

National Association for Behavioral Healthcare



Access. Care. Recovery.

27 November 2023

Sen. Bernie Sanders, Chairman
Senate HELP Committee
428 Dirksen Senate Office Building
Washington, DC 20510
Sent electronically.

Sen. Bill Cassidy, M.D., Ranking Member
Senate HELP Committee
428 Dirksen Senate Office Building
Washington, DC 20510

Dear Sens. Sanders and Cassidy:

The National Association for Behavioral Healthcare (NABH) supports Sen. Cassidy's efforts to assure patient safety through his request for additional research and data collection related to prescribing methadone outside of opioid treatment programs (OTPs). The *Modernizing Opioid Treatment Access Act* (MOTAA) that Sen. Markey and Rep. Norcross introduced is misguided legislation that would deregulate the OTP gold standard of treatment at a dangerous time in the fight against opioid overdoses and mortality. The patient safety risks of deregulating methadone simply do not outweigh the benefits.

NABH represents the entire behavioral healthcare continuum, including not-for-profit and for-profit provider systems that treat children, adolescents, adults, and older adults with mental health and substance use disorders (SUDs) in inpatient behavioral healthcare hospitals and units, residential treatment facilities, partial hospitalization and intensive outpatient programs, medication-assisted treatment centers, specialty outpatient behavioral healthcare programs, and recovery support services in 49 states and Washington, D.C. Many of these companies employ addiction specialists who are concerned about legislation that would permit office-based prescribing of methadone.¹

NABH strongly supports recent federal actions to expand access to care through telehealth services, expanded methadone take-home privileges, and other flexibilities offered through regulatory revisions. However, given our members' front-line perspective on America's opioid crisis, we are obligated to highlight the potential unintended consequences and harms that may result from legislation proposing such abrupt and expansive regulatory changes. These include:

- **The risk of increasing diversion and overall overdose deaths:** Research on office-based methadone programs outside the United States has demonstrated mixed efficacy as well as *implementation failures resulting in relapse, diversion, and death*. In the United States, high levels of buprenorphine diversion are well documented. Even if the diversion is for the purpose of medication treatment for those without access to care, *methadone is a long-acting drug that can result in toxicity and cause overdose and death*. In the pervasive environment of fentanyl, methadone dosing becomes more complex and requires closer monitoring. If buprenorphine diversion serves as a proxy for methadone diversion, the deregulation of methadone will significantly increase the risk of overdose, deaths and other unintended harms.²⁻¹⁰
- **The potential for significant harm to populations that already suffer from health inequities:** Recently published studies of methadone take-home flexibilities showed that the

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regulatory changes were not universally successful, with successful outcomes being limited only in highly stable patients; and, equally important, within the treatment structure of OTPs. Additionally, when examining the complete picture, there are some concerning trends. Notably, *deaths increased by 48% for Hispanic individuals, 31% among non-Hispanic Black individuals, and 16% among non-Hispanic White individuals.*¹¹⁻¹⁶

- **The risk of implementation failure in relying on community pharmacies to fill the gap in patient access to care:** Current proposed legislation provides for community pharmacies to dispense methadone prescribed in an office-based setting without any patient protections. Furthermore, fewer than half of U.S. pharmacies today choose to dispense buprenorphine products, which carry a lower overdose risk than methadone. The three largest pharmacies in the United States – Walmart, Walgreens, and CVS – have recently agreed to billions of dollars in restitution for failing to implement controls that resulted in the very opioid epidemic we are fighting today. However, our nation faces a well-documented critical shortage of pharmacists, particularly in communities that are disproportionately affected by the opioid epidemic.

The Substance Abuse and Mental Health Services Administration’s (SAMHSA) recent regulatory changes will go far to address concerns about access to methadone. Nonetheless, NABH supports finding ways to continue expanding access to treatment for patients with Opioid Use Disorder, and we are grateful for the hard work of the numerous associations and organizations that are proactively trying to effect change. At the same time, we are gravely concerned that proposed changes in your legislation will lead to more overdose deaths and diversion of methadone. While we share your sense of urgency, we advocate for a more cautious approach than that which has been proposed. Specifically, we recommend:

- Pausing to study carefully the effects of the significant recent efforts to expand access, with a specific focus on understanding the root causes behind incremental overdoses as well as the disproportionate harm suffered by marginalized populations.
- Addressing the significant barriers to care that exist today, including restrictive zoning policies, lack of transportation for patients, excessive restrictions on expanding healthcare capacity (e.g., certificate-of-need laws), patients with inadequate insurance coverage, and restrictive prior authorization policies.
- Developing a comprehensive framework for solving the opioid epidemic, including greater transparency, communication, and best-practice sharing around the more than \$50 billion dollars that have been pledged to states and counties from recent opioid settlements.
- Encouraging new models of care whereby OTPs can collaborate with local pharmacies to allow stable patients and patients living in rural settings to pick up their OTP-prescribed methadone outside the OTP setting.
- Studying the potential impact of leveraging community-based pharmacies to dispense methadone widely to patients while ensuring that adequate regulatory controls can be established, given the concerning behaviors by pharmacies that recent court proceedings have documented.

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- Evaluating the likely uptake by office-based prescribers, pharmacies, and their localities to elucidate the minimal expansion of care MOTAA would offer, and the outsized risks relative to the benefits.

Wholesale regulatory change is difficult to implement successfully and is also potentially dangerous. We urge you and your congressional colleagues to evaluate the new regulatory provisions from SAMHSA and pursue our other recommendations before advancing MOTAA.

Thank you for considering our comments. If you have any questions, please contact me directly at shawn@nabh.org or 202-393-6700, ext. 100.

Sincerely,

Shawn Coughlin
President and CEO

¹ Isherwood, PD, MD. Proposed Methadone Treatment Legislation May Put Patients at Risk. MedPage Today. November 19, 2023.

² Krawczyk N, Rivera BD, Levin E, Dooling BCE. Synthesizing evidence of the effects of COVID-19 regulatory changes on methadone treatment for opioid use disorder: implications for policy. *The Lancet* (8). March 2023.

³ Hoffman KA, Foot C, Levander XA, Cook R, Terashima JP, McIlveen JW, Korthius 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 of Substance Abuse Treatment* May (2022)

⁴ Krawczyk et al (2023).

⁵ Figgatt MC, Salazar Z, Day E, Vincent L, Dasgupta N. Take-home dosing experiences among persons receiving methadone maintenance treatment during COVID-19. *J of Substance Abuse Treatment* 123 (2021).

⁶ Joseph G, Torres-Lockhart K, Stein MR, Mund, PA, Nahvi S. Reimagining patient-centered care in opioid treatment programs: Lessons from the Bronx during COVID-10. *J of Substance Abuse Treatment* 122 (2021).

⁷ Gavin B, Wastvedt S, Hodges JS, Rosenthal, R. Did Drug use Increase Following COVID-19 Relaxation of Methadone Take-Out Regulations?" *J of Substance Abuse treatment* 133 (2022).

⁸ Kleinman RA, Sanches M. Methadone-involved overdose deaths in the United States before and during the COVID-19 pandemic. *Drug and Alcohol Dependence*. (242) November 2022.

⁹ Kleinman (2022).

¹⁰ Kaufman DE, Kennalley AL, McCall KL, Piper BJ. Examination of methadone involved overdoses during the COVID-19 pandemic. *Forensic Science International*. 344 (2023).

¹¹ Christian Tjagvad, Svetlana Skurtveit, Kristian Linnet, Ljubica Vukelic Andersen, Dorte J. Christoffersen, and Thomas Clausen. "Methadone-Related Overdose Deaths in a Liberal Opioid Maintenance Treatment Programme." *European Addiction Research* 22, no. 5 (2016)

¹² John Strang, Wayne Hall, Matt Hickman, and Sheila M. Bird. "Impact of Supervision of Methadone Consumption on Deaths Related to Methadone Overdose (1993-2008): Analyses Using OD4 Index in England and Scotland." *BMJ* 341, no. 4851 (2010).

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¹³ D Aldabergenov, L Reynolds, J Scott, MJ Kelleher, J Strang, CS Copeland, and NJ Kalk. "Methadone and Buprenorphine-Related Deaths Among People Prescribed and Not Prescribed Opioid Agonist Therapy During the COVID-19 Pandemic in England." *International Journal of Drug Policy* 110, no. 103877 (2022).

¹⁴ Fugelstad A. What lessons from Sweden's experience could be applied in the United States in response to the addiction and overdose crisis? *Addiction*. Jan 2022.

¹⁵ Kleinman (2023)

¹⁶ Chilcoat HD, Amick HR, Sherwood MR, Dunn KE. Buprenorphine in the United States: Motives for abuse, misuse, and diversion. *J of Substance Abuse Treatment*. July 2019.

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