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United States Department of Justice
United States Drug Enforcement Administration
Attention: DEA Federal Register Representative/DPW
8701 Morrissette Drive
Springfield, Virginia 22152

Re: Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation (Docket No. DEA-407)

Dear Administrator Milgram,

The American Psychiatric Association (APA), the national medical specialty society representing over 38,000 psychiatric physicians and their patients, appreciates the opportunity to comment on DEA's proposed rule on telemedicine prescribing of controlled substances. APA shares the Biden Administration's commitment to increasing efforts to provide evidence-based, accessible, lifesaving medications and services in communities where people most need them. We recognize DEA's obligation to prevent drug diversion, in turn promoting public health. **However, the DEA falls short of the Administration's commitment to mental health with these proposed rules.**

The United States is in an active opioid public health emergency and a national mental health crisis. With the acute shortage of mental health professionals, DEA is encouraged to exercise law enforcement authority to prevent diversion and inappropriate prescribing rather than enforce upstream restrictions on treatment, furthering stigma on legitimate mental health and substance use disorder care. There is no evidence that telemedicine prescribing during the COVID-19 PHE increased diversion or negative outcomes associated with access to controlled substances.^{1, 2} Telehealth initiation of opioid use disorder care has been shown to increase retention in treatment. **Our recommendations below focus on balancing common-sense safeguards for DEA enforcement of the legitimate prescription of controlled substances without decreasing access to lifesaving treatment.**

¹ Trends and Characteristics of Buprenorphine-Involved Overdose Deaths Prior to and During the COVID-19 Pandemic, <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2800689>.

² Outcomes for patients receiving telemedicine-delivered medication-based treatment for Opioid Use Disorder: A retrospective chart review, <https://pubmed.ncbi.nlm.nih.gov/33551692/>.

APA's key recommendations in DEA's finalization of this rule are:

1. Allowance for referring practitioners to not be DEA-registered.
2. Reduction in administrative requirements for referring and prescribing practitioners.
3. Reduction in additional state-based registration requirements.
4. Removal of clinical decision-making from regulation in these proposed rules.
5. Clarification of key inconsistencies in the proposed rules.

1. *Allowance for referring practitioners to not be DEA-registered.*

A requirement for DEA registration for qualified telemedicine referrals would significantly restrict access to care without a compelling benefit to law enforcement. **Requiring only the prescribing practitioner to be DEA-registered generates an audit trail for DEA while maintaining much-needed access to care in locations and populations without physical access to DEA-registered practitioners (e.g., rural settings, individuals with mobility or transportation barriers).**

To make the referring practitioner pathway viable, DEA also must clarify the intent of the requirement for an initial in-person visit by a referring practitioner – medical stability or decreased diversion. In the case of a medical stability rationale, the prescribing DEA-registered practitioner is the one best-suited to determining the physiologic and clinical data necessary to safely issue a prescription. The medical personnel that most frequently take vitals in typical clinical settings are non-advanced practice, and therefore non-DEA-registered, personnel (e.g., registered nurses). In the case of diversion prevention, any in-person encounter with a licensed medical professional provides verification of a legitimate, in-person treatment relationship. There is no evidence that in-person care requirements reduce drug diversion. **APA recommends that the referring practitioner pathway be allowable using existing data that a referring practitioner has about the patient and does not require a new visit for the specific purposes of initiating a referral.**

Requiring that a DEA-registered practitioner conduct an in-person evaluation leads to several systemic harms: first, it may incentivize non-specialist practitioners to treat complex conditions on their own rather than referring a patient to a specialist; second, it incurs significant additional and unnecessary cost to the patient and the health care system by generating duplicative high-cost care rather than making appropriate use of community-based professionals; and third, it penalizes patients with unmet health-related social needs including uninsurance or underinsurance, mobility and transportation challenges, and geographic disparity – all significant, preventable risks to population health.

1. *Reduction in administrative requirements for referring and prescribing practitioners.*

The administrative burden of these proposed rules is significant, and we note that burnout and workforce challenges associated with documentation requirements are already posing widespread risks to access to care.³ In addition, clinical data management systems are not configured with these components in them,

³ Physician stress and burnout: the impact of health information technology, <https://academic.oup.com/jamia/article/26/2/106/5230918>.

and those upgrades are expensive and time-consuming – certainly not feasible within the timeframe of the finalization and implementation of these rules.

There is also a safety risk posed to clinicians. DEA's requirement that practitioners report their physical location at the time the prescription is written – even if that is their home address during a telehealth encounter – is unnecessary and potentially dangerous. We have heard from APA members who have experienced safety issues due to personal information getting into the hands of a few individuals seeking to harm the practitioner.

APA recommends that the following administrative requirements *be removed* in the final rules:

- The requirement for the practitioner to report their physical address during the telemedicine encounter; practitioners should be able to use the business address of their DEA registration.
- The requirement for the prescribing practitioner to be identified specifically, by NPI, by the referring practitioner creates a barrier to care as many practitioners will not be aware of the availability, insurance network participation, and specialty of practitioners to whom they refer. This requirement risks the ability for patients to continue on to appropriate specialty care.
- The requirement to only allow for a 7-day prescription if the PDMP is not accessible. Most states already require clinicians to access the PDMP prior to issuing a prescription for a controlled substance, but those states *do not* restrict access to care for the patient in the uncommon situation that the PDMP is not accessible. PDMP systems issues, including lack of interoperability, access across state lines, and run-of-the-mill outages, should not be used to punish patients. Instead, APA recommends that DEA use its audit and enforcement capabilities to ensure that practitioners are documenting accessing the PDMP and query attempts.
- The requirement to have “telemedicine prescription” written on the prescription. Patients are already facing barriers to having prescriptions filled due to pharmacy policies. We are concerned that this will create further barriers to legitimate prescriptions being filled in a timely manner. Please see the letter sent by APA and the American Academy of Child and Adolescent Psychiatry to DEA on March 24, 2023 outlining the current crisis in access to prescribed stimulants for additional information on the profound negative impact to patients when pharmacies do not or cannot dispense prescribed medications.
- The requirement for any duplicative recordkeeping, beyond what is currently necessary for clinical care. The implementation of documentation requirements in clinical information systems is not feasible in DEA's proposed timeline. DEA's assessment that cost associated with this rule is minimal is incorrect. Clinical information systems often require at least a 12-month grace period to allow for upgrading and configuration of the electronic medical record.

2. *Reduction in additional state-based registration requirements.*

The requirement that prescribing practitioners have a DEA 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 DEA registration and medical licensure in the state the patient is in at the time of the**

visit. This area presents a key opportunity for the DEA to promulgate rules for a telemedicine special registration for eligible prescribing physicians.

APA asks that the DEA consider what the impact would be to patients if their prescriber is, for example, traveling to see family or at a conference when the patient needs a refill. Is the patient to be denied life-saving medication and continuity of care? **Instead, APA recommends that these rules adopt language from the Ryan Haight Act: that the practitioner may prescribe from a state in which the practitioner isn't registered if the practitioner is temporarily out-of-state.** This exception may be required to be documented in the patient's clinical record.

3. Removal of clinical decision-making from DEA regulation in these proposed rules.

We note that there are significant components of this rule that constitute clinical decision-making, including the 30-day telemedicine supply allowance and the requirement for an in-person evaluation prior to initiation of controlled substances. **Duration of treatment and any requisite aspects of in-person evaluation or laboratory testing are clinical decisions and vary based on the medication being prescribed.** Moreover, prescribing providers consider other social determinants of health and other barriers to in-person care such as transportation, employment hours, family-care situations, and stigma and violence for seeking care.

APA recognizes the need for DEA to establish objective guardrails that can be enforced, but there is no evidence that telemedicine prescribing during the COVID-19 PHE increased diversion. APA strongly recommends that rather than the DEA making these clinical decisions that they defer to the prescribing practitioner in these instances. There is a greater individual and public health disservice to remove access to clinically indicated medications in anticipation of potential diversion. **Instead, DEA is encouraged to work in close partnership with HHS agencies and clinical advisors to identify and investigate objective markers of overprescribing that signal increased diversion.**

When DEA needs objective guardrails established, it is strongly recommended that the guardrails not be so restrictive that they are not clinically feasible. In particular, an in-person appointment within 30 days will often be impossible to achieve.⁴ The 180-day "off-ramp" for established telemedicine patients in this proposed rule essentially demonstrates DEA's belief that it is in the patient's best interest to not abruptly end a treatment plan when prescribed a controlled substance. We remind DEA that these restrictive rules punish patients with unmet health-related social needs rather than imposing appropriate safeguards against diversion. **APA recommends a 180-day window for the initial prescription of a controlled substance prior to an in-person evaluation.**

⁴ 2022 Survey of Physician Appointment Wait Times, <https://www.merrithawkins.com/trends-and-insights/article/surveys/2022-physician-wait-times-survey/>.

4. Clarification of key inconsistencies in the proposed rules.

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

- DEA is requested to clarify if this wording in the proposed rule indicates that practitioners are no longer required to have a physical practice location in any state in which they request a DEA registration: “If DEA instead were to require records to be maintained in the state(s) where telemedicine patients are located, practitioners could theoretically have to maintain telemedicine records in over 50 different locations (if they had a nationwide practice), *including states in which they may not retain a physical office location.*” (pg. 12880) **APA encourages DEA to remove any excessively burdensome requirements to have a physical office location in every state in order to obtain a DEA registration. APA also encourages DEA to consider creating a special registration to allow for one DEA registration in coordination with a valid medical license in each state the practitioner is practicing medicine, rather than a separate medical license and DEA registration in every state.**
- DEA is requested to clarify the boundaries and requirements for timeliness and reason for an in-person evaluation as the basis for a telemedicine referral (e.g., when the patient needs to have been seen in person and why). DEA is strongly urged to take an inclusive approach to defining the referral pathway to decrease the creation of duplicative, expensive, and unnecessary physical exams if a patient has a history of in-person evaluation by a referring practitioner and any requisite clinical data is available.
- DEA is requested to clarify that the in-person evaluation with the referring practitioner can happen after a telemedicine visit with the prescribing practitioner.
- DEA is requested to clarify the interaction between the referring practitioner pathway under exception 7 of the Ryan Haight Act and the patient being in a DEA-registered facility under exception 1 of the Ryan Haight Act.
- DEA is requested to clarify where medical records should be kept if practitioners have physical practice locations in multiple states.
- DEA is requested to clarify whether the documentation and registration requirements (e.g., “telemedicine prescription” denotation, 7-day restriction in the absence of a PDMP query, registration in the state in which the prescriber is located in addition to the state in which the patient is located) apply after the initial in-person visit. It is APA’s understanding that, since the rule “does not affect ... the following: Telemedicine consultations by a medical practitioner that has previously conducted at least one in-person medical examination of a patient ... or ... telemedicine consultations by a medical practitioner to whom a patient has been referred by a medical practitioner that has previously conducted an in-person medical examination of the patient,” these administrative rules **only apply in advance of an in-person evaluation by a prescribing or referring practitioner.** However, this component is causing widespread confusion.

APA appreciates DEA's efforts to learn from the lessons of the COVID-19 public health emergency in maintaining access to critical, life-saving care through technology. We caution DEA in taking too many steps backward, re-imposing 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.^{5, 6} 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 Abby Worthen (aworthen@psych.org), Deputy Director, Digital Health.

Sincerely,

A handwritten signature in blue ink that reads "Saul Levin" with "M.D., M.P.A." written in smaller letters to the right. There is a horizontal line under the name "Levin".

Saul M. Levin, M.D., M.P.A., FRCP-E, FRCPSych
CEO and Medical Director
American Psychiatric Association

⁵ 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>.

⁶ 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/>.