

March 31, 2023

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

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

Comment submitted electronically via regulations.gov.

Dear Administrator Milgram,

The National Rural Health Association (NRHA) is pleased to offer comments on the Drug Enforcement Administration's (DEA) proposed rule on prescribing buprenorphine via telemedicine after the public health emergency ends. We thank the DEA for its work to expand access to lifesaving treatments for opioid use disorder, especially as it pertains to rural communities.

NRHA is a non-profit membership organization with more than 21,000 members nationwide that provides leadership on rural health issues. Our membership includes nearly every component of rural America's health care, including rural community hospitals, critical access hospitals, long-term care providers, doctors, nurses, and patients. We work to improve rural America's health needs through government advocacy, communications, education, and research. We appreciate the Department's continued commitment to the needs of the more than 60 million Americans that reside in rural areas, and we look forward to our continued collaboration to improve health care access throughout rural America.

II. Background

NRHA applauds DEA's work to expand access to buprenorphine via telehealth and the flexibilities included in this proposed rule compared to pre-public health emergency (PHE) regulations. We are hopeful that this will increase the number of rural patients that seek treatment for OUD (opioid use disorder).

However, we disagree with DEA's reading of the Ryan Haight Act and urge DEA to reconsider their policy proposal. NRHA maintains that the restrictions in the proposed rule are not well-tailored to the harm that DEA has an interest in preventing. **DEA's proposals are overly restrictive and will increase the risk of destabilizing current patients, leading to a dangerous disruption of maintenance treatment potentially triggering relapses or overdoses.** DEA's interest in preventing misuse or diversion of buprenorphine does not justify the mandate for patients to receive an in-person medical evaluation, especially for individuals residing in rural areas. NRHA believes that the public health implications of disrupting treatment are more dangerous than the low risk of buprenorphine misuse.

The Biden Administration stated that its goals for drug policy includes expanding access to evidence-based treatment, particularly medication for opioid use disorder (MOUD), by removing unnecessary

barriers to buprenorphine prescribing.¹ Accordingly, the federal government has taken several steps recently to increase access to lifesaving medications for opioid use disorder. The proposed rule at hand is antithetical to these recent policy changes and to the Biden Administration's goals for addressing the overdose epidemic. First, in June 2021, DEA finalized a rule that allows narcotic treatment programs to operate mobile medication units to expand access, especially to rural areas.² This rule also applied to OTPs under SAMHSA jurisdiction.³ In 2022, CMS clarified that OTPs may bill Medicare for medically reasonable and necessary services provided at mobile units associated with OTPs along with other favorable Medicare billing changes for OTP services.⁴ In December 2022, SAMHSA released a proposed rule that would, if finalized, modernize and increase access to OTPs.⁵ Importantly, one proposal would allow OTPs to prescribe buprenorphine via telehealth without an in-person evaluation.⁶ Also in late 2022, Congress passed an omnibus package that included a provision to remove the DATA waiver, or X-waiver, requirements for practitioners to submit a Notice of Intent to prescribe buprenorphine.⁷ DEA's proposed rule is inconsistent with the strategy of the Biden Administration to combat opioid use and expand access to treatment and is potentially harmful for rural patients that have benefited from receiving buprenorphine via telehealth during the PHE.

Studies indicate that the further one must travel, the less likely they are to seek treatment.⁸ **Therefore, restricting the use of telemedicine unduly burdens rural patients seeking MOUD.** Telemedicine is essential for rural patients that do not have local or nearby access to practitioners that prescribe MOUD, which is a large swath of rural communities. Providers that are willing and able to prescribe buprenorphine are scarce in rural areas with about one-third of rural residents living in a county without a buprenorphine provider compared to 2.2% of urban residents. Opioid treatment programs (OTPs) are another access point, however, NRHA's internal analysis found that only about 220 of almost 2,000 OTPs are in rural areas. Almost 90% of large rural counties do not have an OTP and that 72% do not have a buprenorphine provider.⁹ Altogether, about three million people live over thirty miles from a buprenorphine provider.¹⁰ The use of telemedicine during the PHE grew the number of patients receiving buprenorphine for OUD significantly while also improving retention and reducing the likelihood of overdoses.¹¹

¹ Press Release, White House, Biden-Harris Administration Announces First-Year Drug Policy Priorities (Apr. 1, 2021), <https://www.whitehouse.gov/ondcp/briefing-room/2021/04/01/biden-harris-administration-announces-first-year-drug-policy-priorities/>.

² 86 Fed. Reg. 33861 (June 28, 2021).

³ Letter from Substance Abuse and Mental Health Services Administration to State Substance Abuse Directors (Aug. 4, 2021), <https://www.samhsa.gov/sites/default/files/2021-letter-state-authorities-mobile.pdf>.

⁴ CY 2023 Payment Policies Under the Physician Fee Schedule, 87 Fed. Reg. 69768 (Nov. 18, 2022).

⁵ Medications for the Treatment of Opioid Use Disorder, 87 Fed. Reg. 77330 (Dec. 16, 2022) (to be codified at 42 C.F.R. pt. 8).

⁶ 87 Fed. Reg. 77357-58.

⁷ Consolidated Appropriations Act of 2023, H.R. 2617, 117th Cong. § 1262 (2022).

⁸ Kyle Beardsley, et al., *Distance traveled to outpatient drug treatment and client retention*, 25 J. SUBSTANCE ABUSE TREATMENT 279 (2003); Susan K. Schmitt, et al., *The influence of distance on utilization of outpatient mental health aftercare following inpatient substance abuse treatment*, 28 ADDICTIVE BEHAVIORS 1183 (2003).

⁹ Rebecca L. Haffajee & Richard G. Frank, *Making the Opioid Public Health Emergency Effective*, 78 JAMA PSYCHIATRY E1, E2 (2018) <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6378105/>.

¹⁰ James R. Langabeer, et al., *Geographic Proximity to Buprenorphine Treatment Providers in the U.S.*, DRUG & ALCOHOL DEPENDENCE, Aug. 2020, at 3.

¹¹ Letter from National Association of Attorneys General to Attorney General Garland, Secretary Becerra, Administrator Milgram, and Assistant Secretary Delphin-Rittmon (Nov. 16, 2022), https://naagweb.wpenginepowered.com/wp-content/uploads/2022/11/NAAG-Policy_45_AG-Telehealth-

Telemedicine helps break down some barriers to access that are unique to rural. Many rural residents have to travel outside of their community to receive MOUD as evidenced by the statistics referenced above on the prevalence of buprenorphine prescribers in rural areas. Since people living in rural have to travel further, and there is no public transportation in rural communities, they must drive. Rural residents without a driver's license or a car face must rely on friends or family for transportation which is not always reliable, and the patient may not feel comfortable sharing the nature of their trip. Even one in-person evaluation before receiving a buprenorphine prescription can serve as a deterrent for a rural resident that must travel a long distance to a provider that can prescribe.¹² Patients may feel more comfortable with seeking treatment via telemedicine because they do not have to go into the community for sensitive services or reveal the nature of travel to care to friends and family.

A critical access hospital (CAH) in rural Ohio is one example of an NRHA member hospital that relies upon telemedicine use for behavioral health needs, OUD treatment, including maintenance and withdrawal management, are difficult to find in the area. The CAH's exclusively furnishes telemedicine visits with non-physician practitioners collaborating to provide the needed face-to-face visits. However, the current on-site practitioner at the CAH does not prescribe buprenorphine. This proposed rule would not be in the best interest of the patients of this CAH as they would no longer have a prescribing practitioner that could meet the face-to-face requirement.

Distance serves as a primary barrier, but other related factors influence a rural resident's choice to seek care. Stigma is a significant concern for access to MOUD in rural communities, both among patients and providers. This includes the stigma associated with both opioid use and seeking treatment for OUD. In a study of seven rural Indiana counties stigma was a consistent theme among all survey respondents, which included clinicians, behavioral health providers, and other stakeholders like clinic directors.¹³ A similar study from the rural Appalachian region of Ohio noted that the general attitude towards drug use, including buprenorphine, is negative.¹⁴ Stakeholders in the Ohio survey indicated that they believe buprenorphine is as harmful as opioids and using MOUD is simply "trading one addiction for another."¹⁵ Additionally, respondents maintained that drug use is a moral or criminal issue and not a medical issue.¹⁶ The DEA's treatment of buprenorphine as a dangerous controlled substance continues its stigma and reputation as such even though experts generally agree that substance use is a medical condition that can be treated effectively through MOUD.

NRHA is concerned that the DEA's proposal furthers the stigma surrounding MOUD as a treatment option and will continue to stifle uptake among rural patients and providers. Behavioral health

[Extension-Letter-1.pdf](#); Christopher M. 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, 79 JAMA Psychiatry 981, (2022).

¹² Indiana University School of Public Health and the Center for Rural Engagement, *Exploring Rural-Based Professionals' and Community Stakeholders' Perceptions Towards the Uptake of Buprenorphine* (Jan. 2023), at 2, <https://scholarworks.iu.edu/dspace/bitstream/handle/2022/28866/MAT%20brief-FINAL.pdf?sequence=1&isAllowed=y>.

¹³ *Id.*

¹⁴ Emma L. Richard, et al., "You are not clean until you're not on anything": Perceptions of Medication-Assisted Treatment in Rural Appalachia, INT. J. DRUG POLICY, Nov. 2020.

¹⁵ *Id.* at 6.

¹⁶ *Id.* at 5-6.

experts generally agree that taking buprenorphine for MOUD is not the same as trading one substance for another; rather it is a medication that can help with a chronic disease.¹⁷

III. Section by Section Discussion of Proposed Rule

§ 1306.34: Requirements for Individual Practitioners Who Conduct the Induction of Maintenance or Detoxification Treatment Via Telemedicine Encounter.

NRHA appreciates that DEA proposes to continue buprenorphine prescriptions via telemedicine and applauds DEA for its proposal to allow prescribing via audio-only technology. Audio-only is an important option because of the lack of broadband infrastructure in many rural areas, along with the technology capabilities of rural households, that may make audio/video technology unusable. Allowing audio-only in states where it is authorized ensures that access to virtual prescribing is available to more rural patients.

Nonetheless, NRHA believes that DEA's proposed rule is too restrictive and in practice does not provide an exception to an in-person medical evaluation prior to prescribing buprenorphine via telehealth. **NRHA believes that the 30-day prescription limit prior to a medical evaluation in proposed 21 C.F.R. § 1306.34(b)(4) should be removed so that all patients can receive a buprenorphine prescription without an in-person evaluation.** We contend that DEA interpreted the Ryan Haight Act too narrowly and must reconsider its reading of the statute.

DEA claims that this proposed rule creates an exception to the Ryan Haight Act's requirement that all virtual prescriptions of controlled substances be predicated on one in-person evaluation. Yet in practice DEA's proposed rule does not provide an exception. The proposals at § 1306.34(b)(5)(ii) and (iii) continue to require an in-person component but with a DEA-registered practitioner other than the prescribing practitioner, which still entails substantial travel on behalf of the rural patient. Even the 30-day prescription of buprenorphine requires an in-person evaluation prior to receiving a subsequent prescription. As further discussed below, DEA has the authority to create a true exception to any in-person evaluation under § 802(54)(G).

The Ryan Haight Act amended the Controlled Substances Act to establish that controlled substances cannot be prescribed online without an in-person medical evaluation. However, the statute allows an exception for practitioners who are "engaged in the practice of telemedicine" to prescribe without an in-person evaluation.¹⁸ The Act defines "practice of telemedicine" by limiting its scope to seven different categories of telemedicine.¹⁹ These seven categories include circumstances in which a patient is located in a hospital or clinic and during a PHE declared under 42 U.S.C. § 247d.²⁰

Importantly, another category is "*any other circumstances* that the Attorney General and the Secretary have jointly, by regulation, determined to be consistent with effective controls against

¹⁷ See Substance Abuse and Mental Health Services Administration, *The Facts About Buprenorphine for Treatment of Opioid Addiction* (2014), at 2-4, <https://store.samhsa.gov/sites/default/files/d7/priv/sma14-4442.pdf>.

¹⁸ 21 U.S.C. § 829(e)(3)(A) (2022).

¹⁹ See 21 U.S.C. § 802(54) (2022).

²⁰ This is how patients have been able to receive buprenorphine prescriptions fully via telemedicine during the COVID-19 PHE.

diversion and *otherwise consistent with the public health and safety.*²¹ **The language in § 802(54)(G) plainly gives the Attorney General discretionary authority to promulgate regulations that would allow practitioners to prescribe buprenorphine via telemedicine and bypass the in-person evaluation.** NRHA urges DEA to use its authority under this subsection to do so.²²

The statute only limits the Attorney General and Secretary of Health's ability to establish another circumstance for the practice of telemedicine by ensuring that it controls against diversion and is otherwise consistent with public health and safety. **There is no evidence to support that one in-person evaluation by a DEA registrant would control against diversion or protect public health.** On the contrary, NRHA contends that mandating an in-person evaluation will lead to disruption of maintenance treatment or discourage individuals with opioid use disorder from seeking MOUD, and lead to more overdoses. When weighing the goals of protecting public health and safety, and preventing misuse and diversion, the proposed rule heavily favors the latter at the expense of the former. We strongly believe that DEA's proposed rules are poorly tailored to its interest in preventing misuse and diversion in comparison to the actual danger of furthering opioid overdoses.

DEA's proposal is not in line with the current understanding of buprenorphine. Research suggests that the risk of misuse and diversion with buprenorphine is low.²³ Buprenorphine, on its own, is unlikely to cause an overdose because it is a partial opioid agonist²⁴ and instead is more likely to keep a patient stable so that they can continue to withdraw from opioid use.²⁵ Naloxone is commonly added to buprenorphine – which creates the FDA-approved combination is known as Suboxone – in order to decrease diversion and misuse potential.²⁶ The skyrocketing rates of overdoses over the past several years can primarily be attributed to fentanyl, not prescription opioids used for MOUD like buprenorphine and methadone.²⁷

²¹ § 802(54)(G) (emphasis added).

²² For further explanation of our belief that the DEA can act under this authority and without further action by Congress, please visit:

https://regulatorystudies.columbian.gwu.edu/sites/g/files/zaxdzs4751/files/downloads/PEW_Opioids/GW%20Reg%20Studies_REPORT_Telemedicine%20and%20Buprenorphine_BDooling%20and%20LStanley.pdf.

²³ Rachna Kumar, Omar Viswanath, & Abdolreza Saadabadi, *Buprenorphine*, National Library of Medicine, National Institutes of Health (Feb. 2023),

<https://www.ncbi.nlm.nih.gov/books/NBK459126/#:~:text=Buprenorphine%2C%20because%20of%20its%20partial,to%20be%20abused%20or%20diverted>; American Society of Addiction Medicine, *The ASAM National Practice Guideline for the Treatment of Opioid Use Disorder* (2020), at 40 https://sitefinitystorage.blob.core.windows.net/sitefinity-production-blobs/docs/default-source/guidelines/npg-jam-supplement.pdf?sfvrsn=a00a52c2_2.

²⁴ Substance Abuse and Mental Health Services Administration, *What is Buprenorphine?* (updated Mar. 21, 2023), <https://www.samhsa.gov/medications-substance-use-disorders/medications-counseling-related-conditions/buprenorphine>.

²⁵ Alcohol and Drug Foundation, *What is Buprenorphine?* (updated Nov. 2021), <https://adf.org.au/drug-facts/buprenorphine/#:~:text=What%20is%20buprenorphine%3F.way%20is%20known%20as%20pharmacootherapy>.

²⁶ Substance Abuse and Mental Health Services Administration *supra* note 24.

²⁷ National Institute on Drug Abuse, National Institutes of Health, *Drug Overdose Death Rates* (Feb. 2023), <https://nida.nih.gov/research-topics/trends-statistics/overdose-death-rates>.

Studies show that buprenorphine flexibilities during the PHE did not lead to more overdoses.²⁸ During the PHE opioid overdose deaths increased but the proportion of buprenorphine-involved overdoses did not increase.²⁹ This suggests that less restrictions did not lead to more misuse or diversion. Overall, buprenorphine overdoses made up 2.6% of overdoses during the PHE period studied.³⁰ Another study that included both pre-PHE and PHE time periods (2015 – 2021) showed similar results – 2.3% of overdose deaths involved buprenorphine.³¹ The deaths that involved buprenorphine almost always (92.7%) included an additional substance such as heroin or fentanyl, which suggests that buprenorphine did not play a major role in the fatal overdose.³² Again, the similar rate of buprenorphine-involved overdoses implies that virtual prescribing did not increase misuse.

Alternative proposal

While NRHA maintains that DEA has the authority to remove all in-person requirements, **we alternatively ask DEA to change the 30-day prescription to a 90-day prescription** if it declines to reinterpret the statute. This change would benefit rural patients and alleviate some of the burdens associated with completing the in-person evaluation. Rural patients may not be able to make a timely appointment for an in-person medical evaluation under proposed § 1306.34(b)(5) because of transportation challenges, appointment wait times, and lack of DEA-registered practitioners. For reference, the average wait time to get an appointment with a family medicine physician was just over 20 days in 2022.³³ This timeframe may vary depending on geographic area and also whether providers accept Medicare or Medicaid patients. NRHA is concerned about patients in areas where they cannot get an appointment within 30 days and their buprenorphine prescription lapses, potentially leading to using opioids again.

In addition, the in-person evaluation requirement should be waived for patients referred from Indian Health Service (IHS) or Veterans Health Administration (VHA) providers to outside DEA-registered providers. IHS and VHA providers are excepted from the rule and therefore the rural patients that receive a referral from these providers should not have to receive an in-person evaluation.

NRHA is disappointed that the DEA did not move forward with the special registration process for telemedicine prescribers in this proposed rule and urges it to do so within the next year. A special registration process is one of the seven categories under DEA’s definition of “practice of

²⁸ Lauren J. Tanz, et al., *Trends and Characteristics of Buprenorphine-Involved Overdose Deaths Prior to and During the COVID-19 Pandemic*, JAMA NETWORK OPEN, Jan. 2023, at 10 (2023)

<https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2800689?source=email>.

²⁹ *Id.*

³⁰ *Id.*

³¹ Brandon del Pozo, et al., *Buprenorphine Involvement in Opioid Overdose Deaths: A Retrospective Analysis of Postmortem Toxicology in Marion County, Indiana, 2015 – 2021*, Drug and Alcohol Dependence Reports, Mar. 2023, at 2,

<https://reader.elsevier.com/reader/sd/pii/S277272462300001X?token=0EEA46AEED23E724A075807034EE000E59D7F003D0D591AA8B26DDD95DCC0518771BF99A6F3AF93BD4673FAC2A180CB0&originRegion=us-east-1&originCreation=20230321172525>.

³² *Id.* at 3.

³³ Merritt Hawkins, *Survey of Physician Appointment Wait Times and Medicare and Medicaid Acceptance Rates* (2022), at 14,

https://www.merrithawkins.com/uploadedFiles/MerrittHawkins/Content/News_and_Insights/Articles/mha-2022-wait-time-survey.pdf.

telemedicine.” This mechanism would allow registered practitioners to virtually prescribe buprenorphine without an in-person evaluation. Congress charged the DEA with implementing this process in fifteen years ago in 2008 as part of the Ryan Haight Act.³⁴ The DEA surpassed its deadline to comply with this mandate by almost 5 years³⁵ and is subverting Congress’ intent to allow certain practitioners to prescribe solely via telemedicine. A special registration rule is even more pertinent now than in 2008 as telemedicine has become more commonplace due to the COVID-19 PHE. NRHA suggests that when the DEA issues this rule it should ensure the registration process is not so onerous that it poses an administrative burden to already strained rural practitioners.

If this rule is finalized as proposed, NRHA strongly urges the DEA to postpone implementation through its authorities under the opioid crisis PHE that has been in place since 2017.³⁶ The DEA began its telemedicine flexibilities under the COVID-19 PHE and should continue to do so under the opioid crisis PHE. This postponement of in-person requirements would comport with the practice of telemedicine at 21 U.S.C. § 802(54)(D).

Information gathered during this time should inform a more evidence-based, appropriate approach to buprenorphine prescriptions in the future. While the implementation is postponed, **DEA must study how prescribing buprenorphine via telemedicine affects patient access, patient outcomes, diversion, and misuse.** During this interim period NRHA suggests that DEA collaborate with HHS to study: (1) Whether prescribing buprenorphine via telemedicine without an in-person evaluation leads to more diversion and misuse compared to when an in-person evaluation is performed; (2) whether patient access is affected when no in-person evaluation is required; (3) whether prescribing buprenorphine via telemedicine leads to meaningful long-term health outcomes; and (4) whether a patient-provider relationship established via telemedicine is materially different than a relationship established in-person.

Last, NRHA urges DEA to grandfather in patients that began a relationship with a DEA provider during the PHE and received buprenorphine prescriptions through telemedicine. For the past three years patients have been prescribed buprenorphine virtually and should not be subject to the proposed in-person requirements.

NRHA thanks DEA for its work on expanding access to buprenorphine and for its consideration of our comments. If you have any questions, please contact Alexa McKinley (amckinley@ruralhealth.us).

Sincerely,



³⁴ 21 U.S.C. § 831(h) (2022).

³⁵ *Id.* (“Not later than 1 year after October 24, 2018, in consultation with the Secretary, the Attorney General shall promulgate final regulations specifying- (A) the limited circumstances in which a special registration under this subsection may be issued; and (B) the procedure for obtaining a special registration under this subsection”) (emphasis added).

³⁶ Secretary Xavier Becerra, Renewal of a Determination that a Public Health Emergency Exists (Dec. 22, 2022), <https://aspr.hhs.gov/legal/PHE/Pages/Opioid-22Dec2022.aspx>.



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