National Rural Health Association

March 12, 2025

Derek Maltz
Acting Administrator
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, VA 22152

RE: Docket No. DEA-407; Special Registrations for Telemedicine and Limited State Telemedicine Registrations.

Comment submitted electronically via regulations.gov.

Dear Acting Administrator Maltz,

The National Rural Health Association (NRHA) thanks the Drug Enforcement Administration (DEA) for the opportunity to comment on the proposed Special Registrations for Telemedicine rule. We are pleased to see that the DEA is moving forward with its charge from Congress to create a special registration process for the use of telemedicine. We urge the DEA to move forward with finalizing this rule, with certain modifications, to ensure that rural patients can access the care that they need.

NRHA is a non-profit membership organization with more than 21,000 members nationwide that provides leadership on rural health issues. Our membership includes nearly every component of rural America's health care, including rural community hospitals, critical access hospitals, long-term care providers, doctors, nurses, and patients. We work to improve rural America's health needs through government advocacy, communications, education, and research.

DEA proposes to create three distinct registration processes, two of which are aimed at clinicians: the Telemedicine Prescribing Registration for schedule III-V controlled substances and Advanced Telemedicine Prescribing Registration for schedule II-V controlled substances. DEA also proposes a registration process for telemedicine platforms. NRHA's comments will be confined to the two clinician focused processes.

Overall, NRHA urges DEA to consider the unique position of rural clinicians in the special registration processes. Rural clinicians often serve patients across large geographic areas because of a lack of providers and perennial rural workforce shortages. **Rural clinicians' ability to prescribe controlled substances via telemedicine has the potential to improve access to care among rural populations. To ensure that rural clinicians participate in the registration processes, the burden of doing so must not outweigh the benefit of registering.** The various registration and documentation requirements proposed in this rule will take significant time and resources for rural clinicians. NRHA supports a Special Registration process to enable clinicians to serve patients via telemedicine, but we remain concerned that some provisions will discourage rural participation. While rural patients may form a provider-patient relationship with an urban clinician under these processes, it is important that they see a clinician that can coordinate with their local healthcare infrastructure who understands the rural experience of seeking healthcare. We support finalizing this proposed rule with NRHA's suggested changes below.

IV. Section-by-Section Discussion of Proposed Rule.

A.1. Three Types of Special Registration and Eligibility of Clinician Practitioners.

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50 F. St., N.W., Suite 520
Washington, DC 20001 | 202-639-0550

"Legitimate need."
Clinicians must demonstrate that they have a "legitimate need" for a special registration under either registration type. For those seeking an advanced registration, they would further be required to show that this "legitimate need" warrants prescribing schedule II controlled substances. NRHA believes that any clinician serving a rural population has a "legitimate need" to prescribe controlled substances via telemedicine given the provider shortages, particularly behavioral health professionals, in rural areas and the transportation barriers that rural patients face when seeking care. Telemedicine is an important tool for ensuring rural residents do not experience delays or disruptions in care and can receive lifesaving medication that they need. NRHA appreciates DEA's example of a legitimate need being "living in remote or distant areas" as they would capture rural residents and their clinicians and request that need be defined to include rural areas.

NRHA cautions against imposing burdens on clinicians to prove their "legitimate need." DEA provided a few examples of a legitimate need in the preamble of the proposed rule; however, it is not clearly defined in either the Ryan Haight Act or the proposed regulatory text. DEA does not lay out specific criteria for determining a "legitimate need." As such, we urge DEA not to require proof of need by rural clinicians that would be overly burdensome.

Limitation on Practice Specialties.
DEA proposes to allow physicians and board-certified mid-level practitioners to register under the Telemedicine Prescribing Registration. However, DEA limits the Advanced Telemedicine Prescribing Registration to physicians in the following specialties or limited circumstances: psychiatrists, hospice care physicians, palliative care physicians, physicians at long-term care facilities, pediatricians, and neurologists. Additionally, mid-level practitioners board-certified in treating psychiatric disorders, hospice care, palliative care, pediatric care, or neurological disorders are also eligible.

NRHA does not support the limit on clinicians eligible for the Advanced process. This arbitrary limitation will naturally exclude many clinicians that could safely prescribe schedule II medications, like family physicians, and thus lead to patients who are not able to receive a prescription for their medication. Additionally, this will exclude many rural providers from prescribing schedule II medications as these specialized providers are often located in more urban areas.

A.2. Ancillary Registration: State Telemedicine Registrations.

Under the proposed rule, special registrant clinicians would be required to obtain a State Telemedicine Registration issued by the DEA in each state in which they intend to issue prescriptions for controlled substances. NRHA is concerned that this ancillary registration is yet another burdensome step for rural clinicians to be able to prescribe medications for their patients. This will prove especially problematic for rural clinicians who may practice in a rural area near a state border and thus serve a large swath of patients in multiple states. We believe that the Special Registration and Advanced Registration are strong enough guardrails to protect against abuse and diversion of prescription-controlled substances.

B.1. Manner of Issuance of Special Registration Prescriptions

NRHA does not support DEA's proposal to only allow prescriptions via audio-video telehealth. This proposal is inconsistent with DEA's other audio-only policies. DEA proposes that clinicians must use audio-video telemedicine to prescribe under both registration frameworks. If finalized, this policy will alienate certain rural patients who cannot access audio-video telemedicine because of broadband limitations. Rural areas are less likely to have the same broadband buildout as urban areas

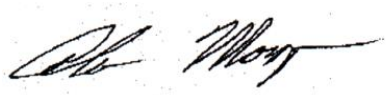
and thus in certain cases audio-only telemedicine is the only option for a remote visit. Further, DEA recently finalized a rule permitting audio-only when prescribing buprenorphine for opioid use disorder, which is a schedule III drug.[1] In order to create uniformity across DEA policies, audio-only should at least be available for clinicians prescribing schedule III-V medications.

Another proposed limitation on prescribing is that a clinician prescribing under the Advanced Registration must be located in the same state as the patient. Again, given the geography of rural areas and large patient base that rural clinicians may serve, this limitation will cut off some rural patients from receiving prescriptions via telemedicine. Additionally, Advanced Registration clinicians must show that schedule II drugs prescribed via telemedicine must constitute less than 50% of all schedule II prescriptions issued. In other words, DEA proposes that over half of prescriptions for schedule II drugs must come from an in-person visit. NRHA does not support this provision and urges DEA to remove this requirement. This threshold would not only be incredibly difficult for clinicians to predict, document, and implement but it will discourage rural providers from participating in the Advanced Registration process. Rural clinicians will face more difficulty meeting this proposal as they are likely to serve rural patients from a large geographic area and cannot guarantee that 50% of their patients who need a schedule II drug would be able to come to an in-person appointment. DEA is continuing to use in-person appointments as a guardrail where there is not sufficient evidence to show that this prevents misuse or diversion.

NRHA supports regulations creating a Special Registration process, as DEA was charged to do by Congress in the Ryan Haight Act. However, assuring that rural patients and clinicians have equal opportunity to participate in these processes is critical. We urge DEA to consider our suggestions to make this opportunity more feasible for rural populations.

NRHA thanks DEA for its work on expanding access to critical medications for rural residents and for its consideration of our comments. If you have any questions, please contact Alexa McKinley Abel (amckinley@ruralhealth.us).

Sincerely,



Alan Morgan
Chief Executive Officer
National Rural Health Association

[1] https://www.federalregister.gov/documents/2025/01/17/2025-01049/expansion-of-buprenorphine-treatment-via-telemedicine-encounter#p-3