March 18, 2025

Drug Enforcement Administration
Attn: DEA Federal Register Representative/DPW
8701 Morrissette Drive
Springfield, Virginia 22152

Re: Comments on DEA Proposed Rule: Special Registrations for Telemedicine and Limited State Telemedicine Registrations (Docket No. DEA–407, RIN 1117–AB40)

Dear Drug Enforcement Administration Officials,

On behalf of the American Association of Psychiatric Pharmacists (AAPP), we appreciate the opportunity to provide feedback on the Drug Enforcement Administration's (DEA) proposed rule on Special Registrations for Telemedicine and Limited State Telemedicine Registrations (proposed rule). Our comments are outlined below.

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 conditions 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

While AAPP appreciates the DEA's forward movement on telemedicine prescribing of controlled substances policy, we are still concerned to see language that restricts patient access to telemedicine rather than narrow protections against diversion of controlled substances. While we understand the need for protections, we encourage DEA to work to ensure there is a clear pathway for medical practitioners, including psychiatric pharmacists, to practice telehealth nationwide without unreasonable burdens or restrictions. We urge you to make the pandemic teleprescribing flexibilities permanent and work with Congress to ensure ongoing access to virtual prescribing for patients and providers of certain controlled substances.

1. Concerns with In-Person Medical Evaluation Requirement

The proposed rule requires an in-person medical evaluation before prescribing Schedule II controlled substances via telemedicine. While we understand the hesitation of eliminating this requirement, it will unfortunately greatly disrupt ongoing treatment for patients who have safely received initial and subsequent controlled substance prescriptions via telehealth during the COVID-19 pandemic. Additionally, it may exacerbate mental health and SUD provider shortages, particularly in rural and underserved areas. For example, as of December 2023, more than half (169 million) of the U.S. population lives in a Mental Health Professional Shortage Area (HPSA) and broader access to telehealth has been crucial in creating new access to care for these individuals as well as those with other conditions. Lastly, while DEA cites diversion as its primary reason for the requirement, there has been no demonstrated prevention of diversion, and this requirement will only increase the administrative burden on providers. As such, we strongly recommend that DEA allow the continued prescribing of controlled substances via telemedicine without requiring an in-person visit, as has been safely done now for nearly five years.

2. Unclear Special Registration Requirements

a. ***Clarification Need on the Term "Legitimate Need":*** We appreciate the DEA's efforts to establish Special Registration pathways for telemedicine prescribing, which will help maintain patient access to necessary treatments. However, we urge the DEA to provide further clarification on the criteria for demonstrating a "legitimate need" for Special Registration. The current definition is vague and may lead to inconsistent application or unnecessary restrictions on qualified practitioners. Without a clear and objective standard, practitioners seeking to provide essential care via telemedicine may face uncertainty in their eligibility, potentially

disrupting treatment for patients who rely on remote access to controlled substances. We recommend that the DEA explicitly define "legitimate need" to ensure that practitioners who serve vulnerable populations, including those in rural or underserved areas, can continue to provide critical care without undue administrative burdens.

b. ***Clarification Needed on Psychiatric Pharmacists' Special Registration Eligibility***: We also request clarification from the DEA on whether psychiatric pharmacists as midlevel practitioners are eligible for Special Registration under the proposed rule, given that 13 states currently grant them prescribing authority, and they already can apply for a DEA license. Psychiatric pharmacists, particularly BCPPs, are highly trained professionals who play a critical role in managing complex mental health and substance use disorder treatments.

   As outlined in previous communications to the DEA, pharmacists in these states already have the authority to prescribe controlled substances and are recognized by state laws as authorized prescribers. However, there have been ongoing concerns regarding outdated federal records, which create unnecessary barriers for pharmacists seeking DEA registration. We urge the DEA to explicitly confirm that psychiatric pharmacists who meet their state's prescriptive authority requirements will be eligible for Special Registrations.

   Additionally, we encourage the DEA to ensure that its online registration system and the "Mid-Level Practitioners Authorization by State" table are regularly updated to reflect state law changes. This will prevent unnecessary administrative burdens and ensure that psychiatric pharmacists can fully utilize their prescribing authority in states where they are authorized to do so.

3. Unnecessary Administrative Burden of Nationwide PDMP Checks

While Prescription Drug Monitoring Program (PDMP) checks are a valuable tool for preventing diversion, the proposed requirement for Special Registrants to conduct nationwide PDMP checks for every telemedicine prescription is an excessive administrative burden. Currently, there is no centralized system for accessing all 50 state PDMPs, meaning providers would face significant logistical and technical challenges in complying with this requirement. The lack of interoperability between state PDMPs further complicates this mandate, increasing the risk of delays in patient care and creating undue strain on healthcare providers. Additionally, requiring PDMP checks across multiple jurisdictions—beyond the state where the patient and provider are located—adds little practical benefit while imposing unnecessary complexity. We urge the DEA to streamline this requirement by limiting PDMP checks to the provider's and patient's respective states, ensuring that the process remains effective without overburdening telemedicine practitioners.

4. Cumbersome State Requirements

The proposed State Telemedicine Registration requirement will impose significant administrative and financial burdens on healthcare providers making it more difficult to deliver care across state lines. In addition, this will serve as a barrier for pharmacy dispensing and lead to delays in lifesaving care. The need for separate registrations for each state—along with associated fees—creates unnecessary bureaucratic hurdles that could discourage providers from offering telemedicine services, particularly in rural and underserved areas. Additionally, placing this registration under DEA administration rather than

state licensure boards may create processing delays and regulatory uncertainty, further disrupting patient care.

We urge DEA to eliminate the state-by-state Special Registration requirement and instead allow a single national registration for telemedicine providers. In addition, a prescriber could obtain the current form of DEA registration for each state in which they intend to prescribe. This streamlined approach would reduce administrative burdens, maintain necessary oversight, and support access to telemedicine-based prescribing, ensuring that providers can continue serving patients without undue regulatory barriers.

5. Unnecessary Restrictions That Limit Access to Care

The proposal to limit Schedule II medications by telemedicine to medical practitioners whose practice is limited to less than 50% of prescriptions by telemedicine is an arbitrary threshold that lacks clear justification and fails to account for the diverse needs of different patient populations. Providers specializing in mental health or substance use disorder treatment may naturally have a higher proportion of Schedule II prescriptions, as these medications are essential for managing conditions like ADHD, severe depression, and opioid use disorder. Imposing a rigid limit on prescribing practices could disincentivize clinicians from treating high-need patients and force them to artificially adjust their prescribing patterns, potentially delaying or denying necessary care.

Additionally, requiring a clinician to be physically located in the same state as the patient creates unnecessary barriers, particularly in areas with mental health and SUD provider shortages or those living near state borders. Many patients rely on telemedicine to access specialized psychiatric care, especially in rural or underserved communities where local providers are scarce. Limiting prescribing authority to in-state providers reduces access to expert care and contradicts the flexibility that telemedicine is intended to provide. We urge DEA to remove both of these restrictions and instead focus on robust monitoring mechanisms that ensure safe prescribing without restricting patient access.

We are also concerned that pharmacists and pharmacies would be responsible for verifying that prescribers have met their obligations under this rulemaking, including: requirements for prescribers who issues a Special Registration Prescriptions for a schedule II controlled substance to be physically located in same state as patient; prescriber compliance with a requirement that Special Registration Prescriptions for schedule II controlled substances constitute less than 50% of the total number of schedule II prescriptions that the clinician issues in both their telemedicine and non-telemedicine practices in a calendar month; requirements for prescribers to check the prescription drug monitoring program prior to issuing a Special Registration Prescription; requirements for prescribers to verify and record patient identification at the first telemedicine encounter; prescriber adherence to the requirements for conducting telemedicine encounters that result in issuance of a Special Registration Prescription; etc. We urge DEA to make clear that pharmacists are not required to discern whether a prescription qualifies as a Special Registration prescription in the absence of the specified prescription data elements. Otherwise, this will lead to confusion for pharmacies and be yet another dispensing barrier impacting patients.

Further, mandating that that a clinician utilize both audio and video to prescribe controlled substances for every telemedicine encounter, whether an initial visit, subsequent visit, or follow-up is burdensome particularly for rural populations that already face higher barriers to accessing health care. For example, patients in remote areas may be unable to utilize visual telehealth, but, under this proposal, would be

unable to request audio-only telehealth for their mental health treatment. This is both and access and equity issue 22 million Americans still lack home broadband access.

There is also a double standard in the proposal – DEA allows audio-only in the buprenorphine final rule in the use for treatment of opioid use disorder, but not for other important care. This inconsistency creates inequities in care access, as patients with mental health or other chronic conditions requiring controlled substances may be unfairly disadvantaged compared to those receiving opioid use disorder treatment. We are concerned that the DEA's focus on how care is delivered is an overstep that regulates the provider-patient relationship (which is already governed by state law and other rules), rather than regulating the risk of diversion of controlled substances.

6. Clarification Needed on Annual Reporting Requirements

The proposed annual reporting requirements may create a significant administrative burden for providers, particularly those serving large patient populations across multiple states. Tracking and compiling detailed data on prescribing patterns at both the state and national levels adds to the regulatory workload and may divert valuable resources away from patient care. Additionally, the methodology DEA intends to use to determine inappropriate prescribing behaviors remains unclear. Without transparency in how prescribing trends will be assessed, providers may face uncertainty about compliance expectations and potential enforcement actions. We urge DEA to clarify the specific criteria and analytical framework it will use to evaluate prescribing practices, ensuring that providers are not unfairly scrutinized for appropriately treating patients with legitimate medical needs.

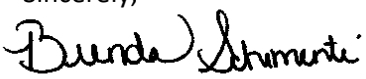
7. Need for a Longer Transition Period

The rule is set to take effect following the expiration of COVID-19 telemedicine flexibilities on December 31, 2025. We recommend at least a two-year transition period, as this is essential to allow providers to adapt and prevent disruptions in care.

Conclusion

Thank you again for the opportunity to comment. We strongly urge the DEA to remove unnecessary barriers to treatment with controlled substances to ensure continued patient access. 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