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DEA Proposed Rule for Special Registrations for Telemedicine and Limited State Telemedicine Registrations

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On January 17, 2025, the Drug Enforcement Administration (DEA) released the proposed rule, "Special Registrations for Telemedicine and Limited State Telemedicine Registrations." The proposed rule marks a significant first step in the DEA's functional establishment of the Special Registration set forth in the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (RHA). The DEA's goal in proposing the Special Registration's framework is to "ensure patient access to care, while maintaining sufficient safeguards to prevent and detect diversion of controlled substances."

The Special Registration History

The RHA requires that all prescription drugs that are dispensed by means of the internet be issued via a valid prescription, which generally requires an in-person medical evaluation, and that the prescription be issued for a legitimate medical purpose in the usual course of professional practice. The RHA provides distinct circumstances in which the practice of telemedicine is permitted, and in turn, the in-person evaluation is not required in order to properly prescribe a controlled substance. The Special Registration is one of these circumstances, and while the Special Registration exception to the in-person requirement was included in the RHA in 2008, it was not developed beyond the text of the RHA until this year, with the promulgation of the proposed rule. The Special Registration was a common topic of presentation in the DEA Listening Sessions in April 2024, and its development has been called for by a variety of stakeholders in the telemedicine industry.

The Special Registration Framework

The proposed rule is organized by category of Special Registration and conditions for the registration's maintenance. Specifically, the proposed rule conceptualizes a unique type of practitioner – a "covered online telemedicine platform." A covered online telemedicine platform means 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 and meets one of four enumerated criteria.

If met, the four criteria reflect that the platform is “integral intermediary in the remote dispensing of controlled substances.” The criteria address platform advertising, associated pharmacy ownership, prescribing guidelines, and handling of medical records. In this way, the proposed rule sets detailed standards, highlights issues that were actively discussed during the DEA Listening Sessions, and defines factors the DEA identifies as indicative of potential diversion or unsafe prescribing. Notably, hospitals, clinics, local in-person medical practices, and insurance providers are excepted from the definition.

Categories of Special Registration

The proposed rule delineates between “clinician practitioners” and “platform practitioners” and sets forth four categories of registration for which a practitioner may apply. Clinician practitioner refers to properly registered physicians and mid-level practitioners. Platform practitioner means a covered online telemedicine platform that dispenses controlled substances by virtue of its central involvement as an intermediary in the remote prescribing of controlled substances by an individual practitioner. Platform practitioners are subject to the requirements imposed upon non-pharmacist practitioners under the Controlled Substances Act, 21 U.S.C. 801-904, and its regulations. The four categories of registration are:

1. The *Telemedicine Prescribing Registration* would authorize the prescribing of Schedule III through V controlled substances by clinician practitioners.
2. The *Advanced Telemedicine Prescribing Registration* would authorize certain specialized clinician practitioners (i.e., certain categories of “specialized” clinicians defined by the rule) to prescribe Schedule II controlled substances in addition to Schedule III through V controlled substances.
3. The *Telemedicine Platform Registration* would authorize covered online telemedicine platforms to dispense Schedule II through V through a clinician practitioner possessing either category of clinician Special Registration above.
4. The *State Telemedicine Registrations*, which would be required to prescribe across states, would allow practitioners issued any of the three categories of registration above to obtain a state registration for every state in which patients to whom special registration prescriptions will be issued are located, with certain exceptions.

The proposed rule sets forth eligibility and requirements for each category of Special Registration, although notably application for a certain registration does not guarantee that it will be granted, as each requirement for Special Registration is lined with agency discretion. Ultimately, the DEA Administrator will issue a Special Registration to an applicant when the applicant meets all eligibility requirements set forth in the proposed rule, which includes a practitioner presenting “legitimate need” for the Special Registration, and the Administrator determines that the Special Registration is consistent with the public interest factors stipulated in 21 U.S.C. 823(g)(1) (i.e., the public interest factors considered for conventional practitioner DEA registrations).

Altogether, engaging in the practice of telemedicine under the proposed rule, the practitioner must possess a conventional DEA registration under 21 U.S.C. 823(g), one of the three types of Special Registration for practitioners, and a State Telemedicine Registration for each state in which a patient prescribed a controlled substance is located.

Other Requirements of the Proposed Rule

The proposed rule also requires certain operational standards for special registrants, including:

- *Disclosure of a Special Registered Location*. Special Registration applicants must designate a location as the physical address of the Special Registration.
- *Certain Disclosures*. Platform practitioners, in their application for Telemedicine Platform Registration, must disclose all employment, contractual relationships, or professional affiliations with any clinician special registrant and online pharmacy.
- *Certain Attestations.* Special Registration applicants must attest that they have a legitimate need for a Special Registration for Telemedicine and to the facts and circumstances that form the basis for their "legitimate need" for the Special Registration.
- Changes to Special Registration information must be updated within 14 business days of the change.
- *Patient Verification.* The proposed rule provides patient identity verification standards, including patient verification requirements for the first telemedicine encounter and a practitioner's storage of patient identification information.
- *Special Registration Prescription Data Reporting.* Special registrants must report to DEA on an annual basis the total number of new patients in each state where at least one special registration prescription has been issued and the total number of special registration prescriptions issued by a registrant across states, among other information.
- *Telecommunications Standards*. The proposed rule requires all prescriptions issued via a Special Registration to be through the use of an audio-video telecommunications system, with only limited circumstances allowing for the issuance of a special registration prescription with audio-only technology.
- *State Law*. The proposed rule explicitly requires compliance with state laws and regulations where the patient is located during the telemedicine encounter, the state where the special registrant is located during the telemedicine encounter, and any state in which the special registrant holds a DEA registration.
- *PDMP Check*. Prior to issuing a special registration prescription, a special registrant must perform a check of the state PDMPs in the state the patient is located, the registrant is located and any state with reciprocity agreements with these states.
- *Prescription Requirements*. Special registration prescriptions must contain certain information specific to the Special Registration number, with liability imposed on a pharmacist for filling a special registration prescription that may be missing information.

Moving Forward

The proposed rule acknowledges the expansive nature of telemedicine post-PHE, addresses key players in the telemedicine industry – from popular telemedicine platforms to local practitioners and pharmacists – and attempts to wrangle these diverse interests into a workable Special Registration. Further, it proposes comprehensive application and reporting requirements to facilitate the tracking of special registration prescription information and telemedicine activities by the DEA, which had traditionally been confined to the state level.

Certain aspects of the proposed Special Registration appear clear, such as the form that will be required for the Special Registration and the patient verification requirements. Other elements, such as the practical threshold for "legitimate need" and the DEA's discretion to grant or deny the Special Registration itself, render logistical aspects of the Special Registration framework unpredictable. Clinician practitioners, platform practitioners, and other telemedicine participants should continue to monitor the development of the proposed rule as, if finalized, a Special Registration will become a key component required for continued telemedicine operations involving the prescription of controlled substances. The written comment period for the proposed rule ended March 18, 2025, and comments are currently under consideration.

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