

March 31, 2023

Scott A. Brinks
Diversion Control Division
U.S. Drug Enforcement Administration
8701 Morrisette Drive
Springfield, Virginia 22152

RE: Docket No. DEA-948, RIN 1117–AB78, Notice of Proposed Rulemaking, 21 CFR Parts 1300, 1304, 1306

Dear Mr. Brinks:

The Pew Charitable Trusts (Pew) is an independent, nonpartisan research and policy organization. Through its Substance Use Prevention and Treatment Initiative (SUPTI), Pew works with states and at the federal level to address the nation’s opioid overdose crisis by developing solutions that improve access to timely, comprehensive, evidence-based, and sustainable treatment for opioid use disorder (OUD).

On March 1, 2023, the U.S. Drug Enforcement Administration (DEA) proposed updating the regulations at 21 CFR Parts 1300, 1304, 1306. (See RIN 1117–AB78, Expansion of Induction of Buprenorphine via Telemedicine Encounter). We acknowledge and welcome the DEA’s commitment to expanding access to buprenorphine via telemedicine encounters as described in the proposed rule, but we believe that certain critical provisions must be modified or removed to fully support patient care and public health. These proposed regulations undermine the valuable policy changes that sought to increase access to buprenorphine treatment via telemedicine and will reduce access to lifesaving treatment, putting public health and patient safety at risk.

Under DEA’s pandemic flexibilities, buprenorphine was safely and effectively prescribed via telemedicine and reached more people, including people that traditionally face challenges accessing buprenorphine, by centering patient access, comfort, and empowerment and reducing barriers to treatment.¹ **These rule changes will increase barriers to OUD treatment by placing arbitrary requirements on buprenorphine access via telemedicine and increase the risk of overdose for patients who lose or cannot access lifesaving treatment.** The proposed rule:

- Requires that practitioners review data in the Prescription Drug Monitoring Program (PDMP) prior to prescribing buprenorphine via telemedicine without citing relevant evidence for the benefits associated with this requirement;
- Places an arbitrary 30-day supply limit on buprenorphine prescriptions via telemedicine, which may reduce access to buprenorphine, increase buprenorphine diversion, and threaten public health and safety;

- Requires an in-person medical evaluation to receive more than a 30-day supply of buprenorphine via telemedicine, although buprenorphine can safely and effectively be prescribed via telemedicine without requiring an in-person visit; and
- Sets recordkeeping requirements that only apply to audio-only telemedicine despite a lack of evidence demonstrating that audio-only telemedicine for buprenorphine is less safe or effective than audio-video telemedicine for buprenorphine.

Evidence shows that buprenorphine is safe and effective, reduces the risk of overdose deaths, reduces illicit drug use, and helps people stay in treatment longer.² Even at high doses, the risk of overdose from buprenorphine is very low because of the medication's ceiling effect where even repeated dosing will not increase the medication's effect.³

Despite buprenorphine's promise as a crucial tool in responding to the overdose crisis, lack of access has been a major challenge. However, DEA's pandemic flexibilities improved access to buprenorphine by allowing patients to start lifesaving medication via telehealth without having to see a provider in person.⁴ Under these flexibilities, telemedicine visits for initiating and continuing buprenorphine treatment increased, and practice and research overwhelmingly showed that buprenorphine can be safely and effectively prescribed via telemedicine without requiring an in-person visit.⁵ Research on the impact of these flexibilities found that providing buprenorphine via telemedicine was feasible, accessible, safe, and popular with patients and providers.⁶ Patients who sometimes face access challenges, including veterans, people experiencing homelessness, individuals involved in the criminal justice system, people living in rural areas, and racial and ethnic minorities, benefited from receiving buprenorphine via telemedicine under these policies.⁷ Increased access, comfort, and empowerment and reduced transportation and geographic barriers and stigma all contributed to patient satisfaction with receiving buprenorphine treatment via telemedicine.⁸ Similarly, prescribing practitioners benefited from these policies, with one survey finding that 85% of prescribing practitioners support making the temporary telehealth flexibilities permanent.⁹

Based on this evidence, Pew submits the following comments and recommendations on the proposed rules for consideration by DEA.

§ 1306.34 (b)(2) – *Pew recommends removing PDMP requirements for buprenorphine prescribing via telehealth.*

Pew recommends that DEA remove the requirement that a practitioner review data in the PDMP prior to prescribing buprenorphine via telemedicine.

In the proposed rule, DEA states that “PDMP are among the most effective interventions for preventing opioid drug poisonings and are correlated with a reduction in the proportion of patients that engage in drug seeking behavior.”¹⁰ However, the single study that is cited to support this claim specifically excludes buprenorphine and other medications for opioid use disorder (MOUD) in its analysis.¹¹ Further, DEA has previously stated that ***lack of access*** to buprenorphine drives buprenorphine diversion, and that increasing access to the medication may be an effective way to prevent diversion.¹² Therefore, the evidence cited to require the use of PDMP for buprenorphine prescribing via telehealth is not relevant to buprenorphine prescribing and the proposed requirement may reduce access to buprenorphine by creating an unnecessary step for practitioners to complete before providing life-saving medication.

DEA should also consider that states already set appropriate requirements for instances where practitioners should consult the PDMP database.¹³ According to CDC, PDMP data may be updated monthly, daily, or within minutes, creating huge variability for when practitioners can access data, and therefore in the utility of this data.¹⁴ Adding a federal PDMP requirement to access lifesaving medication via telehealth when states have already set PDMP requirements and considering the wide variations in access to up-to-date PDMP data, could further reduce access to buprenorphine and increase buprenorphine diversion. While PDMPs may contain information that is valuable in preventing substance use disorder (SUD) or to inform SUD treatment, the current lack of national PDMP standards and the uneven quality and accessibility of this data mean that a federal prescriber requirement could result in harmful disparities in treatment access across states. Pew has a long record of successfully working with states and PDMP administrators to improve their programs. However, these databases should not be used to prevent OUD treatment access, which would be the case with the DEA’s proposed rule.

§ 1306.34 (b)(3) – *Pew recommends removing the 7-day supply limits on prescribing buprenorphine via telehealth if a practitioner is unable to obtain PDMP data.*

If the PDMP requirement in § 1306.34 (b)(2) remains part of the final rule, Pew recommends removing the 7-day supply limit on prescribing buprenorphine via telehealth if a practitioner is unable to obtain PDMP data due to the PDMP database being non-operational or inaccessible.

This limit is not evidence-based, penalizes patients for PDMP technological failures, creates challenges for buprenorphine access, and may increase buprenorphine diversion. If the goal of a 7-day supply limit is to reduce diversion, no evidence is cited to demonstrate that a 7-day supply limit is necessary or effective in reducing buprenorphine diversion. PDMP technological

failures should not dictate patient access to lifesaving medication. This section places an arbitrary limit on buprenorphine access that may increase buprenorphine diversion. States already set time or dosage limits for controlled substances, and those policies would remain in place without this 7-day supply limit.¹⁵

§ 1306.34 (b)(4) and § 1306.34 (b)(5) – Pew recommends removing the in-person medical evaluation requirement to receive more than a 30-day supply of buprenorphine via telemedicine. If this requirement is not removed, patients that began buprenorphine treatment via telemedicine before this rule takes effect should be exempt from this requirement.

Pew recommends that DEA remove the proposed requirement for a medical evaluation in the physical presence of a practitioner as described in § 1306.34 (b)(5) for a patient to receive more than a 30-day supply of buprenorphine via telemedicine.

The proposed 30-day supply limit on buprenorphine prescriptions via telemedicine is not evidence based and fails to meet the DEA's obligation to promulgate regulations consistent with public health and safety. DEA does not cite evidence to show that a 30-day supply limit on buprenorphine decreases buprenorphine diversion, making this an arbitrary limit. DEA has previously stated that increasing access to buprenorphine may be an effective way to prevent buprenorphine diversion.¹⁶ The National Institute on Drug Abuse (NIDA) has also stated that as buprenorphine access increases, buprenorphine diversion decreases.¹⁷ The proposed 30-day supply limit contradicts DEA and NIDA's stated assessment of diversion risk by reducing access to buprenorphine, and may end up increasing buprenorphine diversion, the opposite of the intended effect of this rule. Further, if a patient is unable to see a practitioner within 30 days, they will arbitrarily lose access to buprenorphine and may turn to using drugs which may contain lethal amounts of fentanyl. As DEA points out, the availability of fentanyl is unprecedented, and fentanyl is found in about 70% of drug poisonings.¹⁸ Research has shown that discontinuation of buprenorphine increases risk of suicide/overdose, especially 8 to 14 days after treatment ends.¹⁹ Under these circumstances, these rules are a threat to public health and safety.

As DEA is aware, an overwhelming amount of evidence has demonstrated the safety, effectiveness, and value of buprenorphine for the treatment of OUD. Buprenorphine reduces the risk of overdose deaths, curbs illicit drug use, slows infectious disease transmission, and helps people stay in treatment longer.²⁰ Additionally, the risk for overdose from buprenorphine is very low, even at high doses, due to the medication's ceiling effect where even repeated dosing will not increase the medication's effect.²¹

The conclusive findings from research and clinical practice under DEA's pandemic flexibilities overwhelmingly show that buprenorphine can be safely and effectively prescribed via telemedicine without requiring an in-person visit.²² In March 2020, DEA allowed buprenorphine to be prescribed via telemedicine, including audio-only telemedicine, without an in-person visit.²³ Under these policies, telemedicine visits for initiating and continuing buprenorphine treatment increased, and research on the effect of these policies highlighted the feasibility,

accessibility, safety, and overwhelming popularity of enhanced flexibility among patients and providers.²⁴ Veterans, people experiencing homelessness, individuals involved in the criminal justice system, people living in rural areas, and racial and ethnic minorities all benefited from wider, more consistent access to buprenorphine via telemedicine, including through audio-only methods.²⁵ Patients cited increased access, comfort, and empowerment and reduced transportation and geographic barriers and stigma as reasons for their satisfaction with buprenorphine via telemedicine.²⁶ Providers in day-to-day clinical practice with these patients are also satisfied with buprenorphine provision via telemedicine, with one survey finding that an overwhelming 85% of prescribing practitioners support making the temporary telehealth flexibilities permanent.²⁷ Finally, it is important to note that, even though buprenorphine access increased markedly under pandemic flexibilities, the proportion of overdose deaths involving buprenorphine did not.²⁸

As a result, the requirement for a medical evaluation in the physical presence of a practitioner as described § 1306.34 (b)(5) for a patient to receive more than a 30-day supply of buprenorphine via telemedicine should be removed. If this requirement is not removed, patients that began buprenorphine treatment via telemedicine before this rule takes effect should be exempt from this requirement so that they do not lose access to lifesaving treatment and face increased overdose risk.

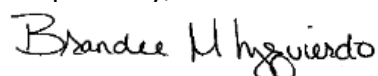
§ 1306.34 (b)(6)– *Pew recommends removing any additional recordkeeping requirements for audio-only telemedicine prescribing.*

Pew recommends that DEA remove the proposed recordkeeping requirements that only apply to audio-only telemedicine prescribing, including § 1306.34 (b)(6)(ii), which requires that a practitioner document a patient’s reason for requesting an audio-only visit.

There is no evidence that demonstrates that audio-only telemedicine for buprenorphine is less safe or effective than audio-video telemedicine for buprenorphine, and therefore audio-only telemedicine for buprenorphine should not be subject to additional, arbitrary requirements which could reduce access to lifesaving medication.²⁹

Thank you for the opportunity to comment on these important regulatory changes. Should you have any questions, please contact David Wallace at dwallace@pewtrusts.org.

Respectfully,



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The Pew Charitable Trusts

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- ¹ N. Krawczyk et al., “Pandemic Telehealth Flexibilities for Buprenorphine Treatment: A Synthesis of Evidence and Policy Implications for Expanding Opioid Use Disorder Care in the U.S,” *medRxiv* (2023): 2023.03.16.23287373, <http://medrxiv.org/content/early/2023/03/17/2023.03.16.23287373.abstract>.
- ² The Pew Charitable Trusts, “Medications for Opioid Use Disorder Improve Patient Outcomes,” <https://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2020/12/medications-for-opioid-use-disorder-improve-patient-outcomes>.
- ³ *ibid.*
- ⁴ Krawczyk et al., “Pandemic Telehealth Flexibilities for Buprenorphine Treatment: A Synthesis of Evidence and Policy Implications for Expanding Opioid Use Disorder Care in the U.S.”
- ⁵ *Ibid.*
- ⁶ *Ibid.*
- ⁷ *ibid.*
- ⁸ *ibid.*
- ⁹ *ibid.*
- ¹⁰ Drug Enforcement Administration, Expansion of Induction of Buprenorphine Via Telemedicine Encounter, 88 FR 12890 (2023), <https://www.federalregister.gov/documents/2023/03/01/2023-04217/expansion-of-induction-of-buprenorphine-via-telemedicine-encounter>.
- ¹¹ T.M. Haegerich et al., “Evidence for State, Community and Systems-Level Prevention Strategies to Address the Opioid Crisis,” *Drug Alcohol Depend* 204 (2019): 107563.
- ¹² Drug Enforcement Administration, “Economic Impact Analysis of Implementation of the Provision of the Comprehensive Addiction and Recovery Act of 2016 Relating to the Dispensing of Narcotic Drugs for Opioid Use Disorder [Docket No. DEA-450]” (2018), <https://docs.house.gov/meetings/IF/IF14/20180517/108343/HMKP-115-IF14-20180517-SD004.pdf>.
- ¹³ The Pew Charitable Trusts, “When Are Prescribers Required to Use Prescription Drug Monitoring Programs?,” <https://www.pewtrusts.org/en/research-and-analysis/data-visualizations/2018/when-are-prescribers-required-to-use-prescription-drug-monitoring-programs>.
- ¹⁴ Centers for Disease Control and Prevention, “Prescription Drug Monitoring Programs (PDMPs),” last modified May 19, 2021, <https://www.cdc.gov/drugoverdose/pdmp/index.html>.
- ¹⁵ Centers for Disease Control and Prevention, “Prescription Drug Time and Dosage Limit Laws ” (2015), https://www.cdc.gov/phlp/docs/menu_prescriptionlimits.pdf.
- ¹⁶ Drug Enforcement Administration, “Economic Impact Analysis of Implementation of the Provision of the Comprehensive Addiction and Recovery Act of 2016 Relating to the Dispensing of Narcotic Drugs for Opioid Use Disorder [Docket No. DEA-450].”
- ¹⁷ National Institute on Drug Abuse, “What Is the Treatment Need Versus the Diversion Risk for Opioid Use Disorder Treatment?” (2021), <http://nida.nih.gov/publications/research-reports/medications-to-treat-opioid-addiction/what-treatment-need-versus-diversion-risk-opioid-use-disorder-treatment>.
- ¹⁸ Drug Enforcement Administration, Expansion of Induction of Buprenorphine Via Telemedicine Encounter.
- ¹⁹ P. Vakkalanka et al., “Association between Buprenorphine for Opioid Use Disorder and Mortality Risk,” *American Journal of Preventive Medicine* 61, no. 3 (2021): 418-27, <https://www.sciencedirect.com/science/article/pii/S0749379721001999>.
- ²⁰ The Pew Charitable Trusts, “Medications for Opioid Use Disorder Improve Patient Outcomes.”
- ²¹ *ibid.*
- ²² Krawczyk et al., “Pandemic Telehealth Flexibilities for Buprenorphine Treatment: A Synthesis of Evidence and Policy Implications for Expanding Opioid Use Disorder Care in the U.S.”
- ²³ *Ibid.*

²⁴ Ibid.

²⁵ Ibid.

²⁶ Ibid.

²⁷ Ibid.

²⁸ L.J. Tanz et al., “Trends and Characteristics of Buprenorphine-Involved Overdose Deaths Prior to and During the COVID-19 Pandemic,” *JAMA Network Open* 6, no. 1 (2023): e2251856-e56, <https://doi.org/10.1001/jamanetworkopen.2022.51856>.

²⁹ Krawczyk et al., “Pandemic Telehealth Flexibilities for Buprenorphine Treatment: A Synthesis of Evidence and Policy Implications for Expanding Opioid Use Disorder Care in the U.S.”