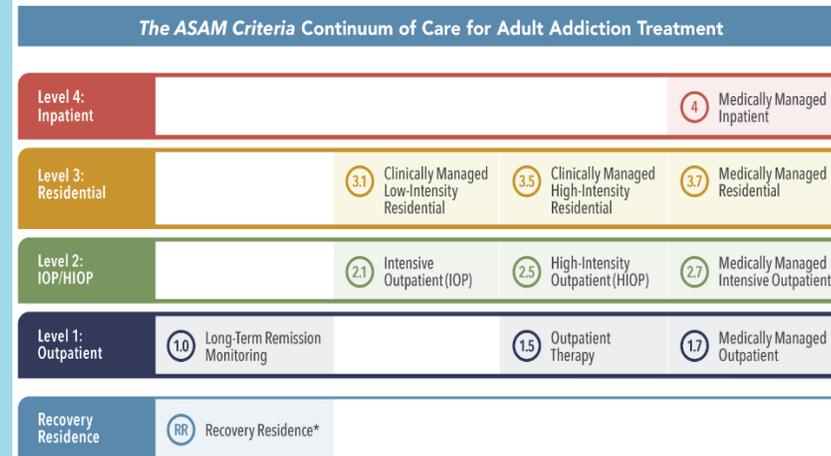
From Kerry Breen, CBS News, published November 17, 2022.

[https://downloads.asam.org/sitefinity-production-blobs/docs/default-source/advocacy/letters-and-comments/methadone-resources/motaa-explainer---v.-2.pdf?sfvrsn=53ea47d1\\_1](https://downloads.asam.org/sitefinity-production-blobs/docs/default-source/advocacy/letters-and-comments/methadone-resources/motaa-explainer---v.-2.pdf?sfvrsn=53ea47d1_1)



# Residential Recovery for Seniors Act

- Congress is currently considering passing this first-of-its-kind legislation
- this bill would *create a new Medicare Part A benefit for evidence-based residential addiction treatment programs* — addressing gaps in coverage for older adults.



Source: ASAM

# Ryan Haight Act & Telehealth Buprenorphine: 2026 Snapshot

- The Ryan Haight Act (2008) generally requires an in-person exam before prescribing controlled substances.
- DEA and HHS have continued COVID-era telemedicine flexibilities through Dec 31, 2026, temporarily waiving the in-person requirement.
- Providers may initiate and continue buprenorphine for opioid use disorder via telehealth, including audio-only visits, under federal rules.
- Permanent DEA pathways (e.g., Special Telemedicine Registration) remain under development; state laws still apply.



# Criminal Legal & Continuity of Care

- expanding *addiction treatment services for people who are incarcerated or under court supervision*
- strengthening **Good Samaritan laws** that protect people seeking emergency help during an overdose.
- **Policy advocacy focuses on** removing barriers to treatment access, including eliminating drug conviction bans for public assistance programs, ending housing evictions based on drug-related activities, and implementing universal health care coverage for addiction services.
- Specific efforts target expanding Medicaid and Medicare coverage to include people in carceral settings.



# Overdose Prevention Centers

- AKA “SIF” Supervised Injection Facility, “SCS” Supervised Consumption Sites”
- Evidence-based harm reduction interventions that save lives and connect people to treatment.
- ASAM supports OPCs as part of a comprehensive, patient-centered continuum of addiction care, alongside MOUD, naloxone, and recovery services.
- Federal law (Controlled Substances Act §856) currently prohibits facilities maintained for illicit drug use; U.S. v. Safehouse (3d Cir.) affirmed this interpretation.
- States and localities (e.g., Rhode Island, Vermont, Minnesota, New York City) have pursued pilots or non-interference models, but federal legal risk limits scale and sustainability.
- ASAM advocates for legal and regulatory reform to allow rigorously evaluated OPC pilots as a public health response to the overdose crisis.



# Summary: Regulatory Status

Jurisdiction	Legal Status	What Exists
<b>Federal</b>	RPCs/supervised sites illegal under 21 U.S.C. § 856	No explicit federal authorization; enforcement risk remains ( <a href="#">Department of Justice</a> )
<b>Rhode Island</b>	State law authorizes OPC pilot	Operational site(s) open under state law ( <a href="#">opcinfo.org</a> )
<b>Vermont</b>	State law authorizes	Planning/early implementation ( <a href="#">opcinfo.org</a> )
<b>Minnesota</b>	Law authorizes safe recovery sites including OPCs	Regulatory framework established
<b>New York City</b>	Municipal authorization (no explicit state law)	Two centers open, operating with local support ( <a href="https://www.nyc.gov/">https://www.nyc.gov/</a> )
<b>Other States (CT, MA, IL, CO, NV, NM)</b>	Legislative proposals under consideration	Not yet authorized; legal debates in progress ( <a href="https://www.mass.gov">https://www.mass.gov</a> )

# Recommended Viewing or Listening

*The National Academies of*  
SCIENCES • ENGINEERING • MEDICINE

**Methadone Treatment for Opioid Use Disorder: Examining Federal Regulations and Laws  
A Workshop**

March 3-4, 2022 | Virtual

**Workshop Objectives:**

A planning committee of the National Academies of Sciences, Engineering, and Medicine will organize and conduct a two-day public workshop that brings together experts and key stakeholders to examine the current federal regulatory and legal landscape regarding provision of and access to methadone for the treatment of opioid use disorder.

Invited presentations and discussions will be designed to:

- Examine current federal regulations governing methadone treatment services, including the current COVID-19 emergency regulatory relief;
- Discuss the impact of these regulations relative to other factors affecting treatment services;
- Explore potential options for modifying federal regulations and laws to expand access to quality treatment with methadone; and
- Explore state laws that may conflict with federal regulations.

<https://www.nationalacademies.org/event/03-03-2022/methadone-treatment-for-opioid-use-disorder-examining-federal-regulations-and-laws-a-workshop>

Hoffman KA, Foot C, Levander XA, Cook R, Terashima JP, McIlveen JW, Korthuis PT, McCarty D. Treatment retention, return to use, and recovery support following COVID-19 relaxation of methadone take-home dosing in two rural opioid treatment programs: A mixed methods analysis. J Subst Abuse Treat. 2022 Oct



# FDA Clarification on Buprenorphine Dosing Limits, 12/26/24

Federal register:

“we recommend several changes to BTOD labeling to clarify that ***neither 16 mg/day nor 24 mg/day should be construed as maximum dosages*** for these medications”

<https://www.fda.gov/media/184748/download?attachment>

[Modifications to Labeling of Buprenorphine-Containing Transmucosal Products for the Treatment of Opioid Dependence](#)



FDA's recommended revisions to Buprenorphine for the Treatment of Opioid Dependence (BTOD) labeling?

- Removal of “target dose”
- Modification of the statement, “Dosages higher than 24 mg daily have not been demonstrated to provide a clinical advantage” to read, **“Dosage higher than 24 mg buprenorphine daily have not been investigated in randomized clinical trials but may be appropriate for some patients”**
- A minor clarification to the Pregnancy section that would align with the preceding changes above.

<https://www.federalregister.gov/d/2024-30776>



# US Department of Justice Civil Rights Division: The Americans with Disabilities Act

- The ADA is a federal law that gives civil rights protections to individuals with disabilities in many areas of life
- The ADA defines a disability as:
  - “a physical or mental impairment that substantially limits one or more major life activities.”
  - people with SUD typically have a disability because they have a drug addiction that substantially limits one or more of their major life activities
  - only applies to individuals who are “no longer engaging in the illegal use of drugs” and are either participating in treatment, have “successfully completed a supervised drug rehabilitation program,” or “have otherwise been rehabilitated successfully.”
- Under the ADA, an individual’s use of prescribed medication, such as MOUD, is not an “illegal use of drugs” if the individual uses the medication under the supervision of a licensed health care professional, including primary care or other non-specialty providers.

### **Example A**

A skilled nursing facility refuses to admit a patient with OUD because the patient takes doctor-prescribed MOUD, and the facility prohibits any of its patients from taking MOUD. The facility’s exclusion of patients based on their OUD would violate the ADA.

### **Example B**

A jail does not allow incoming inmates to continue taking MOUD prescribed before their detention. The jail’s blanket policy prohibiting the use of MOUD would violate the ADA.

### **Example C**

A doctor’s office has a blanket policy of denying care to patients receiving treatment for OUD. The office would violate the ADA if it excludes individuals based on their OUD.

### **Example D**

A town refuses to allow a treatment center for people with OUD to open after residents complained that they did not want “those kind of people” in their area. The town may violate the ADA if its refusal is because of the residents’ hostility towards people with OUD.



# Key Summaries and References for High Dose Prior Authorization Appeals

- Higher buprenorphine doses are associated with improved treatment persistence and reduced risk of early discontinuation. In this study, higher prescribed doses were linked to a significantly lower risk of leaving buprenorphine treatment (hazard ratio 0.84) and a lower likelihood of discontinuing treatment within six months (odds ratio 0.91), supporting higher-dose buprenorphine to improve retention in care.
  - Gryczynski J, et al. Leaving buprenorphine treatment: Patients' reasons for cessation of care. *Journal of Substance Abuse Treatment*. 2014;46(3):356–361. doi:10.1016/j.jsat.2013.10.001.
- Higher buprenorphine dosing is associated with improved treatment outcomes, particularly retention in care. In this study, patients receiving higher doses of buprenorphine (16–32 mg/day) had significantly better treatment retention compared with those receiving lower doses (<16 mg/day), demonstrating a clear dose–response relationship favoring higher-dose therapy.
  - Fareed A, et al. Effect of buprenorphine dose on treatment outcome. *Journal of Addictive Diseases*. 2012;31(1):8–18. doi:10.1080/10550887.2011.642758.
- Higher-dose buprenorphine ( $\geq 24$  mg/day) is associated with substantially better treatment adherence. In a large analysis of prescription drug monitoring program data, patients prescribed  $\geq 24$  mg had markedly higher 180-day buprenorphine adherence compared with those on <16 mg (odds ratio 5.11) and also higher adherence than those on 16–23 mg (estimated odds ratio  $\sim 3$ ). These findings support the clinical rationale for higher-dose buprenorphine in appropriate patients, including for prior authorization appeals.
  - Pizzicato L, et al. Adherence to buprenorphine: An analysis of prescription drug monitoring program data. *Drug and Alcohol Dependence*. 2020;216:108317. doi:10.1016/j.drugalcdep.2020.108317.
- In a multi-site randomized trial comparing buprenorphine/naloxone with methadone, higher buprenorphine doses were associated with improved treatment retention. The highest 24-week completion rate ( $\sim 59\%$ ) occurred among patients receiving 30–32 mg/day, compared with  $\sim 53\%$  among those receiving 22–28 mg/day, indicating a dose–response relationship favoring higher-dose buprenorphine for retention.
  - Hser Y, et al. Treatment retention among patients randomized to buprenorphine/naloxone compared to methadone in a multi-site trial. *Addiction*. 2014;109(1):79–87. doi:10.1111/add.12333.



# Resources

- [ASAM Advocacy](https://www.asam.org/advocacy) <https://www.asam.org/advocacy>
- Department of Justice, The Americans with Disabilities Act and the Opioid Crisis: Combating Discrimination Against People in Treatment or Recovery; [https://archive.ada.gov/opioid\\_guidance.pdf](https://archive.ada.gov/opioid_guidance.pdf)
  - TO FILE A CLAIM WITH THE DOJ:
  - Go to the DOJ Civil Rights Division website and fill out the contact form [file a discrimination claim](#)
  - REPORTS CAN ALSO BE FILED BY PHONE OR MAIL: • Phone: (202) 514-3847 • Mail: U.S. Department of Justice Civil Rights Division 950 Pennsylvania Avenue, NW Washington, D.C. 20530-0001
- Legal Action Center, MAT/MOUD Advocacy Toolkit; • <https://www.lac.org/resource/mat-advocacy-toolkit>
- O'Neill Institute for National and Global Health Law, Access to Evidence-Based Treatment for Substance Use Disorder; <https://oneill.law.georgetown.edu/projects/advancing-evidence-based-treatment-for-opioid-use-disorder/>
- National Commission on Correctional Health Care, Standards; <https://www.ncchc.org/standards/>
- National Sheriffs Association & National Commission on Correctional Health Care, Jail-Based Medication-Assisted Treatment: Promising Practices, Guidelines, and Resources for the Field; <https://www.sheriffs.org/publications/Jail-Based-MAT-PPG.pdf>
- DEA & HHS. Federal Register: Temporary Extension of Telemedicine Flexibilities Through 2026.
- DEA & HHS. Telemedicine Prescribing of Buprenorphine – Final Rule (2025).
- American Society of Addiction Medicine (ASAM). Telehealth and OUD Treatment Policy Statements.
- American Psychiatric Association (APA). Telepsychiatry and Controlled Substances Policy Guidance.



# References

- **H.R.1359 - Modernizing Opioid Treatment Access Act** 118th Congress (2023-2024)
- American Society of Addiction Medicine (ASAM) Policy Statements and Public Policy Resources
- ASAM 2025 Advocacy Agenda. <https://www.asam.org/advocacy>
- American Society of Addiction Medicine. Public Policy Statement on Overdose Prevention Sites. *United States v. Safehouse*, 985 F.3d 225 (3d Cir. 2021). Drug Policy Alliance. Overdose Prevention Centers: Legal and Policy Landscape. *Harm Reduction Journal*. Legal analyses of supervised consumption sites in the U.S.
- [ASAM Op-ed](#) Malik Burnett, MD, Cara Poland, MD, Carlos Tirado, MD, Lucinda Grande, MD, and Margaret Jarvis, MD
- <https://pubmed.ncbi.nlm.nih.gov/30243145/>
- Stone AC, Carroll JJ, Rich JD, Green TC. Methadone maintenance treatment among patients exposed to illicit fentanyl in Rhode Island: Safety, dose, retention, and relapse at 6 months. *Drug Alcohol Depend*. 2018 Nov 1;192:94-97. doi: 10.1016/j.drugalcdep.2018.07.019. Epub 2018 Aug 25. PMID: 30243145; PMCID: PMC10246725.
- U.S. Food & Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993



MASSACHUSETTS  
GENERAL HOSPITAL

PSYCHIATRY ACADEMY

# Thank you!

[lgkehoe@mgh.harvard.edu](mailto:lgkehoe@mgh.harvard.edu)

<https://www.massgeneral.org/substance-use-disorders-initiative>



MASSACHUSETTS  
GENERAL HOSPITAL



HARVARD MEDICAL SCHOOL  
TEACHING HOSPITAL

WWW.MGHCMC.ORG