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Client Alert

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DEA Proposes New Rules for Telemedicine Prescriptions

Would Require In-Person Examination In Many Prescribing Scenarios

Almost fifteen years ago, Congress amended the Controlled Substances Act (CSA) to reduce illegitimate, Internet-based access to controlled drugs while, at the same time, acknowledging the legitimacy of healthcare via telemedicine.[1] This week, the Drug Enforcement Administration (DEA) published two proposed rules that would expressly authorize telemedicine prescribing of medications that are controlled substances, but only in circumstances that generally require at least one in-person patient visit with very limited exceptions.[2] While providing more flexibility than pre-pandemic, the rules will likely increase patient and health system burden and could create confusion about how lawfully to prescribe medications that are controlled substances.

Comments on the proposed rules may be submitted to DEA through **March 31, 2023**. Patients, prescribers, dispensers, and controlled substance manufacturers and distributors alike should consider both the health and safety impacts of the proposed rules, as well as practical compliance challenges that may be of concern.

Proposed Rules Governing "Telemedicine Prescriptions"

The CSA generally requires that prescriptions issued by means of the Internet be predicated on a practitioner's in-person evaluation of the patient.[3] However, there are several qualifications to this requirement that allow practitioners to issue prescriptions without an in-person evaluation, including treatment during a public health emergency or other circumstances specified by regulation.[4]

In March 2020, after the Secretary of Health and Human Services (Secretary) declared a public health emergency due to the coronavirus pandemic, the Secretary and the Acting DEA Administrator confirmed that the exception for public health emergencies would apply to all Schedule II-V controlled substance prescriptions. DEA guidance clarified

that practitioners are required to evaluate patients using real-time, two-way audio-visual communications and reiterated that such prescriptions must be issued for legitimate medical purposes.[5]

Now anticipating the end of the public health emergency in May 2023, DEA's proposed rules would continue to allow some prescriptions to be issued via telemedicine without an in-person evaluation. Specifically, under the proposed rules, practitioners could prescribe the following controlled substances via telemedicine, without an in-person evaluation:

- an initial 30-day supply of Schedule III, IV, or V non-narcotic controlled medications, and
- buprenorphine if for the treatment of opioid use disorder.

Prescriptions under this exception would be called "telemedicine prescriptions," subject to documentation and other requirements. Practitioners who have conducted an in-person evaluation of a patient or are prescribing medications to patients referred by another practitioner who conducted an in-person exam (i.e., a "qualifying telemedicine referral") may prescribe Schedule II-V controlled substances via telemedicine, including narcotics, without relying on the proposed exception.[6] DEA's summary of the proposed rules is attached at the end of this Client Alert.

While the proposed rules maintain some of the flexibility that was permitted during the coronavirus pandemic, there are notable restrictions. Patients requiring Schedule II medications or Schedule III-V narcotic drug products must be evaluated by a practitioner in person before the practitioner can prescribe such medications. In addition, practitioners who established "telemedicine relationships" during the coronavirus pandemic must now conduct in-person evaluations of those patients within 180 days of publication of the final rule in order to continue prescribing controlled medications to those patients.

The proposed rules require practitioners to have DEA registrations in both the state where the patient is located and the state where the practitioner is located.

The proposed rules also create new recordkeeping requirements for telemedicine prescriptions. Practitioners must keep detailed records of such prescriptions and any qualifying telemedicine referrals they send or receive. Any "telemedicine prescription" (defined above; does not include telemedicine prescriptions that follow an in-person examination) must include an affirmative notation indicating it was issued via a telemedicine encounter.[7]

Practical Considerations

Practitioners who issued telemedicine prescriptions during the coronavirus pandemic, or who may do so in the future, should carefully review the proposed rules and consider the changes to current practices that may be necessary. It might be useful to elucidate for DEA in comments to the proposed rules (1) the telemedicine controls already in place to identify legitimate patients who may receive controlled drug prescriptions and to avoid overprescribing or diversion risk, and (2) how patients have benefitted from access to prescription medications through telemedicine. Indeed, practitioners may be well-positioned to comment on the proposed rules' impact on patients currently being treated under the pandemic flexibilities (e.g., whether an in-person examination now should be necessary; whether a 180-day transition period is reasonable). Practitioners also may wish to comment on compliance issues such as:

- Identifying patients with whom the practitioners established a "telemedicine relationship" and notifying/coordinating with affected patients regarding the likely need for an in-person evaluation prior to future prescriptions or refills.
- Identifying patients in states where the HCP is not registered, so that such patients can make alternative arrangements before care is interrupted.

- Determining whether arrangements would be reasonably feasible for patients receiving "telemedicine prescriptions" to be examined by referring HCPs so that the telemedicine care can otherwise continue uninterrupted.
- Updating policies and procedures, as may become necessary, to ensure that telemedicine prescriptions are only issued when appropriate and such prescriptions contain the required information and are maintained at the registered location.
- Educating practitioners and other staff regarding these changes so they can adjust their practices and communicate with patients moving forward.

From a future implementation standpoint, there may be operational considerations, such as if an existing telemedicine network wanted to establish a secondary network for in-person evaluations and would need carefully to consider laws regulating self-referrals and other compliance issues.

Dispensers would need to consider issues related to the identification, interpretation, fulfillment, and maintenance of "telemedicine prescriptions" (subject to limitations), as well as other prescriptions written by telemedicine providers who have examined a patient in-person (not subject to the same limitations). DEA did not address in the proposed rules dispensers' "corresponding obligations" to ensure that prescriptions were issued for a legitimate medical purpose.

Controlled drug manufacturers and dispensers might comment on unnecessary disruptions or burdens the proposed rules will impose on patients who use their products and on HCPs who prescribe and dispense their products. Any available data showing the absence of diversion in the context of telemedicine prescribing could be useful evidence in support of a request for a less restrictive regime. Evidence of enhanced and legitimate patient access during the coronavirus pandemic also would be valuable.

Notably, despite express statutory authorization and repeated encouragement by legislators and stakeholders to enable telemedicine prescribing by legitimate healthcare practitioners, DEA has thus far declined to create a "special registration" for HCPs practicing telemedicine, stating only that "this alternative was deemed potentially burdensome for both prospective telemedicine providers and patients. Therefore, DEA decided against this alternative."[8]

King & Spalding's FDA & Life Sciences and Special Matters practices include attorneys experienced with the CSA and other federal- and state-level controlled substance laws. We have conducted internal investigations, represented registrants in government investigations, and performed compliance reviews for a variety of entities to assess the effectiveness of their policies and procedures and ensure that they comply with new and existing rules. Please contact us if we might assist with fact-specific evaluation or comments on the DEA proposed telemedicine rules.

ABOUT KING & SPALDING

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[1] *See* Ryan Haight Online Pharmacy Consumer Protection Act of 2008, Pub. L. 110-425 (Oct. 15, 2008).
[2] DEA, Notice of Proposed Rulemaking, *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) [hereinafter "*Telemedicine NPRM*"]; DEA, Notice of Proposed Rulemaking, *Expansion of Induction of Buprenorphine via Telemedicine Encounter*, 88 Fed. Reg. 12,890 (Mar. 1, 2023) [hereinafter "*Buprenorphine Telemedicine NPRM*"].
[3] 21 U.S.C. § 829(e).
[4] 21 C.F.R. § 1300.04(i)(1)-(7).
[5] DEA, *COVID-19 FAQ* (visited Feb. 27, 2023), https://www.deadiversion.usdoj.gov/faq/coronavirus_faq.htm#TELE_FAQ2. Telephone evaluations are permissible for buprenorphine prescriptions. *See Buprenorphine Telemedicine NPRM*, 88 Fed. Reg. at 12,899.
[6] *See Telemedicine NPRM*, 88 Fed. Reg. at 12,879; *Buprenorphine Telemedicine NPRM*, 88 Fed. Reg. at 12,898.
[7] *See Telemedicine NPRM*, 88 Fed. Reg. at 12,876.
[8] *Id.* at 12,883.

Proposed Telemedicine Rules Summary

Relationship between prescribing medical practitioner and patient	Prescribing a non-controlled medication	Prescribing Schedule III, IV, or V non-narcotic controlled medications	Prescribing buprenorphine as medication for opioid use disorder	Prescribing Schedule II and/or narcotic controlled medications
Prior in-person medical evaluation by prescribing medical practitioner	Permitted	Permitted	Permitted	Permitted
Referral under the proposed rules from medical practitioner who conducted prior in-person medical evaluation	Permitted	Permitted	Permitted	Permitted
Telehealth visit without: • **Prior in-person medical evaluation by prescribing medical practitioner; or** • **Referral from a medical practitioner who conducted prior in-person medical evaluation**	Permitted	• Up to 30-day initial prescription • In-person visit required for additional prescription	• Up to 30-day initial prescription • In-person visit required for additional prescription	Not permitted

- *Telemedicine prescriptions must be otherwise consistent with applicable state and federal laws.*