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At Long Last, DEA's Remote Prescribing Rules 2.0 Are (Really) Here! (Pending Further Consideration by the Incoming Administration . . .)

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Remote prescribing via telemedicine continues to be a huge area of interest among prescribers and other health care providers.

After publishing a Notice of Proposed Rulemaking ("NPRM") in March 2023 on the prescribing of controlled substances via telemedicine that was widely criticized for being far more restrictive than temporary waivers then in place under the COVID-19 public health emergency, the Drug Enforcement Administration ("DEA") went back to the drawing board.

Additional time and a new year has brought renewed focus. Published January 17 in the Federal Register as one NPRM and two final rules (collectively referred to herein as the "DEA's 2025 Rules"), the DEA's 2025 Rules seek, as DEA indicates in its press release, to "focus[] on the patient to ensure telemedicine is accessible for medical care."

Background

The Ryan Haight Online Pharmacy Consumer Protection Act of 2008 ("Ryan Haight Act") amended the federal Controlled Substances Act ("CSA") to generally mandate that dispensing controlled substances via the Internet requires a valid prescription, which includes at least one (1) in-person medical evaluation. In conjunction with establishing this general rule, however, the Ryan Haight Act 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 apply when:

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, 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. the prescribing activity takes place during a public health emergency ("PHE") 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 and one of its hospitals or clinics, and immediate intervention by the practitioner using controlled substances is required to prevent injury or death; or
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.

In Epstein Becker Green's podcast, "The DEA Is Knocking at Your Door…Are You Prepared," we explained that before the COVID-19 PHE, telemedicine prescribers were required to have at least one in-person visit with a patient before prescribing a controlled substance, with limited exceptions. In response to the PHE, the DEA granted temporary flexibilities to the Ryan Haight Act in an effort to prevent lapses in patient care and which permitted, in certain instances, the prescribing of controlled substances via telemedicine even when there had not been any prior in-person medical evaluation.

The March 2023 NPRM, "Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Visit" ("2023 Proposed Rule"), received a record number of comments—more than 38,000—causing the agency to reconsider its positions (see our previous post on the 2023 Proposed Rule).

In May 2023, DEA temporarily extended the telemedicine flexibilities issued during the COVID-19 pandemic while sifting through the comments, and in September 2023 hosted public listening sessions to hear publicly from stakeholders. In October 2023, DEA and HHS jointly issued a second temporary extension of these flexibilities through the end of 2024.

More recently, in November 2024, DEA and HHS once again jointly issued a third temporary extension of these flexibilities through the end of 2025. DEA stated in the November 2024 temporary rule that "[t]his additional time will allow DEA (and also HHS, for rules that must be issued jointly) to promulgate proposed and final regulations that are consistent with public health and safety, and that also effectively mitigate the risk of possible diversion."

In the latest rulemaking, DEA and HHS released the following guidance:

- Proposed Rule Regarding Special Registration for Telemedicine Providers and Companies
- Final Rule Regarding Access to Buprenorphine Treatment Via Telemedicine
- Final Rule Regarding Veterans' Access to Controlled Substances Via Telemedicine

DEA's 2025 Rules

In DEA's 2025 Rules, the agency is proposing the following:

DEA Proposed Rule Regarding Special Registration for Telemedicine Providers and Companies

DEA is proposing, in a Notice of Proposed Rulemaking, to establish a Special Registration process that will permit patients to receive prescribed controlled substance medications via telemedicine encounters without requiring the prescribing provider to conduct an in-person medical evaluation (the "Special Registration Proposed Rule"). The Special Registration Proposed Rule aims to expand patient access to controlled substances through telemedicine, while balancing the need to prevent misuse and diversion. Through the Special Registration Proposed Rule, the DEA seeks to modernize regulations, provide continuity for telemedicine-based care following the COVID-19 PHE, and align regulations with statutory requirements under federal law. The Special Registration Proposed Rule would implement requirements for registration, heightened prescription standards, recordkeeping, and state-level compliance, aiming to create a robust structure that supports the safe expansion of telemedicine. However, the Special Registration requirements would not apply to the practice of telemedicine authorized under the Ryan Haight Act, including buprenorphine treatment via telemedicine encounter and continuity of care via telemedicine for Veterans Affairs patient, as addressed by the new final rules discussed in further detail below.

In the Special Registration Proposed Rule, DEA has outlined not one, but three separate types of registrations that would be available:

1. A Telemedicine Prescribing Registration, which would be available to health care providers who, as part of their treatment plans for patients, need the ability to prescribe Schedule III through V controlled substances;
2. An Advanced Telemedicine Prescribing Registration, available for certain health care providers who are board certified in specific specialties, including psychiatry, and who need the ability to prescribe Schedule II controlled substances;
3. A Telemedicine Platform Registration, which would establish a new requirement applicable to telemedicine companies—specifically, the online platforms that facilitate connections between patients and health care providers that may result in the prescribing of these medications.

The different types of Special Registrations would make it possible for health care providers with prescribing authority—both physicians and non-physician practitioners—and the telemedicine companies that support the industry's infrastructure to apply for one or more of these registrations in order to prescribe controlled substances via telemedicine without the need for an in-person evaluation of the patient.

As part of the Special Registration Proposed Rule, the DEA also would require the creation of a national prescription drug management program ("PDMP") to provide greater visibility into a patient's prescribed medication history for both prescribing providers and pharmacists. Regardless of the type of registration a provider or telemedicine company holds, the DEA would be establishing the added requirement of the provider or company needing to verify "the identity of the patient and [completing] a nationwide [PDMP] check of all 50 states and any U.S. district or territory that maintains its own PDMP."[1]

Other highlights in the Special Registration Proposed Rule include:

- Requiring, for prescriptions of Schedule II controlled substances: (a) that special registrants be physically located in the same state as the patient when prescribing the Schedule II medication via telemedicine; and (b) that telemedicine prescriptions of Schedule II controlled substances must, on average, make up "less than 50 percent of the total number of Schedule II prescriptions issued by the clinician special registrant in their telemedicine and non-telemedicine practice in a calendar month."[2]
- Requiring, with certain but limited exceptions, that special registrants use audio and video capabilities when prescribing controlled substances via telemedicine, regardless of whether the provider-patient encounter is an initial or follow-up visit.[3]
- Requiring, during any initial visits between a special registrant and a patient, that a photo of the patient presenting federal or state identification is captured, as a means for confirming the patient's identity.[4]
- Requiring special registrants to maintain a State Telemedicine Registration for every state in which a patient is treated by the special registrant, subject to limited exceptions (*g.,* the special registrant is an officer of the U.S. Armed Forces, the Public Health Service, or the Bureau of Prisons authorized to prescribe, or an employee or contractor of the U.S. Department of Veterans Affairs). The State Telemedicine Registration would be issued by the DEA, not the states, and function as an ancillary credential, contingent on the type of special registration held by the special registrant, and the special registrant's authorization under state laws and rules to prescribe controlled substances within that state.[5]

The DEA has requested public comments on the Special Registration Proposed Rule, due no later than March 16, 2025.

Final Rule Regarding Access to Buprenorphine Treatment Via Telemedicine

Under this DEA and HHS final rule, effective February 18, 2025, the Departments are expanding access to buprenorphine treatment via telemedicine encounters (the "Buprenorphine Telemedicine Prescribing Final Rule").

As background, during the COVID-19 PHE, when the DEA issued a waiver to temporarily loosen many of the restrictions on telemedicine prescribing controlled substances, the use of telemedicine prescribing for buprenorphine expanded dramatically as a means of treatment for patients with opioid use disorder ("OUD").

The Buprenorphine Telemedicine Prescribing Final Rule diverges significantly from the 2023 Proposed Rule and codifies and extends many of the telemedicine flexibilities allowed during the pandemic with respect to treatment of patients with OUD. This will not only ensure continuity of care for patients who initiated buprenorphine treatment via telemedicine during the PHE, but also will allow new patients to access the same treatment without requiring an initial in-person visit.

Under the Buprenorphine Telemedicine Prescribing Final Rule, health care providers may prescribe buprenorphine for the treatment of OUD via a telemedicine encounter, including an audio-only telemedicine encounter, for up to six (6) months. To continue a patient's treatment beyond six (6) months, the patient either can obtain an in-person medical evaluation or pursue other forms of telemedicine that are authorized under the Controlled Substances Act. Thus, this final rule permits patients to continue to receive telemedicine prescriptions for buprenorphine without ever receiving an in-person visit, as long as the patient visits conform to existing requirements for telemedicine modalities including audio-visual telemedicine, asynchronous telemedicine (store-and-forward), or remote patient monitoring.

Key requirements for providers to prescribe under the Buprenorphine Telemedicine Prescribing Final Rule include that the provider must be registered by the DEA to prescribe controlled substances, and the provider must review the patient's prescription drug monitoring program data for the state in which the patient is located during the telemedicine visit. The Buprenorphine Telemedicine Prescribing Final Rule also adds a new requirement not included in the proposed rule that the dispensing pharmacist must verify the patient's identity prior to filling the prescription.

In response to public comments DEA and HHS received regarding the 2023 Proposed Rule, the Buprenorphine Telemedicine Prescribing Final Rule significantly reduces or eliminates several of the barriers under the proposed rule that were most heavily criticized. In particular:

- 30-Day Supply: The 2023 Proposed Rule would have allowed only a thirty (30) day supply of buprenorphine to be prescribed via telemedicine before an in-person encounter would need to take place. Public comments to the 2023 DEA Proposed Rule argued that this short window vitiated the purpose of the statutory exception and was insufficient to meaningfully increase access to OUD treatment.
- In-Person Assessment to Continue Treatment: The 2023 Proposed Rule would have required patients to obtain an in-person assessment at the end of the initial prescribing period in order to continue treatment. This requirement meant that access would not have materially improved for the large number of people in rural and underserved areas or who otherwise face barriers to accessing in-person treatment.
- Recordkeeping: The 2023 Proposed Rule would have required providers to comply with a variety of record-keeping requirements, including maintaining a record of whether the encounter was conducted via audio-visual or audio-only means, why the patient chose an audio-only telemedicine encounter, and maintaining copies of all qualifying telemedicine referrals. These requirements would have increased the administrative burden of offering telemedicine services.

The Buprenorphine Telemedicine Prescribing Final Rule dramatically expands access to those who are seeking OUD treatment, allowing these patients to participate in a sustained program of treatment with buprenorphine by extending the prescribing period to six (6) months, allowing patients who initiate treatment via audio-only telemedicine to continue treatment via other forms of telemedicine without an in-person assessment, and eliminating some of the burdensome recordkeeping requirements.

DEA Final Rule Regarding Veterans' Access to Controlled Substances Via Telemedicine

Under this DEA and HHS final rule, entitled "Continuity of Care via Telemedicine for Veterans Affairs Patients," the Departments finalized parts of the 2023 Proposed Rule that specifically pertain to U.S. Department of Veterans Affairs ("VA") practitioners and the VA patients they serve (the "VA Telemedicine Prescribing Final Rule"). This rule becomes effective February 18, 2025.

The VA Telemedicine Prescribing Final Rule will allow VA practitioners acting within the scope of their VA employment and professional practice to prescribe controlled substances via telemedicine to VA patients with whom they have not conducted an in-person medical evaluation, provided that another VA practitioner has previously conducted an in-person medical evaluation with the same patient. Practically speaking, this means that once a VA patient has received an in-person medical examination from **a** VA practitioner, the ongoing practitioner-patient relationship—including the ability to prescribe controlled substances—can be extended to **all** VA practitioners who engage with that patient via telemedicine.

The VA Telemedicine Prescribing Final Rule includes certain conditions that are similar to some being proposed in the Special Registration Proposed Rule. For example, VA practitioners will be required under the VA Telemedicine Prescribing Final Rule, prior to issuing a prescription via telemedicine for any Schedule II through V controlled substances, to review both the patient's electronic medical record with the VA and the PDMP data for the state in which the VA patient is located at the time of the telemedicine encounter—provided the state has such data—to confirm the history of prescriptions for controlled substances that have been issued to the patient.

DEA states in the VA Telemedicine Prescribing Final Rule that the agency's basis for creating a separate, VA-specific rule has been done in response to "the evolving landscape of the healthcare needs of VA patients, advancements in telemedicine, and DEA's capacity to implement safeguards that protect against potential misuse."[6] DEA describes its intended approach as being responsive to and possible because of the specialized health care needs of veterans and the unique structure of the VA health care system. The VA Telemedicine Prescribing Final Rule will ensure that veterans have more consistent and flexible access to care, regardless of their geographic location, while still maintaining oversight and continuity of care through the VA system.

Regulatory Freeze Pending Review

As anticipated, in connection with the transition between Administrations, President Donald Trump implemented a "regulatory freeze" by memorandum issued on January 20, 2025. The freeze applies differently depending on whether or not a rule (including a NPRM) has been published in the Federal Register – contrasted with rules not yet submitted, or rules submitted to the Office of the Federal Register, but not yet published. For rules that have been published to the Federal Register, such as the DEA's 2025 Rules, the White House requires executive departments and agencies to "consider postponing" the rule's effective date until at least March 21, 2025 (sixty (60) days from the issuance of the memorandum), to allow review of any questions of fact, law, and/or policy raised by the rule, and to "consider opening" a comment period for stakeholders to comment on those questions. Executive agencies are also directed to "consider reevaluating" pending petitions involving such rules, which may result in effective dates being further delayed beyond the 60-day period.

As directly applicable here, the two final rules, as published in the Federal Register, are set to be effective February 18, 2025. The comment period for the NPRM ends March 16, 2025. What exactly happens next, and on what timeline, depends on how the DEA administrator exercises the agency's discretion to "consider postponing" the DEA's 2025 Rules. In the meantime, DEA registered prescribers can continue operating under the telemedicine prescribing flexibilities issued during COVID-19 (though December 31, 2025).

Takeaways

The DEA's 2025 Rules offer, on the one hand, clarity that many practitioners and telemedicine companies have been eagerly awaiting in the wake of the PHE. However, the DEA's 2025 Rules also suggest that the industry has its work cut out for it.

Telemedicine providers and companies should begin preparing for the potential regulatory changes that would be imposed by the Special Registration Proposed Rule. Although the rulemaking process may be delayed because of the recent regulatory freeze issued by the Trump Administration, it is never too early to begin thinking about the related operational changes and administrative oversight that may be required to obtain the applicable registration(s).

In the case of the final rules regarding buprenorphine prescribing and veterans, telemedicine providers must begin making plans for how to achieve operational compliance, though the effective date of such regulations may also be delayed.

Epstein Becker Green Attorneys Ann W. Parks and Erin Sutton contributed to the preparation of this post.

ENDNOTES

[1] 90 Fed. Reg. 6541, 6543 (Jan. 17, 2025).

[2] *Id.* at 6556.

[3] *Id.* at 6554. Note that the Expansion of Buprenorphine Treatment via Telemedicine Encounter final rule allows an exception for buprenorphine and other controlled substances used to treat opioid use disorder, discussed in more detail below.

[4] *Id.* at 6557.

[5] *Id.* at 6551.

[6] 90 Fed. Reg. 6523, 6527 (Jan. 17, 2025).

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