September 11, 2023

The Honorable Anne Milgram
Administrator
United States Drug Enforcement Administration
800 K Street NW Suite 500
Washington, D.C. 20001

Dear Administrator Milgram:

Thank you for your willingness to further listen and meet with stakeholders, specifically medical practitioners, on the proposed rules for prescribing controlled substances via telehealth. We, the undersigned, collectively employ approximately 1,600 mental health professionals and treat over one million patients annually. As the largest organizations working in telepsychiatry, we have extensive expertise in the practice of medicine through telehealth, and are committed to responsibly continuing and expanding access to mental health services for patients beyond the traditional in-person office-based model.

We understand the DEA's difficult job in balancing access to care with diversion prevention. To that end, we will be using our time at the listening session to propose a Special Registration process that will accomplish our collective goal of legitimate and safe prescribing without compromising access to needed care for millions of Americans. The following pages outline our recommendations for this Special Registration process.

Thank you for your consideration of what we believe to be a path forward that will allow the DEA to maintain important controls on prescribing, while ensuring practitioners can continue to offer crucial patient care.

Sincerely,

Talkiatry

Quartet Health / innovaTel Telepsychiatry

Array Behavioral Care

Iris Telehealth

DEA Proposal Overview

Overview

Under the proposed rules for telemedicine issued on March 1, 2023[1], many Americans who rely on telemedicine services will lose access to mental health, substance use disorder, and other healthcare services. To prevent this, we recommend the DEA enact a Special Registration for telemedicine to allow the safe prescribing of controlled substances through telemedicine while preventing diversion. This Special Registration will be in addition to the proposed rule that allows for prescribing via telemedicine after a qualified referral from an in-person provider. Under our proposal, the DEA will issue two registration licenses: 1) the commonly known DEA Registration, and 2) a new Special Registration.

The 1) **DEA Registration** will continue to exist for providers prescribing Schedule II-V medications in the circumstances allowed under the current[2] and proposed[1] rule, including the following circumstances:

1. Treat patients in-person,
2. Treat patients via telemedicine where at least one in-person evaluation occurred, or
3. Treat patients via telemedicine that have been referred from a DEA-registered provider that had at least one in-person medical evaluation (see footnote 2 for other limited circumstances allowed)

The 2) **Special Registration** will apply to providers prescribing Schedule IIN non-narcotic, III, IV and V medications ONLY when a provider has not treated a patient in-person nor has a referring provider treated a patient in-person.

DEA Registration		Special Registration
• Allows qualified providers to prescribe Schedule II (any duration) and Schedule III-V (>30 days) medications via telehealth **after** 1) an **in-person visit**, or 2) **qualified referral** from in-person provider (other limited circumstances allowed[2]) • Primarily impacts **incidental telemedicine prescribers** (i.e., providers who see patients in both in-person and virtually)	+	• Allows qualified providers to prescribe Schedule IIN non-narcotic, III, IV, and V medications via **telemedicine** without an in-person visit or referral • Primarily impacts **large provider groups** that see patients predominantly or **exclusively via telemedicine without an in-person evaluation.** • Exemptions from certain requirements for a) providers at not-for-profit organizations or hospitals (for-profit and not-for-profit) and b) buprenorphine prescriptions ***Focus of this document***

Special Registration Details

- Guardrails govern and limit the authority granted by the Special Registration (see next page).
- So long as a provider holds a DEA registration, only **one** Special Registration is required to prescribe controlled substances in all 50 states, D.C. and its territories. Providers would not need a separate registration for each state where they practice.
- Providers would not be required to maintain a physical location or to physically store records in each state where they practice. Providers can store records electronically, in common spreadsheet formats or certified electronic medical records (EMR).

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[1] 88 FR 12875; 88 FR 12890; Telemedicine Encounter Notice of Proposed Rulemaking Rules for Controlled Substances (March 1, 2023)

[2] Exceptions to the Ryan Haight Act are: 1) treatment in a hospital or clinic; 2) treatment in the physical presence of a DEA-registered practitioner; 3) treatment by Indian Health Service or Tribal practitioners; 4) treatment during a public health emergency as declared by the Secretary of Health and Human Services; 5) treatment by a practitioner who has obtained a "special registration"; 6) treatment by Department of Veterans Affairs practitioners during a medical emergency; and 7) other circumstances specified by regulation. See 21 C.F.R. § 1300.04(i)(1)-(7).

- Providers can prescribe controlled substances under the authority of the DEA Registration or the Special Registration, based on the setting of care in which they treat each patient.

Proposed Guardrails for the Special Registration

The following guardrails would minimize diversion without materially restricting access. To avoid creating undue administrative burden, we have broken these out into two categories:

1. Guardrails that apply to all providers prescribing Schedule II-V, with no exemptions
2. Guardrails that apply to all providers prescribing Schedule II-V, with exemptions for:
    a. Providers practicing at not-for-profit organizations (as defined in the IRS Code exempt organizations under 501(c)(3)) or hospitals (both for- and not-for-profit)
    b. Prescriptions of buprenorphine

Category	Guardrail	Rationale
1. Guardrails that apply to all providers prescribing Schedule II-V controlled substances, with **no exemptions**		
Visit Frequency	• Require providers to evaluate the patient at least once every 90 days to continue to prescribe controlled substances	• Regular cadence of care is necessary to appropriately titrate medication
Visit Type	• Require providers to have the capability and to offer synchronous audio/video visits and communicate with patients via a HIPAA compliant platform	• Critical to maintain high quality care
Pharmacy Affiliations	• For controlled substance prescriptions, prohibit telemedicine practitioners from requiring, recommending, referring, or suggesting a patient utilize a specific registered pharmacy, unless the patient initiates the request for a suggestion or recommendation of a pharmacy	• Critical to maintain quality care and avoid misaligned incentives
Authority to prescribe	• Limit the authority for qualified providers to the ***prescription*** of medications for standard of care • The authority to store and dispense these medications on site would not be granted via Special Registration	• Physical locations for storing and dispensing medications are out of scope of the Special Registration
Ketamine	• Exclude ketamine from the list of medications that can be prescribed under the Special Registration (can still be prescribed under the DEA Registration) • If the FDA approves labeling for a ketamine drug for patients to self-administer at their domicile or finds it to be safe for a patient to administer without medical supervision, the DEA will review this prohibition and seek amendment to this regulation	• Ketamine is approved for treatment resistant depression • In-person observation is the standard of care after prescription to allow provider to ***intervene*** if necessary
Schedule II	• Limit Schedule II to Schedule IIN non-narcotic medications • Limit to treatment of mental health conditions • Require prescribers to satisfy one of the following: o Physician	• Schedule IIN non-narcotic drugs are critical to treating legitimate mental health needs, while broader

	○ Certified advanced practice Nurse Practitioner with a Board Certification in Psychiatric-Mental Health from ANCC ○ Physician Assistant with certificate of added qualification of Psychiatry from NCCPA ○ Completed 8 hours of approved State licensing medical board or its equivalent continuing medical education credits related to ADHD	Schedule II have a history of abuse
Category	**Guardrail**	**Rationale**
2. Guardrails that apply to all providers prescribing Schedule II-V controlled substances, **with exemptions** for a) providers practicing at **not-for-profit** organizations or **hospitals** (both for- and not-for-profit) and b) prescriptions of **buprenorphine**		
Limits on Rx volume	● Limit controlled substance prescriptions to 500 per provider per month ***(recommended)*** ● Limit number of patients on a controlled substance to 275 per provider ***(alternate limit)*** ● For either limit recommendation, in specific circumstances where a practitioner exceeds the limit(s), consideration will be given to the reason documented in the patient's medical record ● While roughly equivalent, we recommend a limit on controlled substance prescriptions rather than patients: ○ Prescription volume is easier to track ○ Patients may be prescribed more than one controlled substance ○ Provider coverage (for doctors on vacation or leave) would complicate per provider patient count	● Limits potential for abuse, consistent with pre-existing DEA regulations
Data reporting	● For each provider, report the following non-PHI data to the DEA on a **quarterly basis**: ○ Prescriber DEA registration number ○ Healthcare Entity the prescription was affiliated with ○ Name of drug(s) prescribed ○ Number of prescriptions for each drug ○ Date of prescription(s) ● Providers may delegate reporting authority to others and the delegate will be provided to the DEA ○ For example, if a medical practice employs multiple medical practitioners that are required to report, the practitioners may delegate to the medical practice entity to report on their behalf ○ Alternatively, medical practitioners may delegate the reporting to an administrative	● Allows DEA to access previously hard to get data ● Creates accountability to minimize risk of diversion ● Protects patients' privacy by removing PHI ● DEA to propose the format and mechanism for the sharing of these reports within 6 months of the Special Registration process being created, and to allow sufficient time for public comment

	person or may contract with a third party for reporting ● This data can be stored and reported in common spreadsheet formats, in the format of a Certified Electronic Health Record (CEHR), or in other formats approved by the DEA ● Reports can be submitted to the DEA electronically via online reporting, electronic file upload, or other means as approved by the DEA	● DEA may also consider pharmacy prescription data as not all prescriptions written are filled by patients