

March 7, 2022

The Honorable Edward Markey
255 Dirksen Senate Office Building
United States Senate
Washington, DC 20510

Dear Senator Markey:

The American Academy of Addiction Psychiatry (AAAP) supports improving access to lifesaving medical treatment for opioid use disorder (OUD). We thank Senator Markey for introducing S. 3629, the Opioid Treatment Access Act of 2022, which would codify in law many of the COVID-19 public health emergency regulatory changes that have reduced barriers to methadone treatment for OUD as administered through Opioid Treatment Programs (OTPs).

We applaud provisions in Sections 2 and 3 of the Opioid Treatment Access Act directing the Substance Abuse and Mental Health Services Administration (SAMHSA) to study the impact of COVID-19 methadone exemptions, for allowing OTPs to operate mobile components without a separate DEA registration, and for directing SAMHSA to study and revise the timeline for patients to receive take-home doses of methadone.

However, we are concerned that provisions in Section 4 of the Opioid Treatment Access Act that would allow certain providers to prescribe up to one-month of take-home methadone doses to be dispensed from a community pharmacy may have unintended harmful consequences. Historically, as the U.S. prescription opioid epidemic was gaining momentum in the early 2000s, methadone overdoses increased dramatically in some areas of the United States. The most common source of methadone used in overdose in many states was methadone tablets prescribed for chronic pain and dispensed through local pharmacies. Most of these methadone pills had been diverted to the illicit market; many others were from legitimate prescriptions taken by the intended patient for treatment of chronic pain. Only 5% of methadone overdoses in western Virginia¹ and 3% in Vermont² involved methadone dispensed from OTPs.

Although methadone for OUD is lifesaving when managed appropriately, it can also be dangerous, especially when starting or discontinuing treatment³. The pharmacology of methadone with its slow onset of action, long half-life and increased risk of cardiac arrhythmias makes its initiation more dangerous than that of buprenorphine even under current U.S. laws and regulations

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where initiation occurs with close monitoring in an OTP³.

In France where methadone has been dispensed from pharmacies by prescription since 2008, methadone was the most common substance involved in drug overdoses during the COVID-19 pandemic lockdown cited by the French Addictovigilance Network⁴ (Lapeyre-Mestre, 2020). This was attributed to methadone's pharmacology and a combination of pandemic-related factors including interruptions in methadone therapy from pharmacies with unsupervised restarting of the medication by the intended patient, combining of methadone with other drugs, and diverted methadone obtained by naïve users and through the illicit market. Data on methadone from 2008 to 2017 by the French Addictovigilance Network has shown that methadone was increasingly involved in drug overdoses and deaths even before the pandemic disrupted medication dispensing⁵. By contrast, methadone is much less likely to be involved in drug overdose deaths than prescription opioids or illicit opioids both before and during the COVID-19 pandemic in the United States where initiation and ongoing methadone treatment is closely monitored through OTPs⁶.

We urge caution before changing U.S. laws regarding the dispensing of methadone in community pharmacies for treatment of OUD. We recommend instead funding dissemination of evidence-based strategies to improve access to OTP-based methadone treatment such as the open-access model from the Network for the Improvement of Addiction Treatment (NIATx)⁷ and research to establish appropriate safeguards for dispensing methadone for OUD at the community pharmacy level before changing federal laws in this regard.

We would welcome the opportunity to serve as a resource for this and future legislative initiatives regarding prevention and treatment of substance use disorders. Thank you for your kind attention to our concerns.

Sincerely,



Larissa Mooney, MD
AAAP President

References:

¹ Weimer MB, Korthuis PT, Behonick GS, Wunsch MJ. The source of methadone in overdose deaths in Western Virginia in 2004. *J Addict Med.* 2011 Sep;5(3):188-202. doi: 10.1097/ADM.0b013e318211c56a. PMID: 21844834; PMCID: PMC3156987.

² Madden ME, Shapiro SL. The methadone epidemic: methadone-related deaths on the rise in Vermont. *Am J Forensic Med Pathol.* 2011 Jun;32(2):131-5. doi: 10.1097/PAF.0b013e3181e8af3d. PMID: 21030851.

³ Sordo L, Barrio G, Bravo MJ, Indave BI, Degenhardt L, Wiessing L, Ferri M, Pastor-Barriuso R. Mortality risk during and after opioid substitution treatment: systematic review and meta-analysis of cohort studies. *BMJ*. 2017 Apr 26;357:j1550. doi: 10.1136/bmj.j1550. PMID: 28446428; PMCID: PMC5421454.

⁴ Lapeyre-mestre M, Boucner A, Daveuuy A, Gibaja V, Jouanjus E, Mallaret M, Peyrière H, Micallef J; French Addictovigilance Network. Addictovigilance contribution during COVID-19 epidemic and lockdown in France. *Therapie*. 2020 Jul-Aug;75(4):343-354. doi: 10.1016/j.therap.2020.06.006. Epub 2020 Jun 23. PMID: 32660776; PMCID: PMC7309935.

⁵ Frauger E, Fouilhé Sam-Lai N, Mallaret M, Micallef J; le French Addictovigilance Network (FAN). Améliorer la balance bénéfiques/risques de la méthadone en respectant ses spécificités pharmacologiques [Improve the benefit/risk balance of methadone by respecting its pharmacological specificities]. *Therapie*. 2019 Jun;74(3):383-388. French. doi: 10.1016/j.therap.2018.09.070. Epub 2018 Sep 27. PMID: 31178032.

⁶ Ahmad FB, Rossen LM, Sutton P. Provisional drug overdose death counts. National Center for Health Statistics. 2021. Designed by LM Rossen, A Lipphardt, FB Ahmad, JM Keralis, and Y Chong: National Center for Health Statistics. <https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm>

⁷ Madden LM, Farnum SO, Eggert KF, Quanbeck AR, Freeman RM, Ball SA, Schottenfeld RS, Shi JM, Savage ME, Barry DT. An investigation of an open-access model for scaling up methadone maintenance treatment. *Addiction*. 2018 Aug;113(8):1450-1458. doi: 10.1111/add.14198. Epub 2018 Mar 24. PMID: 29453891.