March 18, 2025

Matthew Strait
Deputy Assistant Administrator
Diversion Control Division
Drug Enforcement Administration
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 Deputy Assistant Administrator Strait:

On behalf of the Big Cities Health Coalition (BCHC), I write to provide comment on the Drug Enforcement Agency's (DEA) proposed rule on Special Registrations for Telemedicine and Limited State Telemedicine Registrations (proposed rule). Our comments are outlined below. BCHC is comprised of health officials leading 35 of the nation's largest metropolitan health departments, who together serve more than 61 million – or about one in five – Americans. Our members work every day to keep their communities healthy and safe.

Role of Big City Health Departments
Big city health departments (including county health departments that serve big cities) not only work to prevent, and reduce harm from, overdoses, but also improve health outcomes for people who use drugs. They are among the first to detect emerging drug trends, identify inequities in fatal and non-fatal overdoses, recognize hot spots, fund and provide supportive services rooted in reducing harm to individuals who use, hold systemwide convenings, and implement quality improvement initiatives. Big city health departments are also the first to identify and respond to local impacts, working to mitigate the effect of overdose and other harmful effects of substance use, including disease transmission. They pilot, implement, and test innovative strategies that are often expanded in communities across their respective states and the country.

BCHC Comments to Proposed Rule
While BCHC 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 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.*

- *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 BCHC understands 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 the pandemic telehealth flexibilities. Additionally, it may exacerbate mental health and substance use disorder provider shortages, particularly in 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. Lastly, while DEA sites 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.

- *Concerns with Special Registration Requirements*

  Complexity of three types of Special Registrations: The Ryan Haight Act requires only that DEA issue a singular Special Registration for Telemedicine (21 U.S.C.A. § 831(h)), however DEA proposes a concept that would see the creation of two Special Registrations for Clinicians, a new federal State Telemedicine Registration for each state in which a prescriber practices telemedicine, and Platform Registration and State Registration numbers for telemedicine platform providers. Such a concept is overly complex and unwieldy, imposing costly and unnecessary burdens on stakeholders. A single Special Registration for Telemedicine could be configured to allow for Schedule II prescribing or just Schedule III-V prescribing. In addition, a prescriber could obtain the current form of DEA registration for each state in which they intend to prescribe. We strongly recommend that the application for a special registration be as minimally burdensome as possible.

  Clarification on the Term "Legitimate Need:" We appreciate DEA's efforts to establish Special Registration pathways for telemedicine prescribing, which will help maintain patient access to necessary treatments. However, we urge 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 DEA explicitly define "legitimate need" to ensure that practitioners can continue to provide critical care without undue administrative burdens.

- *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 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.

- *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 care, especially in 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 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 all their obligations under this rule that could lead to yet another dispensing barrier impacting patients. We urge DEA to make clear that dispensing pharmacists will not be required to access a patient's record to figure out whether the in-person medical evaluation has been conducted or whether an evaluation was completed via telemedicine.

  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 populations that already face higher barriers to accessing care. This is both an access and equity issue as 22 million Americans still lack home broadband access.

Thank you again for the opportunity to comment, and once again, we urge you to remove unnecessary barriers to treatment with controlled substances. *BCHC urges DEA to ensure that final regulations prioritize patient access and provider flexibility.*

Please do not hesitate to contact me at juliano@bigcitieshealth.org if we can be of further assistance.

Sincerely,

Chrissie Juliano, MPP
Executive Director