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Submitted online via Regulations.gov

March 30, 2023

Administrator Anne Milgram
Drug Enforcement Administration
8701 Morrisette Drive
Springfield, Virginia 22152

**Re: Docket No. DEA-948
Expansion of Induction of Buprenorphine
via Telemedicine Encounter**

Dear Administrator Milgram,

The National Health Law Program (NHeLP) is a public interest law firm that fights for equitable access to quality health care for people with low incomes and underserved populations and for health equity for all. For over fifty years, we have litigated to enforce health care and civil rights laws, advocated for better federal and state health laws and policies, and trained, supported, and partnered with health and civil rights advocates across the country. We believe that everyone should have access to high quality, equitable health care and be able to achieve their own highest attainable standard of health. We appreciate the opportunity to provide comments on the Drug Enforcement Administration's (DEA's) proposed rule on expansion of induction of Buprenorphine via telemedicine encounter.¹

We urge the DEA to withdraw the proposed rule related to the induction of buprenorphine via telemedicine and continue the expanded

telemedicine flexibilities under the Opioid Public Health Emergency.² During the COVID-19 public health emergency, the DEA took steps to increase telemedicine services for medications for opioid use disorder (MOUD) pursuant to the Ryan Haight Online Pharmacy Consumer Protection Act.³ This expansion has had a notable effect of improving health outcomes by facilitating access to MOUD, improving treatment retention, and reducing likelihood of an opioid-related overdose.⁴ We oppose the proposed rule, because the proposed requirement of an in-person medical evaluation following a thirty-day supply of buprenorphine could disrupt care for those unable to access in-person care and will prevent others from attempting to initiate or sustain treatment for Opioid Use Disorder (OUD). Requiring in person visits could undo the progress made toward increasing access to this life-saving medication.

I. Buprenorphine through telemedicine is a safe and effective treatment option in response to the Opioid Public Health Emergency

Our current and ongoing overdose epidemic killed almost 108,000 U.S. residents in 2022, with most overdose deaths related to synthetic opioids other than methadone.⁵ The impact is especially striking in racial and ethnic minorities. From 2019 to 2020, overdose death rates increased by 44% among non-Hispanic Black people and 39% among non-Hispanic American Indian or Alaska Native people.⁶

¹ U.S. Drug Enforcement Admin., *Proposed Rule - Expansion of Induction of Buprenorphine via Telemedicine Encounter*, 88 Fed. Reg. 12890 (March 1, 2023) [hereinafter Proposed Rule], <https://www.govinfo.gov/content/pkg/FR-2023-03-01/pdf/2023-04217.pdf>.

² The Opioid Public Health Emergency was declared on October 26, 2017 and last renewed on December 26, 2022. See HHS, Public Health Emergency Declarations, <https://aspr.hhs.gov/legal/PHE/Pages/default.aspx> (last visited March 27, 2023).

³ 21 U.S.C. § 829(e); The COVID-19 Public Health Emergency was declared on January 31, 2020 and last renewed on January 11, 2023. HHS, Public Health Emergency Declarations, <https://aspr.hhs.gov/legal/PHE/Pages/default.aspx> (last visited March 30, 2023).

⁴ Christopher J. Jones *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), <https://jamanetwork.com/journals/jamapsychiatry/fullarticle/2795953>.

⁵ See Centers for Disease Control and Prevention, *Provisional Drug Overdose Death Counts*, <https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm> (last visited March 27, 2023); see also Nat'l Inst. on Drug Abuse, *Drug Overdose Death Rates*, <https://nida.nih.gov/research-topics/trends-statistics/overdose-death-rates> (last visited March 27, 2023).

⁶ Mbabazi Kariisa *et al.*, *Vital Signs: Drug Overdose Deaths, by Selected Sociodemographic and Social Determinants of Health Characteristics — 25 States and the District of Columbia, 2019–*

Buprenorphine is a partial opioid agonist, this means it works by binding to the same receptors in the brain that opioids activate but at a slower rate and with less strength than full opioid agonists.⁷ This helps mitigate withdrawal symptoms and cravings from physical dependence on opioids, increases safety in case of overdose, and lowers the potential for misuse.⁸ Buprenorphine is effective. Comprehensive research has shown that buprenorphine maintenance treatment reduces unhealthy opioid use, decreases symptoms related to OUD, reduces risk of infectious disease transmission, and increases the likelihood that a person will remain in treatment.⁹ Despite the effectiveness of buprenorphine and other MOUD, like methadone, only about one in five of the 2.5 million individuals with OUDs received maintenance treatment in 2021.¹⁰ Buprenorphine is also safe. Because buprenorphine is a partial agonist, it is less likely to suppress breathing than other opioids.¹¹ Buprenorphine can be tapered and is safer even at higher doses than similar medications.¹² Moreover, buprenorphine was involved in only 2.2% of overdose deaths and the proportion of buprenorphine-involved overdose deaths did not increase during the pandemic.¹³

Research has found that there is no statistically significant difference in clinical severity or complexity between patients receiving buprenorphine via telemedicine versus in-

2020, MMWR MORB MORTAL WKLY REP, 71:940–947 (2022),

https://www.cdc.gov/mmwr/volumes/71/wr/mm7129e2.htm?s_cid=mm7129e2_w.

⁷ Nat'l Inst. on Drug Abuse, *How do medications to treat opioid use disorders work?* (April 2021), <https://nida.nih.gov/publications/research-reports/medications-to-treat-opioid-addiction/how-do-medications-to-treat-opioid-addiction-work>

⁸ Substance Abuse and Mental Health Servs. Admin., *What is Buprenorphine?* [hereinafter *What is Buprenorphine*], <https://www.samhsa.gov/medications-substance-use-disorders/medications-counseling-related-conditions/buprenorphine> (last visited March 27, 2023).

⁹ Nat'l Inst. on Drug Abuse, *How effective are medications to treat opioid use disorder?* (Dec. 2021), <https://nida.nih.gov/publications/research-reports/medications-to-treat-opioid-addiction/efficacy-medications-opioid-use-disorder> (last visited March 29, 2023).

¹⁰ Substance Abuse and Mental Health Servs. Admin., *2021 NSDUH Annual National Report: Key substance use and mental health indicators in the United States: Results from the 2021 National Survey on Drug Use and Health*, PEP22-07-01-005, NSDUH SERIES H-57 (2022), <https://www.samhsa.gov/data/report/2021-nsduh-annual-national-report>.

¹¹ Rachna Kumar et al., *StatPearls: Buprenorphine* (2023), <https://www.ncbi.nlm.nih.gov/books/NBK459126/>.

¹² *Id.*

¹³ Lauren J. Tanz et al., *Trends and Characteristics of Buprenorphine-Involved Overdose Deaths Prior to and During the COVID-19 Pandemic*, JAMA NETWORK OPEN (2023) <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2800689>.



person induction.¹⁴ In the 2021 study, only 13.9% of buprenorphine inductions occurred using telemedicine.¹⁵ Those using telemedicine were more likely to be in higher income counties, and the low rate of telemedicine buprenorphine inductions likely related to a lack of access to technology and digital literacy.¹⁶ These findings indicate a need for expanded telemedicine access for low income individuals rather than a concern for diversion. The need to expand telemedicine access is further underscored by a 2023 study, which found that only one in five Medicare beneficiaries received OUD-related telemedicine services and only one in eight received MOUD.¹⁷ Along with several encouraging findings on the use of telemedicine, the researchers noted the need for continued expansion of many potentially life-saving interventions across clinical settings, including in telemedicine.¹⁸

Additionally, other research has found that diverted buprenorphine was often used for therapeutic purposes like preventing withdrawal, maintaining abstinence, or to self-wean off opioids.¹⁹ Of those who did use diverted buprenorphine, 33% reported issues finding a doctor or obtaining buprenorphine. Finally, a meta-analysis of fifty-seven studies found that among samples of people receiving buprenorphine for OUD treatment, diversion peaked at 4.8%.²⁰ There is no clear evidence that telemedicine usage increases diversion risk. However, there is clear evidence that access to buprenorphine is a barrier to successfully treating OUD.

¹⁴ Benjamin A. Barsky, et al., *Use of Telemedicine for Buprenorphine Inductions in Patients With Commercial Insurance or Medicare Advantage*, JAMA NETWORK OPEN (2022), <https://pubmed.ncbi.nlm.nih.gov/34989798/>.

¹⁵ *Id.*

¹⁶ *Id.*

¹⁷ Christopher M. Jones et al., *Association of Receipt of Opioid Use Disorder–Related Telehealth Services and Medications for Opioid Use Disorder With Fatal Drug Overdoses Among Medicare Beneficiaries Before and During the COVID-19 Pandemic*, JAMA PSYCHIATRY (2023), <https://jamanetwork.com/journals/jamapsychiatry/fullarticle/2802946>.

¹⁸ *Id.*

¹⁹ Theodore J. Cicero et al., *Understanding the use of diverted buprenorphine*, Drug and Alcohol Dependence, 193, 117–123 (2018), <https://pubmed.ncbi.nlm.nih.gov/30359928/>.

²⁰ Stephanie K. Rubel et al., *Scope of, Motivations for, and Outcomes Associated with Buprenorphine Diversion in the United States: A Scoping Review*, SUBSTANCE USE & MISUSE, 58(5), 685–697 (2023), <https://pubmed.ncbi.nlm.nih.gov/36803159/>.

II. Telemedicine expands services for opioid use disorders (OUD) and mental health conditions and helps address access barriers

Many people in the U.S. experience barriers that prevent or limit their access to necessary behavioral health care services. Health care-associated costs and transportation are some of the most common barriers to behavioral health care access.²¹ Often, people are reluctant or unable to access services because of reasons such as lack of transportation, long commute times, or obligations including work and child care.²² These barriers are especially true for those who are low income, immigrants, and people of color, as they may have less capacity to take time off from work, locate alternative child care, or have reliable transportation to physically go to a provider's office. People who live in rural areas experience similar physical barriers, as the availability of transportation and resources are often scarce in these areas.²³

Telemedicine helps provide people more ways, or sometimes the only way, to access behavioral health care services. As the nation continues to experience a shortage in the behavioral health workforce, telemedicine allows people who may not have immediate access to a provider to finally receive OUD and mental health care.²⁴ Telemedicine also helps address the access barrier of stigma surrounding substance use and addiction.²⁵ A Substance Abuse and Mental Health Services Administration study found that of people who did not seek behavioral health care, 20% of them had concerns about confidentiality or worries that their neighbors or community would have a negative perception of them.²⁶ Delivery of substance use disorder and mental health treatment

²¹ USC Price, *How to Improve Access to Health Care: Current Issues and Potential Solutions*, <https://healthadministrationdegree.usc.edu/blog/how-to-improve-access-to-health-care/> (last visited March 21, 2023).

²² Linda Wang et al., *Telemedicine increases access to buprenorphine initiation during the COVID-19 pandemic*, J SUBSR ABUSE TREAT 124:108272 (2021), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7833481/>.

²³ Rural Health Info. Hub, *Telehealth Use in Rural Healthcare*, <https://www.ruralhealthinfo.org/topics/telehealth#improve-access> (last visited March 27, 2023).

²⁴ GAO, *Available Workforce Information and Federal Actions to Help Recruit and Retain Providers* (Oct. 2022), <https://www.gao.gov/assets/gao-23-105250-highlights.pdf>.

²⁵ Nora Volkow, Nat'l Inst. on Drug Abuse, *Addressing the Stigma that Surrounds Stigma* (2020), <https://nida.nih.gov/about-nida/noras-blog/2020/04/addressing-stigma-surrounds-addiction>.

²⁶ Committee on the Science of Changing Behavioral Health Social Norms, *Ending Discrimination Against People with Mental and Substance Use Disorders: The Evidence for Stigma Change* (2016).

via telemedicine can be as effective as in-person care.²⁷ Having the option is, in many cases, life-saving.

III. The thirty-day in-person requirement related to induction of buprenorphine via telemedicine is unnecessary and burdensome

We oppose the proposed requirement that patients receiving buprenorphine receive an in-person medical evaluation meeting within thirty days of being prescribed buprenorphine, because the thirty-day in-person requirement is both unnecessary and burdensome.

As discussed above, people who need substance use disorder or mental health treatment experience many barriers to care and telemedicine helps address these barriers. The effectiveness of MOUD is not dependent on the inclusion of other services and buprenorphine initiation should not be delayed simply because an individual declines other supports.²⁸ With the COVID-19 expansion of telemedicine, people with OUD can access buprenorphine, often on the same day that they express interest without additional barriers. However, if an in-person visit is required within thirty days of the initial prescription, treatment that was only made possible due to telemedicine might be disrupted, as people will still be experiencing the same access barriers in thirty days.

The proposed thirty-day in person requirement does not reduce risk of buprenorphine misuse. The proposed rule recognizes that buprenorphine was involved in a small portion of overdose deaths in 2021 and the proportion of buprenorphine-related overdose deaths did not increase during the pandemic.²⁹ Research also confirms that buprenorphine misuse is primarily motivated by the need to self-treat withdrawal

²⁷ Zara Abrams, Am. Psychological Ass'n., *How well is telepsychology working?* (July 1, 2020), <https://www.apa.org/monitor/2020/07/cover-telepsychology>.

²⁸ Nat'l Inst. on Drug Abuse, *Effective Treatments for Opioid Addiction*, <https://www.drugabuse.gov/publications/effective-treatments-opioid-addiction> (last visited March 27, 2023).

²⁹ Lauren J. Tanz *et al.*, *Trends and Characteristics of Buprenorphine-Involved Overdose Deaths Prior to and During the COVID-19 Pandemic*, JAMA NETWORK OPEN (2023), <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2800689>.

symptoms.³⁰ The benefits of increasing access to MOUD far outweighs any risk that may exist. The risk of misuse can and should be addressed by other existing or new mechanisms, such as the proposed reporting and recordkeeping requirement in Proposed Rule § 1306.34(b)(6).³¹

The proposed rule mentions that the in-person requirement is necessary because during in-person visits, “practitioners are able to assess conditions which may or may not be available in audio-only or even audio-video telemedicine encounters.”³² This reasoning not only minimizes the clinician’s ability to make clinical assessments via telemedicine, but also presupposes patients cannot adequately self-report their progress. In any case, the DEA should address the advantages of in-person assessments by encouraging its use rather than mandating an in-person visit within thirty days of initiation. Such an approach would guarantee that individuals who may be unable to attend an in-person assessment do not lose access to potential life-saving treatment.

The proposed rule is also not consistent with the Ryan Haight Online Pharmacy Consumer Protection Act.³³ Although the Act requires a prescribing practitioner to conduct at least one in-person medical evaluation with the patient before “delivering, distributing, or dispensing controlled medications via the internet with a valid prescription,” it clearly states that the in-person requirement does not apply to “the delivery, distribution, or dispensing of a controlled substance by a practitioner engaged in the practice of telemedicine.”³⁴ Additionally, conditioning access to a medication that stops painful withdrawal symptoms on an in-person visit can negatively impact the trust in a provider-patient relationship, which has been found to be essential to the effectiveness of treatment.³⁵

Although the proposed rule is framed as an expansion of access, it is truly a restriction. Since the COVID-19 pandemic, telemedicine has provided new and existing patients

³⁰ Beth Han *et al.*, *Trends in and Characteristics of Buprenorphine Misuse Among Adults in the US*, JAMA NETWORK OPEN (2021), <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2785011>.

³¹ Proposed Rule, *supra* note 1.

³² *Id.*

³³ 21 U.S.C. § 829(e).

³⁴ *Id.*

³⁵ Centers for Disease Control and Prevention, *Talking to your patient*, <https://www.cdc.gov/hiv/clinicians/treatment/patient-provider.html> (last visited March 23, 2023).

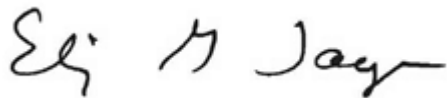
with access to buprenorphine at the moment people express interest, often with same-day evaluations and prescriptions, without additional barriers presenting at a traditional in-person setting.³⁶ We should not disregard something that has been proven to work to accept the status quo or a lower standard.

IV. Conclusion

For the above reasons, we urge the DEA to withdraw the proposed thirty-days in-person requirement related to induction of buprenorphine via telemedicine and continue the telemedicine flexibilities under the Opioid Public Health Emergency to ensure ongoing access to life-saving medications for individuals with OUD.

Thank you for the opportunity to comment on these important issues. If you have any questions or need any further information, please contact Alexis Robles-Fradet, Health Policy Analyst, at robles-fradet@healthlaw.org or Nancy Lam, Equal Justice Works Fellow at lam@healthlaw.org.

Sincerely,



Elizabeth G. Taylor
Executive Director

³⁶ Linda Wang et al., *supra* note 22, at 1.