March 30, 2023

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

Re: Expansion of Induction of Buprenorphine via Telemedicine Encounter [RIN 1117-AB780]

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 Expansion of Induction of Buprenorphine via Telemedicine Encounter (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.

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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 urges the DEA to eliminate the in-person evaluation when prescribing more than a 30-day supply of buprenorphine via telemedicine and to promulgate consistent policies across federal agencies.**

AAPP urges the DEA to eliminate the proposed requirement for an in-person evaluation when prescribing more than a 30-day supply (across prescriptions) of Schedule III-V medications approved for SUD treatment (including buprenorphine for opioid use disorder (OUD)) who engage in the practice of telemedicine, as defined in 21 U.S.C. 802(54)(G), and, instead, reinforce the long-standing precedent and the DEA's expectation that services and procedures rendered, including for the evaluation and management of OUD, be adequately documented in the medical record. This is consistent with the Substance Abuse and Mental Health Services Administration (SAMHSA) released a proposed rule allowing opioid treatment centers (OTPs) to allow the initiation and continued treatment of OUD with buprenorphine via telehealth.

Additionally, the DEA should reconsider whether the proposed recordkeeping requirements are consistent with the public health imperative to expand appropriate access to addiction medications and whether there are less complex mechanisms to achieve the DEA's goals without requiring prescribers of addiction medications to alter their practice workflows.

Recently, the Substance Abuse and Mental Health Services Administration (SAMHSA) released a proposed rule allowing OTPs to allow the initiation and continued treatment of OUDs with buprenorphine via telehealth. The decision for such a rule "draws on experience from the COVID-19 PHE as well as more than 20 years of practice-based research."[1] The OTP proposed rule also recognized the hurdles faced by individuals with OUDs, including disruption to daily life (e.g., employment), and unreliable access to transportation. Most importantly, it acknowledges the importance of the practitioner-provider relationship, and that OUD treatment should be based on clinical judgment of the treating provider. If a provider believes that a telehealth visit is sufficient to initiate treatment for OUD, then that judgment should not be overruled by an arbitrary regulation.

Contrastingly, the DEA proposed rule only allows clinicians to provide a 30-day supply of buprenorphine when initiating treatment via telehealth. If a patient has already been receiving prescriptions by telemedicine during the PHE, the DEA will defer the in-person exam requirement for an additional 180 days.

[1] SAMHSA, Medications for the Treatment of Opioid Use Disorder, 87 FR 77330.

We strongly urge DEA to take the same path as SAMHSA at this critical juncture of the polysubstance overdose epidemic. Indeed, as DEA has noted, the epidemic is getting worse, and one solution is to increase access to appropriate treatment. While we appreciate the DEA's concern related to diversion of buprenorphine, we believe the rule as proposed is a step too far and will create barriers for patients seeking treatment. A medical evaluation and treatment of the patient via telemedicine are appropriate, so long as the physician or other clinician can maintain the standard of care.

2. In the absence of Congressional action, AAPP urges the DEA to promulgate a rule to allow prescribing of buprenorphine via telehealth permanently.

There is now three years of data to support the safety and efficacy of initiating and maintaining buprenorphine treatment via telehealth. For example:

- An August 2022 study in *JAMA Psychiatry* examined telehealth service use, treatment engagement, and medically treated overdoses among Medicare beneficiaries following the institution of the COVID flexibilities.[2] The study found that telehealth access was widely used by Medicare beneficiaries initiating opioid use disorder (OUD) treatment. In addition, beneficiaries that received telehealth services had improved treatment retention and "lower odds of medically treated overdose."

- A recent study in *JAMA Open Network* examining patients with OUD on commercial insurance or Medicare found "no evidence that telemedicine was unsafe or overused or was associated with increased access to or improved quality of OUD care, suggesting that telemedicine may be a comparable alternative to in-person OUD care."[3]

- Furthermore, a study by the National Institute on Drug Abuse (NIDA) determined that the proportion of opioid overdose deaths involving buprenorphine did not increase in the months after the COVID-19 prescribing flexibilities were in place.[4] The study's findings call for more equitable access to MOUD and greater flexibility in prescribing as critical components to the response to the overdose crisis.

This research and data confirm that treating OUDs with buprenorphine through telehealth services is safe, increases access, and reduced stigma. We urge DEA to follow the route taken by SAMHSA related to OTPs and allow for individuals with OTPs to be treated with buprenorphine via telehealth permanently.

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[2] Jones CM, Shoff C, Hodges K, et al. Receipt of Telehealth Services, Receipt and Retention of Medications for Opioid Use Disorder, and Medically Treated Overdose Among Medicare Beneficiaries Before and During the COVID-19 Pandemic. *JAMA Psychiatry.* 2022;79(10):981–992. DOI: 10.1001/jamapsychiatry.2022.2284.

[3] Hailu R, Mehrotra A, Huskamp HA, Busch AB, Barnett ML. Telemedicine Use and Quality of Opioid Use Disorder Treatment in the US During the COVID-19 Pandemic. JAMA Netw Open. 2023;6(1):e2252381. DOI: 10.1001/jamanetworkopen.2022.52381.

[4] Lauren J. Tanz, Scd; Christopher M. Jones, PharmD, DrPH, Nicole L. Davis, PhD, Trends and Characteristics of Buprenorphine-Involved Overdose Deaths Prior to and During the COVID-19 Pandemic, JAMA Netw Open, January 20, 2023. Accessed at: https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2800689?utm_source=For_The_Media&utm_medium=referral&utm_campaign=ftm_links&utm_term=012023.

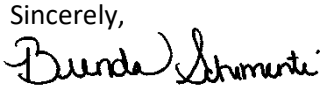
Additionally, further studies have demonstrated that diversion of buprenorphine to get high is negligible.[5, 6] Two surveys of people with opioid use disorder found that a majority of those who used illicit buprenorphine reported that they used it for therapeutic purposes (i.e., to reduce withdrawal symptoms, reduce heroin use, etc.).[7, 8] Instead of creating a new option under the "other circumstances specified by regulation" exception in the Ryan Haight Act, we urge DEA to instead promulgate regulations related to the "treatment by a practitioner who has obtained a special registration" exception of the Ryan Haight Act and structure the special registration to allow the prescription of buprenorphine permanently via telehealth.

3. AAPP urges consistent use of PDMPs across providers and settings.

The rule requires a practitioner to review and consider PDMP data prior to prescribing buprenorphine. AAPP agrees with this DEA requirement. Unfortunately, OTPs are not currently required to report to PDMPs, limiting the line-of-sight psychiatric pharmacists and all health care providers need when treating patients who receive treatment in OTPs. For example, if an individual is receiving treatment at an OTP and that treatment is not reported, a fatal drug interaction may be missed if a psychiatric pharmacist checks the PDMP and is not privy to information alerting him to the patient taking methadone or buprenorphine. To increase patient safety, we urge consistency across clinical settings and provider in reporting to the PDMP. To increase patient safety, we urge consistency across clinical settings and providers in reporting to the PDMP.

Thank you again for the opportunity to comment on this issue that is critical to increasing access and reducing barriers to treatment. 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

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[5] Cicero TJ, Surratt HL, Inciardi J. Use and misuse of buprenorphine in the management of opioid addiction. J Opioid Manag. 2007 Nov-Dec;3(6):302-8. doi: 10.5055/jom.2007.0018. PMID: 18290581.

[6] Cicero TJ, Ellis MS, Surratt HL, Kurtz SP. Factors contributing to the rise of buprenorphine misuse: 2008-2013. Drug Alcohol Depend. 2014 Sep 1;142:98-104. doi: 10.1016/j.drugalcdep.2014.06.005. Epub 2014 Jun 18. PMID: 24984689.

[7] Bazazi AR, Yokell M, Fu JJ, Rich JD, Zaller ND. Illicit use of buprenorphine/naloxone among injecting and noninjecting opioid users. J Addict Med. 2011 Sep;5(3):175-80. doi: 10.1097/ADM.0b013e3182034e31. PMID: 21844833; PMCID: PMC3157053.

[8] Schuman-Olivier Z, Albanese M, Nelson SE, Roland L, Puopolo F, Klinker L, Shaffer HJ. Self-treatment: illicit buprenorphine use by opioid-dependent treatment seekers. J Subst Abuse Treat. 2010 Jul;39(1):41-50. doi: 10.1016/j.jsat.2010.03.014. PMID: 20434868.