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United States Department of Justice
United States Drug Enforcement Administration
Attention: DEA Federal Register Representative/DPW
8701 Morrissette Drive
Springfield, Virginia 22152

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

Dear Administrator Milgram,

The American Psychiatric Association (APA), the national medical society representing over 38,000 psychiatric physicians and their patients, appreciate the opportunity to comment on the prescribing of buprenorphine for the treatment of opioid use disorder (OUD) via telemedicine. APA shares the Biden Administration's commitment to increase efforts to provide evidence-based, accessible, lifesaving medications and services in communities where people most need them to beat the opioid epidemic and tackle the nation's mental health crisis. **However, the DEA falls short of the Administration's commitment to mental health with the proposed rule on the Expansion of Induction of Buprenorphine via Telemedicine Encounter.**

Buprenorphine, an opioid partial agonist, is the only Schedule II narcotic approved by the U.S. Food and Drug Administration for treatment of OUD. Many of DEA's partner agencies have voiced their support for the safe and effective prescribing of the lifesaving controlled substance. In the Treatment Improvement Protocol 63: Medications for Opioid Use Disorder (OUD), the Substance Abuse and Mental Health Services Administration (SAMHSA) states that "home induction can be safe and effective" while providing evidence-based guidelines for providers.¹ By requiring an in-person examination within 30 days of initiation of buprenorphine, the proposed rule is not just suboptimal but potentially fatal for the most vulnerable populations. At-home induction of buprenorphine has become the standard of care to achieve optimal outcomes. There is no evidence that telemedicine prescribing during the COVID-19 PHE increased diversion or negative outcomes associated with access to

¹ <https://store.samhsa.gov/sites/default/files/pep21-02-01-002.pdf>

controlled substances.^{2, 3} In fact, initial data indicates that telehealth initiation in OUD care increased retention in treatment.

Since 2017, the Secretary of Health and Human Services has declared and renewed that a public health emergency (PHE) exists nationwide as a result of the continued consequences of the opioid crisis. From October 2021 until October 2022, more than 107,000 Americans died due to a drug overdose, mainly driven by synthetic opioids.⁴ The Administration has taken unprecedented steps to reverse that trend and now is not the time to put a chilling effect on the united efforts to provide effective treatment to the millions of individuals either actively in care or eventually seeking care.

APA supports the DEA promulgating common-sense safeguards that align to clinically proven guidelines that expand access to life saving medications for Opioid Use Disorder (MOUD). However, the proposed rule does not strike the correct balance between protecting public health and saving lives. As the DEA notes, buprenorphine was involved in a very limited number of overdose deaths (2.2%) and that number did not increase during the flexibilities provided during the COVID-19 PHE.⁵ APA is concerned that by increasing the regulatory burdens on clinical decision making for prescribing buprenorphine, fewer physicians will be willing to treat those patients suffering from OUD, and those who are not able to access treatment will turn to synthetic opioids including fentanyl.

Our recommendations below focus on balancing common-sense safeguards for DEA enforcement of the legitimate prescription of buprenorphine without decreasing access to lifesaving treatment.

APA's key recommendations in DEA's finalization of this rule are:

1. Removal of the in-person requirements for buprenorphine when clinically indicated.
2. Allowance for referring practitioners to not be DEA-registered.
3. Reduction in administrative requirements for referring and prescribing practitioners.
4. Reduction in additional state-based registration requirements.
5. Removal of clinical decision-making from regulation in these proposed rules.
6. Clarification of key inconsistencies in the proposed rules.

1. Removal of the in-person requirements for buprenorphine when clinically indicated.

The existing healthcare workforce that provides MOUD is far too limited to meet the current and future needs of patients. Moreover, stigma and administrative burdens remain high for not only those prescribing, but also for patients in communities that may only have one DEA-registered provider, if any.

² Trends and Characteristics of Buprenorphine-Involved Overdose Deaths Prior to and During the COVID-19 Pandemic, <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2800689>.

³ Outcomes for patients receiving telemedicine-delivered medication-based treatment for Opioid Use Disorder: A retrospective chart review, <https://pubmed.ncbi.nlm.nih.gov/33551692/>.

⁴ Ahmad FB, Cisewski JA, Rossen LM, Sutton P. Provisional drug overdose death counts. National Center for Health Statistics. 2023 <https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm>

⁵ 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. 20, 2023)

APA also notes the inaccurate reference that a nationwide shortage of prescribers of buprenorphine no longer exists.⁶ Fifty-five percent of U.S. counties have no psychiatrists, and 130 million people live in areas with a shortage of mental health providers.⁷ ⁸ While psychiatrists are not the only DEA-registered prescribers of buprenorphine, other prescribers are often not willing or not confident in treating complex OUD patients, and that should not be a death sentence to a person in a provider or appointment shortage area. APA is confident that the removal of the X-waiver and the associated OUD education will help reduce the deeply rooted stigma that exists, but that alone will not ensure that providers will be available in every community.

DEA has a role in reducing diversion of controlled substances, including buprenorphine. However, there is a greater individual and public health disservice to remove a safe medication for the treatment of OUD in anticipation of potential diversion. DEA is encouraged to instead identify and investigate markers of overprescribing that objectively lead to increased diversion in close partnership with HHS agencies and clinical advisors.

APA recommends that the DEA remove the in-person requirements for the prescribing of buprenorphine for the treatment of OUD via telemedicine when clinically indicated. If the DEA does not permanently remove the in-person requirement for the prescribing of buprenorphine for the treatment of OUD via telemedicine, APA strongly encourages DEA to continue the waiver of the in-person requirement for the duration of the opioid PHE. The flexibilities during the COVID-19 PHE have allowed practitioners to use clinical decision-making to determine when and how often to see a patient in-person, and we recommend that this flexibility continue.

2. Allowance for referring practitioners to not be DEA-registered.

A requirement for DEA registration for qualified telemedicine referrals would significantly restrict access to care without a compelling benefit to law enforcement. **Requiring only the prescribing practitioner to be DEA-registered generates an audit trail for DEA while maintaining much-needed access to care in locations and populations without physical access to DEA-registered practitioners (e.g., rural settings, individuals experiencing health disparities, individuals with mobility or transportation barriers).**

To make the referring practitioner pathway viable, DEA also must clarify the intent of the requirement for an initial in-person visit by a referring practitioner – medical stability or decreased diversion. In the case of a medical stability rationale, the prescribing DEA-registered practitioner is the one best-suited to determining the physiologic and clinical data necessary to safely issue a prescription. The medical personnel that most frequently take vitals in typical clinical settings are non-advanced practice, and therefore non-DEA-registered, personnel (e.g., registered nurses). In the case of diversion prevention, any in-person encounter with a licensed medical professional provides verification of a legitimate, in-

⁶ DEA, *supra* note 2, 88 Fed. Reg. at 12894.

⁷ Mapping Supply of the U.S. Psychiatric Workforce, <https://www.behavioralhealthworkforce.org/wp-content/uploads/2019/01/Y3-FA1-P2-Psych-Mapping-Full-Report-with-Appendix.pdf>.

⁸ Where the Mental Health Clinician Shortage Is at Its Worst, <https://bhbusiness.com/2022/06/24/where-the-mental-health-clinician-shortage-is-at-its-worst/>.

person treatment relationship. There is no evidence that in-person care requirements reduce drug diversion. **APA recommends that the referring practitioner pathway be allowable using existing data that a referring practitioner has about the patient and does not require a new visit for the specific purposes of initiating a referral.**

Requiring that a DEA-registered practitioner conduct an in-person evaluation leads to several systemic harms: first, it may incentivize non-specialist practitioners to treat complex conditions on their own rather than referring a patient to a specialist; second, it incurs significant additional and unnecessary cost to the patient and the health care system by generating duplicative high-cost care rather than making appropriate use of community-based professionals; and third, it penalizes patients with unmet health-related social needs including uninsurance or underinsurance, mobility and transportation challenges, and geographic disparity – all significant, preventable risks to population health.

3. Reduction in administrative requirements for referring and prescribing practitioners.

The administrative burden of these proposed rules is significant, and we note that burnout and workforce challenges associated with documentation requirements are already posing widespread risks to access to care.⁹ In addition, clinical data management systems are not configured with these components in them, and those upgrades are expensive and time-consuming – certainly not feasible within the timeframe of the finalization and implementation of these rules.

There is also a safety risk posed to clinicians. DEA's requirement that practitioners report their physical location at the time the prescription is written – even if that is their home address during a telehealth encounter – is unnecessary and potentially dangerous. We have heard from APA members who have experienced safety issues due to personal information getting into the hands of a few individuals seeking to harm the practitioner.

APA recommends that the following administrative requirements *be removed* in the final rules:

- The requirement for the practitioner to report their physical address during the telemedicine encounter; practitioners should be able to use the business address of their DEA registration.
- The requirement for the prescribing practitioner to be identified specifically, by NPI, by the referring practitioner creates a barrier to care as many practitioners will not be aware of the availability, insurance network participation, and specialty of practice to whom they refer. This requirement risks the ability for patients to continue on to appropriate specialty care.
- The requirement to only allow for a 7-day prescription if the PDMP is not accessible. Most states already require clinicians to access the PDMP prior to issuing a prescription for a controlled substance, but those states *do not* restrict access to care for the patient in the uncommon situation that the PDMP is not accessible. PDMP systems issues, including lack of interoperability, access across state lines, and run-of-the-mill outages, should not be used to punish patients.

⁹ Physician stress and burnout: the impact of health information technology, <https://academic.oup.com/jamia/article/26/2/106/5230918>.

Instead, APA recommends that DEA use its audit and enforcement capabilities to ensure that practitioners are documenting accessing the PDMP and query attempts.

- The requirement to have telemedicine prescription written on the prescription. Patients are already facing barriers to having prescriptions filled due to pharmacy policies. We are concerned that this will create further barriers to legitimate prescriptions being filled in a timely manner. Please see the letter sent by APA and the American Academy of Child and Adolescent Psychiatry to DEA on March 24, 2023 outlining the current crisis in access to prescribed stimulants for additional information on the profound negative impact to patients when pharmacies do not or cannot dispense prescribed medications.
- The requirement for any duplicative recordkeeping, beyond what is currently necessary for clinical care. The implementation of documentation requirements in clinical information systems is not feasible in DEA's proposed timeline. DEA's assessment that cost associated with this rule is minimal is incorrect. Clinical information systems often require at least a 12-month grace period to allow for upgrading and configuration of the electronic medical record.

4. Reduction in additional state-based registration requirements.

The requirement that prescribing practitioners have a DEA registration in the state they are in when they are issuing the prescription is a needless restriction on access to care. **Patient protection is already ensured through DEA registration and medical licensure in the state the patient is in at the time of the visit.** This area presents a key opportunity for the DEA to promulgate rules for a telemedicine special registration for eligible prescribing physicians.

APA asks that the DEA consider what the impact would be to patients if their prescriber is, for example, traveling to see family or at a conference when the patient needs a refill. Is the patient to be denied life-saving medication and continuity of care? **Instead, APA recommends that these rules adopt language from the Ryan Haight Act: that the practitioner may prescribe from a state in which the practitioner isn't registered if the practitioner is temporarily out-of-state.** This exception may be required to be documented in the patient's clinical record.

5. Removal of clinical decision-making from regulation in these proposed rules.

We note that there are significant components of this rule that constitute clinical decision-making, including the 30-day telemedicine supply allowance and the requirement for an in-person evaluation prior to initiation of controlled substances. **Duration of treatment and any requisite aspects of in-person evaluation or laboratory testing are clinical decisions and vary based on the medication being prescribed.** Moreover, prescribing providers consider other social determinants of health and other barriers to in-person care such as transportation, employment hours, family-care situations, and stigma and violence for seeking care.

APA recognizes the need for DEA to establish objective guardrails that can be enforced, but there is no evidence that telemedicine prescribing during the COVID-19 PHE increased diversion. APA strongly recommends that rather than the DEA making these clinical decisions that they defer to the prescribing practitioner. There is a greater individual and public health disservice to remove access to clinically

indicated medications in anticipation of potential diversion. **Instead, DEA is encouraged to work closely with HHS agencies and clinical advisors to identify and investigate objective markers of overprescribing that signal increased diversion.**

When DEA needs objective guardrails established, it is strongly recommended that the guardrails not be so restrictive that they are not clinically feasible. In particular, an in-person appointment in 30 days will often be impossible to achieve.¹⁰ In the “Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation” proposed rule, DEA is proposing a 180-day “off-ramp” for established telemedicine patients, essentially demonstrating DEA’s belief that it is in the patient’s best interest to not abruptly end a treatment plan when prescribed a controlled substance. We remind DEA that these restrictive rules punish patients with unmet health-related social needs rather than imposing appropriate safeguards against diversion. **APA recommends a 180-day window for the initial prescription of buprenorphine prior to an in-person examination, if the in-person requirement is not removed.**

6. Clarification of key inconsistencies in the proposed rules.

APA is requesting clarification regarding if a removal of the in-person requirement is not implemented, whether the 180-day grace period (described in the “Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation” proposed rule), for those who established a telemedicine relationship during the COVID-19 public health emergencies applies to this proposed rule. APA recommends DEA implement this option if it implements an in-person examination requirement for buprenorphine in addition to other classes of controlled substances.

APA is also requesting clarification as to whether the VA pathway described in the “Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation” proposed rule – that VA patients can be prescribed to via telemedicine without a referral by a VA practitioner if they have ever been seen in-person in a VA facility – also applies to this rule. If not, DEA is requested to clarify why not, and APA recommends DEA implement this option for buprenorphine in addition to other classes of controlled substances.

APA appreciates DEA’s efforts to learn from the lessons of the COVID-19 PHE in maintaining access to critical, life-saving care through technology, including allowing audio-only initiation and maintenance of buprenorphine when the patient requests that modality. We caution DEA in taking too many steps backward, re-imposing unnecessary limitations on the practice of medicine during an opioid public health emergency and nationwide mental health and access to care crisis. DEA has the opportunity to get the balance right by finalizing rules that facilitate, rather than prevent, access to high-quality care.

¹⁰ 2022 Survey of Physician Appointment Wait Times, <https://www.merrithawkins.com/trends-and-insights/article/surveys/2022-physician-wait-times-survey/>

Thank you for your review and consideration of these comments. If you have any questions or would like to discuss any of these comments further, please contact Brooke Trainum, Director, Practice Policy, btrainum@psych.org.

Sincerely,

A handwritten signature in blue ink that reads "Saul Levin" with "M.D., M.P.A." written in smaller letters to the right. There is a horizontal line under the name "Levin".

Saul M. Levin, M.D., M.P.A., FRCP-E, FRCPsych
CEO and Medical Director
American Psychiatric Association