

**FOR IMMEDIATE RELEASE****Health Policy Advocates Oppose Federal Opioid Treatment Bill**

*Opponents say the bill, which claims to authorize methadone dispensing in pharmacies, is unnecessary and would erode quality of care*

May 17, 2023 – Washington, DC – Health policy professionals are pushing back on a federal bill that would “authorize” pharmacy-based dispensing of methadone to treat opioid use disorder (OUD). According to the Center for U.S. Policy, the *Modernizing Opioid Treatment Access Act* is not necessary because dispensing methadone in pharmacies is already permissible through opioid treatment program (OTP) medication units.

Advocates for people with OUD have called for Congress to pass the Modernizing Opioid Treatment Access Act to authorize pharmacy-based dispensing of methadone for the treatment of OUD. They may not be aware that OTP medication units already can be (and are) co-located in pharmacies.

“Patient advocates are right in that eliminating barriers to methadone is necessary to facilitate access to individually appropriate OUD treatment,” said Olivia Backhaus, Counsel to the Center for U.S. Policy. “But current law already allows pharmacy-based dispensing of methadone. A more direct and efficient approach to enhancing access is to reduce regulatory burdens and delays hindering the establishment of OTP medication units in pharmacies and other settings.”

**The Drug Poisoning Crisis Persists**

Three million people in the U.S. live with OUD. Opioid-involved poisonings killed more than 78,000 Americans in the 12 months ending November 2022.

Three FDA-approved medications for OUD (methadone, buprenorphine, and naltrexone) are effective and help save lives, especially when used as part of a comprehensive treatment approach that may also include counseling, peer supports, primary care, or wrap-around services. Evidence-based treatment guidelines recommend that all three FDA medications be made available to

patients with OUD.<sup>1</sup> Yet, many Americans who could benefit from such treatments do not get them.

### **The Critical Role of Opioid Treatment Programs**

OTPs are clinics specializing in addiction medicine that deliver evidence-based treatment to people with OUD. OTPs offer all three FDA-approved medications for OUD. Other than hospitals, OTPs are the only health care programs that can provide methadone for OUD.

OTPs are typically staffed by physicians, nurses, and counselors and make medical, psychosocial, vocational, educational, and other assessment and treatment services available to all patients. “Opioid treatment program medication units serve patients who would otherwise have to travel often unreasonable distances to obtain treatment for their opioid use disorder,” said addiction medicine specialist Andrea G. Barthwell, M.D.

Under current federal laws, OTPs are authorized to establish satellite clinics, known as medication units, to dispense methadone for OUD. Medication units may be freestanding entities or co-located, if permitted by state law, in pharmacies, hospitals, homeless shelters, jails, prisons, public health departments, and federally qualified health centers.

If the *Modernizing Opioid Treatment Access Act* passed, office-based addiction treatment providers could circumvent the OTP and prescribe methadone themselves. This approach would reduce emphasis on, and participation in, the multimodal therapies and support system available to patients through OTPs.

### **Reframing the Issue – Eliminating Regulatory Burdens**

According to the Center for U.S. Policy, obtaining federal authorization for a medication unit is unnecessarily complicated and time-consuming, and OTP medical personnel’s focus is better directed toward ensuring the quality of treatment. The authorization process entails a Substance Abuse and Mental Health Services Administration (SAMHSA) notification and Drug Enforcement Administration (DEA) documentation and inspection requirements.

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<sup>1</sup> NAT’L ACAD. SCI, ENG’G, AND MED., *Medications for Opioid Use Disorder Save Lives* (Alan I. Leshner and Michelle Mancher eds., 2019).

“The DEA should reduce its documentation requirements to a single, simple form that the OTP and pharmacy can easily complete, sign, and submit,” Ms. Backhaus said. “It should also act swiftly and speed up the approvals of OTP medication units.”

Making regulatory approvals for medication units easier and faster under current law would expand access to high-quality, multimodal OUD treatment directed by OUD specialists and supported by nurses and counselors at OTPs.

### **Building On Success**

A clinical trial conducted in 2020 investigated the feasibility of an OTP physician directing the dispensing of methadone for OUD through collaboration with a pharmacy. This trial found OTP physician-directed, pharmacy-based dispensing of methadone for OUD to be feasible and acceptable. The treatment retention rate at month three was 80 percent (16 of 20 participants). Medication adherence among the 16 patients who were retained was 100 percent.

Entities interested in dispensing methadone or any other controlled medication should obtain legal counsel from an attorney with experience in drug law.

For more detailed information on the dispensing of methadone for OUD, see:

- [\*Federal Guidelines for Opioid Treatment Programs\*](#) (SAMHSA)
- [\*Narcotic Treatment Program Manual\*](#) (DEA)
- [\*Pharmacy-Based Dispensing of Methadone for Opioid Use Disorder: Permissibility and Feasibility\*](#) (CUSP)
- [\*Pharmacy-Based Dispensing of Methadone for Opioid Use Disorder: How It Happens\*](#) (CUSP)
- [\*Opioid Treatment Program and Community Pharmacy Collaboration for Methadone Maintenance Treatment: Results from a Feasibility Clinical Trial\*](#) (Society for the Study of Addiction)

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## **About the Center for U.S. Policy (CUSP)**

CUSP is a nonpartisan, 501(c)(3) not-for-profit research and education organization dedicated to enhancing Americans' health, safety, and economic opportunity. CUSP's 2023 priorities include preventing substance use disorder and drug poisonings, and supporting people affected by substance use.

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