



February 10, 2023

Dr. Delphin-Rittmon, Ph.D.
Assistant Secretary
Substance Abuse and Mental Health Services Administration
Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20857

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

On behalf of the American Association of Psychiatric Pharmacists (AAPP), we appreciate the opportunity to provide feedback on the Substance Abuse and Mental Health Services Administration's (SAMHSA) proposed rule on Medications for the Treatment of Opioid Use Disorder.

About AAPP

AAPP is a professional association of nearly 3,000 members who envision a world where all individuals living with mental illness, including those with substance use and neurologic disorders, receive safe, appropriate, and effective treatment. Members are specialty pharmacists, and most are Board Certified Psychiatric Pharmacists (BCPPs) who specialize in psychiatry, substance use disorders (SUDs), psychopharmacology. With a significant shortage of mental health care professionals, psychiatric pharmacists offer another resource to improve outcomes for patients with psychiatric and SUDs.

Role of Psychiatric Pharmacists

Pharmacists graduate with a Doctor of Pharmacy degree, requiring six to eight years of higher education to complete, and have more training specific to medication use than any other health care professional. Psychiatric pharmacists, a specialty within clinical pharmacy, are primarily board certified and residency-trained mental health care practitioners who have specialized training in providing direct patient care and medication management for the complete range of psychiatric disorders and SUDs. Psychiatric pharmacists work as treatment team members but also in decision-making and leadership roles in state and federal organizations, academia, and industry.

Psychiatric pharmacists are an important member of the health care team working in collaboration with the patient and other health care providers including, but not limited to, psychiatrists, other physicians, therapists, social workers, and nurses (including advanced practice nurses). Psychiatric pharmacists provide expert, evidence-based Comprehensive Medication Management (CMM) services for the most complex patients with mental health disorders and SUDs. Psychiatric pharmacists increase capacity of the health care team to provide care and psychopharmacology expertise, as well as improve patient outcomes and reduce overall health care costs.

AAPP Comments on Notice of Proposed Rulemaking

The current regulation, which has not been updated for more than 20 years, perpetuates stigma for individuals seeking care and may create barriers to care, including requiring recurrent visits to the

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provider and requiring in-person dosing. As such, AAPP applauds SAMHSA for making the proposed changes to opioid treatment program operations.

Specifically, AAPP supports:

- **Making permanent the ability to use telehealth to initiate buprenorphine treatment.**

An August 2022 study¹ in *JAMA Psychiatry* examined telehealth service use, treatment engagement, and medically treated overdoses among Medicare beneficiaries following the institution of the COVID flexibilities. The study found that telehealth access was widely used by Medicare beneficiaries initiating opioid use disorder (OUD) treatment. In addition, beneficiaries that received telehealth services had improved treatment retention and “lower odds of medically treated overdose.”

A recent study in *JAMA Open Network* examining patients with OUD on commercial insurance or Medicare found “no evidence that telemedicine was unsafe or overused or was associated with increased access to or improved quality of OUD care, suggesting that telemedicine may be a comparable alternative to in-person OUD care.”² Furthermore, a study by the National Institute on Drug Abuse (NIDA) determined that the proportion of opioid overdose deaths involving buprenorphine did not increase in the months after the COVID-19 prescribing flexibilities were in place.³ The study’s findings call for more equitable access to MOUD and greater flexibility in prescribing as critical components to the response to the overdose crisis.

- **Updating the criteria for the provision of take-home doses of methadone and allowing early access to take-home doses of methadone for all patients to promote flexibility in treatment plans and support everyday needs like employment or support individuals with transportation limitations.**

A recently published synthesis of studies⁴ found that allowing more patients with OUD to take doses of methadone at home during the COVID-19 pandemic—instead of requiring them to travel daily to receive treatment in person—benefited both patients and health care providers and did not lead to increased overdose deaths. Across the studies reviewed, researchers found that these flexibilities substantially improved patients’ quality of life, including feelings of self-esteem and autonomy and lessened burdens

¹ Jones CM, Shoff C, Hodges K, et al. Receipt of Telehealth Services, Receipt and Retention of Medications for Opioid Use Disorder, and Medically Treated Overdose Among Medicare Beneficiaries Before and During the COVID-19 Pandemic. *JAMA Psychiatry*. 2022;79(10):981–992. DOI: [10.1001/jamapsychiatry.2022.2284](https://doi.org/10.1001/jamapsychiatry.2022.2284)

² Hailu R, Mehrotra A, Huskamp HA, Busch AB, Barnett ML. Telemedicine Use and Quality of Opioid Use Disorder Treatment in the US During the COVID-19 Pandemic. *JAMA Netw Open*. 2023;6(1):e2252381. DOI: [10.1001/jamanetworkopen.2022.52381](https://doi.org/10.1001/jamanetworkopen.2022.52381).

³ Lauren J. Tanz, Scd; Christopher M. Jones, PharmD, DrPH, Nicole L. Davis, PhD, Trends and Characteristics of Buprenorphine-Involved Overdose Deaths Prior to and During the COVID-19 Pandemic, *JAMA Netw Open*, January 20, 2023, available at https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2800689?utm_source=For_The_Media&utm_medium=referral&utm_campaign=ftm_links&utm_term=012023. Last visited February 8, 2023.

⁴ Noa Krawczyk, Bianca D. Rivera, Emily Levin, Bridget C.E. Dooling. medRxiv 2022.12.15; <https://doi.org/10.1101/2022.12.15.22283533>.

associated with daily in-person treatment, such as long travel times, and reduced the number of stressful in-person treatment encounters for patients.

Unnecessarily stringent restrictions on take-home methadone undermine a patient's autonomy and propagates stigma against patients with SUD – a bona fide medical condition, as they are attempting to access the treatment for that condition. A patient should not have to be threatened with the precipitation of withdrawal, the risk of using street opioids, or losing access to treatment should that flexibility be needed.

- **Removing outdated terms such as detoxification.**

AAPP lauds SAMHSA for their continued effort to remove stigmatizing language and to educate providers and the public on the role of language in perpetuating SUD stigma. AAPP has made concerted efforts to educate our membership and other pharmacists on the impact stigmatizing language surrounding substance use disorder treatment can have on patients not engaging in the care they need.

- **Strengthening the patient-practitioner relationship through promotion of shared and evidence-based decision making.**

AAPP is a strong advocate for shared decision-making when providing medication management for psychiatric and substance use disorders. In 2017, only 23% of SUD treatment clinics regularly invited patients into care decision-making meetings when their cases were discussed. Patient-centered care variables have been found to significantly correlate with service utilization.⁵ AAPP members are trained in shared decision-making as part of their professional education and AAPP believes patient-centered care in SUD treatment can enhance utilization of evidence-based services

- **Updating admission criteria and removing the requirement that an OTP only admits people with a year of an opioid addiction.**

There is no requirement in the diagnostic criteria of OUD for individuals to have symptoms for one year to be considered to have an OUD. There are countless clinician anecdotes that such an arbitrary delay can lead to overdose. Furthermore, studies have shown that medications for OUD can increase treatment retention, reduce drug use, and reduce fatal overdoses by 50%-70%,⁶ a statistic which strongly supports a medication-based treatment approach for OUDs. Studies have also demonstrated that effective agonist medication used for an indefinite period of time is the safest option for treating OUDs.⁷ As such, AAPP strongly supports removing the one-year requirement from the admission criteria for OUD, which is a significant barrier to treatment.

⁵ Park SE, Mosley JE, Grogan CM, Pollack HA, Humphreys K, D'Aunno T, Friedmann PD. Patient-centered care's relationship with substance use disorder treatment utilization. J Subst Abuse Treat. 2020 Nov; 118:108125. DOI: [10.1016/j.jsat.2020.108125](https://doi.org/10.1016/j.jsat.2020.108125). Epub 2020 Sep 3. PMID: 32972650; PMCID: PMC7528396.

⁶ Rachel P. Winograd, Ned Presnall, Erin Stringfellow, Claire Wood, Phil Horn, Alex Duello, Lauren Green & Tim Rudder (2019) The case for a medication first approach to the treatment of opioid use disorder, The American Journal of Drug and Alcohol Abuse, 45:4, 333-340. DOI: [10.1080/00952990.2019.1605372](https://doi.org/10.1080/00952990.2019.1605372)

⁷ Sordo et al., Medications for Opioid Use Disorder Save Lives, The Effectiveness of Medication-Based Treatment for Opioid Use Disorder, 2017, available at <https://www.ncbi.nlm.nih.gov/books/NBK541393/>. Last visited February 8, 2023.

We urge SAMHSA to swiftly finalize this rule to ensure these important changes can begin to benefit individuals with OUD that seek care at OTPs.

Broadening the Scope of Telehealth for Buprenorphine Treatment

As SAMHSA notes in the preamble to the proposed rule, a growing body of research has demonstrated that initiating buprenorphine treatment via telehealth has “facilitated access to treatment and eliminated criteria that promote stigma and discourage people from accessing care from OTPs.”⁸ We believe this benefit should extend to individuals outside of OTPs since often, those with OUDs are unable to leave the house due to complications of their illness or transportation issues.

Currently, the Drug Enforcement Administration (DEA) has a proposed rule pending at the Office for Management and Budget to establish a special registration process for providers which would allow them to utilize telemedicine to prescribe buprenorphine. As you are aware, Congress recently passed the Mainstream Addiction Treatment (MAT) Act that eliminates the barrier of requiring providers to obtain an X-waiver before prescribing buprenorphine. While this reduces the burden on providers, individuals who need treatment still contend with stigma and the burden of traveling for treatment. However, it is unclear how the MAT Act will affect the pending DEA rule. While we are hopeful that telehealth will continue to be available to patients without barriers for OUD treatment, we urge SAMHSA to monitor and if necessary, advocate to Congress for legislation to make the use of telehealth for buprenorphine permanent.

Thank you again for the opportunity to comment. If you have any questions, please do not hesitate to contact me or our Health Policy Consultant, Laura Hanen at lahanen@venable.com.

Sincerely,



Brenda K. Schimenti
Executive Director

⁸ Proposed Rule, 87 Fed. Reg. 77331.