



NABH Concerns and Recommendations for MOTAA (H.R. 1359, S. 644)

OUR CONCERNS

1. 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. Successful outcomes were limited to highly stable patients. Equally important, take-homes were provided within the treatment structure of Opioid Treatment Programs (OTPs) that offered a range of comprehensive support services that helped to assure the success of take-homes. 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.

2. 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 some 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, and assuming a similar level of diversion, office-based methadone would create serious unintended harm, including an escalation in overdoses and death.

3. 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. In addition, our nation faces a well-documented critical shortage of pharmacists, particularly in communities that are disproportionately affected by the opioid epidemic.



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OUR RECOMMENDATIONS

- 1. *Pausing to study carefully*** the effects of the significant recent efforts (such as the SAMHSA regulatory changes and the removal of the buprenorphine “x-waiver”) 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.
- 2. *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.
- 3. *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.
- 4. *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.
- 5. *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.
- 6. *Directing the Substance Abuse and Mental Health Services Administration to convene relevant national stakeholders***, including opioid treatment programs, addiction medicine specialists, recovery advocates, and others as determined by the Assistant Secretary, to identify appropriate measures to safely address these recommendations and expand access to methadone treatment.

Questions? Please contact NABH Director of Quality and Addiction Services [Sarah Wattenberg](#).