March 28, 2023

Administrator Anne Milgram
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, VA 22152

Re: Expansion of Induction of Buprenorphine via Telemedicine Encounter [RIN 1117-AB780]

Dear Administrator Milgram:
On behalf of the Big Cities Health Coalition (BCHC), I write to provide comment on the Drug Enforcement Agency's (DEA) proposed rule on the Expansion of Induction of Buprenorphine via Telemedicine Encounter. 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 emerging drug trends, identify inequities in fatal and non-fatal overdoses, recognize hot spots, fund and provide supportive services rooted in reducing harm among individuals who use, 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 to Proposed Rule

1. *BCHC urges the DEA to eliminate the in-person evaluation when prescribing more than a 30-day supply of buprenorphine via telemedicine and to promulgate consistent policies across federal agencies.*

   BCHC urges the DEA to eliminate the proposed requirement for an in-person evaluation when clinicians prescribing more than a 30-day supply (across prescriptions) of Schedule III-V medications approved for SUD treatment (including buprenorphine for opioid use disorder) engage in the practice of telemedicine, as defined in 21 U.S.C. 802(54)(G). Instead, we urge DEA to reinforce the long-standing precedent and the Agency's own expectation that services and procedures rendered, including for the evaluation and management of opioid use disorder (OUD), be adequately

documented in the medical record. This is consistent with the Substance Abuse and Mental Health Services Administration (SAMHSA) proposed rule permitting opioid treatment centers (OTPs) to allow the initiation and continued treatment of OUD with buprenorphine via telehealth.

Additionally, the DEA should reconsider whether the proposed recordkeeping requirements are consistent with the public health imperative to expand appropriate access to addiction medications and whether there are less complex mechanisms to achieve the DEA's goals without requiring prescribers of addiction medications to alter their practice workflows.

As noted above, recently, SAMHSA released a proposed rule permitting OTPs to allow the initiation and continued treatment of OUDs with buprenorphine via telehealth. The decision for such a rule "draws on experience from the COVID-19 PHE as well as more than 20 years of practice-based research."[i] The OTP proposed rule also recognized the hurdles faced by individuals with OUDs, including disruption to daily life (e.g., employment) and unreliable access to transportation. Most importantly, it acknowledges both the importance of the practitioner-provider relationship and the fact that OUD treatment should be based on the clinical judgment of the treating provider. If a provider believes a telehealth visit is sufficient to initiate treatment for OUD, then that judgment should not be overruled by an arbitrary regulation.

Contrastingly, the DEA proposed rule only allows clinicians to provide a 30-day supply of buprenorphine when initiating treatment via telehealth. If a patient has already been receiving prescriptions by telemedicine during the PHE, the DEA will defer the in-person exam requirement for an additional 180 days.

We strongly urge DEA to take the same path as SAMHSA at this critical juncture of the polysubstance overdose epidemic. Indeed, as DEA has noted, the epidemic is getting worse, and one solution is to increase access to appropriate treatment. While we appreciate the DEA's concern related to diversion of buprenorphine, we believe the rule as proposed is a step too far and will create barriers for patients seeking treatment. A medical evaluation and treatment of the patient via telemedicine are appropriate, so long as the physician or other clinician can maintain the standard of care.

2. *In the absence of Congressional action, BCHC urges the DEA to promulgate a rule to allow prescribing of buprenorphine via telehealth permanently.*

Three years of data support the safety and efficacy of initiating and maintaining buprenorphine treatment via telehealth. For example:

- 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 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."[iii]

- 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 introduced.[iv] The study's findings call for more equitable access to medications for opioid use disorder (MOUD) and greater flexibility in prescribing as critical components to the response to the overdose crisis.

- Finally, recent data shared in *Inside Health Policy* by Bicycle health, a national telehealth company, suggests a drop off of about half of their patients in the state of Alabama following a state law changed that required patients to see a prescribing provider just once a year in person.[v]

This research and data confirm that treating OUDs with buprenorphine through telehealth services is safe, increases access, and reduced stigma. We urge DEA to follow SAMHSA's approach related to OTPs and allow individuals with OTPs to be treated with buprenorphine via telehealth permanently.

Additionally, further studies have demonstrated that diversion of buprenorphine to get high is negligible.[vi, vii] Two surveys of people with OUD found that a majority of those who used illicit buprenorphine reported they used it for therapeutic purposes (i.e., to reduce withdrawal symptoms, reduce heroin use, etc.).[viii, ix] Instead of creating a new option under the "other circumstances specified by regulation" exception in the Ryan Haight Act, we urge DEA to instead promulgate regulations related to the "treatment by a practitioner who has obtained a special registration" exception of the Ryan Haight Act and structure the special registration to allow the prescription of buprenorphine permanently via telehealth.

3. *BCHC urges consistent use of PDMPs across providers and settings.*

The rule requires a practitioner to review and consider PDMP data prior to prescribing buprenorphine. BCHC agrees with this DEA requirement. 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. To increase patient safety, we urge consistency across clinical settings and providers in reporting to the PDMP.

Thank you again for the opportunity to comment. We urge the DEA to remove unnecessary barriers to treatment with controlled substances. 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] SAMHSA, Medications for the Treatment of Opioid Use Disorder, 87 FR 77330.
[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] 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.
[iv] 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. Accessed at: https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2800689.
[v] Beavins, Emma. *Inside Health Policy's Inside TeleHealth*, Bicycle Health: Alabama's Experience Shows Need To Amend DEA Buprenorphine Rule, March 23, 2023.
[vi] Cicero TJ, Surratt HL, Inciardi J. Use and misuse of buprenorphine in the management of opioid addiction. J Opioid Manag. 2007 Nov-Dec;3(6):302-8. doi: 10.5055/jom.2007.0018. PMID: 18290581.
[vii] Cicero TJ, Ellis MS, Surratt HL, Kurtz SP. Factors contributing to the rise of buprenorphine misuse: 2008-2013. Drug Alcohol Depend. 2014 Sep 1;142:98-104. doi: 10.1016/j.drugalcdep.2014.06.005. Epub 2014 Jun 18. PMID: 24984689.
[viii] Bazazi AR, Yokell M, Fu JJ, Rich JD, Zaller ND. Illicit use of buprenorphine/naloxone among injecting and noninjecting opioid users. J Addict Med. 2011 Sep;5(3):175-80. doi: 10.1097/ADM.0b013e3182034e31. PMID: 21844833; PMCID: PMC3157053.
[ix] Schuman-Olivier Z, Albanese M, Nelson SE, Roland L, Puopolo F, Klinker L, Shaffer HJ. Self-treatment: illicit buprenorphine use by opioid-dependent treatment seekers. J Subst Abuse Treat. 2010 Jul;39(1):41-50. doi: 10.1016/j.jsat.2010.03.014. PMID: 20434868.