



February 14, 2023

The Honorable Miriam E. Delphin-Rittmon
Assistant Secretary for Mental Health and Substance Use
Substance Abuse and Mental Health Services Administration
U.S. Department of Health and Human Services
5600 Fishers Lane, Room 13-E-30
Rockville, MD 20857

RE: Medications for the Treatment of Opioid Use Disorder- RIN 0930-AA39

Dear Assistant Secretary Delphin-Rittmon,

The Association for Behavioral Health and Wellness (ABHW) appreciates the opportunity to submit comments on the U.S. Department of Health and Human Services (HHS) and Substance Abuse and Mental Health Services Administration (SAMHSA) notice of proposed rulemaking (NPRM or proposed rule) for Medications for the Treatment of Opioid Use Disorder.

ABHW serves as the national voice for payers that manage behavioral health insurance benefits. ABHW member companies provide coverage to approximately 200 million people in public and private sectors to treat mental health (MH), substance use disorders (SUDs), and other behaviors impacting health and wellness.

Our organization aims to increase access, drive integration, support prevention, raise awareness, reduce stigma, and advance evidence-based treatment and quality outcomes. Furthermore, through our policy work, we strive to promote equal access to quality treatment and address the stark inequities created by systemic racism. We are deeply concerned about health disparities in this country in the areas of MH and SUD services and are committed to promoting health equity in the healthcare system.

We applaud HHS and SAMHSA for this proposed rule that seeks to streamline access and delivery of Medications for Opioid Use Disorder (MOUD). At a time when opioid overdoses and deaths are increasing, the flexibilities of this NPRM will enable more Outpatient Treatment Programs (OTP) to treat more patients.

Federal Opioid Use Disorder Treatment Standards

ABHW strongly supports removing the requirement that a person must have an addiction to opioids for one year before admission to treatment in an OTP, a vestige of a prior version of the Diagnostic and Statistical Manual of Mental Disorders (DSM). Current federal treatment standards for opioid use disorder (OUD) do not reflect the changes in treatment that have occurred over the last twenty years. This proposed rule will broaden access to those who meet diagnostic criteria for a moderate to severe OUD, individuals with active moderate to severe OUD or OUD in remission, or those at high risk for overdose or recurrence of use.

ABHW also supports the revised clinical standards that emphasize clinical judgment, consideration of the severity of usage, and comorbid conditions. Lastly, we appreciate removing stigmatizing language in Part 8, such as legitimate medications, detoxification, and drug abuse.

Expanded Definition of Provider

ABHW fully endorses expanding the definition of providers eligible to prescribe and dispense MOUD at OTPs to include physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, or certified nurse midwives. There is currently more demand for MOUD treatment than workforce capacity to deliver services, and numerous OTPs have patient waitlists. Increasing the pool of eligible practitioners will enhance access to SUD treatment. This addition will be easy to operationalize since nurse practitioners and physician assistants are already providing services in OTPs and, with appropriate guidance, will be able to widen the scope of their work.

Since the publication of the proposed rule, Congress passed the Mainstreaming Addiction Treatment Act (MAT) and the Medication Access and Training Expansion (MATE) Act in the Consolidated Appropriations Act of 2023 (CAA). Among these provisions of the CAA, Congress repealed the requirements under 21 U.S.C. 823(g) requiring providers to separately register with the Drug Enforcement Administration (DEA) for the prescription of buprenorphine for the treatment of OUD. ABHW encourages SAMHSA to update the proposed rule to remove reference to this now outdated requirement for providers to have a DATA-Waiver registration.

Take-Home Methadone

ABHW supports making permanent the ability to take-home doses of methadone. This flexibility began during the COVID-19 pandemic, and our members appreciate that the guardrails around these provisions have not been removed but have been updated to align with current evidence. Multiple studies have shown that there have been few reports of overdose or harm related to take-home doses.¹ Patient feedback has been positive and

¹ <https://www.healthaffairs.org/doi/10.1377/forefront.20220524.911965/>

demonstrated that patients prefer these doses. Data also highlights that this change can help keep patients engaged in care. Our members support the evidence-based and person-centered approach in this NPRM that allows clinical judgment to weigh the decision for take-home doses of methadone.

Prescription of Buprenorphine via Telehealth

ABHW strongly supports the removal of the in-person initiation requirement for buprenorphine via telehealth and is pleased to see the removal of this requirement at OTPs in the proposed rule. Enhancing access to Medications for Opioid Use Disorder (MOUD) is more critical than ever, with increasing annual deaths from opioid overdoses. The Centers for Disease Control (CDC) estimates that in 2021, there were more than 107,000 deaths due to opioid overdoses, and in 2020 there were over 93,000. The Kaiser Family Foundation reports that in 2020, 31% of these deaths were Black, Hispanic, or Asian. The in-person evaluation required before prescribing controlled substances via telemedicine only results in reduced access to care. During the COVID-19 public health emergency (PHE), the DEA waived the in-person requirement, enabling providers to prescribe controlled substances using telemedicine safely. A Journal of Substance Abuse Treatment study found that removing the in-person requirement significantly increased access to care and addressed health inequities in primary care programs providing buprenorphine treatment. We strongly support removing this requirement that currently hinders SUD care.

We also appreciate the proposal to codify the flexibility to allow OTP providers to continue prescribing buprenorphine via audio-only or audio-visual appointments. ABHW believes in-person requirements can be fulfilled at virtual visits and is supportive of the increased flexibility for patients who might otherwise not be able to get to their appointments due to difficulties traveling.

While we are supportive of these changes in OTPs, we urge you to work with the DEA to release the long overdue rule creating a special registration for providers to prescribe controlled substances via telemedicine beyond OTPs. This rule was due in 2019 under the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) Act. The deadline has long passed without action from the DEA. Promulgation of this rule will result in increased access to MOUD, and we urge you to work with the DEA for its release. It is essential to create a glide path for implementation before the end of the PHE to allow for continued care for patients.

Methadone Treatment via Telehealth

ABHW supports the change to allow methadone treatment via an audio-visual telehealth visit. We agree with the distinction between audio-visual and audio-only visits, as Methadone's risk for sedation in patients makes this distinction appropriate while enabling increased access to needed care. Our members also appreciate that while this rule extends telehealth flexibilities, the first dose of methadone would be provided under direct supervision. This ensures patient safety, the medication is tolerated, and the patient has

connected with other treatment team members.

Conclusion

Thank you for the opportunity to provide feedback on this proposed rule. We are committed to engaging with CMS and other partners on opportunities to improve behavioral health access. If you have questions, please contact Kathryn Cohen, Senior Director of Regulatory Affairs, at cohen@abhw.org.

Sincerely,

A handwritten signature in cursive script that reads "Pamela Greenberg".

Pamela Greenberg, MPP
President and CEO