Talkiatry

June 30, 2024

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

Dear Administrator Milgram,

Talkiatry applauds <u>recent actions</u> by the Department of Justice (DOJ) in removing bad actors from telemedicine as a result of investigations by the Drug Enforcement Administration (DEA) of a company reportedly offering fraudulent health care services and illegally prescribing over the internet. We write today to reemphasize that the illicit practices allegedly conducted by this company could have been prevented or stopped sooner with the proposed safeguards for a Special Registration regulation as <u>outlined</u> by Talkiatry during the <u>September 2023 Public Listening Sessions</u> on Telemedicine Regulations. We ask that you review the safeguards as outlined below in order to protect patients from inappropriate prescribing of controlled substances while responsibly continuing and expanding access to mental health services for patients beyond the traditional in-person office-based model.

Responding directly to recent events and building on themes in our previously shared <u>recommendations</u>, we believe the following prohibitions would be extremely effective in preventing future bad actors and companies fraudulently offering prescriptions over the internet:

- Pharmacy Affiliations: For controlled substances prescriptions, DEA should 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. This would include prohibiting a practitioner from prescribing controlled substances via telemedicine if they are practicing with any entity or management services organization that requires, recommends, refers, or suggests a patient utilize a specific registered pharmacy unless the patient initiates the request for a suggestion or recommendation of a pharmacy.
- <u>Subscription-Based Payment Models:</u> For controlled substances prescriptions, DEA should
 prohibit telemedicine practitioners from operating a subscription-based payment model. This
 would include prohibiting a practitioner from prescribing controlled substances via telemedicine
 if they are practicing with any entity or management services organization that operates a
 subscription-based payment model. This is critical to maintain quality care and avoid misaligned
 incentives.
- <u>Practitioner Expertise:</u> DEA should restrict Schedule IIN treatments to practitioners with explicit training in the prescribing of controlled substances, including stimulants, by require prescribers to satisfy one of the following:
 - o Physician
 - Certified advanced practice Nurse Practitioner with a Board Certification in Psychiatric-Mental Health from AANC

- Limit prescription volume: DEA should limit controlled substance prescriptions for non-physicians to 100 per month. On average, physicians have <u>sixteen times</u> more training than nurse practitioners. Physicians average 12,000 to 16,000 hours of training, including a residency, there are no online only medical schools. In stark contrast, nurse practitioners average 500-750 hours of training in as little as 18 months with no residency required and online only programs allowed. This recommendation limits potential for abuse, consistent with pre-existing DEA regulations and the recent IQVIA study that has shown nurse practitioners drove a 57% increase in stimulant prescribing over the last 10 years while physicians were flat. nurse practitioners are now the largest prescribers of stimulants in the nation, outpacing Psychiatrists. We recommend this limit on controlled substance prescriptions rather than patients because:
 - Prescription volume is easier to track
 - o Patients may be prescribed more than one controlled substance
 - Provider coverage (for practitioners on vacation or leave) would complicate per provider patient count.
- <u>Data Reporting:</u> DEA should require each provider to report the following non-PHI data on a
 quarterly basis, which would allow DEA access to previously hard to get data and create
 accountability to minimize risk of diversion:
 - o Prescriber DEA registration number
 - Healthcare Entity the prescription was affiliated with
 - Name of drug(s) prescribed
 - Number of prescriptions for each drug
 - Data of prescription(s)

We appreciate your attention to this matter. We understand and respect the DEA's concerns about the risk of diversion of controlled substances, and we believe these concerns can be addressed while balancing the pressing national need for access to mental health across every community in America – access that can realistically only be met by leveraging telemedicine and a geographically diverse network of providers. We believe these recommendations are especially appropriate as you continue to review proposed rule *Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have not had a Prior In-Person Medical Evaluation* in accordance with Public Law 115 - 271 (SUPPORT for Patients and Communities Act) that requires the DEA create a registration for telemedicine practitioners who would not be subject to mandatory in-person medical evaluations.

Talkiatry is meeting this need without cutting any corners or risking patient safety. We are a national, physician-led, group telepsychiatry practice that provides in-network care. Talkiatry provides patients with the care they need and creates mental health care access where it did not exist.

Thank you for your consideration of our proposed recommendations. We hope you will consider these as you examine ways to continue access for clinically appropriate mental health treatments. If you have any additional questions, please do not hesitate to contact myself or Dr. Gaveras at robert.krayn@talkiatry.com or georgia.gaveras@talkiatry.com.

Sincerely,

Robert Krayn

Robert Krayn

Georgia Gaveras, DO

Show Show.

Attachment: Joint Telehealth Prescribing Letter, Sept 11, 2023

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