

DEA PUBLISHES LONG-AWAITED RULES FOR TELEMEDICINE PRESCRIBING

This past week, the Drug Enforcement Administration (“DEA”) and the U.S. Department of Health and Human Services (“HHS,” and together with the DEA, the “Agencies”) announced the release of three highly anticipated rules related to the prescription of controlled substances through telemedicine. These new rules include:

- A **final rule** on the “Expansion of Buprenorphine Treatment via Telemedicine Encounter,” which allows practitioners to prescribe up to a six-month supply of buprenorphine via an audio-only telemedicine interaction;
- A **proposed rule** to establish “Special Registrations for Telemedicine and Limited State Telemedicine Registrations”; and
- A **final rule** promoting “Continuity of Care via Telemedicine for Veterans Affairs Patients.”

By way of background, the Agencies originally issued proposed rules relating to the remote prescription of controlled substances in early 2023 (“Original Proposed Rules”). The Original Proposed Rules were expected to be finalized prior to the end of the COVID-19 public health emergency. The intent being, to make permanent some of the COVID-era telemedicine flexibilities in order to facilitate patient access to controlled medications via telemedicine, when consistent with public health and safety, and while maintaining effective controls against diversion. However, those Original Proposed Rules were the subject of intense industry and stakeholder scrutiny, amassing more than 38,000 public comments. As a result, the DEA and HHS subsequently extended the COVID-era telemedicine flexibilities three times (most recently through the **third temporary rule published in November 2024**), while they worked to finalize permanent telemedicine regulations and take into consideration the multitude of public comments received both in response to the Original Proposed Rules and during the Agencies’ September 2023 **Telemedicine Listening Sessions**. Having considered the extensive commentary, the Agencies have significantly revised the Original Proposed Rules and are now finalizing a modified permanent rule setting forth parameters for the induction of medication-assisted therapy using buprenorphine via telemedicine and promulgating new proposals to establish Special Registrations to prescribe controlled substances via telemedicine more broadly.

Those evaluating these new/proposed rules should additionally note, though, that following the Inauguration, President Trump signed multiple Executive Orders, including an **order freezing all executive agency rulemaking activities** until they are reviewed by the new agency heads. This regulatory freeze halts work on all pending proposed rules, including those relating to the Special Registration requirements; however, because the buprenorphine and VA practitioner exemptions final rules have been published, they are expected to become effective as scheduled on February 18, 2025, unless reversed by Congressional intervention or by the new administration through the regular rulemaking process.

EXPANSION OF BUPRENORPHINE TREATMENT VIA TELEMEDICINE ENCOUNTER

The Agencies finalized the 2023 proposed rule that permits DEA-registered practitioners to prescribe certain Schedule III-V controlled substances to treat Opioid Use Disorder (“OUD”) through audio-video and audio-only telemedicine visits under certain circumstances when an in-person medical examination has not been performed. In finalizing this rule, the Agencies expanded the initial 30-day prescription supply limitation via audio-only telemedicine to a six-month supply limitation, eliminated certain burdensome recordkeeping requirements and removed the requirement that in order to prescribe more than the initial supply of buprenorphine, an in-person medical examination of some sort must be conducted.

Barring Congressional intervention, the final rule is expected to become effective on February 18, 2025. As finalized, it will allow DEA-registered practitioners to initiate prescriptions for Schedule III-V controlled substances approved by the FDA to treat OUD, such as buprenorphine, and continue to prescribe it, as medically appropriate, for up to six months via audio-only telemedicine interactions and without having first conducted an in-person evaluation, provided that:

- The practitioner first reviews the Prescription Drug Monitoring Program (“PDMP”) data for the state in which the patient is located, in accordance with established look-back period requirements, documents in the patient’s medical record the date and time that such a review was conducted and abides by additional prescribing limitations applicable in the event that a state PDMP is inaccessible or

unavailable;

- Prior to dispensing any prescription issued pursuant to this process, the filling pharmacist verifies the identity of the patient with a state or federal government-issued photo ID card or other form of identification; and
- Such prescriptions comply with all other relevant DEA regulations. Therefore, such prescriptions must be dated and signed and must include the patient's name and address, the name, strength, dosage, form and quantity of the drug, directions for use and the practitioner's name, address and DEA registration number.

After the initial six-month period, practitioners may issue subsequent prescriptions only after the practitioner has met with the patient for a follow-up evaluation through either any form of telemedicine authorized under the Ryan Haight Act, including through any Special Registration process finalized by the DEA, or through an in-person medical examination of the patient by the prescribing practitioner.

SPECIAL REGISTRATIONS FOR TELEMEDICINE AND LIMITED STATE TELEMEDICINE REGISTRATIONS

Shortly after publishing its final rule, "Expansion of Buprenorphine Treatment via Telemedicine Encounter," the DEA additionally published its long-awaited (updated) proposed rule addressing the prescription of controlled substances through telemedicine.

The proposed rule, titled "Special Registration for Telemedicine and Limited State Telemedicine Registrations," follows multiple extensions of the COVID-era flexibilities, which have allowed eligible practitioners since that time to prescribe controlled substances through telemedicine without the prior in-person medical examination that is otherwise required by the Ryan Haight Online Pharmacy Consumer Protection Act of 2008. Electronic comments in relation to this proposed rule must be submitted, and written comments must be postmarked, on or before March 18, 2025.

Per the executive summary of the proposed rule:

This NPRM introduces the three types of *Special Registrations for Telemedicine*: (1) a *Telemedicine Prescribing Registration*, authorizing qualified *clinician practitioners* to prescribe Schedule III-V controlled substances via telemedicine, (2) an *Advanced Telemedicine Prescribing Registration*, authorizing qualified, specialized *clinician practitioners* (e.g., psychiatrists, hospice care physicians) to prescribe Schedule II-V controlled substances via telemedicine, and (3) a *Telemedicine Platform Registration*, authorizing *covered online telemedicine platforms*, in their capacity as *platform practitioners*, to dispense Schedule II-V controlled substances. To satisfy the statutory requirements under **21 U.S.C. 831(h)**, DEA would also require the *special registrant* to maintain a *State Telemedicine Registration* for every state in which a patient is treated by the *special registrant*, unless otherwise exempted. The *State Telemedicine Registration* would be issued by DEA, not the states, and operate as an ancillary credential, contingent on the *Special Registration* held by the *special registrant*.

The proposed rule sets forth particular state and federal registration requirements and processes, as well as associated registration costs, for each new Special Registration category. The new rule additionally sets forth particular requirements/restrictions in relation to the physical location of the prescribing practitioner, PDMP checks, use of audio and visual technology (with limited exception) and heightened record-keeping requirements (such as particular requirements related to patient identification).

In short, the proposed rule represents a much more robust approach to telemedicine prescribing and the associated requirements. Pending further agency review by the new administration as noted above, it will be critical for those health care providers and entities utilizing telemedicine to fully appreciate and plan for the implementation of these rules (once finalized) prior to the end of 2025, when the recently extended Covid-era waiver is currently scheduled to expire.

CONTINUITY OF CARE VIA TELEMEDICINE FOR VETERANS AFFAIRS PATIENTS

Additionally, in consultation with the U.S. Department of Veterans Affairs ("VA"), the Agencies issued a final rule that would exempt VA practitioners from Special Registration requirements, subject to certain conditions, if another VA practitioner has previously conducted an in-person medical evaluation of the VA patient.

PRACTICAL TAKEAWAYS

Given the fluid regulatory environment of a new administration, practitioners and interested stakeholders should continue to monitor for updates on the regulation status and new developments. The Senate is working through agency appointments, and we expect more clarity on policy direction as health care appointees are confirmed into their positions and staff up.

Expansion of Buprenorphine Treatment via Telemedicine Encounter

- DEA-registered practitioners will be permitted to prescribe buprenorphine to treat OUD, as medically appropriate, for up to six months via audio-only telemedicine interactions and without first conducting an in-person evaluation or obtaining a Special Registration (once those requirements are finalized).
- Practitioners should bear in mind that these remote prescribing requirements only apply to prescriptions issued for the treatment of OUD. Even if a Schedule III-V controlled substance is approved by the FDA for use in other medical uses, the remote prescribing rules still only apply when the medication is being prescribed for OUD treatment.
- Practitioners should note that these permanent DEA requirements for prescribing buprenorphine for OUD do not negate any state or payor-specific requirements that may otherwise apply to remote prescribing and/or require in-person examination. It is critical that practitioners ensure their prescribing practices conform not only to applicable DEA rules but to all other applicable state and payor requirements.

Special Registrations for Telemedicine and Limited State Telemedicine Registrations

- Three types of Special Registrations for Telemedicine are now proposed, including: (1) a Telemedicine Prescribing Registration, authorizing qualified clinician practitioners to prescribe Schedule III-V controlled substances via telemedicine; (2) an Advanced Telemedicine Prescribing Registration, authorizing qualified, specialized clinician practitioners (e.g., psychiatrists, hospice care physicians) to prescribe Schedule II-V controlled substances via telemedicine; and (3) a Telemedicine Platform Registration, authorizing covered online telemedicine platforms, in their capacity as platform practitioners, to dispense Schedule II-V controlled substances.
- The proposed rule sets forth particular restrictions, requirements and processes for provider registration, physical location of the prescribing practitioner, PDMP checks, use of audio and visual technology and heightened record-keeping requirements (such as particular requirements related to patient identification).
- The proposed rule, if implemented, represents a significant departure from the current DEA waiver. It will therefore be critical for those health care providers and entities utilizing telemedicine to fully appreciate and plan for the implementation of these rules (once finalized).

For more information regarding the DEA and HHS proposed rules or other considerations related to telehealth prescriptions, please contact:

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