American Academy of PAs

March 31, 2023

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

RE: Expansion of Induction of Buprenorphine via Telemedicine Encounter (RIN 1117-AB78/Docket No. DEA-948)

Dear Administrator Milgram:

On behalf of the more than 168,000 PAs (physician associates/assistants) throughout the United States, the American Academy of PAs (AAPA) appreciates the opportunity to submit these comments to the Drug Enforcement Administration (DEA) on the proposed rule on Expansion of Induction of Buprenorphine via Telemedicine. PAs practice in all medical and surgical specialties in all 50 states, the District of Columbia, U.S. territories, and in the uniformed services. PAs provide high quality, cost-effective medical care in virtually all health settings. PAs undertake rigorous education and clinical training and are established as fully qualified and prepared to manage the treatment of patients who present with physical and/or mental illnesses.[1] Recognized in federal law as providers in opioid treatment programs, PAs provide care for patients with substance use disorder (SUD) as well as comorbid mental, physical, and behavioral health concerns. PAs are authorized to prescribe controlled medications in all 50 states and the District of Columbia.

The COVID-19 pandemic brought policy changes and flexibilities that increased the use of telemedicine for the delivery of buprenorphine to patients with opioid use disorder (OUD). Studies have found that undoing this progress and reducing telemedicine, including telephone-only access, could disrupt treatment and exacerbate healthcare disparities for vulnerable patient populations.[2] Before the COVID-19 pandemic, telehealth accounted for less than 1 percent of outpatient mental healthcare. At the peak of the pandemic, telehealth use increased to 40 percent of outpatient mental health and substance use visits.[3] Although telehealth use for other visits has decreased significantly since the height of the pandemic, telehealth for SUD and mental health treatment remains around 36 percent – significantly higher than pre-pandemic.

AAPA commends the administration and the DEA for their ongoing efforts to reduce the devastating impact of the ongoing opioid epidemic. Exacerbated during the COVID-19 pandemic, overdose deaths rose in the United States

[1] https://www.aapa.org/download/103483/?tmstv=1679436646
[2] 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
[3] https://www.kff.org/coronavirus-covid-19/issue-brief/telehealth-has-played-an-outsized-role-meeting-mental-health-needs-during-the-covid-19-pandemic/

by nearly 30 percent[4] between October 2019 and October 2020 – a staggering number for a 12-month period. However, AAPA has concerns with the limiting and unclear language in the proposed rule and the potential for harm this proposed rule may pose for patients. AAPA stands ready to work with DEA to ensure that access to life-saving healthcare is available for all patients.

Documentation

The Proposed Rule would require a record of a "supervising physician(s)" name and DEA number for all schedule III-V prescriptions written by a PA or Nurse Practitioner (NP) with specific language deference to state law in one instance[5], but without such language in the subsequent summary[6]. In addition to this discrepancy, AAPA is concerned that this vague and limiting language is counterintuitive to the intent of the proposed rule and could lead to significant delays in patients receiving needed medication assisted treatment (MAT). Undue and cumbersome statutory requirements without basis in patient care or state law create additional barriers to care in an already overloaded healthcare system. Confusing requirements like this can cause treatment delays and miscommunication with what should be a seamless communication between a provider and pharmacy. Additionally, DEA estimates that it would take prescribers two minutes to make these recordings or notations. However, DEA assumes that providers are already performing this recordkeeping and tasks as usual and ordinary practice without considering the additional cost and burden as such additional requirements are not existing ordinary practice.

Ensure recordkeeping proposals are consistent with the greater public health interest in expanding appropriate access to addiction medications. Documentation requirements should be streamlined and simplified to achieve the DEA's goals without undue burden on prescribers. Appropriate recordkeeping should not negatively impact provider practice, workflow, create delays in patient care, or exceed what is required under state law.

Diversion

AAPA appreciates the administration's dedication to combatting overdose deaths in the United States and supports efforts to end the ongoing opioid epidemic. Although buprenorphine diversion is a serious concern, research has shown that diverted and non-prescription use of buprenorphine was consistent with intended therapeutic use and at least partially driven by barriers to access.[7] The nation is currently facing a significant shortage of mental healthcare and addiction medicine providers, which is only projected to grow in the coming years. During the current crisis, PAs remain on the front line working to address the gaps in service across the healthcare system. **AAPA appreciates the work done by this administration to confront the national crisis and urges DEA to decrease, not increase barriers to care for patients.**

Special Registration Process

DEA has the authority to promulgate regulations to determine best practices and develop a special registration process to authorize providers to prescribe controlled substances through a telemedicine encounter without an

[4] https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm
[5] https://www.federalregister.gov/d/2023-04217/p-149
[6] https://www.federalregister.gov/d/2023-04217/p-174
[7] Cicero, T. J., Ellis, M. S., & Chilcoat, H. D. (2018). Understanding the use of diverted buprenorphine. *Drug and alcohol dependence*, *193*, 117–123. https://doi.org/10.1016/j.drugalcdep.2018.09.007

in-person evaluation. First outlined in the Ryan Haight Act (2009)[8] and again in the SUPPORT Act (2018), the DEA has not activated the rule to allow qualified providers, such as PAs, to prescribe controlled substances, like buprenorphine via telemedicine. **AAPA urges DEA to fulfil the statutory obligations and release the special registration for telemedicine.** This special registration process would increase transparency to DEA while allowing the practice of medicine to remain the appropriate responsibility of providers, like PAs.

Outdated and Inaccurate Language

PAs are medical providers who diagnose illness, develop and manage treatment plans, prescribe medications, and often serve as a patient's primary healthcare provider. With thousands of hours of medical training, PAs are versatile and collaborative and practice in every state and in every medical setting and specialty, improving healthcare access and quality. PAs are not mid-level providers, physician extenders, or non-physician providers. Since the profession was established more than fifty years ago, the role of PAs and the language used to describe them has evolved to better reflect modern PA practice and their role in patient care. Inaccurate and outdated descriptors such as "mid-level provider" applied to PAs is confusing for patients and the public and should not be used. **AAPA urges DEA to refrain from using such outdated and damaging terms and requests that they are removed from this proposed rule.**

Additional Recommendations

- Eliminate the proposed requirement of in-person patient evaluation when prescribing more than a 30-day supply of medications (schedule III-V), including buprenorphine, for the treatment of Substance and Opioid Use Disorders through the practice of telemedicine as defined in 21 U.S.C. 802(54)(G). PAs and other providers have provided care for patients with the understanding that such services and care for the evaluation and management of SUD/OUD is for a legitimate medical purpose within the usual course of medical practice and documented in a patient's medical record. **DEA should finalize the rule with allowances for such decisions to be made within the confines of a patent-provider relationship.**

- In September 2022, Secretary of Health and Human Services Xavier Becerra again renewed the determination that a public health emergency (PHE) exists nationwide as a direct result of the opioid crisis. Under 319 of the Public Health Service (PHS) Act, the Secretary has the authority to declare and/or renew a PHE. With this authority, the HHS secretary, in coordination with the DEA administrator may modify the practice of telemedicine and the use of controlled substances during a PHE. **AAPA urges the Administration to consider exercising its authority under the ongoing Opioid PHE to ensure that buprenorphine remains accessible via telemedicine.**

PAs provide high-quality care throughout the United States with patients reporting high satisfaction in the quality of their care. Studies show that when a PA is on a patient's care team, access to all providers improves, wait times decrease and overall patient satisfaction and positive outcomes rise.[9] At a time when overdose and death due to OUD is steadily increasing, patients deserve access to evidence-based, proven treatments. According to the Centers for Disease Control and Prevention (CDC), more than 2 million Americans live with OUD, and overdose deaths increased by more than 15 percent between 2020 and 2021. Studies have shown that PAs (and NPs)

[8] Ryan Haight Act (21 U.S.C.802(54)(E)) ("The practice of telemedicine is being conducted by a practitioner who has obtained from the [DEA] Administrator a special registration"

[9] Hooker RS, Moloney-Johns AJ, McFarland MM. Patient satisfaction with physician assistants/associate care: an international scoping review. Hum Resour Health. 2019;17(1):104.

significantly increase access to MAT in rural and underserved communities.[10] During the height of COVID-19 restrictions, telemedicine allowed patients with OUD to access life-saving treatment and has proven to be a comparable alternative to in-person care.[11] Clinicians surveyed during this time indicated high comfort levels treating patients via telemedicine and a strong desire to continue post-pandemic.[12] Expanded access to care for OUD patients remains a critical component in combatting overdose deaths.

AAPA thanks DEA and the Biden-Harris Administration for their ongoing dedication to patients and our nation's healthcare systems. We are committed to working with you to advance our shared mission of improving access to high-quality healthcare and ending the opioid epidemic. If we can be of assistance on this or any issue, please do not hesitate to contact Tate Heuer, AAPA Vice President, Federal Advocacy, at (571) 319-4338 or theuer@aapa.org.

Sincerely,

Lisa M. Gables, CPA
Chief Executive Officer

[10]https://jamanetwork.com/journals/jama/fullarticle/2730102?widget=personalizedcontent&previousarticle=2737024
[11] https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2800718?resultClick=1
[12] https://doi.org/10.1016/j.drugalcdep.2021.108999