



ASAM American Society of
Addiction Medicine



Association for Multidisciplinary
Education and Research in
Substance Use and Addiction



THE MODERNIZING OPIOID TREATMENT ACCESS ACT

SUPPORT H.R. 1359 AND S.644¹

Putting the Patient, Not a Program, At the Center

The importance of responsibly expanding access to methadone treatment for opioid use disorder (OUD) cannot be overstated. Methadone, a synthetic, long-lasting opioid agonist, is a gold standard medical treatment for OUD. OUD is associated with a 20-fold greater risk of early death due to overdose, infectious disease, trauma, and suicide.² Methadone is the most well-studied pharmacotherapy for OUD, with the longest track record.³

Methadone is safe and effective for patients when indicated, dispensed, and consumed properly.⁴

While the Substance Abuse and Mental Health Services Administration (SAMHSA)'s liberalization of clinical decision-making and take-home methadone doses for OUD from opioid treatment programs (OTPs) and their clinicians⁵ has received widespread OTP stakeholder support, some of those same OTP stakeholders have expressed concerns with the provisions in M-OTAA that would allow addiction specialist physicians - defined as physician holding board certification in addiction medicine or addiction psychiatry - to prescribe methadone for OUD that can be dispensed from retail pharmacies.⁶ Critics falsely claim that M-OTAA would allow those physicians to prescribe methadone for OUD outside of the OTP setting "with no safeguards or oversight." When criticisms are more closely examined, however, they are misleading, illogical, and put more patients with OUD at risk for overdose in a time of an unprecedented death toll.

1. Ninety-four stakeholder organizations have endorsed this legislation in a letter of support, dated May 16, 2023. https://downloads.asam.org/sitefinity-production-blobs/docs/default-source/advocacy/letters-and-comments/23.05.16_motaa-stakeholder-endorsement.pdf?sfvrsn=7a7a2519_3
2. Schuckit MA. Treatment of Opioid-Use Disorders. *N Engl J Med.* 2016;375(4):357-368. doi:10.1056/NEJMr1604339
3. Substance Abuse and Mental Health Administration. Medications for Opioid Use Disorder: For Healthcare and Addiction Professionals, Policymakers, Patients, and Families. Treatment Improvement Protocol (TIP) Series, No. 63. Chapter 3B: Methadone; 2018. Accessed March 31, 2022. <http://www.ncbi.nlm.nih.gov/books/NBK535269/>
4. Baxter LES, Campbell A, DeShields M, et al. Safe Methadone Induction and Stabilization: Report of an Expert Panel. *J Addict Med.* 2013;7(6):377-386. doi:10.1097/01.ADM.0000435321.39251.d7
5. Substance Abuse and Mental Health Services Administration. Medications for the Treatment of Opioid Use Disorder. Proposed Rule; <https://www.federalregister.gov/documents/2022/12/16/2022-27193/medications-for-the-treatment-of-opioid-use-disorder>; Substance Abuse and Mental Health Services Administration. Methadone Take-Home Flexibilities Extension Guidance, <https://www.samhsa.gov/medications-substance-use-disorders/statutes-regulations-guidelines/methadone-guidance>
6. Ironically, several states require OTPs to be licensed or registered as pharmacies and/or apply general pharmacy regulations to OTPs. In addition, over a dozen states require OTPs to hire a pharmacist or a consultant pharmacist who can provide guidance on the appropriateness and safety of methadone use. See The Pew Charitable Trust. Overview of Opioid Treatment Program Regulations by State Published September 19, 2022. Accessed June 2, 2023, <https://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2022/09/overview-of-opioid-treatment-program-regulations-by-state>

OPPOSITION STATEMENTS

A HELPFUL EXPLANATION

The bill increases access to medication only.

The Controlled Substances Act (CSA) does not prohibit non-OTP clinicians from providing other therapies and recovery supports; thus, no related amendments to the CSA are needed. M-OTAA would (1) provide a legal mechanism for board-certified physicians in addiction medicine or addiction psychiatry, who do not work at OTPs, to prescribe methadone for OUD that can be dispensed from retail pharmacies, by creating a new registration process with the Drug Enforcement Administration (DEA) for that purpose, so that such act is no longer criminalized at the federal level, and (2) establish additional federal safeguards for those prescribers.

It will likely result in physicians prescribing a powerful medication with no guardrails to limit diversion, or provide counseling and drug testing.

The DEA currently registers clinicians to “prescribe powerful medications,” including methadone for pain, that can be picked up from retail pharmacies. Without the M-OTAA’s legislative fix or change in interpretation of 21 USC 823(h) by the Biden Administration, however, an outdated prohibition on the prescribing of a singular FDA-approved medication for an FDA-approved indication (methadone for OUD) that can be picked up at retail pharmacies will continue to tie the hands of addiction specialist physicians across the country.

Non-OTP clinicians and pharmacies would remain subject to a variety of federal (and state) laws and regulations that guard against diversion of controlled medications. Expert clinical discretion would determine the frequency of counseling and drug testing in patient care, subject to any applicable state regulations. M-OTAA would not change the longstanding federal requirement that all controlled medication prescriptions by authorized prescribers must be issued for a legitimate medical purpose in the usual course of professional practice.

M-OTAA would also provide the following safeguards at the federal level:

- Require prescriptions of methadone for OUD to be issued exclusively by electronic prescribing and to be dispensed only to patients;
- Continue to require methadone treatment for OUD be subject to SAMHSA’s restrictions listed in section 8.12(i)(3) of title 42, Code of Federal Regulations (or successor regulation or guidance) regarding unsupervised supply; and
- Make it logistically possible for retail pharmacists, who regularly input prescription data into state prescription drug monitoring programs (PDMPs), to include prescriptions for methadone for OUD in PDMPs, which is largely not happening in the case of methadone dispensed from OTPs and would allow for improved patient safety.

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There is also no mechanism to evaluate effectiveness of this proposed system.

The CSA does not require the evaluation of the clinical effectiveness of the medical provision of any controlled medication, including methadone dispensed by OTPs. Such evaluations are outside the purview of the CSA, which is largely administrative/criminal law in nature.

A continued myopic focus on expanding access to methadone for treatment of OUD through the current OTP system would unwisely invest limited resources in perpetuating a siloed system of clinics that primarily provides one medication (methadone) for one indication (OUD) – essentially guaranteeing that the nation will be caught flat-footed for the next drug-related crisis.

Adding methadone treatment for OUD into PDMP systems can assist states in conducting evaluations of methadone, similar to buprenorphine, and analyze these data for trends in geographic or systematic gaps in access and adherence.

Board certified physicians are well trained; however, not necessarily in an OTP. Training alone is necessary but not sufficient to provide safe treatment. Treatment is comprised of much more than prescribing medicine.

Board certified physicians in addiction medicine or addiction psychiatry are well trained/⁷very experienced in the comprehensive treatment of patients with substance use disorder (SUD), not limited to OUD or to methadone treatment.

While it is true that not all board-certified addiction specialist physicians elect to work in an OTP (e.g., some may work in more intensive settings, such as intensive outpatient programs, partial hospitalization programs, residential treatment programs, or hospitals), it is also true that not all clinicians hired to work in OTPs previously worked in another OTP. Obviously, this does not mean that addiction specialist physicians and OTP clinicians do not understand how to provide methadone for OUD in a safe manner.

7. The American College of Graduate Medical Education (ACGME) sets the program requirements for graduate medical education in addiction medicine and addiction psychiatry. For example, ACGME common core program requirements for addiction medicine fellowships include: pharmacotherapy and psychosocial interventions for SUDs across the age spectrum, (IV.B.1.c).(1).(k)); the mechanisms of action and effects of use and abuse of alcohol, sedatives, opioids, and other drugs, and the pharmacotherapies and other modalities used to treat these (IV.B.1.c).(1).(m)); the safe prescribing and monitoring of controlled medications to patients with or without SUDs (IV.B.1.c).(1).(n)); at least three months of structured inpatient rotations, including inpatient addiction treatment programs, hospital-based rehabilitation programs, medically-managed residential programs where the fellow is directly involved with patient assessment and treatment planning, and/or general medical facilities or teaching hospitals where the fellow provides consultation services to other physicians in the Emergency Department for patients admitted with a primary medical, surgical, obstetrical, or psychiatric diagnosis; (IV.C.3.a).(1)); at least three months of outpatient experience, including intensive outpatient treatment or “day treatment” programs, addiction medicine consult services in an ambulatory care setting, pharmacotherapy, and/or other medical services where the fellow is directly involved with patient assessment, counseling, treatment planning, and coordination with outpatient services (IV.C.3.a).(2)).

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A HELPFUL EXPLANATION

The OTP structure is what makes methadone safe and effective for OUD. Suggesting that methadone is safe and effective for OUD in any other setting is not evidence-based.

Under SAMHSA's existing rules⁸ and take-home extension guidance⁹ for methadone treatment for OUD:

- Must a clinician in an OTP be a physician to order methadone for OUD through an OTP for a patient's unsupervised use? **NO**
- Must a clinician in an OTP have prior experience treating OUD with methadone to order methadone for OUD through an OTP for unsupervised use? **NO**
- To serve as an OTP medical director, must a physician be board certified in addiction medicine or addiction psychiatry? **NO**
- To serve as an OTP medical director, must a physician complete a medical residency and have board certification? **NO**
- To serve as an OTP medical director, must a physician have prior experience treating OUD with methadone? **NO**

Addiction specialist physicians are dedicated to increasing access to, and improving the quality of, addiction treatment, as well as promoting the appropriate role of physicians in the care of patients with addiction. Addiction specialist physicians practice in a variety of different settings and at all levels of care to meet different patients' needs, including in opioid treatment programs, office-based practices, intensive outpatient programs, residential treatment facilities, and hospitals. In fact, *The ASAM Criteria*, developed by addiction specialist physicians, provides a consistent way to assess a person's biopsychosocial circumstances, identify an appropriate level of care based on individual needs, and define the services that should be provided at each level of care. Patients are at the center of addiction specialist physicians' efforts to ensure access to lifesaving addiction treatment, which sometimes includes the medical provision of methadone for OUD.

Five federal reports issued in the 2000s* found that the majority of methadone mortality is attributed to physician's prescribing methadone in private practices.

Increased methadone mortality that occurred in the 2000s was *importantly context-specific*, during a time of overprescribing of opioids for pain, including the prescription of methadone for pain by non-pain medicine specialists. In stark contrast, M-OTAA would decriminalize methadone treatment for OUD if, and only if, prescribed by specially-registered addiction specialist physicians and OTP prescribing clinicians, subject to SAMHSA regulation/guidance on unsupervised use. The context specificity of 2023 and M-OTAA differ substantially.

Of note, it remains legal today for clinicians (including non-physicians) to prescribe methadone for *treatment of pain* that can be picked up from retail pharmacies.

8. 42 C.F.R. Part 8.

9. Substance Abuse and Mental Health Services Administration. Methadone Take-Home Flexibilities Extension Guidance. <https://www.samhsa.gov/medications-substance-use-disorders/statutes-regulations-guidelines/methadone-guidance>

*SAMHSA, 2004i; DOJ, 2007ii; SAMHSA, 2007iii; GAO, 2009iv; SAMHSA, 2010v

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Buprenorphine and methadone have considerably different properties, hence different FDA scheduling. Buprenorphine is unlikely to cause respiratory depression like methadone. Methadone is slow to act and accumulates in the body, making it more lethal if misused.

Moreover, despite exponential increases in buprenorphine prescriptions over the past 20 years, ODs and deaths have increased every year. More prescriptions do not stop ODs.

A HELPFUL EXPLANATION

Yes, buprenorphine and methadone have considerably different properties, hence different FDA scheduling. Addiction specialist physicians are aware.

The number of OTPs in the U.S., 1,754 in 2020, increased by about 42% over the prior 11 years.¹⁰ Despite a substantial increase in OTPs over the last decade, overdoses and deaths have increased. [More OTPs do not stop ODs. *(CAUTION: Of course, this is faulty logic for all the same reasons it is for buprenorphine prescriptions.)*]

The adulteration of the illicit drug supply with illicit fentanyl and fentanyl analogs has created an unprecedented and catastrophic moment in U.S. history. Restrictions that continue to limit methadone treatment for OUD to OTPs are a well-recognized vulnerability in the response to the opioid overdose crisis.¹¹

10. Substance Abuse and Mental Health Services Administration, National Survey of Substance Abuse Treatment Services (N-SSATS): 2020. Data on Substance Abuse Treatment Facilities. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2021.

11. NASEM. Methadone Treatment for Opioid Use Disorder Examining Federal Regulations and Laws A Workshop | National Academies. Published 2021. Accessed December 6, 2021. <https://www.nationalacademies.org/event/03-03-2022/methadone-treatment-for-opioid-usedisorder-examining-federal-regulations-and-laws-a-workshop>

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Strang study found that “...supervised methadone dosing was followed by substantial declines in deaths related to overdose of methadone in both Scotland and England.” Supervised dosing refers to the dispensing and monitoring process required at OTPs, where patients consume treatment medication on-site in the presence of medical personnel. Pharmacy-filled prescriptions do not require this process.

A HELPFUL EXPLANATION

Historical and contemporary research supports access to methadone treatment through office-based settings for selected patients with OUD.¹² M-OTAA would allow addiction specialist physicians to use their expert clinical judgement in determining, appropriately, the amount of methadone that patients can take home for unsupervised use, subject to SAMHSA regulations or guidance from time to time regarding unsupervised supplies of methadone for OUD. SAMHSA is the same federal agency that regulates unsupervised, take-home supplies of methadone for OUD for OTPs. Increased physician decision-making with methadone take-home doses for treatment of OUD is associated with lower risks of opioid overdose, treatment interruption, and treatment discontinuation in the subsequent six months.¹³

12. Salsitz EA, Joseph H, Frank B, et al. Methadone medical maintenance (MMM): treating chronic opioid dependence in private medical practice—a summary report (1983-1998). *Mt Sinai J Med N Y.* 2000;67(5-6):388-397; McCarty D, Bougatsos C, Chan B, et al. Office-Based Methadone Treatment for Opioid Use Disorder and Pharmacy Dispensing: A Scoping Review. *Am J Psychiatry.* 2021;178(9):804-817. doi:10.1176/appi.ajp.2021.20101548; Novick DM, Salsitz EA, Joseph H, Kreek MJ. Methadone Medical Maintenance: An Early 21st Century Perspective. *J Addict Dis.* 2015;34(2-3):226-237. doi:10.1080/10550887.2015.1059225

13. Gomes T, Campbell TJ, Kitchen SA, et al. Association Between Increased Dispensing of Opioid Agonist Therapy Take-Home Doses and Opioid Overdose and Treatment Interruption and Discontinuation. *JAMA.* 2022;327(9):846-855. doi:10.1001/jama.2022.1271

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Furthermore, a Canadian study found that patient one-year retention rates for prescribed and pharmacy pick-up medications was 11.9% compared to a retention rate of 57.3% at OTPs.

A HELPFUL EXPLANATION

While it is true that patients in other countries can access methadone for OUD at retail pharmacies, none of those countries limit methadone prescribers to addiction specialist physicians board-certified in the U.S., of course. In the limited one-year treatment span in the Canadian study mentioned,¹⁴ the study's authors explicitly note that the patients who chose to be dispensed methadone at pharmacies lacked access to an addiction specialist who could have fixed dispensing problems, and that patients in both cohorts had the same level of positive toxicology screens.

In addition, the authors note that certain patient factors were not assessed that could have played a causal role in worse treatment outcomes, including 1) co-occurring mental health disorders and/or severity of, or poly-substance, use and 2) other reasons for treatment discontinuation unrelated to dispensing location, such as death, incarceration, hospitalization, or transfer to a new clinic.

Opponents of M-OTAA argue that proposals for real innovation and increased access to evidence-based opioid use disorder treatment are as follows:

- Make permanent the provisions of the SUPPORT Act that require Medicare and Medicaid coverage of OTP services;
- Allow OTPs to admit patients to treatment using telehealth;
- Expand access for all three medications approved to treat OUD in jails and prisons; and
- Fund pilot programs for OTPs to develop innovative partnerships with hospitals and FQHCs in rural areas.

Passage of M-OTAA and such measures does not represent an “either/or” situation. As we continue to confront an ever-worsening public health crisis of deaths from increasingly potent opioids, a critical evaluation of the evidence and a dedication to protecting the health of Americans requires a “both/and” approach to this crisis.

14. Gauthier, Graham, Joseph K. Eibl, and David C. Marsh. "Improved Treatment-Retention for Patients Receiving Methadone Dosing within the Clinic Providing Physician and Other Health Services (Onsite) versus Dosing at Community (Offsite) Pharmacies." *Drug and Alcohol Dependence* 191 (October 1, 2018): 1–5. <https://doi.org/10.1016/j.drugalcdep.2018.04.029>.