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FDA & Health Care and Administrative Law & Regulatory Update

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DEA Proposes New Rule to Restrict Telemedicine Prescriptions

Gibson Dunn has deep expertise related to controlled substances laws, with partners across practice groups having served in leading enforcement and regulatory government roles. We are available to help clients understand the new proposed rule and consider how to respond to it.

On January 17, 2025, the Drug Enforcement Administration (DEA) announced a new proposed rule that would provide limited pathways for telemedicine prescriptions of certain controlled substances, marking a shift away from the broad flexibilities granted during the COVID-19 public health emergency. The proposed rule comes nearly two years after the DEA first proposed a new telemedicine regime. The proposed rule would establish a special registration pathway for telemedicine prescribing and impose additional restrictions and requirements on telemedicine practitioners. The rule is likely to be of significant concern to prescribers, patients, and healthcare systems. Comments to the proposed rule, which are essential to any potential challenge to an eventual final rule, currently must be submitted to the DEA by March 18, 2025. However, President Trump announced a regulatory freeze shortly after taking office, and it is unclear how the freeze will impact the timing of the proposed rule or whether it moves forward. Unless DEA promulgates a new rule, a temporary COVID-era rule remains in effect until the end of 2025.[1]

Statutory Background. The Ryan Haight Online Pharmacy Consumer Protection Act of 2008, 21 U.S.C. § 801 *et seq.*, generally prohibits the "delivery, distribution, or dispensing of a controlled substance" via telemedicine without a valid prescription.[2] The Act requires healthcare providers in most instances to conduct an in-person examination of a patient before

issuing a controlled substance prescription via telemedicine. The Act also directed the Drug Enforcement Administration (DEA) to promulgate regulations allowing certain providers to issue telemedicine-based prescriptions if they obtained "special registrations."[3] But DEA ignored that mandate for over sixteen years, including even after Congress again instructed DEA to promulgate a rule allowing special registrations in the SUPPORT Act of 2018, 21 U.S.C.§ 301 *et seq*.

Pandemic Flexibilities and the Proposed Rule. In response to the COVID-19 public-health crisis in March 2020, DEA granted temporary exceptions to the Ryan Haight Act and its implementing regulations to facilitate access to telemedical care.[4] Those exceptions authorized providers to prescribe Schedules II–V controlled substances via telemedicine for the duration of the declared public-health emergency, even without an initial in-person visit.[5] The exceptions also allowed the interstate provision of telemedicine services, regardless of the prescribing practitioner's state of registration.[6]

In March 2023, DEA, jointly with the Department of Health and Human Services (HHS), published a proposed rule to regulate telemedicine prescriptions after the public health emergency expired.[7] The rule would have permanently allowed practitioners to prescribe certain drugs by telemedicine, but it also would have imposed more restrictive limitations, conditions, and requirements than the flexibilities in effect during the public health emergency.[8] For example, the proposed rule would have limited telemedicine prescriptions without an in-person examination to 30-day supplies of drugs and would have imposed onerous recordkeeping and other administrative requirements on providers.[9] DEA and HHS received more than 38,000 predominantly negative public comments on the proposed rule within the first 30 days after its publication.[10] In light of this public response, DEA and HHS delayed promulgating a final rule and issued three temporary rules extending the COVID-19-era policies.[11]

The New Proposed Rule. On January 17, 2025, DEA issued a new notice of proposed rulemaking to fulfill its obligations under the Ryan Haight Act.[12] The proposed rule would establish a three-part "Special Registration" framework, under which registered providers could prescribe controlled substances through telemedicine without first conducting an in-person examination. It also proposes to impose new recordkeeping, disclosures, and prescription-labeling requirements on telemedicine practitioners.

The proposed three-part Special Registration framework would operate as follows:

- (1) Telemedicine Prescribing Registration. Qualifying clinician practitioners could prescribe Schedule III – V controlled substances via telemedicine.[13] "Physicians and board-certified mid-level practitioners" would be eligible for this registration category if they could "demonstrate that they have a legitimate need" for a special registration, *e.*, they "anticipate that they will be treating patients for whom" requiring in-person examinations prior to prescribing Schedule III – V controlled substances could "impose significant burdens on *bona fide* practitioner-patient relationships."[14] Practitioners "may" qualify if they treat patients that face "significant challenges" to attending an in-person examination, such as those who live in severe weather conditions or remote areas or have communicable diseases.[15] The proposed rule includes special registration provisions for Schedule III – V drugs approved by the Food and Drug Administration to treat opioid use disorder (OUD) (currently only buprenorphine), which would allow special

registered clinicians to prescribe an initial six-month supply without an in-person appointment.[16]

- (2) Advanced Telemedicine Prescribing Registration. Qualifying clinician practitioners could prescribe Schedule II controlled substances via telemedicine, in addition to Schedules III – V, if they "demonstrate that they have a legitimate need" for a special registration *and* that they are engaged in the treatment of "particularly vulnerable patient populations," a term that the proposed rule does not define.[17] Only certain specialists, such as psychiatrists, hospice or palliative care physicians, physicians at long term care facilities, pediatricians, or neurologists, or board-certified mid-level practitioners, may qualify for an Advanced Telemedicine Prescribing Registration.[18] These special registrations would be reserved for the "most compelling use cases" to ensure that Schedule II prescribing through telemedicine is used only when necessary.[19]

- (3) Telemedicine Platform Registration. "Covered online telemedicine platforms" (essentially online pharmacies) could dispense Schedules II – V controlled substances via telemedicine if they have a "legitimate need."[20] They must attest that they "anticipate providing necessary services" to introduce or facilitate connections between patients and clinician practitioners via telemedicine for diagnosing and prescribing those substances; are compliant with state and federal regulations; can provide oversight over clinician practitioners' prescribing practices; and can take measures to "prioritize patient safety and prevent diversion, abuse, or misuse of controlled substances."[21]

In conjunction with the new special registration provisions, the proposed rule would impose many new administrative burdens on registrants. Clinician and platform special registrants, for instance, would need to apply for an ancillary State Telemedicine Registration for every state in which they intend to issue telemedicine prescriptions for controlled substances to patients.[22] Applicants also would need to fill out a Form 224, pay $888 per special registration, and renew their status every three years.[23] Clinician special registrants would need to establish and maintain patient and telemedicine prescription records at a designated "special registered location," which would serve as DEA's point of contact for telemedicine inquiries.[24] They would also need to maintain certain telemedicine encounter records for a minimum of two years from the date of each telemedicine encounter.[25] And, for each special-registration prescription clinicians issue, providers would need to run a Prescription Drug Monitoring Program check and list their special registration numbers on the prescription.[26]

Why It Matters. Healthcare providers may have serious concerns about the proposed rule's impact, if finalized, on their ability to provide quality care to patients, compared to pandemic-era flexibilities:

- The Special Registration framework's "legitimate need" requirement would significantly limit existing access to telemedicine prescriptions.
- The proposed rule would make it especially difficult for patients to receive Schedule II controlled substance prescriptions through telemedicine.
- The proposed rule would require clinicians to keep the "average number" of prescriptions they issue for Schedule II drugs through their special registration authorization at "less than 50 percent of the total number of Schedule II prescriptions" they issue in a calendar

month, through telemedicine or otherwise.[27] This would reduce providers' ability to treat first-time patients via telemedicine in emergent situations.

The proposed rule inflicts onerous new recordkeeping requirements, as discussed above.

- The proposed rule also would impose significant geographic restrictions on telemedicine prescriptions by requiring special registrants to apply for a separate State Telemedicine Registration for each state in which they seek to prescribe prescriptions to patients.
- Online telemedicine platforms would be required to maintain records, including of patients' identities and providers' medical credentials.
- Pharmacies would be required to submit monthly reports to DEA that contain aggregate data for special-registration prescriptions.

Providers should analyze the proposed rule's potential effect on their operations and consider submitting comments to DEA. Submission of comments is critical to ensuring that the DEA is able to consider relevant viewpoints in preparing any final rule and to preparing for any potential challenge to a final rule.

[1] *See* Third Temporary Extension of COVID-19 Telemedicine Flexibilities for Prescription of Controlled Medications, 89 Fed. Reg. 91,253, https://tinyurl.com/y93su2bt.

[2] *Id.* § 309, 122 Stat. 4820, 4820 (21 U.S.C. § 829(e)); https://www.congress.gov/bill/110th-congress/house-bill/6353.

[3] 21 U.S.C. § 831(h).

[4] DEA, Dear Registrant (Mar. 25, 2020), https://tinyurl.com/vxv2xwae; DEA, Dear Registration (Mar. 31, 2020), https://tinyurl.com/475wr3n9.

[5] *Id.*

[6] DEA, Dear Registrant (Mar. 25, 2020), https://tinyurl.com/vxv2xwae.

[7] Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation, 88 Fed. Reg. 12,875 (Mar. 1, 2023) (to be codified at 21 CFR pts. 1300, 1304, 1306).

[8] *See generally id.*

[9] *Id.* at 12,882.

[10] Temporary Extension of COVID-19 Telemedicine Flexibilities for Prescription of Controlled Medications, 88 Fed. Reg. 30,037, 30,037 (May 10, 2023) (codified at 21 CFR pt. 1307) (effective through November 11, 2024).

[11] See Temporary Extension of COVID-19 Telemedicine Flexibilities for Prescription of Controlled Medications, 88 Fed. Reg. 30037 (November 19, 2024) (codified at 42 CFR pt. 1307) (effective through December 31, 2025).

[12] Special Registrations for Telemedicine and Limited State Telemedicine Registrations, 90 Fed. Reg. 6541 (Jan. 17, 2025) (to be codified at 21 CFR pts. 1300, 1301, 1304, 1306).

[13] *Id.* at 6549.

[14] *Id.*

[15] *Id.*

[16] *Id.* at 6555. Separately, DEA and HHS announced a final rule that allows patients to receive an initial six-month supply of buprenorphine, the only Schedule III-V narcotic drug FDA has approved to treat opioid-use disorder, following a phone or video call with a healthcare provider. After the initial six-month supply, practitioners can prescribe buprenorphine via other forms of telemedicine or an in-person visit.

[17] *Id.*

[18] *Id.* at 6549–50.

[19] *Id.* at 6549.

[20] *Id.* at 6550.

[21] *Id.*

[22] *Id.* at 6550–52.

[23] For platform special registrants, the fee is $888 per special registration and for each state in which a State Telemedicine Registration is sought. Clinician special registrants must only pay the $888 special registration fee and $50 for each state in which they seek a State Telemedicine Registration. *Id.*

[24] *Id.* at 6552.

[25] *Id.* at 6558.

[26] *Id.* at 6554, 6557.

[27] *Id.* at 6556.

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Gibson Dunn's lawyers are available to assist in addressing any questions you may have regarding these developments. Please contact the Gibson Dunn lawyer with whom you usually work, any member of the firm's FDA and Health Care or Administrative Law and Regulatory practice groups, or the following practice leaders and authors:

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