BOCHNER PLLC
1040 Avenue of the Americas, 15TH Floor, New York, NY 10018
o 646.971.0685 e law@bochner.law w bochner.law

DEA Announces Three New Rules for Telemed Practitioners

Quick Tips and Need to Know

- The Covid-19 protocols for the Ryan Haight Act will remain in effect through December 31, 2025
- To date, legislators have promulgated three extensions to the Covid -19 Ryan Haight Act temporary rule.
- Legislators have proposed a new rule which would allow practitioners with a Special Registration to prescribe Schedule III-V controlled substances and, under specific conditions, Schedule II substances via telemedicine.

On January 16, 2025, the Drug Enforcement Administration (DEA) announced three new rules to "make permanent some temporary telemedicine flexibilities established during the COVID-19 public health emergency while also establishing new patient protections." The publication of these rules follows after years of debate regarding tele prescribing protocols in a post-pandemic world.

For context, how Providers tele-prescribe controlled substances is regulated under the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (the "Ryan Haight Act"). Presently, the Ryan Haight Act allows practitioners to prescribe controlled medications to patients only after the practitioner has conducted an in-person evaluation of the patient. During the Covid-19 public health emergency, the DEA, in collaboration with HHS, adopted exceptions to the condition that Practitioners first meet the patient in person prior to prescribing a controlled substance allowing practitioners to use telehealth modalities when prescribing controlled medications without first evaluating the patient in person. *See generally* Federal Register :: Second Temporary Extension of COVID-19 Telemedicine Flexibilities for Prescription of Controlled Medications.

These rules have remained in effect as legislators struggle to finalize amendments to the Act. *See* our most recent Client Alert on the third temporary extension of the Covid-19 Telemedicine flexibilities for tele prescribing.

Current State of Affairs

The DEA's newly proposed rules would "establish special registrations that will permit a patient to receive prescribed medications through telemedicine visits without ever having an in-person medical evaluation from a medical provider." DEA Announces Three New Telemedicine Rules that Continue to Open Access to Telehealth Treatment while Protecting Patients. The DEA notes that the "Special Registration" would be available to providers who treat patients for whom they will prescribe Schedule III-V controlled substances.

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Special Registrations

Categories and Eligibility

The proposed rule establishes the following categories of Special Registrations and eligibility requirements:

- **Telemedicine Prescribing Registration:** This registration would allow clinician practitioners to prescribe Schedule III-V controlled substances. Clinician practitioners would need to demonstrate a legitimate need for the registration. Physicians, nurse practitioners, physicians, and other mid-level practitioners defined under 21 C.F.R. § 1300.01 ("mid-level practitioners") would have a legitimate need to prescribe Schedule III-V controlled substances if they expect to treat patients for whom in-person exams would be burdensome. Examples include patients who experience severe weather conditions, live in remote or distant areas, or have communicable diseases.
- **Advanced Telemedicine Prescribing Registration:** This registration would allow certain specialized clinician practitioners to prescribe Schedule II-V controlled substances. Specialized clinician practitioners would need to demonstrate a legitimate need for the registration and justify the additional authorization to prescribe Schedule II medications. These practitioners would need to provide information demonstrating their specialized training on their Special Registration application. Specialized physicians and board-certified mid-level practitioners would have a legitimate need to prescribe Schedule II-V controlled substances when treating vulnerable patient populations. This includes individuals who face significant barriers to accessing care and who suffer from debilitating or terminal illnesses. Only specialized physicians and board-certified mid-level practitioners in the following limited circumstances or practice specialties are eligible: Psychiatrists; Hospice care physicians; Palliative care physicians; Practitioners rendering treatment at long-term care facilities; Pediatricians; Neurologists; and 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.
- **Telemedicine Platform Registration:** This registration would allow covered online telemedicine platforms to dispense Schedule II-V controlled substances through a clinician practitioner who holds a Telemedicine Prescribing Registration or Advanced Telemedicine Prescribing Registration (*i.e.*, a platform practitioner). Covered online telemedicine platforms would need to demonstrate a legitimate need for the registration. Covered online telemedicine platforms, in their capacity as platform practitioners, would have a legitimate need to dispense Schedule II-V controlled substances when they: Expect to provide necessary services that connect patients with clinician practitioners via telemedicine for the diagnosis, treatment, and prescription of controlled substances; Comply with federal and state regulations; Oversee the clinician practitioner's prescribing practices; and Implement safeguards to prioritize patient safety and prevent diversion, abuse, or

misuse of controlled substances. Platform practitioners would need to attest to their legitimate need on their Special Registration application.

Notably, the proposed rule introduces several new definitions, some of which include:

- **Clinician practitioner** — an individual practitioner who provides direct patient care or assesses, diagnoses, or treats medical conditions.
- **Platform practitioner** — 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. Sections 801-904, and its regulations.
- **Covered online telemedicine platform** — 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: The entity explicitly promotes or advertises the prescribing of controlled substances through the platform; 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; 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 The entity has control or custody of the prescriptions or medical records of patients who are prescribed controlled substances through the platform.

Impact on YOU

IS THIS RULE IN EFFECT?

No. This is a proposed rule for which the DEA will be seeking public comments through March 18, 2025. The DEA has specifically noted that the agency will request comments on additional medical specialists that should be authorized under the new rule to prescribe Schedule II medications. Providers should continue to adhere to the Covid-19 exceptions to the Ryan Haight Act when tele prescribing controlled substances.

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WHAT IS GOING TO BE ALLOWED UNDER THE NEW RULE?

Use of Telehealth Modality
Practitioners would be allowed to prescribe Schedule III-V controlled substances approved by the U.S. Food and Drug Administration for treating opioid use disorder (currently limited to buprenorphine) via audio-only telemedicine visits. (For more details, see our discussion on the DEA's final buprenorphine rule.)
Audio-only visits would be permitted only if the practitioner has the capability to conduct audio-video visits, but the patient is either unable to use video technology or declines to consent to its use. However, unlike the final buprenorphine rule, initiating treatment would require an audio-video visit, and the practitioner must have completed at least one medical examination of the patient via audio-video.
Prescriptions that do not meet these criteria could only be issued through audio-video visits.

Tele prescribing of Schedule II Controlled Substances if in same state
Practitioners would be allowed to prescribe Schedule II controlled substances via telemedicine only if they are ***physically present*** in the same state as the patient during the encounter when the prescription is issued. Furthermore, the monthly average of Schedule II prescriptions issued via telemedicine must account for less than 50% of the practitioner's total Schedule II prescriptions, including both telemedicine and in-person prescriptions.

WILL THERE BE NEW REGULATORY PROTOCOLS?

PDMP Check
Effective immediately, if the proposed rule is finalized, practitioners with a Special Registration would be required to review the patient's-controlled substance prescription data in Prescription Drug Monitoring Programs (PDMPs) of certain jurisdictions before issuing a prescription for controlled substances via telemedicine. The practitioner would need to review the PDMPs for any controlled substance prescriptions issued to the patient within the last year, or, if less than a year is available, for the entire available period.

For more information on how the DEA's new rules on tele prescription of controlled substances may affect you and your business, please contact Matthew Shatzkes at matthew@bochner.law or Chase Howard at choward@bochner.law.