BIG CITIES HEALTH COALITION

February 14, 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; 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) Medications for the Treatment of Opioid Use Disorder notice of proposed rulemaking to update 42 CFR Part 8. BCHC is comprised of health officials who lead 35 of the nation's largest metropolitan health departments; together they 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 and County Health Departments

Big city health departments work not only to prevent and reduce harm from overdoses, but also to 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 designed to reduce harm to individuals who use drugs, 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 and test innovative strategies that are often later implemented in communities across their respective states and the country.

BCHC Comments on the Notice of Proposed Rulemaking

42 CFR Part 8, which has not been updated for more than 20 years, perpetuates stigma for individuals seeking care; it may even create barriers to care by requiring both recurrent visits to the provider and in-person dosing. As such, BCHC applauds SAMHSA for making the proposed changes to opioid treatment program (OTP) operations.

Specifically, BCHC supports:

- **Making permanent the ability to use telehealth to initiate buprenorphine treatment in OTPs.** BCHC supports making permanent the flexibility for the initiation of buprenorphine via telehealth provided during the COVID-19 public health emergency. This flexibility was put into place in March 2020, allowing numerous patients to continue treatment and others to establish clinical relationships for the first time. Virtual care isn't just a stopgap until patients can see their provider again in person; for some, virtual care is the most viable (and sometimes only) option due to socioeconomic factors, convenience, or preference.

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

- **Updating the criteria for the provision of take-home doses of methadone including upon initiation of treatment in OTPs.**
  BCHC supports making permanent the ability for OTPs to dispense 28 days of take-home methadone doses to stable patients and up to 14 doses of take-home methadone for less stable patients who are determined to be able to safely manage this level of take-home medication. This is an important step in reducing the ultra-restrictiveness and stigma tied to methadone. A recently published synthesis of studies 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.[iii] 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 associated with daily in-person treatment, such as long travel times, and reduced the number of stressful in-person treatment encounters for patients.[iv]

- **Updating admission criteria and removing the requirement that an OTP only admits people with a year of opioid addiction.**
  BCHC strongly supports removing the one-year requirement from the admission criteria for OUD, which is a significant barrier to treatment. People should have access to treatment upon request.

- **Initial dosing flexibility if clinically indicated and documented.**
  BCHC supports flexibility in initial dosing of methadone due to higher opioid tolerance associated with increasing rates of fentanyl exposure and opioid overdose. While the proposed rule maintains initial dosing at 30mg, not to exceed 40mg on the first day, the incorporation of a provision for higher doses if clinically indicated and documented in the patient's record is essential to allow for clinical judgment.

- **Removing outdated terms such as detoxification.**
  BCHC lauds SAMHSA for their continued effort to remove stigmatizing language and to educate providers and the public on the role of language in stigmatizing people who use drugs and who seek treatment.

- **Strengthening the patient-practitioner relationship through promotion of shared and evidence-based decision making.**
  BCHC believes patient-centered care in SUD treatment can enhance utilization of evidence-based services. 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.[v]

BCHC urges SAMHSA to swiftly finalize this rule to ensure these important changes can begin to benefit individuals with OUD who seek care at OTPs.

Broadening Access to 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."[vi] BCHC supports making permanent the flexibility to allow prescribing of buprenorphine via telehealth beyond OTPs, including audio-only services, thus enabling 24-hour access to medications for opioid use disorder (MOUD). We also support removing the required, initial in-person visit, as included in the Ryan Haight Act of 2008 (PL 110-425).[vii]

Further, BCHC urges SAMHSA and DEA to remove barriers and incentivize pharmacies to stock buprenorphine, as about one in five pharmacies currently refuse to dispense.[viii] We urge SAMHSA to monitor and, if necessary, advocate to Congress for legislation to make the use of telehealth for treatment with buprenorphine permanent and remove barriers in access.

BCHC also supports allowing methadone to be available outside of an OTP and encourages SAMHSA to collaborate with DEA to **create a pilot program to allow pharmacies to dispense methadone in partnership with appropriate governmental health authorities.** The overdose epidemic requires new thinking and new approaches, and our members stand ready to work with you on such activities.

In closing, let me reiterate that BCHC lauds SAMHSA for their leadership in seeking to make permanent the Public Health Emergency flexibilities for OTPs. We believe this is an important first step to easing barriers to MOUD and look forward to working with you and the DEA to make further policy changes to increase access to treatment. Please do not hesitate to contact me at juliano@bigcitieshealth.org if we can be of further assistance.

Sincerely,

Chrissie Juliano, MPP
Executive Director

[i] 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.

[ii] 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

[iii] Noa Krawczyk, Bianca D. Rivera, Emily Levin, Bridget C.E. Dooling. *medRxiv* 2022.12.15; doi: https://doi.org/10.1101/2022.12.15.22283533.

[iv] Ibid.

[v] 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. Epub 2020 Sep 3. PMID: 32972650; PMCID: PMC7528396.

[vi] Proposed Rule, 87 Fed. Reg. 77331.

[vii] 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.

[viii] 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/.