



SUMMARY:

Telemedicine prescribing of controlled substances when the practitioner and the patient have not had a prior in-person medical evaluation (RIN: 1117-AB40)

Drug Enforcement Administration Notice of Proposed Rulemaking

Public comments due 30 days after publication in the Federal Register (March 31, 2023)

DEA Resources:

- [Rule Text](#)
- [Highlights for Medical Practitioners](#)
- [DEA Summary Chart](#)

Proposed Rule Overview

The Ryan Haight Act of 2008 directed the DEA Administrator, in conjunction with the Secretary of Health and Human Services ("Secretary"), to promulgate rules that would allow practitioners to treat patients via telemedicine using controlled substances without having had an in-person evaluation in certain circumstances. Federal statute authorized this regulation for telemedicine in those instances where:

- 1) the prescribing practitioner has not conducted an in-person medical evaluation with the patient;
- 2) the prescription was issued pursuant to a telemedicine encounter **and**
- 3) the telemedicine encounter results in a prescription for controlled medications.

The regulatory requirements proposed in this rulemaking would only apply to practitioners who issue prescriptions pursuant to telemedicine encounters (as authorized under [802\(54\)\(0\)](#)). They would not apply to providers who have completed an in-person visit. Additionally,

- 1) such prescriptions must be in accordance with applicable Federal and State laws; and
- 2) such practitioners must possess an active DEA dispensing registration issued pursuant to [21 CFR 1301.13\(e\)\(I\)\(iv\)](#) in the State in which the practitioner is located (unless exempted).

Key Rule Takeaways

DEA is proposing to specify the circumstances under which telehealth practitioners may prescribe controlled medications in the following ways:

- Curtail any practitioner practicing telemedicine to offering a 30-day supply of a controlled substance to a patient. After 30 days, an in-person visit is required, by either that practitioner or an eligible referring practitioner.
- Allow for the prescription of non-narcotic schedule III-V controlled medications (**BUT NOT SCHEDULE II or IIN**) when other circumstances and conditions met, including use of a PDMP. (DEA notes the companion special standalone regulation to allow for the prescribing of



buprenorphine via a telemedicine encounter for "maintenance treatment" and "detoxification treatment" of opioid use disorder.)

- The only realistic path mitigating the above restrictions will be a referral from another DEA-registered medical practitioner who has conducted an in-person medical evaluation and documented a referral.
- There will be a 180-day grace period for patient-provider relationships established during the public health emergency.
- DEA will require practitioners to keep detailed records regarding prescriptions issued as a result of a telemedicine encounter at the location of their primary DEA registration (not in multiple states), in digital or paper form that is readily accessible, including a notation on the face of the prescription, or within the prescription order if prescribed electronically, that the prescription has been issued via a telemedicine encounter.

Alliance For Connected Care Commentary: We believe these restrictions as written would effectively end most patient-provider relationships established over the last three years which rely on a telehealth practitioner prescribing a controlled substance.

Section-by-Section Summary of Proposed Rule

A. DEFINITIONS

- Telemedicine: DEA recognizes updates to the regulatory definitions of telemedicine (in the 15 years since passage of the Ryan Haight Act requiring issuance of this regulation) and generally defers to updated Center for Medicare and Medicaid Services regulatory definitions for telemedicine under [42 CFR 410.78\(a\)\(3\)](#). Of particular note is the clarification that Medicare's updated requirements for audio-only telehealth would also apply for purposes of this DEA rule.
- Qualifying telemedicine referral: For the purposes of this rulemaking, "a qualifying telemedicine referral" would require the referring practitioner to have conducted at least one medical evaluation of the patient in the physical presence of the referring practitioner, without regard to whether portions of the evaluation are conducted by other practitioners.
 - This means that if multiple practitioners were physically present during the medical evaluation, they would all have the ability to issue a qualifying telemedicine referral under this section as long as they otherwise complied with DEA regulations.
 - Any other referrals, such as those predicated on a telemedicine visit exclusively, would not constitute a qualifying telemedicine referral. Both the referring practitioner and the prescribing practitioner would be required to maintain records of the referral.
(Note that while this definition does not clearly state that the referring practitioner needs to have a DEA license the proposed regulatory text under § 1306.31 does say this)
- Telemedicine prescription: Prescription issued pursuant to § 1306.31 by a physician, or a "mid-level practitioner" as defined in 21 CFR 1300.01(b). Mid-level practitioner is defined as an

individual practitioner 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.

- Telemedicine relationship established during the COVID-19 public health emergency: A relationship where the practitioner has not conducted an in-person medical evaluation of the patient and has prescribed one or more controlled medications based on telemedicine encounters during the nationwide public health emergency. The rule uses this defined term to facilitate a 180-day transition period for those patients which will be cut-off from their telehealth providers by the provisions in this rule.

B. PART 1304: RECORD OF REGISTRANTS

DEA is proposing to amend [21 CFR part 1304](#) to impose certain additional recordkeeping requirements for controlled substance prescriptions issued pursuant to telemedicine encounters

- Written or electronic logs: Proposed§ 1304.03(i) would require a practitioner to maintain a written or electronic log for each prescription issued pursuant to a telemedicine encounter indicating the date the prescription was issued; the full name and address of the patient; the drug name, strength, dosage form, quantity prescribed, and directions for use; the address at which the practitioner, and the city and State in which the patient, is located during the telemedicine encounter; if issued through a qualifying telemedicine referral, the name and National Provider Identifier ("NPI") of the referring practitioner, a copy of the referral and any communications shared pursuant to§ [1306.31\(d\)\(3\)\(i\)-\(iii\)](#) (*persons entitled to issue prescriptions*); and all efforts to comply to access the PDMP system (and, if employed by the Department of Veterans Affairs, Department of Veterans Affairs internal prescription database).
- Referral Records:
 - Proposed§ 1304.03(j) would require practitioners to maintain copies of all qualifying telemedicine referrals they issue and
 - Proposed § 1304.03(k) would set requirements for maintaining records related to medical evaluations conducted by a prescribing practitioner with the patient and another DEA practitioner physically together at the other end of an audio-video link pursuant to § 1306.31(d)(2) – Including a requirement that both practitioners participating in a medical evaluation maintain the data and time of the evaluation; the NPI of the DEA-registered healthcare worker physically present with the patient; the address at which the prescribing practitioner is located during the telemedicine encounter; and the address at which the DEA-registered healthcare worker is

physically present.

- Record Access: Proposed 1304.04(i) would require a practitioner to maintain all records at the location of the practitioner's DEA registration (under [21 CFR 1301.13\(e\)\(l\)\(iv\)](#)) in digital or paper form that is readily accessible. (DEA notes that they believe this option is far superior to the other option of requiring practitioners to maintain records in each state.)

C. PART 1306: PRESCRIPTIONS

- Documentation of telemedicine encounter: DEA proposes to require all telemedicine prescriptions issued pursuant to § 1306.31 to include on the face of the prescription, or within the prescription order if prescribed electronically, that the prescription was issued via a telemedicine encounter.
- Requirements for telehealth prescribing:
 - Legitimate medial visit: Proposed § 1306.31(a)(l) stipulates that telemedicine may only be used to issue a prescription if that prescription is issued pursuant to a telemedicine encounter and is issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice.
 - Within United States: Proposed § 1306.31(a)(2) would require all practitioners using telemedicine to prescribe controlled medications be located inside the United States.
 - Authorized by states: Proposed § 1306.31(a)(3)(i) would require that a practitioner using telemedicine to prescribe a controlled substance be authorized to prescribe that basic class of controlled substance under registrations in the State where the practitioner is located, as well as the State where the patient is located.
 - Documentation of telemedicine encounter: Proposed § 1306.31(a)(4), (like proposed § 1306.05(i) above) would require the practitioner to include on a prescription issued pursuant to a telemedicine encounter that the prescription has been issued based on a telemedicine encounter.
 - Limitation to Schedules III-V: Proposed 1306.31(c)(l)(A) would only authorize practitioners to use telemedicine to prescribe non-narcotic controlled substances in schedules III-V (*Overview of schedules attached as an appendix*).
 - The proposed rule states that Congress permitted DEA to determine the precise circumstances that were most appropriate to authorize the use of telemedicine. DEA believes that, given the ongoing opioid epidemic, allowing for the prescription of any schedule II substances or the general prescription of

- narcotic controlled substances as a result of telemedicine encounters would pose too great a risk to the public health and safety.
- DEA notes that in the case of a prescribing practitioner who has received a qualifying telemedicine referral for that patient from a referring practitioner who has conducted a medical evaluation as described in paragraph proposed § 1306.31(d)(3), the prescription may be issued for any controlled substance that they are otherwise authorized to prescribe under applicable laws and regulations.
 - 30-day Limitation: Proposed § 1306.31(c)(2) would restrict the prescribing of controlled substances as a result of a telemedicine encounter to a 30 day supply. Once the 30-day mark is reached, starting from the date of issuance of the first prescription pursuant to a telemedicine encounter, an in-person medical evaluation is required before any additional prescribing.
 - The prescribing practitioner would be permitted to issue multiple prescriptions for the patient, provided, however, that the prescriptions do not authorize the dispensing of more than a total quantity of a 30-day supply of the controlled medication.
 - To continue prescribing beyond the 30-day window, the prescribing practitioner would have to either:
 1. See the patient for an in-person medical evaluation - removing the prescription from the bounds of the Ryan Haight Act's telemedicine restrictions –
 2. Receive a medical evaluation under one of the schemes provided by DEA under this rule. Those options include:
 - Under proposed 1306.31(d)(2) the patient would not be in the physical presence of the prescribing practitioner, but the patient would have to be being treated by, and in the physical presence of, another DEA-registered practitioner. This other non-prescribing practitioner would have to be acting in the usual course of professional practice and the individuals would need to be in a real-time telemedicine conference.
 - Under proposed § 1306.31(d)(3) the prescribing practitioner could receive a qualifying telemedicine referral from an in-person DEA registered practitioner who has written a qualifying telemedicine referral to the prescribing practitioner based on the diagnosis, evaluation, or treatment that was provided for the medical issue upon which the medical evaluation was predicated.

C. DEA REQUEST FOR PUBLIC COMMENTS

- DEA is requesting comments on whether the rule should limit the issuance of prescriptions for controlled medications to the FDA-approved indications contained in the FDA-approved labeling for those medications.
- DEA invites comments on the proposed practitioner recordkeeping obligations.
- DEA seeks comment, including data from research and clinical practice, that provides evidence that an alternate maximum day supply (rather than 30 days) would be more appropriate than the one proposed in this rulemaking.
- DEA also seeks comments about additional safeguards or flexibilities that should be considered with respect to this rule.
- DEA invites comments on whether the Notice of Proposed Rulemaking, entitled "Expansion of Induction of Buprenorphine via Telemedicine Encounters" (RIN 1117- AB78 should be combined with this rulemaking when publishing the Final Rule as both documents refer to prescribing via telemedicine.

OTHER

In its supplemental materials DEA mentions three alternatives that it considered instead of the 30-day prescribing restriction and controlled substance limitations in this rule. These discussed alternatives may be useful for those wishing to understand DEA thinking and perspectives.

- an alternative only allowing the practice of telemedicine pursuant to an application and issuance of a "special registration" allowing such practice. Upon further consideration, this alternative was deemed potentially burdensome for both prospective telemedicine providers and patients.
- an alternative only allowing the practice of telemedicine pursuant to a special registration allowing such practice and limiting special registration to the prescribing of non-narcotic controlled substances to patients located in rural areas. DEA concluded that, while patients residing in rural areas have barriers to obtaining in-person medical evaluations this is true of patients in other areas as well.
- an alternative only allowing the practice of telemedicine pursuant to a special registration allowing such practice but requiring patients to be located at a qualified originating site (such as a physician office or hospital). However, upon further consideration, this alternative was deemed too restrictive, with the potential of creating a substantial burden on prospective patients.
- DEA believes the chosen option was the most permissive because it "is less restrictive and likely to benefit more patients."

Summary Chart

Status if rule finalized as written	Controlled Substance Schedules
<p>May <u>only</u> be prescribed through telemedicine with the qualifying referral of a DEA-registered provider who has seen the patient in person.</p>	<p>Schedule II/IIN Controlled Substances (2/2N) Examples of Schedule II narcotics include: hydromorphone (Dilaudid®), methadone (Dolophine®), meperidine (Demerol®), oxycodone (OxyContin®, Percocet®), and fentanyl (Sublimaze®, Duragesic®). Other Schedule II narcotics include: morphine, opium, codeine, and hydrocodone.</p> <p>Examples of Schedule IIN stimulants include: amphetamine (Dexedrine®, Adderall®), methamphetamine (Desoxyn®), and methylphenidate (Ritalin®). Other Schedule II substances include: amobarbital, glutethimide, and pentobarbital.</p>
<p>Practitioners may issue prescriptions for substances to the extent otherwise authorized by their DEA registration(s) but are limited to 30 days of a controlled substance before an in-person visit is required.</p> <p>Beyond 30 days only be prescribed through telemedicine with the qualifying referral or participation of an in-person DEA-registered provider.</p>	<p>Schedule III/IIIN Controlled Substances (3/3N) Examples of Schedule III narcotics include: products containing not more than 90 milligrams of codeine per dosage unit (Tylenol with Codeine®), and buprenorphine (Suboxone®).</p> <p>Examples of Schedule IIIN non-narcotics include: benzphetamine (Didrex®), phendimetrazine, ketamine, and anabolic steroids such as Depo®-Testosterone.</p> <p>Schedule IV Controlled Substances Examples of Schedule IV substances include: alprazolam (Xanax®), carisoprodol (Soma®), clonazepam (Klonopin®), clorazepate (Tranxene®), diazepam (Valium®), lorazepam (Ativan®), midazolam (Versed®), temazepam (Restoril®), and triazolam (Halcion®).</p> <p>Schedule V Controlled Substances Examples of Schedule V substances include: cough preparations containing not more than 200 milligrams of codeine per 100 milliliters or per 100 grams (Robitussin AC®, Phenergan with Codeine®), and ezogabine.</p>

For Reference: [Lists of Scheduling Actions, Controlled Substances, Regulated Chemicals \(PDF\)](#)