Now & Next
Healthcare Alert

January 27, 2025

DEA announces proposed regulations on telemedicine prescribing of controlled substances

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The proposed rule establishes a framework for special registrations, including registration for online telehealth platforms, recordkeeping procedures, prescription drug monitoring program checks and further potential safeguards for high-risk prescriptions.

What's the impact?

- The proposed rule establishes three special registrations that waive in-person requirements prior to prescribing controlled substances via telehealth, including a registration for online telehealth platforms.
- Clinicians are required to conduct Prescription Drug Monitoring Program (PDMP) checks for the state in which the patient is located, the state where the clinician is located, and any other relevant state with PDMP reciprocity. The 50-state nationwide check requirement has been postponed for three years to provide time for the development of a nationwide search system.
- Detailed records must be maintained for in-person evaluations,

telehealth prescriptions, and telemedicine referrals.

- While the proposed rule can be seen as a step forward in making certain COVID-19 flexibilities permanent for prescribing via telehealth, it remains unclear whether the new administration will shelve the proposed rule in its entirety or permit comments and then revise to fit its policy objectives. Certain industry organizations and legislators' initial reviews have criticized the rule as too burdensome.

On January 15, 2025, the Drug Enforcement Administration (DEA) announced one proposed rule and two final rules to permanently extend certain telemedicine flexibilities temporarily implemented during the COVID-19 public health emergency (PHE), alongside the introduction of additional patient protections.[ii] After the PHE concluded in May 2023, the DEA temporarily extended these flexibilities. The agency issued a third extension in November 2024, with the flexibilities now set to expire on December 31, 2025. The proposed rule discussed in this alert establishes a thorough framework for special registrations, outlines detailed application and recordkeeping procedures, and introduces specific safeguards for high-risk prescriptions (e.g., Schedule II medications).

The Ryan Haight Online Pharmacy Consumer Protection Act

The Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (Ryan Haight Act) generally mandates an in-person medical evaluation before prescribing controlled substances. The general rule under the Ryan Haight Act is that a practitioner must conduct at least one in-person medical evaluation of a patient prior to issuing a prescription for a controlled substance.

There are seven exceptions to the in-person requirement, where certain methods of telemedicine may be conducted; however, the exceptions do not easily align with direct-to-patient service models frequently sought by patients in areas such as telepsychiatry (e.g., where the patient is at their home at the time of the telemedicine consult). The Ryan Haight Act also identified a "special registration exception," which the DEA had not been implemented nor proposed to be implemented until now. Special registration under the proposed rule is required only for practitioners who intend to prescribe controlled substances to patients they have not seen in person.

Special registrations

Three types of special registrations are outlined that will not require an in-person visit prior to prescribing controlled substances by telehealth. As proposed, a prescriber must also obtain a State Telemedicine Registration for each state where a patient is treated (this is a new DEA

requirement and not connected to any state-controlled substance registration currently required by state agencies).

TELEMEDICINE PRESCRIBING REGISTRATION

The first special registration would authorize qualified clinician practitioners with a legitimate need to prescribe Schedule III-V controlled substances via telemedicine. The DEA has determined that physicians and board-certified mid-level practitioners have a legitimate need to prescribe Schedule III through V controlled substances when they expect to treat patients for whom requiring in-person medical evaluations could place undue burdens on bona-fide practitioner-patient relationships (e.g., living in rural areas). Whether or not prescribing via telehealth for the mere convenience of the patient and/or practitioner is consistent with a demonstration of "legitimate need" is unclear.

ADVANCED TELEMEDICINE PRESCRIBING REGISTRATION

The second special registration authorizes qualified specialized clinician practitioners with a legitimate need to prescribe Schedule II-V controlled substances via telemedicine when treating vulnerable patients. This authorization is reserved for what the DEA has determined as the "most compelling cases," ensuring that prescriptions are issued only when absolutely necessary. Such cases would be only for certain board-certified practitioners, such as pediatricians, psychiatrists, palliative care physicians, and similarly certified mid-level practitioners. When a clinician prescribes a Schedule II controlled substance, like Adderall, to a minor, the proposed rule requires the mandatory presence of the minor's parent or guardian.

TELEMEDICINE PLATFORM REGISTRATION

The third special registration authorizes qualified covered online telemedicine platforms to dispense Schedule II-V controlled substances. The proposed rules defines a *covered online telemedicine platform* as 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.[iii]" It is important to note that this definition does not include hospitals, local in-person medical practices, clinics, or insurance providers.

The DEA has determined that covered online telemedicine platforms have a legitimate need when they expect to offer essential services that connect patients with clinician practitioners via telemedicine for the diagnosis, treatment, and prescription of controlled substances. While telehealth platforms connecting patients to prescribers of controlled substances are not typically seen as "dispensing" platforms or as "practitioners," the DEA's proposed rule clarifies that "dispense" includes delivering controlled substances to patients under a healthcare provider's

direction, and as intermediaries for prescribers, certain platforms should be considered "practitioners" under the Controlled Substances Act.

The DEA proposes that any telehealth platform meeting one or more of the proposed criteria be required to register. Such criteria include whether the telehealth platform "explicitly promotes or advertises the prescribing of controlled substances through the platform." If there is any doubt about an entity's role as a dispenser, "registering may be advisable to avert the risk of enforcement action based on potential unregistered, and, thus, illegal, dispensing of controlled substances."

Once appropriately registered, clinician practitioners would be designated *clinician special registrants*, while covered online telemedicine platforms would be recognized as *platform special registrants*.

Registration and recordkeeping

A new DEA Form 224S would be introduced to complete these registrations, which are proposed to occur on a three-year cycle. Telehealth platforms would be required to disclose details of their "employment, contractual relationships, or professional affiliations with any clinician special registrant and online pharmacy, along with their respective registration numbers" and clinician special registrants would be required to "attest to all employment, contractual relationships, and professional affiliations, including, but not limited to, those with covered online telemedicine platforms."

Clinician special registrants are required to establish and maintain photographic records for patient verification and maintain their special registration prescription records at one designated registered location. Platform special registrants are required to maintain and update credential verification and documentation records. Pharmacies dispensing special registration prescriptions must report monthly aggregated data on Schedule II and certain Schedule III-V controlled substances to the DEA. Additionally, special registrants must provide annual aggregated information about their telemedicine practice. This includes the number of new patients treated via telemedicine and the total number of special registration prescriptions for Schedule II and certain Schedule III-V controlled substances dispensed in the previous year. Special reporting requirements are included for Ketamine, Tramadol, and any depressant that constitutes a benzodiazepine. The pharmacy must report the number of prescriptions filled, the volume of the controlled substance dispensed, and the number of patients prescribed the controlled substance.

PDMP

The proposed rule also mandates providers to check the state Prescription Drug Monitoring Program (PDMP) in the states where both the patient and the provider are located, as well as in

any state that has a PDMP reciprocity agreement with those states. After three years, providers would need to check the PDMPs of all 50 states, assuming they are available. The DEA acknowledged that it is currently not possible for providers to access all state PDMPs, but it anticipates that state registry interoperability will improve in the near future.

Potential additional requirements

The DEA is requesting public comments in various areas, including which additional medical specialists should be authorized to prescribe Schedule II medications pursuant to the advanced registration and potential patient protections for prescribing Schedule II medications via telemedicine. This includes questions such as whether the prescribing provider should be required to be located in the same state as the patient, whether telemedicine prescriptions for Schedule II medications should be limited to providers whose practice involves less than 50% telemedicine prescriptions, and what the appropriate timeline is for implementing the proposed rules.

Next steps

Certain industry organizations have already expressed that the proposed rule would be significantly burdensome for current telehealth platforms and are requesting President Trump to withdraw the proposed rule. US Senator Mark R. Warner, who previously, along with Senator John Thune, expressed concerns about the previous DEA proposed rule in 2023 for prescribing by telehealth, applauded the DEA for taking a "huge step forward" to provide certainty for patients reliant on telehealth prescribing. However, he noted that the new proposed rule has "proposed guardrails" that "are overly restrictive and do not reflect the legitimate ways telemedicine is safely conducted today."

In a series of executive orders initiated by President Trump, a regulatory freeze was enacted. Without further action from the current administration, the notice and comment period of the proposed rule will continue; however, any final rule would require approval from a Trump appointee prior to being published and becoming effective. Comments to the proposed rule must be submitted on or before March 18, 2025.

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[ii] The other regulations include (i) the final rule for permitting prescribing of buprenorphine through a telephone consultation with a provider allowing patients to have 6-month supply, and (ii) the final rule for exempting U.S. Department of Veteran Affairs practitioners from special registration requirements proposed by the DEA.

[iii] Special Registrations for Telemedicine and Limited State Telemedicine Registrations (proposed Jan. 17, 2025) (to be codified at 21 CFR § 1300, 1301, 1304, and 1306).