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Headquarters
One Empire Drive, Rensselaer, NY 12144
518.431.7600

Washington, DC Office
499 South Capitol Street SW, Suite 410
Washington, D.C. 20003
202.488.1272

March 18, 2025

Derek Maltz
Acting Administrator
Drug Enforcement Administration
Attn: DEA Federal Register Representative
DPW, 8701 Morrissette Drive
Springfield, Virginia 2215

Submitted electronically: www.regulations.gov

RE: DEA-2023-0029-39155: Special Registration for Telemedicine

Dear Acting Administrator Maltz:

The Healthcare Association of New York State, on behalf of our member nonprofit and public hospitals, nursing homes, home health agencies and other healthcare providers, welcomes the opportunity to comment on the proposed rule to establish special registrations for providers to prescribe Schedule II-IV controlled substances without requiring an in-person visit.

While we support the creation of a special registration process without in-person requirements, HANYS is concerned that the proposed process would be inefficient and overly burdensome for hospitals and health systems. We believe key provisions require clarification and adjustment to ensure workability and effectiveness, particularly for hospitals and health systems. Restricting patient access to care is not an evidence-based strategy for preventing diversion, which we know is of concern to the DEA.

> **<u>Recommendation:</u> HANYS recommends that the DEA distinguish between direct-to-consumer telemedicine companies, which provide services and prescribe prescriptions on a totally remote basis, and hospitals and health systems that provide a combination of in-person and remote services.**

HANYS and our members are committed to ensuring all New Yorkers, regardless of age, race, ethnicity, gender, income level or geographical location, have access to the care they deserve. Telehealth allows patients to receive care in the comfort of their homes, which reduces potential exposure among sick patients, improves access for rural and underserved communities, provides flexibility to schedule visits without taking time off from work and helps patients with limited mobility and/or transportation options.

In addition, persistent stigma and discrimination against individuals with mental illness and substance use disorders are a well-documented barrier to seeking in-person care. Telehealth offers a more discreet way to access treatment.

The elimination of the in-person visit requirements for the prescription of controlled substances during the public health emergency addressed longstanding obstacles to care, including transportation, childcare, stigma and access to local prescribing practitioners.

An appropriate medical evaluation is essential to prescribing controlled substances. Our members adhere to rigorous care delivery standards for the diverse services they provide. They conduct telehealth visits in compliance with the rules and quality reporting requirements of multiple governing bodies including the Centers for Medicare and Medicaid Services, the State of New York, Medicaid and other payers, accrediting organizations and their own governing boards.

The Ryan Haight Act of 2008 outlined specific requirements for in-person evaluations prior to prescribing controlled substances. This law also outlined categories where an in-person evaluation could be waived:

- treatment in a hospital or clinic;
- treatment in the physical presence of a DEA-registered practitioner;
- treatment by Indian Health Service or Tribal practitioners;
- treatment during a public health emergency as declared by the Secretary of Health and Human Services;
- treatment by a practitioner who has obtained a ‘‘special registration’’;
- treatment by Department of Veterans Affairs practitioners during a medical emergency; and
- other circumstances specified by regulation.

Concerns about the telemedicine special registration eligiblity requirements

The proposed rule authorizes qualified, specialized practitioners to prescribe Schedule II-V controlled substances through telemedicine by creating a framework with three tiers of provider registration:

- **Tier one**, the Telemedicine Prescribing Registration, would authorize qualified clinician practitioners, such as physicians and board-certified mid-level practitioners, to prescribe Schedule III-V controlled substances via telemedicine.
- **Tier two**, the Advanced Telemedicine Prescribing Registration, would allow qualified specialists, such as psychiatrists and hospice care physicians, to prescribe Schedule II-V controlled substances via telemedicine.
- **Tier three**, the Telemedicine Platform Registration, would authorize covered online telemedicine platforms to dispense Schedule II-V controlled substances through a clinician practitioner possessing either a Telemedicine Prescribing Registration or an Advanced Telemedicine Prescribing Registration.

The DEA proposes two additional requirements for special registration prescriptions of Schedule II drugs that would impose a burden on hospital and health system practitioners.

First, without any clinical justification, the agency proposes that special registrants prescribing Schedule II drugs be physically located in the same state as the patient. This arbitrary requirement defeats the purpose of telemedicine: expanding access to care. In addition, this ignores the many situations where states’ geographic borders are in proximity and patients regularly cross state lines to access care. Restricting special registration practitioners to prescribing Schedule II drugs only to patients in their state would not help with existing provider shortages.

Furthermore, this proposal would reverse existing capabilities that clinicians and patients already rely on, thus risking damage to relationships that cross state lines and raising concerns over patient abandonment. If practitioners are abiding by federal and state statutes, and conforming to standards issued by state licensing boards, the DEA should not arbitrarily limit access to services. New York is bordered by five states with patients living in close proximity — NJ, CT, PA, VT and MA — who regularly seek care from New York providers.

> Recommendation: **HANYS strongly urges the DEA to remove the requirement that the provider and patient be in the same state for prescribing Schedule II drugs.**

Second, the agency proposes a mandate that special registrant prescriptions for Schedule II controlled substances average less than 50% of the special registrant's prescriptions per calendar month, for both in-person and telemedicine prescriptions. This cap does not account for the unique needs of specialized providers such as psychiatrists and pain management specialists; nor does it consider that many counties lack access to a single licensed psychiatrist.

> Recommendation: **HANYS asks that the DEA not finalize this provision.**

In addition, the DEA's proposal contains several restrictive measures on prescribing Schedule II-V controlled substances that, although well-intended, may restrict access to care or interfere with the ongoing treatment of many individuals.

The proposed rule fails to address how the special registration will work for graduate medical education programs. Hospital residents typically use a hospital DEA registration number when prescribing controlled substances in accordance with their residency program.

> Recommendation: **HANYS urges the agency to issue clarifying guidance on how residents will fit into the special registration framework.**

For the *Advanced Telemedicine Prescribing Registration* category, the DEA limits the specialty of eligible clinicians to:

- psychiatrists;
- hospice care physicians;
- palliative care physicians;
- physicians rendering treatment at long-term care facilities;
- pediatricians;
- neurologists; and
- mid-level practitioners and physicians from other specialties who are board-certified in treating psychiatric or psychological disorders, hospice care, palliative care, pediatric care or neurological disorders unrelated to the treatment and management of pain.

The list excludes primary care physicians and general medicine practitioners unless they can meet the "most compelling use case" standard by demonstrating their "need warrants authorization of prescribing of Schedule II controlled substances." PCPs are often the first point of care for patients — particularly at a time when there is a heightened effort to integrate behavioral health and primary care.

It also excludes other specialties serving patients who would greatly benefit from these flexibilities, such as a geographically remote patient with cancer receiving pain medications from an oncologist.

Recommendation: HANYS requests that the DEA expand its list of eligible providers for the Advanced Telemedicine Prescribing Registration category. Otherwise, the DEA should make available all data showing that its selected specialties will have a greater impact on mitigating or preventing diversion of Schedule II controlled substances than it would have by expanding the list to ensure greater access to care.

HANYS is particularly concerned that the Telemedicine Platform Registration proposal holds direct-to-consumer telemedicine companies to a less rigorous standard than providers who see patients via a mix of in-person and telemedicine. Under the proposed rule, platform providers under this designation would be able to prescribe Schedule II-V drugs, the same as advanced registration clinicians; however, the requirements to demonstrate need are aligned instead with the standard telemedicine registration clinicians who are able to prescribe only Schedule III-V drugs.

Recommendation: HANYS requests that the DEA clarify its intent.

Audio-video requirements

While we understand the agency's desire to create additional safeguards, we caution against a blanket audio-video requirement. Many communities, including large parts of New York state, have substandard broadband. New York permits the use of audio-only in certain circumstances. In addition, CMS permits the use of audio-only when "the patient is not capable of, or does not consent to, the use of video technology."

Recommendation: HANYS requests that the DEA amend the proposal to allow the use of audio-only when the patient is unable to use video technology.

State registration applications and fees

For each of the three tiers, the DEA proposes that practitioners would need to complete a state registration for every state in which they treat a patient; this would be a new, separate and ancillary credential administered by the DEA. As part of it, the DEA proposes two new forms (224S and 224S-M for modifications) that practitioners completing special registration and state registration would need to submit.

HANYS is concerned that the unprecedented new licensure is overly burdensome and duplicates existing licensure standards. The existing general DEA registration process already asks providers for information on their state medical licenses. If the goal is to track where prescriptions are being given, then the DEA could simply add a question to its existing registration form.

Recommendation: The DEA should remove the proposed requirement to complete state-specific registration forms.

Furthermore, practitioners, hospitals, clinics, pharmacies and others are already required to complete applications for registration and renewal of registrations for prescribing controlled substances through forms 224 and 224a.

Recommendation: We urge the DEA to add any additional information it may need on special registration to forms 224 and 224a that are already in use rather than create a second process with new forms.

In addition to the administrative burden a separate state registration would cause, HANYS is concerned that the proposed fees could create an economic disincentive for many providers, thereby reducing access to care in rural and medically underserved areas.

> Recommendation: **HANYS urges the DEA to lower the registration fee for the Telemedicine Prescribing Registration and Advanced Telemedicine Prescribing Registration categories, and to eliminate the proposal that clinicians in those two categories pay an additional fee per state where prescribing.**

Prescription Drug Monitoring Program requirements

The DEA proposes that for the first three years after the rule is finalized, providers would need to complete PDMP checks for the states where the patient is located, where the clinician is located and for any state with a reciprocity agreement to the patient/clinician locations. After three years, the DEA proposes that providers would need to review the PDMPs of all 50 states and territories when prescribing a controlled substance via telemedicine for each patient.

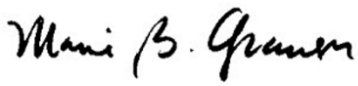
Although PDMPs can provide useful information on patients' prescription histories, the proposal to perform PDMP reviews for all 50 states and territories is operationally infeasible and unlikely to offer additional protection against diversion. HANYS acknowledges that PDMPs are very helpful state-level interventions that can improve surveillance on inappropriate prescriptions; however, there is still significant room for improvement in each state's PDMP, including here in New York, and serious interoperability limitations exist across state programs.

> Recommendation: **We strongly urge the DEA to remove the requirements for additional PDMP reviews beyond current standards for in-person prescribing of controlled substances and limit the requirement to the state where the provider and patient are located.**

> Recommendation: **Considering our comments, we ask the DEA to extend the timeline for implementing the proposed special registrations, which would also require a further extension of the relevant waiver flexibilities, until the final rule is published.**

If you have questions, please contact me at bgrause@hanys.org or 518.431.7765, or Victoria Aufiero, vice president, insurance, managed care and behavioral health, at 518.431.7889 or vaufiero@hanys.org.

Sincerely,



Marie B. Grause, RN, JD
President