



March 13, 2023

Dr. Miriam Delphin-Rittmon
Assistant Secretary for Mental Health and Substance Use
Substance Use and Mental Health Services Administration
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 Big Cities Health Coalition (BCHC), I write to provide comment 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. BCHC is comprised of health officials leading 35 of the nation's largest metropolitan health departments, who together serve more than 61 million – or about one in five – Americans. Our members work every day to keep their communities healthy and safe.

Role of Big City Health Departments

Big city health departments (including county health departments that serve big cities) not only prevent, and reduce harm from, overdoses, but also improve outcomes for people who use drugs. They are among the first to detect trends in emerging drugs, identify inequities in fatal and non-fatal overdoses, recognize hot spots, fund and provide supportive services rooted in reducing harm to individuals using, hold systemwide convenings, and implement quality improvement initiatives. Big city health departments are also the first to identify and respond to local impacts, working to mitigate the effect of overdose and other harmful effects of substance use, including disease transmission. They pilot, implement, and test innovative strategies that are often expanded in communities across their respective states and the country.

BCHC Comments on the 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 opioid use disorder (OUD). SAMHSA seeks comment on unintended consequences and benefits for people in Opioid Treatment Programs (OTPs). BCHC 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- **The rule removes outdated barriers that prevent health care providers from prescribing a safe and effective treatment for OUD.**¹ Buprenorphine and related medications cut the risk of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 generic form. Buprenorphine is considered a gold standard of care for OUD because it saves lives and helps individuals secure long-term recovery.²
- **The rule will increase access to buprenorphine.** Only about 1 in 10 people with opioid use disorder receive medications for the condition.³ Additionally, 40% of U.S. counties lack a single health care provider who can prescribe buprenorphine for OUD.⁴ This lack of access to buprenorphine is devastating families and communities and causing tens of thousands of preventable overdose deaths each year.⁵
- **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.⁶
- **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 MOUD is dangerous for patients.⁷ However, there is still much work to be done to reduce stigma at a social and structural level.

¹ 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.

² 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>.

³ 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>.

⁴ 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>.

⁵ 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>.

⁶ 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.

⁷ 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/).

- **Removal of the waiver requirement saves lives.** This was especially important in the pandemic-related increase in overdose deaths. Fewer overdoses, less acute care use and retention in treatment is associated with better outcomes.⁸
- **Buprenorphine is a safe medication.** There are very few overdose deaths related to buprenorphine use.⁹

Broadening Access to Treatment

BCHC supports making permanent the flexibility to allow prescribing of buprenorphine via telehealth beyond just OTPs, including audio-only services, thus enabling 24-hour access to MOUD. Further, BCHC 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.¹⁰ 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 visit¹¹ 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 Act of 2008 (PL 110-425).¹² 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 also urge SAMHSA to monitor and if necessary, recommend Congress 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 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 clinician checks the PDMP and is not privy to information alerting him to the patient taking methadone or buprenorphine. To increase patient safety measures, we urge SAMHSA to consider mandating OTPs to report to the PDMP in future rulemaking. Further, we urge SAMHSA to require states, as part of federal funding agreements, to provide local health departments with real-time access to Prescription Drug Monitoring Program data.

⁸ 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.

⁹ 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 (2023).

¹⁰ 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/>.

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

¹² 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>.

BCHC lauds SAMHSA for their leadership in taking important steps to increase access and reduce barriers in access to MOUD. Please do not hesitate to contact me at juliano@bigcitieshealth.org if we can be of further assistance.

Sincerely,

A handwritten signature in black ink that reads "Chrissie Juliano". The signature is written in a cursive, flowing style.

Chrissie Juliano, MPP
Executive Director