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, DC 20001

RE: Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation, Docket No. DEA-407

Dear Administrator Milgram,

The Association for Behavioral Health and Wellness (ABHW) appreciates the opportunity to submit comments on the Drug Enforcement Administration (DEA) Notice of Proposed Rule Making on the Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation (NPRM or proposed rule). We are grateful to the DEA for the flexibility and quick response during the COVID-19 public health emergency (PHE), which expanded access to necessary substance use treatment via telemedicine. We also understand and appreciate the DEA's responsibility to provide adequate controls against diversion and protect public health and safety. However, ABHW believes this proposed rule impedes access to treatment and does not effectively mitigate the risks of diversion in prescribing controlled substances through telehealth.

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.

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.

On July 4, 2022, the Biden Administration renewed the determination that the Opioid Public Health Emergency (Opioid PHE) exists nationwide under section 319 of the Public Health Service Act, 42 USC § 247d. The COVID-19 pandemic and opioid crisis have skyrocketed demand for MH and SUD services. In 2021, 40% of adults reported symptoms of anxiety or depression — compared with 11% pre-COVID. Over time, this percentage dipped to 33% in June 2022, still higher than pre-pandemic levels.[1] Our nation's overdose epidemic – now driven primarily by synthetic opioids – claimed the lives of nearly 108,000 Americans for the year ending October 2022. With the acute shortage of behavioral health professionals, we encourage the DEA to continue to exercise its law enforcement authority to prevent diversion and inappropriate prescribing instead of enforcing upstream restrictions on care. This NPRM inhibits the use of clinical judgment and furthers stigma by putting up barriers to effective MH and SUD treatment.

Please see our detailed comments below on the provisions of the proposed rule.

I. Removal of Clinical Decision-Making Provisions from NPRM – 30-day Supply & In-Person Requirement

Many components of this rule constitute clinical decision-making. These include but are not limited to the 30-day telemedicine supply allowance and the requirement for an in-person physical examination before initiating controlled substances. The duration of treatment and the specific data needed to prescribe are clinical decisions that vary based on the patient and the prescribed medications. Moreover, there is no unified standard of care that describes prerequisites for non-narcotic, schedule III-V controlled medications. Additionally, it is not always possible for patients with behavioral health needs to see a provider in-person within 30 days, especially with the ongoing behavioral health workforce shortages and for patients in rural areas. **ABHW urges the DEA to withdraw these proposals and defer the clinical decision-making to the appropriate treating clinicians.**

Nonetheless, we recognize the need for the DEA to establish objective guardrails to reduce diversion. We encourage the DEA, in close partnership with the Department of Health and Human Services (HHS) agencies and clinical advisors, to continue to identify and investigate markers of overprescribing and prescribing practices that objectively lead to increased diversion.

II. Delay Implementation until the End of the Opioid PHE

ABHW recommends that the implementation of this NPRM, with the suggested modifications, be delayed until after the expiration of the Opioid PHE. There is an unprecedented need for behavioral health treatment and an urgency to expand mental health and Medications for Opioid Use Disorder (MOUD) access.

[1] https://www.aamc.org/news-insights/growing-psychiatrist-shortage-enormous-demand-mental-health-services

ABHW appreciates that this proposal delays implementation for patients that have developed a telehealth relationship during the pandemic and allows for an additional 180 days after the effective date of this rule. Unfortunately, because of the behavioral health workforce shortage, ABHW believes that many of those patients will have trouble finding an in-person provider and will lose the continuity of their care after the 180 days lapse. **ABHW recommends that patients that have established relationships during the COVID-19 pandemic can continue seeing their provider via telehealth into perpetuity.**

III. Referring Practitioner & DEA Registration Provisions

Allowance for Referring Practitioners to Not be DEA-Registered

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. 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

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.

IV. 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 special registration 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.**

V. 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 U.S. Food and Drug Administration (FDA) for maintenance or detoxification treatment 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. ABHW is committed to working with DEA and other partners to improve access to behavioral health treatment for all Americans. If you have questions, please contact Kathryn Cohen, Senior Director of Regulatory Affairs, at cohen@abhw.org.

Sincerely,

Pamela Greenberg, MPP
President and CEO

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