ABHW
Advancing Health Care Policy
for Mental Health and Addiction

March 31, 2023

The Honorable Anne Milgram
Administrator
United States Drug Enforcement Administration
800 K Street NW Suite 500
Washington, D.C. 20001

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

Dear Administrator Milgram,

The Association for Behavioral Health and Wellness (ABHW) appreciates the opportunity to submit comments on the Drug Enforcement Administration's (DEA) proposed rule on the Expansion of Induction of Buprenorphine via Telemedicine Encounter (NPRM or proposed rule). As discussed in our comments on the companion regulation, Telemedicine Prescribing of Controlled Substances when the Practitioner and the Patient have not had a Prior In-Person Medical Evaluation (Telehealth Prescribing of Controlled Substances), ABHW is grateful to DEA for the flexibility and quick response during the COVID-19 public health emergency (COVID -19 PHE). We appreciate DEA's responsibility to provide adequate controls against diversion and protect public health and safety. However, ABHW believes that the proposed rule will impede access to treatment. The data on the use of existing flexibilities on telehealth under the COVID-19 PHE has demonstrated that the risk of diversion in prescribing buprenorphine is low.[1]

ABHW is the national voice for payers managing behavioral health insurance benefits. ABHW member companies provide coverage to approximately 200 million people in the public and private sectors to treat mental health (MH), substance use disorders (SUDs), and other behaviors that impact health and wellness.

[1] Center for Disease Control, buprenorphine has a low intrinsic activity at the mu receptor; however, at increasing doses, unlike a full Opioid agonist, the agonist effects of buprenorphine reach a maximum and do not continue to increase linearly with increasing doses of the drug-the ceiling effect. Trends and characteristics of buprenorphine-involved overdose deaths before and during the COVID-19 pandemic, January 2023

Our organization aims to increase access, drive integration, support prevention, raise awareness, reduce stigma, and advance evidence-based treatment and quality outcomes. Furthermore, through our policy work, we strive to promote equal access to quality treatment and address the stark inequities created by systemic racism. We are deeply concerned about health disparities in MH and SUD services in this country and are committed to promoting health equity in the healthcare system. Across the nation, the opioid crisis has been exacerbated by the COVID-19 pandemic, and the barriers to access to Medication for Opioid Use Disorder (MOUD) treatment have further come to the forefront, especially in communities of color. With increasing annual deaths from opioid overdoses, enhancing access to MOUD is more critical than ever.

Drug overdose deaths skyrocketed in the U.S. during the first year of the COVID-19 pandemic, increasing by 30.6% in 12 months. Black, American Indian, and Alaska Native people have the highest overdose death rates and limited access to Opioid Use Disorder (OUD) medications. There is a particular need for OUD treatment and immediacy to expand buprenorphine and other MOUD access.

ABHW recognizes the need for appropriate guardrails to minimize controlled substance misuse. However, this NPRM is too limiting and will create unnecessary barriers for people seeking SUD treatment. Please see our detailed comments below on the provisions of the proposed rule.

1) Specific Recommendations for the Expansion of Induction of Buprenorphine via Telemedicine Encounter NPRM

I. Special Allowance for Prescribing Buprenorphine

Buprenorphine is one of the gold standards of care for OUD. The medication prevents painful withdrawal symptoms and, in doing so, helps people secure long-term recovery and cuts the risk of overdose death in half. The drug has been approved by the U.S. Food and Drug Administration (FDA) for nearly twenty years. Data demonstrates that it is one of the safest medications healthcare providers prescribe - far safer than common medications like insulin and blood thinners. The increased flexibility for buprenorphine-based treatment for OUD during the COVID-19 pandemic has not been associated with an increased proportion of overdose deaths.[2]

Removal of In-Person Requirement for Buprenorphine

ABHW urges the DEA to withdraw mandating the in-person evaluation before prescribing buprenorphine. This in-person requirement will result in reduced access to care. Buprenorphine telehealth treatment does not heighten the risk of unlawful activity or

[2] Trends and characteristics of buprenorphine-involved overdose deaths before and during the COVID-19 pandemic, January 2023

diversion. Reports and investigations during the COVID-19 PHE from the U.S. Department of Health and Human Services (HHS) Office of the Inspector General (OIG) have found cases of fraud via telehealth in the Medicare program have been rare despite the lifting of restrictions such as in-person requirements, and that fraud that does occur mirrors that found in the in-person modality.

The in-person evaluation required before prescribing controlled substances via telemedicine only results in reduced access to care. During the COVID-19 PHE, the DEA waived the in-person requirement, enabling providers to safely prescribe controlled substances using telemedicine. A Journal of Substance Abuse Treatment study found that removing the in-person requirement significantly increased access to care and addressed health inequities in primary care programs providing buprenorphine treatment. ABHW strongly supports removing the in-person requirement for buprenorphine as it will hinder access to care.

Alternatively, ABHW urges the DEA to allow a provider the flexibility to prescribe buprenorphine without an in-person visit if there is a valid reason and the provider documents this in the patient's health record. The DEA should allow for clinical decision-making on a case-by-case basis.

The recent Substance Abuse and Mental Health Services Administration (SAMHSA) proposed rule for the Medications for the Treatment of Opioid Use Disorder provides flexibilities for using buprenorphine, including eliminating the in-person visit requirement to initiate buprenorphine at Opioid Treatment Programs (OTP). The SAMHSA NPRM allows OTP providers to continue prescribing buprenorphine via audio-only or audio-visual appointments, allowing flexibility for patients who might otherwise not be able to get to their appointments due to difficulties traveling. **ABHW supports audio-only initiation and maintenance of buprenorphine when the patient requests that modality.**

II. Delay Implementation until the End of the Opioid Public Health Emergency

ABHW recommends that the implementation of this NPRM, with the suggested modifications, be delayed until after the expiration of the Opioid PHE. Additionally, the existing waivers on telehealth prescribing under the COVID-19 PHE should be extended for buprenorphine under the Opioid PHE.

At a minimum, the DEA should at least ensure that the 180-day off-ramp discussed in the companion proposed Telemedicine Prescribing of Controlled Substances rule will be applicable for buprenorphine as well. Unfortunately, even with 180 days, many patients may continue to have trouble finding an in-person provider and will lose access to care. **ABHW recommends that patients that have established relationships during the COVID-19 pandemic should be able to continue seeing their provider via telehealth into perpetuity.**

III. Prescription Drug Monitoring Program Review

Prescription Drug Monitoring Programs (PDMP) are effective tools for states to intervene and prevent fraud, waste, and abuse of controlled substances. Information from PDMPs can help understand and identify problem prescribers and individuals who are "doctor shopping" for multiple prescriptions. ABHW supports the consistent use of PDMPs, including allowing health insurance plans access to these databases to improve interoperability across systems that promote patient safety and coordination of care.

In the proposed rule, the DEA indicates that providers must review the PDMP before prescribing buprenorphine via telemedicine. ABHW supports this requirement for providers prescribing buprenorphine in person or via telemedicine to help ensure safe prescribing and coordinated patient care and to reduce potential diversion. While we recognize and understand the benefits of PDMPs, not all states have them. Additionally, those states with programs do not include reporting for the same medications for treating OUD or SUD. This NPRM requires a practitioner to review recent PDMP data before issuing a prescription. **ABHW is concerned that this provision will hinder the ability to prescribe MOUD in the eight states that do not have operational PDMPs.[3] As a result, ABHW requests the establishment of a national PDMP. Additionally, the DEA should suggest to states to include reporting for medications for evidence-based behavioral health treatment.**

2) <u>Overlapping Comments with Telemedicine Controlled Substance Prescribing Rule</u>
Please see ABHW's comments on the below provisions that were also raised in our letter on the companion Telemedicine Controlled Substance Prescribing proposed rule:

I. Remove the Proposed 30- Day Supply Limit on Prescriptions for Controlled Medications

ABHW urges the DEA to withdraw the proposal to limit the supply of controlled medications and defer clinical decision-making in these instances to clinical experts. While we recognize the need for DEA to establish objective guardrails that can be enforced to reduce diversion, we encourage the DEA to continue to identify and investigate markers of overprescribing and prescribing practices that objectively lead to increased diversion in close partnership with HHS agencies and clinical advisors. Additionally, it is not always possible for patients needing behavioral health care to see a provider in-person within 30 days, especially with the ongoing behavioral health workforce shortages, and for those individuals in rural areas.

II. Referring Practitioner & DEA Registration Provisions

Allowance for Referring Practitioners to Not be DEA-Registered

[3] The Prescription Drug Monitoring Program Training and Technical Assistance Center (PDMP TTAC) reports eight states, including AK, KS, ME, MO, NH, OR, SC, and VT, do not have PDMPs that collect information on Schedule V drugs, Data available at https://www.pdmpassist.org/Policies/Maps/PDMPPolicies

The proposed requirement that the qualified telemedicine referral must have a DEA registration will significantly impede access to care without a compelling benefit to law enforcement. **ABHW requests that the DEA withdraw the proposal to require that the referring practitioner be DEA-registered.** It is sufficient to require the prescribing practitioner to be DEA-registered as this alone will generate an audit trail for DEA while maintaining much-needed access to care in locations and populations without physical access to DEA-registered practitioners, such as rural settings or for patients that have mobility or transportation barriers. Additionally, requiring an initial DEA-registered practitioner to conduct a physical exam will likely encourage non-specialist practitioners to treat complex conditions independently rather than referring the patient to a licensed therapist.

Pharmacists with DEA Registrations Should Have Prescribing Abilities

The definition of "practice of telemedicine" within the proposed rules references its applicability to a practitioner "other than a pharmacist." The proposed rules also include a definition of "telemedicine prescription" that appears to allow pharmacists with DEA registrations as mid-level practitioners to prescribe in applicable states. **ABHW urges the DEA to clarify that pharmacists with DEA registrations as mid-level practitioners may prescribe in states where this practice is allowed.**

Recommendation for Referrals to a Group Rather than a Specific Clinician

The proposed definition and standards for a qualifying telemedicine referral to a specific practitioner should be more flexible. Given the well-documented behavioral health workforce shortage, especially in areas like psychiatry – and standard wait times even for telehealth appointments, it would be untenable to require the referring provider to know with specificity which clinician the patient will ultimately end up seeing at the time of making the referral. For example, behavioral health care is highly personal, and patients need time to find the right provider for them and to meet their preferences regarding provider type, including gender, age, and ethnicity.
Additionally, for integrated health systems that coordinate patient care, identifying a specific practitioner for the referral will create operational hurdles and unnecessarily delay patient care. **ABHW urges the DEA to allow the referring provider to refer the patient to a medical group, clinical department, health system practice, or collaborative agreement instead of a specifically named clinician at the National Provider Identifier (NPI) level.** The group, department, or practice should then have the authority to assign the patient to a clinically appropriate provider for ongoing treatment via telehealth. This approach is consistent with current provider medical referrals.

Streamline DEA Registration Requirement to Practitioners' State

Lastly, **ABHW recommends that the proposed rule be streamlined to require a DEA registration only in the state where the practitioner is located.** It is overly burdensome for the provider to be DEA-registered in each state where the patient is located. It is sufficient that practitioners comply with individual state laws on licensure and telehealth

limitations. This suggestion aligns with the language in the proposed rule that DEA-registered providers maintain a physical address and records in one state rather than in each state where they practice.

III. Develop a Less Restrictive Special Registration Pathway for Telehealth Prescribing

This NPRM should not be a substitute for the congressionally mandated special registration required under the Ryan Haight Act and the SUPPORT Act. ABHW is concerned that this rule does not satisfy multiple congressional directives for the DEA to establish a process for providers to prescribe controlled substances via telemedicine. **This proposed rule should form the baseline of telehealth prescribing for all DEA-registered providers. ABHW urges the DEA to issue a special registration to provide a separate enhanced pathway to less restrictive telehealth prescribing for providers.**

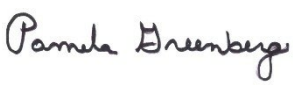
IV. Keep Controlled Substance & Expansion of Buprenorphine Regulations Separated

ABHW encourages the DEA to keep this regulation separate from the regulation on the Telehealth for Controlled Substance Prescribing rule to ensure clarity with training and technical assistance. Buprenorphine is currently the only Schedule III narcotic drug approved by the FDA for maintenance or detoxification of OUD. However, having these rules separate once new drugs are approved will ease the implementation.

Conclusion

Thank you for the opportunity to provide feedback on this proposed rule. We are committed to engaging with the DEA and other partners on opportunities to improve behavioral health care access. If you have questions, please contact Kathryn Cohen, Senior Director of Regulatory Affairs, at cohen@abhw.org.

Sincerely,



Pamela Greenberg, MPP
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