AMERICAN PSYCHIATRIC ASSOCIATION

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March 18, 2025

The Honorable Derek Maltz
Acting Administrator
Drug Enforcement Administration
700 Army Navy Drive
Arlington, VA 22202

RE: Special Registration for Telemedicine and Limited State Telemedicine Registrations Proposed Rule (Docket No. DEA-407)

Dear Acting Administrator Maltz,

The American Psychiatric Association (APA), the national medical society representing over 39,200 psychiatric physicians and their patients, appreciates the opportunity to comment on the proposed rule to establish special registrations for providers and telemedicine platforms to prescribe controlled substances II-V without requiring an in-person visit. We recognize DEA's obligation to prevent drug diversion, in turn promoting public health and we support establishing a special registration process to protect public health through access to mental health and substance use care. However, we recommend that key provisions in this proposed rule be clarified and adjusted to enhance practicality and effectiveness. APA recognizes the DEA's work to expand access via telemedicine technologies to ensure the continuity of care for some of the most vulnerable patients our members care for, including the recent expansion of buprenorphine via telemedicine. Our recommendations below focus on ways to provide safe prescribing of controlled substances via telemedicine while striking a balance between our country's great need for additional health care workforce, quality clinical practice, the evolving landscape of psychiatric practice, and DEA's charge to protect the safety and wellbeing of citizens.

Special Registration Eligibility Requirements

APA appreciates the DEA's recognition of the expertise that psychiatrists have, the unique medical needs of patients that psychiatrists treat, and therefore the ability to treat patients fully remote. We highlight information that DEA reported in their Fall 2024 diversion presentation, that for the first time in 2022, nurse practitioners wrote the highest number of stimulant prescriptions (23.4%). Moreover, while the number of stimulant prescriptions dispensed by psychiatrists, pediatricians, and family physicians have either declined or remained stable, stimulant prescriptions from nurse practitioners have more than tripled since 2012. This data highlights the importance of the high-quality training and education that physicians go through to provide evidenced-based care to patients whether in-person or virtually. Excluding

certain primary care physicians from the special registration could create unnecessary barriers to care, especially in rural and underserved communities where such providers are scarce. These exclusions also undermine efforts to integrate behavioral health with primary care, limiting the potential of innovative clinical models designed to address societal needs amid a shrinking healthcare workforce[1]. **Therefore, APA suggests that primary care physicians including internists, family medicine, as well as addiction medicine specialists be included in the advanced telemedicine prescribing registration**.

State Telemedicine Registrations

The requirement that prescribing practitioners have a DEA special registration in the state they are in when they are issuing the prescription is a needless restriction on access to care. Patient protection is already ensured through a prescriber's current DEA registration and medical licensure in the state the patient is in at the time of the visit. For many physicians who are using a hybrid model to care for patients, requiring an additional two or three registrations and the associated fees for each state they may be caring for patients, in-person and/or virtual, would reduce the physician workforce in many areas that are already facing workforce shortages. Fifty-five percent of U.S. counties have no psychiatrists, and 130 million people live in areas with a shortage of mental health providers.[2,3] The additional costs and administrative burdens may unintentionally prohibit uptake of registrations and therefore limit access to physicians who are trained to treat mental health and substance use disorders.

The APA is also concerned that a second DEA registration number may further complicate and delay the dispensing of legitimate prescriptions for controlled substances. We have heard concerns from members and their patients about arbitrary rules that many pharmacies have put in place around dispensing controlled medications for legitimate telemedicine prescriptions. For example, only dispensing medications if there has been an in-person visit in the last year or if the patient lives or provider practices within 25 miles of the pharmacy. We appreciate the role pharmacies play in protecting patients, but many patients and their parents/caregivers travel long distances, often by public transportation, and any delay in accessing prescribed medications may lead to a delay in care and ultimately serious complications. **The APA suggests that the DEA rescind the proposal of requiring a separate registration for each state in which telemedicine patients are located**.

Nationwide Prescription Drug Monitoring Program (PDMP) Check

APA supports PDMP checks as a safeguard against diversion, however there are challenges in a nationwide PDMP check due to the lack of uniformity across state PDMPs. APA urges the DEA to provide clear guidance on achieving compliance, especially if certain states have not begun sharing information before the proposed rule's three-year grace period expires. Establishing a federal PDMP database that mandates states' participation would allow for consistent and accessible data. However, the lack of standardized data, interoperability challenges in integrating PDMPs with EHRs, and additional cost to build the

[1] Grimm, C.A. (2020). Geographic disparities affect access to buprenorphine services for opioid use disorder (No. OEI-12-17-00240). Office of the Inspector General. Jan 2020

[2] https://bhbusiness.com/2022/06/24/where-the-mental-health-clinician-shortage-is-at-its-worst/

[3] Healthgrades, 7 things to know about the psychiatrist shortage. June 2023. https://resources.healthgrades.com/pro/7-things-to-know-about-the-psychiatrist-shortage#:~:text=3.,live%20in%20these%20underserved%20areas.

infrastructure for this nationwide system will take time. **We encourage the DEA to develop avenues for aligning PDMP information across states in an expediated way and extend the timeframe for a nationwide PDMP check an additional five years**.

Audio/Visual Telehealth Visits

It is evident that the proposed rule seeks to balance the need for secure prescribing practices with the imperative to maintain access to care. Currently, under the telehealth flexibilities, the DEA allows for audio-only visits for mental health care telehealth visits. The proposed special registration rule, however, requires audio-visual telemedicine for prescribing controlled substances. This shift may pose challenges for patients and providers with limited access to video conference technology or broadband. Roughly, three in ten rural Americans do not have broadband internet connection in their homes.[4] Not allowing audio-only telehealth visits pose restrictive rules and punishes patients with unmet health-related social needs rather than imposing appropriate safeguards against diversion. **APA recommends for the allowance of both audio/visual as well as audio-only telehealth prescribing for practitioners with an advanced telemedicine registration in order to prevent further exasperating the health inequities that exist today.**

Schedule II Controlled Substance Prescription Proposals Impacting Advanced Telemedicine Prescribing Registrants

Clinician special registrant be physically located in the same state as the patient

APA encourages DEA to reconsider the proposal that the special registrant be physically located in the same state as the patient in order to prescribe schedule II-controlled medications. More than half the U.S. population lives in a Mental Health Professional Shortage Area contributing to the unmet behavioral health needs of people of all ages.[5] Psychiatrists are highly trained physicians who are able to treat patients with the highest acuity. If psychiatrists are limited to treating patients in the same state, states such as Idaho, Montana, Mississippi, Nevada, and Indiana will be the hardest hit, having the lowest number of psychiatrists per resident.[6] Urban and underserved communities will also be negatively impacted. This could lead to psychiatrists selecting patients with a diagnosis that does not require controlled substances for treatment and will impact patients who see specialists that are not available in the state they currently reside. The use of telehealth is already limited by state-based licensure laws, and there is no need to contribute to additional barriers to care by adding an arbitrary restriction that has not been shown to reduce the risk of diversion. **APA requests that the DEA rescinds the requirement that the special registrant be physically located in the same state as the patient in order to prevent discontinuation of care.**

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[4] Pew Research Center. Some digital divides persist between rural, urban, and suburban America. August 19, 2021. Some digital divides between rural, urban, suburban America persist | Pew Research Center

[5] HRSA Behavioral Health Workforce, 2023. Found at: https://bhw.hrsa.gov/sites/default/files/bureau-health-workforce/Behavioral-Health-Workforce-Brief-2023.pdf

[6] Beckers Behavioral Health, All 50 states ranked by psychiatrists per capita. https://www.beckersbehavioralhealth.com/behavioral-health-news/all-50-states-ranked-by-psychiatrists-per-capita.html#:~:text=The%20U.S.%20may%20face%20a,from%20the%20U.S.%20Census%20Bureau.

Schedule II controlled substances constitutes less than 50 percent of the total number of Schedule II prescriptions

There is lack of evidence on how the proposed requirement for schedule II-controlled substances to be less than 50 percent of a practices' monthly prescription would help prevent diversion. Instead, this requirement could lead to significant disruptions in patient care solely due to a practices need to stay below the 50 percent threshold. It would further contribute to access-to-care issues by requiring in-person visits for a substantial proportion of patients, even though many mental health professionals who offer in-person care may not have a patient panel that allows more than 50 percent of visits to occur in person or that controlled substances are prescribed at a comparable rate in both settings. Limiting the number of schedule II prescriptions could lead to unintended consequences, such as practitioners having to forgo seeing patients who require schedule II medication in order to not exceed the limit requirements. Additionally, practitioners may have to choose which patients to see in-person versus telehealth based exclusively on trying to meet this limit rather than on patients' needs. This provision could potentially limit patient access to necessary medications particularly for vulnerable patient populations relying on community health centers, residential health facilities, outpatient clinics and other areas where specialists are not available.

Additionally, EHR systems do not have an easy way to track this information, even in retrospective reports. To avoid exceeding the 50 percent limit, practitioners would need to manually track prescriptions or rely on an integrated EHR dashboard—technology that currently does not exist. This is simply not practical, especially in a small practice. It is also unclear whether patients who were already seen in-person but were prescribed Schedule II through a telehealth visit are counted towards the 50 percent limit. **APA strongly recommends not moving forward with this proposed requirement and encourages DEA to not impose arbitrary limits on potential life-saving medication**.

Parent/Guardian Present During Telemedicine Visit for Minors

APA aligns with DEAs commitment to safeguarding the well-being of minors as rates of childhood mental health diagnosis and suicide continue to rise. Child and adolescent psychiatrists are specifically trained to diagnosis and treat mental health disorders that affect children, adolescents and their families. As currently drafted, family dynamics especially for children in foster care, juvenile justice settings, intensive treatment settings, school-based treatment settings, or those with parents/guardians who work, would prevent the continuity of care for many children under the age of 18. For many minors, parents attend the appointment if they are able to take off work or other duties that impact their schedule. But for many others, they are receiving virtual care while in school or another treatment setting.

The proposed rule also does not take into account that the refill of medications do not always align with appointments and often occur asynchronously. APA members shared that while parents may not always attend appointments with minors, the psychiatrist will call the parents to give them an update about the appointment and do not make changes to medication without talking to the parent or guardian first. **APA recommends that the DEA remove this requirement in the final rule to prevent the unintentional consequence of care being disrupted for minors due to a multitude of factors that impact family dynamics**. If the DEA chooses to keep this requirement in the final rule, we request the DEA clarify that it does not apply to refills of current medications between telemedicine visits, or to telemedicine visits

which result in refills of current medications. We request that the DEA clarify that this requirement only applies to an initial telemedicine visit that results in the prescription of a Schedule II medication to the minor and to changes to the current treatment medications, and that other representatives (including school nurses, other school administrators, treatment staff, etc) can be present as part of the care team if the parent or guardian cannot attend.

Impact of Proposed Rule on Physician Trainees

Physician trainees are in various practice settings working under different agreements in order to prescribe controlled substances depending on the medical center or residency/fellowship. For some trainees, they work under the hospital DEA registration. Requiring a special registration for individuals who do not have an individual DEA number could be problematic and cause delays in care. These trainees often spend significant periods working on inpatient services and rotate through outpatient services (where the use of telemedicine is more prevalent) for a limited period of time (e.g., for a few weeks or for a year) seeing patients and prescribing under the attending supervision. Current electronic prescribing formats list the resident as the prescriber but also provide the name of the supervising attending. Any new requirements should not place additional telehealth restrictions on residents than already exist. Another example is trainees that are currently working under their own DEA registration but have a time-limited fellowship where they may be providing fully remote care in a telemedicine clinic. It would be impractical for the trainee or the facility to pay for a three-year registration for a one-year position, since physician residents and fellows are under the supervision of faculty. **APA requests that the DEA provide an exception for physician trainees (residents and fellows) who are affiliated with medical centers allowing them to continue to prescribe controlled substances via telemedicine without the need for a special registration because they are under the supervision of faculty.**

Administrative Burden

The administrative burden of this proposed rule is significant, and we note that burnout and workforce challenges associated with documentation requirements are already posing widespread risks to access to care.[7] In addition, clinical data management systems are not configured with these components in them, they are costly to upgrade, and not feasible to do within the timeframe of finalization and implementation of the rule. **We recommend that any areas where there is duplicative administrative action with a prescribers' non-special registration should be removed within this framework to reduce burden and costs.**

14-day notification requirement for changes to special registration

APA requests the DEA reconsider the 14-business day requirement to notify the DEA of any changes to the information provided in the registrants original Special Registration form. **We request that the DEA extend this requirement to at least 30 business days to allow for compliance.**

Patient Verification

[7] Physician stress and burnout: the impact of health information technology, https://academic.oup.com/jamia/article/26/2/106/5230918.

APA appreciates the DEA considering information from the listening session to apply to the proposed rule. We also appreciate the acknowledgment in the proposed rule that not all patients have government issued identifications. However, the proposal still underestimates the interoperability capabilities of the electronic health record and telehealth software. Additional software would need to be acquired in-order to screen capture while using a cloud-based telehealth platform and then multiple steps to save securely into the electronic health record. This is not practical for small and solo practitioners. Moreover, we also are concerned about the effect on the pediatric population. In the proposed rule, the DEA gives alternatives to the government issued identification for minors, however, many appointments for pediatric appointments happen during the school day and the minor may not have access to a form of identification. **APA recommends that the DEA consider requiring the prescriber to document the patient verification and the method to verify (showing an id on screen, verification from parent for child, confirmation of birthdate or other identifying information, etc.) rather than require screen shots of the variable methods of identification shared in the proposed rule.**

Reporting of Special Registration Prescription Data

Data is important for the DEA to prevent diversion of controlled medications and ensure a supply of life saving medications as discussed in the proposed rule. However, APA is concerned that the reporting structure within the proposed rule does not help the DEA reach the goal of detecting timely fraud and abuse. The concerning business models that DEA highlights in the proposed rule could be better addressed with different reporting structures for different types of practices, such as more frequent reporting from direct-to-consumer companies and monthly reporting of aggregated data by pharmacies. Such reporting requirements has the potential to provide real-time data to DEA and will ensure the DEA reaches its goal to detect fraud and abuse, as well as help identify shortages prior to becoming a crisis.

Unless electronic health records are structured to pull all the reports the DEA is requiring, small and solo prescribers who often have little or no administrative support will be overly burdened to report this information in 7 days of the new year. **APA requests the DEA to consider different reporting structures for prescribers based on the business model and extend the reporting timeframe for advanced special registration prescribers to allow for accurate data reporting.**

Clarification of Key Inconsistencies in the Proposed Rule

Key elements of this proposed rule are unclear and would likely contribute to reductions in access to clinically indicated medications unless clarified and modified.

- Clarify if the 50 percent rule is finalized, whether patients who were seen in-person (therefore not prescribed a schedule II via the special registration) but were prescribed Schedule II through a telehealth visit is counted towards the 50 percent limit.
- Clarify if every telehealth appointment that involves the clinician special registrant refilling a schedule-II controlled substance (especially those when the medication has remained stable) for minors requires the presence of the minor's parents or guardian.
- Clarify high-risk telehealth practice characteristics and how the proposals target the contributors to that increased risk.

We caution the DEA in taking too many steps backward, reimposing unnecessary limitations on the practice of medicine during an opioid public health emergency and nationwide mental health and access-to-care crisis. Fifty-five percent of U.S. counties have no psychiatrists, and 130 million people live in areas with a shortage of mental health providers.[8, 9] DEA has the opportunity to get the balance right by finalizing rules that facilitate, rather than prevent, access to high-quality care.

Thank you for your review and consideration of these comments. If you have any questions or would like to discuss any of these comments further, please contact Zuhal Haidari (zhaidari@psych.org), Deputy Director, Digital Health.

Sincerely,

Marketa Wills, MD, MBA
CEO and Medical Director

[8] Mapping Supply of the U.S. Psychiatric Workforce, https://www.behavioralhealthworkforce.org/wp-content/uploads/2019/01/Y3-FA1-P2-Psych-Mapping-Full-Report-with-Appendix.pdf.
[9] Where the Mental Health Clinician Shortage Is at Its Worst, https://bhbusiness.com/2022/06/24/where-the-mental-health-clinician-shortage-is-at-its-worst/.