



March 10, 2023

Dr. Delphin-Rittmon
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: Removal of the DATA-2000 Waiver Requirements [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) supplemental notice of proposed rule on Medications for the Treatment of Opioid Use Disorder: Removal of the DATA-2000 Waiver Requirements.

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 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), and 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, 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 patients with the complex medication regimens often required for the treatment of mental health and SUDs. Psychiatric pharmacists contribute psychopharmacology expertise and increase capacity of the health care team to provide care, as well as improve patient outcomes and reduce overall health care costs.

Psychiatric pharmacists have a deep understanding of Medications for Opioid Use Disorder (MOUD) that extends beyond that of most other health care providers. When included in the provision of MOUD

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services through a collaborative practice arrangement, psychiatric pharmacist involvement has been demonstrated to improve patient adherence and success with buprenorphine treatment for opioid use disorders (OUD); reduce per patient dosing of buprenorphine through improved medication management, monitoring and titration; and reduce overall costs for treating patients with SUDs by relieving providers from delivering services including medication management, education, monitoring and follow-up visits.¹

AAPP Comments on Supplemental Notice of Proposed Rulemaking

The rule implements Section 1262(a)(1) of the Consolidated Appropriations Act, 2023 which removes the Drug Enforcement Administration (DEA) DATA-2000 waiver requirement for providers that prescribe schedule III-IV drugs including medication for OUD. SAMHSA seeks comment on unintended consequences and benefits for people in Opioid Treatment Programs (OTPs). AAPP strongly believes that removal of the DATA Waiver requirements is essential to expanding access to MOUD.

Benefits to persons with OUD:

- **The rule removes outdated barriers that prevent health care providers from prescribing a safe and effective treatment for OUD.**² Buprenorphine and related medications cut the risk of overdose death in half and reduce fentanyl use by preventing painful withdrawal symptoms and stemming opioid cravings. The medication has been FDA-approved for OUD for twenty years and is available in a generic form. Buprenorphine is considered a gold standard of care for OUD because it saves lives and helps individuals secure long-term recovery.³
- **The rule will increase access to buprenorphine.** Only about 1 in 10 people with OUD receive medications for the condition.⁴ Additionally, 40% of U.S. counties lack a single health care provider who can prescribe buprenorphine for OUD.⁵ This lack of access to buprenorphine is devastating

¹ Lindsay M. Mailoux, PharmD, et.al., Development and implementation of a physician-pharmacist collaborative practice model for provision and management of buprenorphine/naloxone, *Ment Health Clin.* 2021 Jan; 11(1): 35-39; Published online 2021 Jan 8. doi: [10.9740/mhc.2021.01.035](https://doi.org/10.9740/mhc.2021.01.035).

² Sordo L, Barrio G, Bravo MJ, Indave BI, Degenhardt L, Wiessing L, Ferri M, Pastor-Barriuso R. Mortality risk during and after opioid substitution treatment: systematic review and meta-analysis of cohort studies. *BMJ.* 2017 Apr 26;357:j1550. doi: [10.1136/bmj.j1550](https://doi.org/10.1136/bmj.j1550). PMID: 28446428; PMCID: PMC5421454.

³ National Academy of Sciences, Engineering, and Medicine, Consensus Study Report: Medications for Opioid Use Disorder Save Lives, *Nat'l Acad. Press* (2019); U.S. Commission on Combating Synthetic Opioid Trafficking, Final Report, at p. 30-31. Accessed at <https://nap.nationalacademies.org/catalog/25310/medications-for-opioid-use-disorder-save-lives>.

⁴ Substance Abuse and Mental Health Services. Admin., Key Substance Use and Mental Health Indicators in the United States: Results from the 2020 National Survey on Drug Use and Health, at p. 41 (Oct. 2021). Accessed at: <https://www.samhsa.gov/data/sites/default/files/reports/rpt35325/NSDUHFFR1PDFWHTMLFiles2020/2020NSDUHFFR1PDFW102121.pdf>.

⁵ U.S. Department of Health and Human Services, Office of Inspector General, Geographic Disparities Affect Access to Buprenorphine Services for Opioid Use Disorder, Report in Brief and p. 10 (Jan. 2020). Accessed at: <https://oig.hhs.gov/oei/reports/oei-12-17-00240.pdf>.

families and communities as well as causing tens of thousands of preventable overdose deaths each year.⁶

- **Removal of the waiver will help historically underserved communities gain access to treatment for OUD.** Rural populations and communities of color have difficulty accessing and receiving buprenorphine because there are few or no X-waivered providers available in their region.⁷
- **Removal of the waiver requirement will help to destigmatize MOUD for patients and providers** by addressing the misconception that treatment of OUD with buprenorphine is different from other lifesaving and life-extending therapies or that the MOUD is dangerous for patients.⁸ However, there is still much work to be done to reduce stigma at a social and structural level.
- **Removal of the waiver requirement saves lives.** This was especially important given the pandemic-related increase in overdose deaths. Fewer overdoses, less acute care use and retention in treatment is associated with better outcomes.⁹
- **Buprenorphine is a safe medication.** There are very few overdose deaths related to buprenorphine use.¹⁰

Broadening Access to Treatment

AAPP supports making permanent the flexibility to allow prescribing of buprenorphine via telehealth beyond OTPs, including audio-only services, thus enabling 24-hour access to MOUD. Further, AAPP urges SAMHSA and DEA to remove barriers and reduce stigma by educating and incentivizing pharmacies to stock buprenorphine, as about one in five pharmacies currently refuse to dispense.¹¹ A recent letter in the New England Journal of Medicine demonstrates that patients can safely start care for OUD in a community pharmacy without a physician visit¹² and pharmacies should be prepared to provide such treatment. We also support removing the required, initial in-person visit, as included in the Ryan Haight

⁶ See Kevin Fiscella, MD, MPH, Sarah E. Wakeman, MD, Leo Beletsky, JD, MPH, Buprenorphine Deregulation and Mainstreaming Treatment for Opioid Use Disorder: X the X Waiver, 76(3) JAMA Psychiatry 229-30 (2018). Accessed at: <https://jamanetwork.com/journals/jamapsychiatry/article-abstract/2719455>.

⁷ Lagisetty PA, Ross R, Bohnert A, Clay M, Maust DT. Buprenorphine Treatment Divide by Race/Ethnicity and Payment. JAMA Psychiatry. 2019 Sep 1;76(9):979-981. doi: [10.1001/jamapsychiatry.2019.0876](https://doi.org/10.1001/jamapsychiatry.2019.0876). PMID: 31066881; PMCID: PMC6506898.

⁸ Cheetham A, Picco L, Barnett A, Lubman DI, and Nielsen S. The Impact of Stigma on People with Opioid Use Disorder; Opioid Treatment and Policy. Subst Abuse Rehabil. 2022; 13: 1-12. doi: [10.2147/SAR.S304566](https://doi.org/10.2147/SAR.S304566). PMID: [35115860](https://pubmed.ncbi.nlm.nih.gov/35115860/).

⁹ Wakeman SE, Larochelle MR, Ameli O, et al. Comparative Effectiveness of Different Treatment Pathways for Opioid Use Disorder. JAMA Netw Open. 2020;3(2):e1920622. doi:[10.1001/jamanetworkopen.2019.20622](https://doi.org/10.1001/jamanetworkopen.2019.20622).

¹⁰ LJ Tanz, et al. Trends and Characteristics of Buprenorphine-Involved Overdose Deaths Prior to and During the COVID-19 Pandemic. JAMA Network Open. DOI: [10.1001/jamanetworkopen.2022.51856](https://doi.org/10.1001/jamanetworkopen.2022.51856) (2023).

¹¹ Kazerouni N, Irwin A, et al. Pharmacy-Related buprenorphine access barriers: An audit of pharmacies in counties with a high opioid overdose burden. Drug and Alcohol Dependence. 2021; 224. Accessed at: <https://pubmed.ncbi.nlm.nih.gov/33932744/>.

¹² Study shows pharmacists can safely, effectively start treatment for patients with opioid use disorder, University of Rhode Island, College of Pharmacy, available at <https://web.uri.edu/pharmacy/2023/01/11/study-shows-pharmacists-can-safely-effectively-start-treatment-for-patients-with-opioid-use-disorder/>. Last visited March 6, 2023.


Act of 2008 (PL 110-425).¹³ While DEA recently proposed two rules related to the in-person requirement and expanding access to buprenorphine using telehealth, those rules do not acknowledge the special registration process which can be used to permanently circumvent the in-person requirement. We urge SAMHSA to monitor and if necessary, recommend Congress to pass legislation to make the use of telehealth beyond OTPs permanent for OUD treatment with buprenorphine.

Increasing Patient Safety

Prescription drug monitoring programs (PDMPs) can help inform point of care clinical decision making to improve patient safety.¹⁴ In fact, the [2022 CDC Clinical Practice Guideline for Prescribing Opioids for Pain](#) (2022 Clinical Practice Guideline) recommends that clinicians who are prescribing initial opioid therapy should first review a patient's history of controlled substance prescriptions using a state PDMP.¹⁵ Unfortunately, OTPs are not currently required to report to PDMPs, limiting the line-of-sight psychiatric pharmacists and all health care providers need when treating patients who receive treatment in OTPs. For example, if an individual is receiving treatment at an OTP and that treatment is not reported, a fatal drug interaction may be missed if a psychiatric pharmacist checks the PDMP and is not privy to information alerting him to the patient taking methadone or buprenorphine. In an effort to increase patient safety measures, we urge SAMHSA to consider mandating OTPs to report to the PDMP in future rulemaking.

Thank you again for the opportunity to comment on this issue that is critical to increasing access and reducing barriers in access to MOUD. If you have any questions, please do not hesitate to contact me at bschimenti@aapp.org or our Health Policy Consultant, Laura Hanen at lahanen@venable.com.

Sincerely,



Brenda K. Schimenti
Executive Director

¹³ Ryan Haight Online Pharmacy Consumer Protection Act of 2008, Public Law 425, U.S. Statutes at Large 122 (2008): 4820-4834. Accessed at <https://www.congress.gov/110/plaws/publ425/PLAW-110publ425.pdf>.

¹⁴ CDC, Prescription Drug Monitoring Programs (PDMPs). Accessed at: <https://www.cdc.gov/opioids/healthcare-professionals/pdmps.html>

¹⁵ *Id.*