March 30, 2023

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

Re: Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation [RIN 1117-AB40]

Dear Administrator Milgram:

On behalf of the American Association of Psychiatric Pharmacists (AAPP) (f.k.a. the College of Psychiatric and Neurologic Pharmacists), we appreciate the opportunity to provide feedback on the Drug Enforcement Agency's (DEA) proposed rule on the Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation (proposed rule). We greatly appreciate the steps that the DEA has taken to ensure access to controlled substances via telemedicine after the public health emergency ends. However, AAAP is concerned that the rule as proposed does not go far enough in preserving patient access to controlled substances for treatment of mental health and substance use disorders (SUDs).

About AAPP

AAPP is a professional association of nearly 3,000 members who envision a world where all individuals living with mental illness, including those with substance use and neurologic disorders, receive safe, appropriate, and effective treatment. Members are specialty pharmacists, and most are Board Certified Psychiatric Pharmacists (BCPPs) who specialize in psychiatry, substance use disorders (SUDs), and psychopharmacology. With a significant shortage of mental health care professionals, psychiatric pharmacists offer another resource to improve outcomes for patients with psychiatric and SUDs.

Role of Psychiatric Pharmacists

Pharmacists graduate with a Doctor of Pharmacy degree, requiring six to eight years of higher education to complete, and have more training specific to medication use than any other health care professional. Psychiatric pharmacists, a specialty within clinical pharmacy, are primarily board certified and residency-trained mental health care practitioners who have specialized training in providing direct patient care and medication management for the complete range of psychiatric disorders and SUDs. Psychiatric pharmacists work as treatment team members but also in decision-making and leadership roles in state and federal organizations, academia, and industry.

Psychiatric pharmacists are important members of the health care team working in collaboration with the patient and other health care providers including, but not limited to, psychiatrists, other physicians,
therapists, social workers, and nurses (including advanced practice nurses). Psychiatric pharmacists provide expert, evidence-based Comprehensive Medication Management (CMM) services for the most complex patients with mental health disorders and SUDs. Psychiatric pharmacists increase capacity of the health care team to provide care and psychopharmacology expertise, as well as improve patient outcomes and reduce overall health care costs.

Psychiatric pharmacists have a deep understanding of Medications for Opioid Use Disorder (MOUD) that extends beyond that of most other health care providers. When included in the provision of MOUD services through a collaborative practice arrangement, psychiatric pharmacists' involvement has been demonstrated to improve patient adherence and success with buprenorphine treatment for opioid use disorders; reduce per patient dosage of buprenorphine through improved medication management, monitoring and titration; and reduce overall costs for treating patients with SUDs by relieving providers from delivering services including medication management, counseling, monitoring and follow-ups.

AAPP Comments to Proposed Rule

1. AAPP supports expansive definition of "home".

AAPP supports DEA's definition of home to include temporary lodging such as hotels and homeless shelters as well as locations a short distance from the patient's home (e.g., if the patient, for privacy or other personal reasons, chooses to travel a short distance aways from the exact home location during a telehealth service). It is critically important to maintain flexibility to serve those who are experiencing or at risk for homelessness and in need of treatment.

2. AAPP urges more expansive use of audio-only.

Under the rule, the use of audio-only is limited and situational. The rule lays out four requirements before audio-only equipment is allowed: 1. Telehealth services must be furnished for purposes of diagnosis, evaluation, or treatment of a mental health disorder; 2. Telehealth services must be provided to a patient located in their home; 3. Provider must meet audio-video interactive communication standard; and 4. Patient is not capable or does not consent to the use of video technology. If all requirements are met the practitioner can then use audio-only to conduct a telemedicine encounter and prescribe a controlled substance to the patient and must document the requirements in the patient's record. AAPP believes this is too

restrictive. A recent study[1] among Veterans Health Administration Patients found that reducing telephone-only access could "have an outsized effect on groups who have historically faced disparities in buprenorphine access."

3. AAPP urges DEA not to push patients off a telemedicine "cliff".

During the public health emergency (PHE), patients received prescriptions for all controlled substances without an in-person visit. This policy change not only kept individuals safer from COVID exposure, but it also relieved the workforce shortage which has only been exacerbated during the PHE. In this proposed rule, the DEA is proposing to revert to pre-pandemic policies and again require in-person visits in relation to prescribing Schedule II controlled substances, a change that will likely drive individuals in need of controlled substances off a telemedicine cliff. While allowing telehealth for Schedule III or higher medications for 30 days but requiring an in-person visit before a refill is less harmful, it is still disruptive to patient care. Particularly with buprenorphine, patients who have initiated treatment via telehealth and then for a legitimate reason cannot fulfill the in-person requirement may discontinue treatment altogether, potentially leading to an overdose. We believe the 30-day requirement is arbitrary and discretion should be left to the treating clinician as to when an in-patient visit is appropriate. As such, we strongly urge DEA to reconsider its proposed rule as the impact of this policy change may harm patient health and impact patient access to care.

4. AAPP urges the DEA not to set an arbitrary limit on the supply dispensed to a patient when a PDMP is not operational.

AAPP urges the DEA to remove the 7-day supply limitation if the PDMP is non-operational. § 1306.31 proposed paragraph (e)(2)(i) would require, in those circumstances where the PDMP system is non-operational, practitioners to limit their prescriptions to patients to no more than a 7-day supply until they are able to access the PDMP system again. We do not support this requirement. This raises an equity concern, as it financially penalizes patients for a technological issue outside their realm of control. A requirement to make multiple trips and payments to a pharmacy to obtain more than one prescription may lead to treatment discontinuation, relapse, opioid misuse, and increased overdose risk. AAPP would support language such as, "If the PDMP is non-operational, the prescriber is not limited to prescribing a 7-day supply if they have checked the PDMP before for that patient and not found to have safety concerns."

5. AAPP urges DEA to eliminate cumbersome additional reporting requirements for prescriptions of controlled substances.

AAPP urges the DEA to eliminate the cumbersome additional recordkeeping requirements for controlled substance prescriptions issued pursuant to telemedicine encounters that DEA is

[1] Frost MC, Zhang L, Kim HM, Lin L. Use of and Retention on Video, Telephone, and In-Person Buprenorphine Treatment for Opioid Use Disorder During the COVID-19 Pandemic. JAMA Netw Open. 2022;5(10):e2236298. doi:10.1001/jamanetworkopen.2022.36298.

proposing to impose in amending 21 CFR part 1304. Specifically, the additional recordkeeping requirements for telemedicine prescriptions of controlled substances: 1) without an in-person visit, 2) if issued through a qualifying telemedicine referral, and 3) based on a visit with a referring provider. Referring providers' DEA and National Provider Identifier numbers and addresses are not routinely readily available and place additional burden on the provider or clinic to locate and include. The proposed additional recordkeeping would require development and maintenance of tracking systems and documentation outside the medical record. This involves additional effort and separate storage of Protected Health Information. The risks and burden of this additional recordkeeping outweigh potential benefit.

6. In the absence of Congressional action to make the use of telehealth for buprenorphine treatment permanent, AAPP urges DEA to promulgate a rule to create a special registration exception of the Ryan Haight Act.

The Ryan Haight Act contains seven "practice of telemedicine" exceptions to the in-person evaluation requirement: 1) treatment in a hospital or clinic; 2) treatment in the physical presence of a DEA-registered practitioner; 3) treatment by Indian Health Service or Tribal practitioners; 4) treatment during a public health emergency as declared by the Secretary of Health and Human Services; 5) treatment by a practitioner who has obtained a "special registration"; 6) treatment by Department of Veterans Affairs practitioners during a medical emergency; and 7) other circumstances specified by regulation.

Since 2008, Congress and stakeholders have been urging DEA to promulgate a rule related to the "treatment by a practitioner who has obtained a special registration" exception that would allow for health care providers to evaluate a patient and prescribe controlled substances over telehealth platforms safely.[2] The efficacy and safety of allowing telemedicine for prescriptions of controlled substances, particularly for buprenorphine, now has nearly three years of data due to the PHE.[3] Instead, DEA decided to create a new option under the catchall exception of "other circumstances specified by regulation" that severely limit access to life saving medications.

Furthermore, the proposed rule worsens the workforce shortage of mental health providers nationwide as more than half of U.S. counties do not have a single psychiatrist.[4] As Senator Warner's states, telehealth helped expand access to controlled substances because individuals

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[2] Statement of U.S. Sen. Mark R. Warner on Proposed DEA Rule on Future of Telehealth Prescriptions, March 1, 2023, *available at* https://www.warner.senate.gov/public/index.cfm/2023/3/statement-of-u-s-sen-mark-r-warner-on-proposed-dea-rule-on-future-of-telehealth-prescriptions. Last visited March 8, 2023.

[3] Tofighi B., McNeely J., Walzer D., Fansiwala K., Demner A., Chaudhury C.S., Subudhi I., Schatz D., Reed T., Krawczyk N. A telemedicine buprenorphine clinic to serve New York City: initial evaluation of the NYC public hospital system's initiative to expand treatment access during the COVID-19 pandemic. *J. Addict. Med.* 2022;16(1):e40–e43. doi: 10.1097/ADM.0000000000000809.

[4] Stacy Weiner, A growing psychiatrist shortage and an enormous demand for mental health services, AAMC, August 9, 2022, *available at* https://www.aamc.org/news-insights/growing-psychiatrist-shortage-enormous-demand-mental-health-services/. Last visited March 9, 2023.

no longer had to take time off work, commute to a medical facility, wait to be seen by the prescriber; now they can quickly have access to a provider from nearly any location.[5]

Given the overwhelming public benefit of allowing controlled substances to be prescribed via telemedicine, we strongly urge DEA to retract this proposed rule and promulgate a new rule related to the special registration exception, as requested by Congress and stakeholders.

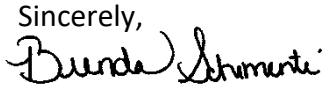
7. DEA should be aware of other unintended consequences of this proposed rule.

Recent reporting has revealed that telemental health stakeholders and policy experts are considering urging physicians and telehealth companies to call for Food and Drug Administration (FDA) risk evaluation and mitigation strategies (REMS) for certain controlled substances used to treat mental health disorders, a move they hope may sway DEA to pull back this proposed rule.[6] However, there are potential downsides to utilizing REMS for controlled substances. For example, the REMS process for the schizophrenia drug clozapine has resulted in access barriers to patients that can have fatal consequences.

Lastly, lack of access to buprenorphine is a greater public health problem in terms of record overdose deaths than diversion. As DEA states in the proposed rule, the amount of fentanyl seized in 2022 is enough "to supply a potentially lethal dose to every member of the U.S. population." While we understand DEA's concern, AAPP believes that the overwhelming supply of fentanyl and other substances requires removal of these barriers to save lives.

Thank you again for the opportunity to comment and once again urge you to remove unnecessary barriers to treatment with controlled substances. If you have any questions, please do not hesitate to contact me at bschimenti@aapp.org or our Health Policy Consultant, Laura Hanen at lahanen@venable.com.

Sincerely,



Brenda K. Schimenti
Executive Director

[5] *Id*.
[6] Cara Smith, Telemental Stakeholders Eye FDA REMS as Way to Appease DEA's Concerns over Telehealth Rx, Inside Health Policy, March 8, 2023.