

24 March 2023

Rep. Donald Norcross 2427 Rayburn House Office Building Washington, DC 20515 Sen. Edward Markey 255 Dirksen Senate Office Building Washington, DC 20510

Dear Rep. Norcross and Sen. Markey:

On behalf of the National Association for Behavioral Healthcare, which represents the entire behavioral healthcare continuum – including provider systems that treat children, adolescents, adults, and older adults with mental health and substance use disorders 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. – we must express our deep disappointment about your recent comments comparing our nation's opioid treatment programs (OTPs) with cartels and characterizing this healthcare segment as an industry protecting its profits.

These comments are highly stigmatizing to the approximately 18,000 staff who work in OTPs and have dedicated their careers to delivering life-saving services to individuals with opioid use disorders (OUD). Your comments also perpetuate the ongoing stigma against medication-assisted treatment (MAT) that plagues our society. This stigma is one of the primary reasons that people with OUD do not seek, nor receive, MAT, even though it is the evidence-based, gold standard of care for patients suffering from OUD. We are confident you both agree that with our nation facing an overdose epidemic with one death every five minutes, we cannot afford to lose ground in the battle against stigmatization in addiction care.

In contrast to your assertions, the OTP community strongly supports recent federal actions to expand access to care vis-à-vis telehealth services, expanded take-home privileges, and other flexibilities offered through regulatory revisions. However, given our members' front-line perspective of America's opioid crisis, we are obligated to highlight the potential unintended consequences and harms that may result from legislation proposing abrupt and expansive changes to current regulations without regard to patient safety issues. These include:

- The potential for significant harm to patients, particularly in populations that already suffer from health inequities: Recently published studies of methadone take-home flexibilities showed that the 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.¹⁻⁹
- 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. Given the increased risk of overdose with methadone compared with buprenorphine, this creates the potential for serious unintended harm if methadone were diverted to the same extent as buprenorphine. 10-15

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• 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. Lastly, 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 shares your concern that we must find ways to continue expanding access to treatment options for patients with OUD, 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, as well as eroding confidence in, and creating more stigma against, MAT. While we share your sense of urgency, we advocate for a more cautious approach than what 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 in the United States 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.

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 before moving forward with your current legislative proposal.

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We also ask that you demonstrate greater regard for the providers who work in OTPs, who have spent decades working to destigmatize methadone treatment, and the patients they serve. We encourage you to visit some of our OTP programs so that you can see the good work that they do.

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

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⁹ Kaufman DE, Kennalley AL, McCall KL, Piper BJ. Examination of methadone involved overdoses during the COVID-19 pandemic. Forensic Science International. 344 (2023)

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¹³ 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.

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¹⁵ 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.