Committee on Energy & Commerce
United States House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

Committee on Health, Education, Labor, & Pensions
United States Senate
428 Senate Dirksen Office Building
Washington, DC, 20510

March 30, 2023

Dear United States Senators and Representatives:

We write from the frontlines of our nation's addiction and overdose crisis, as board-certified physicians in addiction medicine or addiction psychiatry, some of whom work in opioid treatment programs (OTPs). As you help lead us out of this public health emergency, we humbly ask that you consider this message with the seriousness it deserves. Our aim is to inform recent discourse on the delivery of high-quality and effective treatment for people with opioid use disorder (OUD) with methadone, and provide critical clarifications to complex issues that have arisen in the context of that discussion on Capitol Hill.

Currently, federal law limits the availability of methadone for OUD to heavily regulated OTPs at both the federal and state level, a structure that has implications for access to, and quality of, care. During the COVID-19 pandemic, public health recommendations for social distancing compelled the federal government to reform federal regulations governing methadone treatment for OUD at OTPs. As a result, a natural experiment occurred,[1] and our nation learned that the federal government could move quickly and responsibly to protect patients' health and safety, while ensuring that they receive the addiction care they need. Thus, as you consider next steps to tackle our nation's addiction and overdose crisis, we urge you to support swift passage of the bipartisan and bicameral Modernizing Opioid Treatment Access Act (S.644/H.R. 1359) (the "M-OTAA").

The Modernizing Opioid Treatment Access Act

The M-OTAA would modernize federal law governing the delivery of OUD treatment with methadone – law which has largely remained unchanged since 1974, despite the scientific and medical consensus, dating as far back as 1995, calling for the federal government to regulate methadone for OUD more in alignment with other Schedule II Food and Drug Administration (FDA)-approved medications.[2] Notably, existing federal law predates the establishment and recognition by the American Board of Medical Specialties of the medical subspecialties of addiction medicine and addiction psychiatry. This explains one reason for the prescriptive federal laws enacted in the 1970s that were to govern methadone treatment for OUD in a practice

environment without recognized addiction specialist physicians. In brief, the M-OTAA would authorize the Drug Enforcement Administration (DEA) to issue special registrations for physicians who are board-certified in addiction medicine and/or addiction psychiatry, as well as OTP prescribing clinicians, who could then use their clinical expertise in prescribing methadone for OUD treatment that could be dispensed by community pharmacies, subject to SAMHSA rules or guidance on supply of methadone for unsupervised use.

Areas of Concern: Patient and Public Safety, the Current Quandary in Outpatient Treatment with Buprenorphine, and High-Quality and Effective OUD Treatment and Persistent Stigma

Methadone is a lifesaving medication that also has risks that we take very seriously. It can be a challenge to balance the risk of adverse individual and community-related impacts associated with the inappropriate provision, and diversion, of the medication against the well-established individual and public health benefits of properly treating certain patients with OUD with methadone. Our aim with this letter is to provide salient information on three relevant areas of concern: 1) the safety of patients with OUD who may be treated with methadone, and more broadly, of the public, 2) the current quandary in outpatient treatment with buprenorphine (a partial agonist) for patients with OUD who are increasingly using fentanyl or other high potency synthetic opioids, and 3) what constitutes high-quality and effective treatment for patients with OUD and the persistent stigma that surrounds those patients.

Patient and Public Safety

Evidence gathered over the last several decades illustrates that, for many people with OUD, treatment with methadone is critical to preventing overdose and promoting remission and recovery.[3] In addition, because methadone is also a very effective analgesic and has a long half-life, it is also sometimes used to treat chronic pain in pain management practice.

Decades Ago, Methadone-Involved Overdoses Correlated With Its Use in the Treatment of Pain

As an opioid analgesic for pain, methadone was swept up in the confluence of factors that lead to the inappropriate prescribing of opioids for pain treatment in the 1990s and 2000s.[4] The scientific and medical consensus after examining these trends concluded that there was a strong, positive correlation between rates of methadone prescription for use in pain treatment and methadone diversion and overdose deaths.[5] Methadone for use in pain treatment and its involvement in overdoses, however, drastically declined as public health and law enforcement agencies took measured steps to limit its injudicious use for pain, while still making it available via prescription and pharmacy dispensing when clinically appropriate for pain treatment.[6]

New Studies Have Been Used Opportunistically, And Their Nuances Have Not Been Explained

With that said, we share concerns expressed by others of methadone becoming a potential contributor of more overdoses and deaths if careful policy changes are not enacted. For example, there was an increase in methadone-involved overdose deaths in 2020; however, evidence shows such increase was likely associated with the synthetic opioid-driven spike in drug overdose deaths that year.[7] Unfortunately, some advocates use that increase opportunistically to convey a fatalistic approach that risks paralyzing lawmakers and preventing any progress. Further, those same advocates may even mention two other studies published in January 2023 that raise questions about the role of federal regulatory OTP flexibilities during the

COVID PHE – which allowed for more unsupervised use of methadone in the treatment of OUD *within OTP settings* – to increases in methadone-involved overdoses deaths. Specifically, one such study found an increase in methadone-involved overdose deaths in the year after March 2020 compared with prior trends, both with and without co-involvement of synthetic opioids;[8] the other found an increase of methadone-involved overdose deaths by 48.1% in 2020 relative to 2019.[9]

Neither of those two studies, however, includes or examines additional, provisional overdose death data after March 2021, when the rate of methadone-involved overdose deaths stabilized and declined. The authors' failure to include this data may bias the models in their studies. Indeed, the relative rate of methadone-involved overdose deaths has declined by 9.5% between August 2021 and August 2022,[10] while overdose deaths related to a lack of access to medications for OUD increased in the same period.[11]

In addition, there is no direct evidence of causality that links any change in federal OTP take-home policies to an increase in methadone-involved overdose deaths, as is noted in one study.[12] Nor do the authors in the other study wish to add to misconceptions about the safety of methadone for OUD, as stated by those authors themselves.[13] If anything, these two studies demonstrate that modernizing treatment with methadone for OUD – *within the OTP setting* – must be carried out with caution and with federal agencies' continual, longitudinal regulations and monitoring for unintended consequences, notwithstanding the widespread support of making such federal take home policy changes permanent by OTP organizations and associations. By way of contrast, our experience and training as addiction specialist physicians, coupled with the thoughtful guardrails in the M-OTAA, enables us to lead models of methadone treatment for OUD responsibly and safely, while we manage risks to patient and public health. In the absence of continued DEA and SAMHSA federal regulations, oversight, and monitoring of OTPs on several fronts, however, these two studies do illustrate why we cannot say the same yet for *all* clinicians *within the OTP setting*. While some OTP medical directors are board-certified addiction specialist physicians, the federal government does not require them to be so credentialed; thus, some are not.

Recently Published Systematic Review Finds No Increased Risk of Methadone Overdose From Federal Regulatory Flexibilities That Allowed For More Unsupervised Use of Methadone

We also draw your attention to a review that synthesized peer-reviewed research between March 2020 and September 2022 on the effect of the federal regulatory flexibilities on OTPs' operations, the perspectives of patients and providers, and health outcomes of patients at OTPs, including for methadone-involved overdoses, which found no evidence of increased risk of methadone overdose.[14] We do understand from this review, on the other hand, that many OTPs limited their uptake of the federal regulatory flexibilities and did not universally provide the maximum ceiling of doses allowed for take home methadone, driven in part due potential consequences to patients, concerns about reduced OTP revenue, and uncertainty about when this temporary regulatory flexibility would end.[15]

One Explanation for the Spike in Methadone-Involved Overdoses Is The Increase of Synthetic Opioids in the Non-Pharmaceutical Drug Supply

As previously noted, a plausible explanation for changes in trends in methadone-involved overdose deaths in 2020 is the dominating role that fentanyl and other high potency synthetic opioids have been playing in our non-pharmaceutical drug supply. For example, another recent analysis found an increase in overdose deaths, with and without methadone, in March 2020. Then, overdose deaths not involving methadone continued to increase by approximately 69 deaths per month, while methadone-involved overdose deaths remained stable. In terms of the implementation of the federal regulatory flexibilities for unsupervised use of methadone at OTPs, in the period before this policy change, and after it, there were similar rates of decline in the percentage of methadone-involved overdose deaths.[16] This study therefore suggests, in light of this data, that in the early months of the COVID-19 pandemic, the spike in drug overdose deaths overall in March 2020 was associated with the increase in synthetic opioids in the drug supply among people who were being treated with methadone from an OTP, not due to methadone risks associated with federal regulatory flexibilities for OTPs.

Multiple Factors Explain Methadone Being Preferentially Listed on Overdose Death Certificates

Finally, it is important for lawmakers to understand that methadone's long half-life is an additional, confounding variable that can result in the preferential listing of methadone on death certificates, during a period when overdose deaths frequently involve multiple substances. Novel psychoactive substances permeate the non-pharmaceutical drug supply as well, for which drug overdose deaths are not routinely assessed. Moreover, the decentralization of authority in death certification policy and procedure also creates substantial differences in how overdose deaths are characterized and reported, and there is a high error rate in death certificates for overdose deaths.[17]

The Current Quandary in Outpatient Treatment with Buprenorphine for Patients with OUD Involving Fentanyl or Other High Potency Synthetic Opioids

Under the Code of Federal Regulations Title 21 1306.07(b), the DEA permits an exception to methadone dispensing requirements for DEA-registered physicians outside of OTPs to provide emergency treatment for patients with methadone for OUD for one day, and to carry out such treatment for no more than three days, while planning for the patients' referral to treatment.[18] Last March 2022, the DEA started allowing certain DEA-registered physicians to dispense a three day supply of methadone at one time, so long as the exception is requested.[19] While this change is theoretically helpful, it does not help us face a terrible quandary when we attempt to initiate buprenorphine treatment with patients with OUD involving illegal fentanyl or other high potency synthetic opioids.

Federal Law Currently Prevents the Use of Methadone for the Treatment of Patients Via a "Low Dose Buprenorphine with Opioid Continuation" Initiation Process

Patients who use fentanyl in the unregulated drug supply, which increasingly has unpredictable and hazardous novel contaminants, have significant challenges with initiation of buprenorphine (a partial agonist), another highly effective medication for OUD treatment. Under current law, however, it is illegal to prescribe full opioid agonists such as hydromorphone, oxycodone, or

morphine for OUD during buprenorphine initiation and titration. Thus, we are sometimes left with a dangerous alternative, which is to advise patients that use of opioids from the unregulated supply should be continued while undergoing buprenorphine initiation via a low dose buprenorphine with opioid continuation initiation process. Access to methadone would be a safe full agonist alternative to use for individuals who are undergoing a low dose buprenorphine with opioid continuation initiation process, and the M-OTAA could allow this to be safely done under expert physician guidance.

Restrictions on Methadone for OUD Limit Treatment Options for Patients with OUD Who Do Not Stabilize on Buprenorphine

In addition, methadone is an excellent alternative medication treatment recommended for patients with OUD who do not stabilize on buprenorphine. However, unless it's being dispensed from an OTP, we can only dispense methadone to those patients for up to three days. This limitation restricts our being able to offer this critically important medication to those patients, even when they face insurmountable geographical, financial, transportation, or other barriers to continue their treatment at OTPs. In these medical scenarios, the absurdity of antiquated federal laws that govern methadone for OUD treatment is extremely clear. When the laws are applied to an ever and rapidly changing unregulated drug supply, the laws' out-of-date nature is obvious and distressing.

High-Quality and Effective OUD Treatment and Persistent Stigma

High-Quality and Effective Treatment for OUD Does Not Make Engagement in Psychosocial Counseling a Condition of Receiving Medication

Patients with OUD who are treated with medications for OUD have over 50% lower overdose rates.[20] For this reason and to fulfill our medical mission to save lives, our first, most immediate goal is to reach more people with moderate to severe OUD with this life-saving medication.[21] Patients who receive medication for OUD, including methadone, have better rates of retention in treatment; behavioral therapies, alone, do not increase patient retention in treatment.[22] While psychosocial treatment and other services are an important component of quality care and beneficial to many people with OUD,[23] the scientific and medical consensus is that psychosocial treatment should be made available to patients in treatment for OUD, but a patient's willingness to engage in such treatment should not be a condition of the patient receiving medication.[24]

High-Quality and Effective Treatment for OUD Is Patient-Centered

In an office-based practice of addiction medicine or addiction psychiatry, an expert physician may counsel patients with OUD who are willing to engage in psychosocial treatment as part of the physician's medical management; a multidisciplinary team member in the practice may provide more intensive counseling for patients with OUD, or the practice may refer some of those patients to another practice for even more psychosocial treatment. While we are grateful for SAMHSA's recently proposed modifications to 42 CFR Part 8 which, if finalized, should significantly improve the quality of treatment services at OTPs, by making it less "program centered" and more "patient centered" – like expert-led office-based practices – patients with OUD need more options for their care, and more OTPs need to face high-quality competition as an incentive to continue to improve their services.

Existing Stereotypes Lend Themselves to Prescriptive, Rigid Models of Methadone Treatment for OUD

Finally, we know that patients with OUD face persistent stigma, including stereotypes that they are non-compliant, out-of-control, unwilling to change risk behaviors, and do not have strong communities.[25] We are extremely concerned that these stereotypes lend themselves to prescriptive, rigid approaches to methadone treatment for OUD. The existing, siloed infrastructure for methadone treatment for OUD in the U.S. has compounded such stigma, and despite methadone's strong evidence as a life-saving medication, there is neither broad acceptance of methadone as a treatment intervention by the public, nor by healthcare providers, including some addiction providers.[26]

The Integration of Methadone Treatment with Other Medical Care Will Improve the Quality of OUD Care

The separateness of methadone treatment for OUD - which results in methadone dispensed from OTPs, rather than pharmacies, being nearly universally excluded from prescription drug monitoring programs - has rather served to focus OTP services on the administration of one medication for one medical indication.[27] In contrast, the modernization of methadone treatment for OUD, as contemplated by the M-OTAA, will give Americans with addiction involving polysubstance use more conveniently located, comprehensive treatment options that can treat and manage their uncontrolled use of any substance, as well as other chronic, often comorbid diseases with OUD, such as depression, diabetes, bipolar disorder, and hypertension. [28] These additional options are urgently needed, so that we may safely integrate treatment with methadone for OUD with the rest of general healthcare, and continue to improve the treatment of OUD with methadone in this country.

We stand ready to discuss this information further with you at any time. We are hopeful that we can work together to save as many lives as possible. We look forward to hearing from you.

Sincerely,

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The views expressed are those of the authors and do not necessarily represent the views of their institutions.

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[1] Krawczyk, Noa, Bianca D. Rivera, Emily Levin, and Bridget C. E. Dooling. "Synthesising Evidence of the Effects of COVID-19 Regulatory Changes on Methadone Treatment for Opioid Use Disorder: Implications for Policy." The Lancet Public Health 8, no. 3 (March 1, 2023): e238–46. https://doi.org/10.1016/S2468-2667(23)00023-3.
[2] In 1995, experts at the Institute of Medicine (IOM) wrote, "In light of these considerations, the committee urges reassessment of the appropriate balance between the risks of methadone and its benefits. The current regulations foster situations where addicts cannot obtain a treatment program tailored to their individual circumstances, physicians are unable to exercise professional judgment in treating individual patients, programs are isolated from mainstream medical care (thus depriving patients of important ancillary services), and significant economic costs are incurred in assuring compliance with regulatory requirements—costs that are shared by programs, insurers, patients, and taxpayers. We have concluded that there is no compelling medical reason for regulating methadone differently from all other medications approved by FDA, including schedule II controlled substances. Nevertheless, the committee is not recommending abolition of the methadone regulations. The regulations serve important functions, not the least of which is to maintain community support for methadone treatment programs by assuring that the programs maintain standards and are subject to outside review." See Institute of Medicine (US) Committee on Federal Regulation of Methadone Treatment; Rettig RA, Yarmolinsky A, editors. Federal Regulation of Methadone Treatment. Washington (DC): National Academies Press (US); 1995. Available from: https://www.ncbi.nlm.nih.gov/books/NBK232108/ doi: 10.17226/4899.
[3] National Academies of Sciences, Engineering, Health and Medicine Division, Board on Health Sciences Policy, Committee on Medication-Assisted Treatment for Opioid Use Disorder, Michelle Mancher, and Alan I. Leshner. The Effectiveness of Medication-Based Treatment for Opioid Use Disorder. Medications for Opioid Use Disorder Save Lives. National Academies Press (US), 2019. https://www.ncbi.nlm.nih.gov/books/NBK541393/.
[4] Paulozzi, Leonard, Karen Mack, and Christopher M. Jones. "Vital Signs: Risk for Overdose from Methadone Used for Pain Relief — United States, 1999–2010," July 6, 2012. https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6126a5.htm.
[5] Jones, Christopher M., Grant T. Baldwin, Teresa Manocchio, Jessica O. White, and Karin A. Mack. "Trends in Methadone Distribution for Pain Treatment, Methadone Diversion, and Overdose Deaths — United States, 2002–2014." Morbidity and Mortality Weekly Report 65, no. 26 (2016): 667–71.
[6] Id.
[7] Jones, Christopher M., Wilson M. Compton, Beth Han, Grant Baldwin, and Nora D. Volkow. "Methadone-Involved Overdose Deaths in the US Before and After Federal Policy Changes Expanding Take-Home Methadone Doses From Opioid Treatment Programs." JAMA Psychiatry 79, no. 9 (September 1, 2022): 932–34. https://doi.org/10.1001/jamapsychiatry.2022.1776.
[8] This study examines absolute counts rather than relative rate increases in methadone-involved overdose deaths. Relative rates are in proportion to the whole, while absolute counts are not, and the use of absolute counts rather than relative rates limits the usefulness of this analysis. See Kleinman, Robert A., and Marcos Sanches. "Methadone-Involved Overdose Deaths in the United States before and during the COVID-19 Pandemic." Drug and Alcohol Dependence 242 (January 1, 2023): 109703. https://doi.org/10.1016/j.drugalcdep.2022.109703
[9] This study points out that the rate of methadone-involved overdose deaths in 2020 was much lower than its peak in 2006-2008, and that these methadone-involved overdose deaths have been largely attributed to methadone prescribed for pain. See Kaufman, Daniel E., Amy L. Kennalley, Kenneth L. McCall, and Brian J. Piper. "Examination of Methadone Involved Overdoses during the COVID-19 Pandemic." Forensic Science International 344 (January 31, 2023): 111579. https://doi.org/10.1016/j.forsciint.2023.111579
[10] See statistical examination of provisional overdose death data from the CDC's National Center for Health Statistics Vital Statistics System. Volkow, Nora, D. Presentation to the American Society of Addiction Medicine Advocacy Conference, "National Institute of Drug Abuse: What Radical Change Means," March 6, 2023.
[11] Kariisa, Mbabazi. "Vital Signs: Drug Overdose Deaths, by Selected Sociodemographic and Social Determinants of Health Characteristics — 25 States and the District of Columbia, 2019–2020." MMWR. Morbidity and Mortality Weekly Report 71 (2022). https://doi.org/10.15585/mmwr.mm7129e2.
[12] "This study is observational and does not allow for a causal attribution of the increase in methadone-involved overdose deaths to any specific factor," and "this study cannot distinguish whether individuals who die from methadone-involved overdoses receive methadone through OTPs, as prescriptions for pain, or through other sources, including diverted methadone." See Kaufman, et al., (2023).
[13] "We hope that these findings will not add to further misconceptions about the safety of methadone relative to other less widely prescribed Schedule II opioids," see Kleinman, et al., (2023).
[14] The systematic review of 29 peer-reviewed studies published between March 1, 2020, and September 6, 2022, includes six studies that assessed the association between pandemic flexibilities and overdose risk, which used OTP records or state-level mortality data, national poison-control or mortality data, or qualitative data. See Krawczyk, Noa,

Bianca D. Rivera, Emily Levin, and Bridget C. E. Dooling. "Synthesising Evidence of the Effects of COVID-19 Regulatory Changes on Methadone Treatment for Opioid Use Disorder: Implications for Policy." The Lancet Public Health 8, no. 3 (March 1, 2023): e238–46. https://doi.org/10.1016/S2468-2667(23)00023-3.

[15] Findings include three studies of OTP providers, three surveys of OTP patients, and one multi-state survey of 170 OTP providers. Krawczyk, Noa, Bianca D. Rivera, Emily Levin, and Bridget C. E. Dooling. "Synthesising Evidence of the Effects of COVID-19 Regulatory Changes on Methadone Treatment for Opioid Use Disorder: Implications for Policy." The Lancet Public Health 8, no. 3 (March 1, 2023): e238–46. https://doi.org/10.1016/S2468-2667(23)00023-3.

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