DEA Issues Telemedicine Prescribing Rules

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On January 15, 2025, the Drug Enforcement Administration (DEA) issued a series of telemedicine prescribing rules, including a Notice of Proposed Rulemaking (NPRM), Special Registrations for Telemedicine and Limited State Telemedicine Registrations, Continuity of Care via Telemedicine for Veterans Affairs Patients final rule, and the Expansion of Buprenorphine Treatment via Telemedicine Encounter final rule.

This NPRM aims to expand patient access to controlled substances through telemedicine, while balancing the need to prevent misuse and diversion. Through this NPRM, the DEA seeks to modernize regulations, provide continuity for telemedicine-based care following the COVID-19 public health emergency (PHE), and align regulations with statutory

requirements under federal law. This NPRM proposes requirements for registration, heightened prescription standards, recordkeeping, and state-level compliance, aiming to create a robust structure that supports the safe expansion of telemedicine.

As background, the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (Ryan Haight Act) amended the Controlled Substances Act (CSA) to generally mandate that dispensing controlled medications via the internet requires a valid prescription, which includes at least one in-person medical evaluation. However, the law created seven telemedicine exceptions that allow a practitioner to prescribe controlled substances to a patient without an in-person evaluation as long as the practice complies with applicable federal and state laws and meets other specific requirements. These exceptions include:[1]

1. a patient is physically located at a DEA-registered hospital or clinics, and the remote prescribing practitioner is DEA-registered in the state in which the patient is located,
2. a patient is being treated by a prescribing practitioner, and in the physical presence of a DEA-registered practitioner in the state in which the patient is located,
3. the prescribing practitioner is an employee or contractor of the Indian Health Service (IHS), acting within the scope of the practitioner's employment, who has been designated an Internet Eligible Controlled Substances Provider by the U.S. Department of Health and Human Services (HHS),
4. it takes place during a public health emergency declared by HHS under section 247d of title 42;
5. the practitioner has obtained a Special Registration with DEA,
6. there is a medical emergency that prevents the patient from being in the physical presence of an employee or contractor of the Veterans Health Administration (VHA) and one of its hospitals or clinics, and immediate intervention by the practitioner using controlled substances is required to prevent injury or death, and

7. any other circumstances that DEA and HHS have jointly determined to be consistent with effective controls against diversion and otherwise consistent with the public health and safety.

Notably, the Ryan Haight Act does not apply to practitioners who have performed a prior in-person medical evaluation of a patient.



In response to the COVID-19 PHE, the DEA granted temporary flexibilities to the Ryan Haight Act to prevent lapses in care by permitting in certain instances the prescribing of controlled medications via telemedicine encounters even when there had been no in-person prior medical evaluation. On November 15, 2024, HHS and the DEA jointly issued a rule, titled 'Third Temporary Extension of COVID-19 Telemedicine Flexibilities for Prescription of Controlled Medications' that extends the telemedicine flexibilities that have been in effect since March 2020 for the prescribing of controlled medications **through December 31, 2025.** See our prior Alliance Daily[PH1] article covering the Third Temporary Extension.

This NPRM would introduce a new framework under the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 to regulate telemedicine prescribing of controlled substances. If finalized, this regulatory framework would include three separate Special Registrations that providers must apply for to prescribe controlled substances without an in-person medical evaluation.

Telemedicine Prescribing Registration: This registration would permit qualified clinician practitioners to prescribe Schedule III-V controlled substances via telemedicine. Under this

registration, clinician practitioners must demonstrate they have a legitimate need for a Special Registration, where in-person visits could impose significant burdens on patient-practitioner relationships, such as when a patient would experience significant challenges in attending an in-person visit due to sever weather, living in a remote area, or having a communicable disease.

Advanced Telemedicine Prescribing Registration: This registration would permit qualified, specialized clinician practitioners (e.g., psychiatrists, hospice care and palliative care physicians) to prescribe Schedule II-V controlled substances via telemedicine. In addition to satisfying the above, practitioners must demonstrate a legitimate need to prescribe Schedule II controlled substances via telemedicine when treating vulnerable patient populations. In consideration of the high potential abuse for Schedule II controlled substances, the DEA indicates that only certain physicians and practitioners qualify for this registration:

- psychiatrists;
- hospice care physicians;
- palliative care physicians;
- physicians rendering treatment at long term care facilities;
- pediatricians;[2]
- neurologists; and
- mid-level practitioners[3] (which must be board-certified) 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.

As proposed, the DEA would incorporate CMS's current hospice and palliative care definitions and standards. This NPRM would also require clinician practitioners applying for the Advanced Telemedicine Prescribing Registration to disclose their practice

specialties, which the DEA intends to use to detect and prevent diversion.

For this determination, the DEA considered feedback from stakeholders and listening sessions that highlighted the unique challenges faced by vulnerable patient population which necessitate increased flexibility. In 2023, the Alliance met with the White House Office of Management and Budget and the DEA emphasizing the challenges faced by patients suffering from serious and life-limiting illness.

Telemedicine Platform Registration: This registration would permit covered online telemedicine platforms, in their capacity as platform practitioners, to dispense Schedule II-V controlled substances. To be eligible for this registration, a covered online telemedicine platform under proposed § 1301.11(c)(4) must demonstrate a legitimate need to dispense Schedules II through V controlled substances to facilitate connections between patients and clinicians for telemedicine services, provided they comply with federal and state regulations, oversee prescribing practices, prioritize patient safety, and prevent misuse, and attest to this need in their special registration application.

Under the proposed regulation at § 1301.11(c)(1)(A)), applicants for any of the three types of Special Registration must hold at least one DEA registration to prescribe (for clinician practitioners) or dispense (for platform practitioners) controlled substances in the state where they are licensed or authorized to do so through telemedicine, unless otherwise exempted. In addition, the DEA would 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.

To streamline the application process for Special Registrations, the NPRM introduces **Form 224S**, a new registration application form, through which special registration applicants would apply for one of the three registration types. For any of the three types of Special Registration, the NPRM proposes a three-year cycle for Special Registrations, with a tiered fee structure. As proposed, the registration fee for any Special Registration type, including the Platform Practitioner State Telemedicine Registration, would be $888. The DEA proposes to discount this fee for the Clinician Practitioner State Telemedicine Registration to $50 for each state in which registration is sought.

This NPRM would also require clinician special registrants to review nationwide Prescription Drug Monitoring Programs (PDMP) three years from the date the final rule becomes effective.

Proposals under the NPRM would not apply to the practice of telemedicine authorized under the Expansion of Buprenorphine Treatment via Telemedicine Encounter final rule or the Continuity of Care via Telemedicine for Veterans Affairs Patients final rule, both similarly released by the DEA on the Federal Register Public Inspection desk on January 15. These final rules permit certain prescribing practitioners to prescribe controlled medications by telemedicine, without a prior in-person evaluation or fulfilling Special Registration requirements proposed in the NPRM.

The DEA's final rule, Expansion of Buprenorphine Treatment via Telemedicine Encounter, enables practitioners to prescribe a six-month supply of Schedule III-V medications through audio-only telemedicine without a prior in-person evaluation. Additional prescriptions can be issued after a two-way audio-visual telemedicine encounter or an in-person visit, with a requirement for providers to review the state PDMP. The final rule, Continuity of Care via Telemedicine for Veterans Affairs Patients, would enable Department of Veterans Affairs (VA)

practitioners to prescribe controlled substances via telemedicine without a prior in-person medical evaluation, to the extent permitted within their scope of practice and VA employment.

While the intent to safeguard against diversion is clear in the NPRM, the Alliance is investigating the practical implications of these proposals and their potential to create barriers for patients served by providers and practitioners in the home. If you have feedback or questions, please reach out to regulatory@allianceforcareathome.org.

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[1] See page 12 of the unpublished rule.

[2] The NPRM would also require a child's parent or guardian to be present in the room when the patient is issued a prescription for a Schedule II controlled substance.

[3] Mid-level practitioner is defined at 21 CFR 1300.0. This includes "individual practitioner, other than a physician, dentist, veterinarian, or podiatrist, who is licensed, registered, or otherwise permitted by the United States or the jurisdiction in which he/she practices, to dispense a controlled substance in the course of professional practice. Examples of mid-level practitioners include, but are not limited to, health care providers such as nurse practitioners, nurse midwives, nurse anesthetists, clinical nurse specialists and physician assistants who are authorized to dispense controlled substances by the State in which they practice."

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