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Vizient Office of Public Policy and Government Relations

Special Registrations for Telemedicine and Limited State Telemedicine Regulations

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Background & Summary

On January 15, 2025, the Drug Enforcement Administration (DEA) issued a proposed rule, "Special Registrations for Telemedicine and Limited State Telemedicine Registrations" (hereinafter, Proposed Rule), to establish a Special Registration framework and authorize three types of Special Registration (i.e., Telemedicine Prescribing Registration; Advanced Telemedicine Prescribing Registration; Telemedicine Platform Registration) related to telemedicine prescribing of controlled substances (CS). In addition, the Proposed Rule includes additional requirements for those registering through the Special Registration Framework and provides additional information regarding state telemedicine registration.

DEA also clarifies that the Proposed Rule applies only to practitioner-patient relationships where the prescribing practitioner intends to prescribe CS and has never conducted an in-person medical evaluation of the patient prior to the issuance of the prescription. The Proposed Rule aims to focus on telemedicine practiced under a Special Registration and would not apply to other forms of practice of telemedicine (e.g., telemedicine authorized under recently finalized rules: Expansion of Buprenorphine Treatment via Telemedicine Encounter or the Continuity of Care via Telemedicine for Veterans Affairs Patients).

Comments in response to the Proposed Rule are due on March 18, 2025.

Special Registration for Telemedicine Framework

In the Proposed Rule, DEA emphasizes its view that registration is critical to control for manufacturing, distribution, and dispensing of CS. As a result, DEA proposes a Special Registration for a telemedicine framework to establish appropriate circumstances and guardrails for telemedicine-based prescribing and dispensing of CS where an in-person medical evaluation has never been performed by the prescribing practitioner.[1] DEA proposes three categories of Special Registration and additional requirements for each type of Special Registration, as shown in Table 1.

Also, to clarify, once registered under the Special Registration framework, clinician practitioners would be considered *clinician special registrants;* and *covered online telemedicine platforms,* in their capacity as *platform practitioners,* would be considered *platform special registrants.*

[1] Appendix A of the Proposed Rule (pg. 6562) provides a chart to help clinician practitioners determine whether a Special Registration is required to treat a patient.

Table 1. Summary of DEA's Proposed Special Registration Framework

Types of Registration*	Telemedicine Prescribing Registration	Advanced Telemedicine Prescribing Registration	Telemedicine Platform Registration
Function	Clinician practitioners may prescribe schedule III-V CS.	Certain specialized clinician practitioners may prescribe schedule II-V CS.	Covered online telemedicine platforms[2] may dispense schedule II-V CS through a clinician practitioner. The clinician practitioner must possess either a telemedicine prescribing registration; or an advanced telemedicine prescribing registration.
General eligibility requirements	Must have one or more DEA registrations to prescribe (if a clinician practitioner) or dispense (if a platform practitioner) CS in a state in which they are licensed, registered, or otherwise permitted to prescribe or dispense CS via telemedicine (unless exempt). DEA registrations under existing law for dispensing require licensing of the activity by the state in which DEA registration to dispense is sought.		
Additional eligibility requirements	Clinician practitioners (i.e., physicians, mid-level practitioners) who show they have a legitimate Special Registration need.	Only certain specialized[3] physicians and board-certified mid-level practitioners[4] that have a legitimate need to prescribe schedule II CS when treating particularly vulnerable patient populations. *- DEA seeks input on whether other types of practitioners should be included in this category; and methods to ensure those prescribing pursuant to this category have appropriate training and expertise to do so safely*.	Covered online telemedicine platforms would need to demonstrate a legitimate need to dispense schedule II-V CS.[5]

[2] DEA proposes to define covered online telemedicine platform to mean an entity that facilitates connections between patients and clinician practitioners, via an audio-video telecommunications system, for the diagnosis and treatment of patients that may result in the prescription of controlled substances, but is not a hospital, clinic, local in-person medical practice, or insurance provider, and meets one or more of the following criteria: (1) The entity explicitly promotes or advertises the prescribing of controlled substances through the platform; (2) The entity has financial interests, whether direct incentives or otherwise, tied to the volume or types of controlled substance prescriptions issued through the platform, including but not limited to, ownership interest in pharmacies used to fill patients' prescriptions, or rebates from those pharmacies; (3) The entity exerts control or influence on clinical decision-making processes or prescribing related to controlled substances, including, but not limited to: prescribing guidelines or protocols for clinician practitioners employed or contracted by the platform; consideration of clinician practitioner prescribing rates in the entity's hiring, retention, or compensation decisions; imposing explicit or de facto prescribing quotas; directing patients to preferred pharmacies; and/or (4) The entity has control or custody of the prescriptions or medical records of patients who are prescribed controlled substances through the platform.

[3] DEA is not proposing regulations that would delineate specific criteria for clinicians falling into the designated practice specialties. Clinician practitioners would need to include information on their Special Registration applications to demonstrate their specialized training (e.g., board certification in a specialty; specialized training; percentage of clinician practitioner's overall practice the falls within one of the specialized practices).

[4] In the Proposed Rule, DEA clarifies the following limited circumstances or practice specialties: (1) psychiatrists; (2) hospice care physicians; (3) palliative care physicians; (4) physicians rendering treatment at long term care facilities; (5) pediatricians;[1] (6) neurologists; and (7) mid-level practitioners and physicians from other specialties who are board certified in the treatment of psychiatric or psychological disorders, hospice care, palliative care, pediatric care, or neurological disorders unrelated to the treatment and management of pain.

[5] DEA further details that a legitimate need is apparent when the covered online telemedicine platform anticipates providing necessary services to introduce or facilitate connections between patients and clinician practitioners via telemedicine for the diagnosis, treatment, and prescription of CS, are compliant with federal and state regulations, provide oversight over clinician practitioners' prescribing practices, and take measures to prioritize patient safety and prevent diversion, abuse, or misuse of CS.

Issuance of Special Registration prescriptions	DEA proposes additional clarifications and requirements for when a Special Registration prescription is issued by clinician special registrants, including: prescription origination within the United States; all Special Registration prescriptions to be issued via electronic prescribing for controlled substances (EPCS); nationwide prescription drug monitoring program (PDMP) check[6]; utilization of both audio and video components of an audio-video telecommunications system to prescribe under the Special Registration framework for every telemedicine encourage (e.g., initial visit, follow-up).[7] DEA also proposes two additional requirements for Special Registration prescriptions: (1) the Special Registration numbers of the clinician practitioner and platform practitioner (if applicable); and (2) State Telemedicine Registration numbers of the clinician practitioner and platform practitioner (if applicable).		
Additional prescribing requirements		- Clinician special registrant is physically located in the same state as the patient when issuing a Special Registration prescription for a schedule II CS; and - The average number of Special Registration prescriptions for schedule II CS constitutes less than 50% of the total number of prescriptions issued by the by the clinician special registrant in their telemedicine and non-telemedicine practice in a calendar month.	

*DEA also proposes a limited type of registration for a lower registration fee, the *State Telemedicine Registration.* As proposed, a clinician special registrant would be required to obtain a *State Telemedicine Registration,* which is DEA-issued, for every state in which they intend to prescribe for CS via telemedicine. DEA clarifies that a State Telemedicine Registration for a given state would allow the special registrant to prescribe only via telemedicine encounters as to that state, and only for the scheduled CS authorized by their Special Registration (i.e., Telemedicine Prescribing Registration, Advanced Telemedicine Prescribing Registration, or Telemedicine Platform Registration). Also, DEA details two categories of exemptions to the state registration requirement in the Proposed Rule (pg. 6551).

Application Forms and Fees

DEA proposes issuing a new registration application, Form 224S (Application for Special Registration for Telemedicine Under the Controlled Substances Act). Applicants would use Form 224S to apply for one of the three types of Special Registrations, as well as the State Telemedicine Registrations for each state in which telemedicine patients will be located. DEA proposes a three-year cycle for the Special Registrations and the registration fee would be $888 (DEA may adjust these fees).[8]

DEA also proposes supplemental requirements on the Special Registration Application (e.g., special registered location; supplementary disclosures and attestations; clinician practitioner disclosure of

[6] In the Proposed Rule, DEA indicates that for a period of three years from the date that the final rule becomes effective, before issuing any Special Registration prescription for a CS to a patient, the individual special registrant would be required to check the PDMPs for: (1) the state or territory where the patient is located; (2) state or territory where the clinician practitioner is located; and (3) any state or territory with PDMP reciprocity agreements with either the state or territory where the clinician practitioner is located. After three years, the individual special registrant would be required, before issuing any Special Registration prescription for CS to a patient, to check the PDMPs of all 50 states and the any other U.S. District or territory that maintains its own PDMP. In the Proposed Rule (pg. 6554), DEA does address the circumstance if a nationwide PDMP is not available in three years.

[7] DEA also permits audio-only telecommunications systems to be used when prescribing for Schedule III-V CS for the treatment of Opioid Use Disorder (OUD) (more information is available in the Proposed Rule (pg. 6555-6556).

[8] The fee for the Telemedicine Registration would be $888 for each state in which a State Telemedicine Registration is sought; however, the Clinician Practitioner State Telemedicine Registration would be discounted to $50 for each state in which the clinician practitioner sought a State Telemedicine Registration.

practice specialties). Special registrants would have 14 business days to notify DEA of any changes to the information provided in their Special Registration using Form 224S-M.

Recordkeeping and Reporting

In addition to meeting existing recordkeeping and reporting requirements, DEA proposes supplemental reporting requirements within the Special Registration framework. Specifically, clinician special registrants would be required to establish and maintain photographic records for patient verification[9] and maintain their Special Registration prescription records at their designated Special Registration location. Alternatively, platform special registrants would be required to maintain and update credential verification and documentation records. Special registrants would also be required to report annually aggregated information about their telemedicine practice (e.g., number of new patients they treat through telemedicine; total number of Special Registration prescriptions for schedule II CS, and certain schedule III-V CS, including Ketamine, Tramadol, and any depressant constituting a benzodiazepine, dispensed for the preceding year).

Also, pharmacies dispensing Special Registration prescriptions would be required to report monthly aggregated Special Registration prescription data on schedule II CS and certain schedule III-V CS.

Request for Comments

As noted in the Proposed Rule, DEA invites comments regarding the need for any clarifications or suggested modifications to the proposed regulations. In addition, DEA seeks comments on the potential inclusion of a severability clause in the final rule. DEA clarifies that under such a clause, if any specific provision of the rule is found to be invalid by or unenforceable by a court, the remaining provisions would continue to be operative and enforceable.

What's Next?

As of this time, it is unclear when DEA will publish a final rule. The comment period closes on March 18, 2025.

Vizient's Office of Public Policy and Government Relations looks forward to hearing continued member feedback on this proposed rule. Stakeholder input plays a major role in shaping future changes to policy. We encourage you to reach out to our office if you have any questions or comments regarding any aspects of this proposed regulation – both positive reactions and provisions that cause you concern. Please direct your feedback to Jenna Stern, AVP, Regulatory Affairs and Public Policy.

[9] In the Proposed Rule, DEA clarifies the photographic record shall be maintained by the individual special registrant and renewed a minimum of every two (2) years. Other forms of identification may also be permitted in certain circumstances, as outlined in the Proposed Rule (pg. 6596).