Westlaw Today
powered by Reuters

DEA proposes modest flexibilities for telehealth prescribing

By Jeremy Sherer, Esq., Hooper, Lundy & Bookman*

MARCH 20, 2023

On February 24th, 2023, the U.S. Drug Enforcement Administration (the "DEA") issued its long-awaited proposal outlining how controlled substances medications can be prescribed via telehealth after the COVID-19 public health emergency (the "PHE") terminates on May 11th, 2023 (the "Proposed Rule").

Concurrently, the DEA issued a separate, but very similar, rule addressing how buprenorphine can be prescribed via telehealth for treatment of opioid use disorder ("the "Buprenorphine Proposed Rule").

Industry stakeholders have 30 days to submit comments to the Proposed Rule and the Buprenorphine Proposed Rule. After considering those comments, DEA will issue proposed final versions of the two rules.

This alert summarizes:

(1) the new telemedicine prescribing options outlined in the Proposed Rule;

(2) the proposed 6-month "off-ramp" for practitioner-patient relationships established during the PHE pursuant to which controlled medication has been prescribed;

(3) the significant recordkeeping requirements for controlled medications outlined in the Proposed Rule;

(4) the Buprenorphine Proposed Rule; and

(5) other observations from the Proposed Rule relevant to healthcare providers utilizing telehealth technology.

New telemedicine prescribing options for controlled medication

"Telemedicine Prescription." Under the Proposed Rule, DEA-registered practitioners can issue up to a 30-day supply of schedule III-V, non-narcotic controlled medications to patients without first examining the patient in person.

To avoid diversion, the practitioners issuing "telemedicine prescriptions" will be required to check the applicable state Prescription Drug Monitoring Program, or "PDMP," database before prescribing. If the practitioner cannot access the PDMP, then only a 7-day supply of medication may be prescribed.

Telemedicine prescriptions must be issued for legitimate medical purposes and in the usual course of professional practice.

In order to prescribe additional controlled medication after that 30 day period, the patient must be examined in-person (though not necessarily by the prescribing practitioner). As always, the patient can be examined in-person, and prescribed more medication if clinically appropriate.

However, the Proposed Rule also creates two new pathways pursuant to which practitioners may prescribe controlled medication without *personally* examining the patient in person:

> **3-way consultation**. The patient, a DEA-registered practitioner physically located with the patient, and a remote prescribing practitioner participate in a 3-way, interactive audio-video consultation, during which the prescribing practitioner issues a prescription for a controlled medication.
>
> Conceptually, the prescribing practitioner is relying upon the examination performed by the practitioner located with the patient in-person when issuing the prescription for controlled medication.
>
> "**Qualifying telemedicine referral**." The patient has an in-person examination with a "referring" DEA-registered practitioner, who issues a "qualifying telemedicine referral to a "prescribing practitioner." The referral must communicate the results of the referring practitioner's examination of the patient, including at least the "diagnosis, evaluation, and treatment of the patient."

Then, after reviewing the report from the referring practitioner, the prescribing practitioner conducts a telemedicine examination of the patient, and may prescribe controlled medication if clinically appropriate.

Importantly, the Proposed Rule makes clear that the "qualifying telemedicine referral" pathway is not available unless the prescribing practitioner has received and reviewed information regarding the results of the in-person examination performed by the "referring" practitioner.

6-month off-ramp for 'telemedicine relationships established during the COVID-19 PHE'

During the COVID-19 PHE, hundreds of thousands of Americans were prescribed controlled substance medication via telehealth without first seeing the prescribing practitioner in-person, relying on temporary waivers of the Ryan Haight Act's prior in-person examination requirement.

To avoid disruptions in patient care which could result from reinstating the in-person exam requirement immediately once the PHE ends, the DEA resolved to provide a 180-day transition period before requiring the practitioner to perform an in-person examination, or a telemedicine examination under one of the pathways outlined in the Proposed Rule.

For purposes of this waiver, a "telemedicine relationship" is one which a) was established during the PHE; b) resulted in the patient being prescribed a controlled substance medication via telehealth; and c) involves a practitioner who has never conducted an in-person exam of the patient.

It remains to be seen exactly when the 180-day clock "starts ticking." The Proposed Rule calls for flexibility to remain for 180 days after the later of 1) the end of the PHE ends on May 11th (*i.e.*, November 7th, 2023) or 2) 180 days after the Proposed Rule is finalized. Said differently, if the proposed rule is finalized after May 11th, 2023, the flexibilities pertaining to telemedicine relationships established during the COVID-19 PHE will remain in place for 180 days after that "finalization date."

While the public only has 30 days to weigh in with the DEA, industry reaction thus far suggests the DEA will be buried in submissions later this month. It is possible that the final rule will not be issued before the PHE ends on May 11th, 2023, though stakeholders should assume the DEA will move as expeditiously as possible to get these rules in place.

Significant records requirements

The DEA articulates that "the remote prescribing of controlled medications through the internet to patients who have not been seen in person by the prescriber presents a heightened risk of diversion." As such, the Proposed Rule would impose significant recordkeeping and documentation requirements upon all practitioners utilizing the workflows described above.

Records for telemedicine prescriptions. Practitioners would need to maintain written or electronic logs for each telemedicine prescription detailing:

(1) The date on which the prescription was issued;

(2) The full name and address of the patient;

(3) The drug name, strength, dosage form, quantity prescribed, and directions for use;

(4) The address at which the practitioner is located during the telemedicine encounter;

(5) The city and State in which the patient is located during the telemedicine encounter;

(6) For "qualifying telemedicine referrals," the name and National Provider Identifier ("NPI") of the referring practitioner, a copy of the referral and any communications shared between the practitioners about the patient examination; and

(7) All efforts to comply with the requirement to review 12 months' information about the patient on the relevant state PDMP System.

Records for 3-way consultations. There would also be recordkeeping requirements for medical evaluations conducted using the three-way-consultation pathway described at proposed 21 CFR § 1306.31(d)(2).

For such evaluations, the "prescribing" practitioner would need to maintain records of:

(1) The date and time of the evaluation;

(2) The NPI of the DEA-registered healthcare worker physically present with the patient; and

(3) The address at which the "prescribing" practitioner and the "examining" practitioner were respectively located during the telemedicine encounter.

Records for qualifying telemedicine referrals. The Proposed Rule would require practitioners to maintain copies of all qualifying telemedicine referrals that they issue. As defined, a qualifying telemedicine referral must note the name and NPI of the practitioner to whom the patient is being referred.

Centralized records

The Controlled Substances Act as amended by the Ryan Haight Act requires practitioners to register with the DEA in their home state and any state in which they prescribe controlled substances medication to patients. While that requirement was waived for the duration of the COVID-19 PHE, there is no indication that this requirement will not retake effect when the PHE ends. The Proposed Rule would require practitioners to maintain all records involving telemedicine prescriptions, "3-Way Consultations" and qualifying telemedicine referrals at the physical address where the practitioner is registered with the DEA "in digital or paper form that is readily accessible." DEA explains that practitioners treating patients in multiple jurisdictions can retain a single set of records for all states in a centralized location.

Notably, the Proposed Rule does not specify whether the waiver of the state-specific registration requirement will also be extended 180 days.

Separate, but very similar, rule for buprenorphine

The DEA released a second rule specific to telemedicine prescriptions for buprenorphine concurrently with the Proposed Rule (the "Buprenorphine Proposed Rule").

The Buprenorphine Proposed Rule contains very similar technical requirements to those listed above, including that the initial "telemedicine prescription" can be for up to thirty days of medication, but that before prescribing additional medication, the patient must either be examined in-person, through a 3-Way Consultation, or pursuant to a qualifying telemedicine referral.

The Buprenorphine Proposed Rule makes clear that practitioners cannot prescribe buprenorphine via telemedicine in reliance upon this specific flexibility for pain or any other purpose besides treatment of opioid use disorder. There are also similar recordkeeping requirements to those outlined in the Proposed Rule.

Other observations

The Proposed Rule does not create a telemedicine registration. Congress amended the Controlled Substances Act (the "CSA") via the Ryan Haight Act in 2008.

At that time, Congress called upon the DEA to establish a registration process to enable practitioners to prescribe controlled substances via telehealth. That registration process is the fifth "practice of telemedicine" exception under the Ryan Haight Act at 21 USC § 802(54)(E); the Proposed Rule creates number seven, located at 21 USC § 802(54)(G).

The DEA's comments suggest, without explanation, the agency's belief that the proposed exception satisfies its obligation to create a registration set forth in the CSA.

It is also confusing that the DEA does so in the name of combatting diversion efforts, as the registration would surely subject providers to a more rigorous registration process before prescribing, along the lines of the now-extinct "X Waiver" for prescribing buprenorphine.

The rationale isn't entirely explained in the Proposed Rule, though it does state that this exception intends to satisfy Congressional intent to combat the opioid epidemic and cut down on diversion of narcotics (though the proposed rule excludes all schedule II drugs, including those that are neither opioids nor narcotics).

Qualifying telemedicine referral pathway not limited to Schedule III-V. The 30-day "telemedicine prescription" outlined in the Proposed Rule is only available for non-narcotic, schedule III-V controlled substance medication. However, the "qualifying telemedicine referral" process is also available for schedule II and narcotic controlled substance medication.

Audio-only communication. In the Proposed Rule, the DEA attempts to align its treatment of audio-only services with that of the Centers for Medicare & Medicaid Services, which recently revised its requirements concerning telehealth technology to require "multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner."

While most situations will require audio-video interaction (*i.e.*, a video visit), audio only communication may be sufficient to prescribe controlled substances if 4 requirements are satisfied:

(1) The treatment provided must be "furnished for purposes of diagnosis, evaluation, or treatment of a mental health disorder";

(2) The mental health treatment must be furnished to a patient located in the home;

(3) The treating practitioner is capable of using either audio-video technology or audio-only technology; and

(4) The patient is not capable of using audio-video technology, or does not consent to using audio-video technology.

In practice, this means that practitioners need to be prepared to treat patients with either audio-video or audio-only technology, but may only utilize audio-only technology at the patient's request.

Telemedicine prescription labeling requirement. Under the Proposed Rule, all prescriptions for controlled substance medication issued pursuant to the new telehealth pathways would need to "include on the face of the prescription ... that the prescription was issued via a telemedicine encounter."

No prescriptions by practitioners located abroad. DEA's commentary accompanying the Proposed Rule states, "a practitioner cannot use telemedicine to prescribe controlled medications while the practitioner is located outside the United States."

State law still applies. The CSA as amended by the Ryan Haight Act (including, if finalized in its current form, the Proposed Rule") sets a federal "floor" for controlled substances prescribing. However, every state has its own controlled substances prescribing rules, too. While the laws of many states are either less restrictive than the Ryan Haight Act or expressly state that prescribing which complies with the Ryan Haight Act is also permitted under state law, some states have laws that are stricter than the Ryan Haight Act regarding in-person examination requirements, and treatment of specific controlled medications.

No detail regarding subsequent in-person exams. The Proposed Rule does not impose requirements for examinations after an initial satisfactory examination is performed. Once that has occurred, "the proposed rule would allow a practitioner to continue prescribing a controlled medication to a patient without additional evaluations, so long as doing so was consistent with legitimate medical purposes and a subsequent evaluation was not required by law." Subsequent evaluations may, in fact, be required under applicable state law.

What's next?

Stakeholders should make every effort possible to submit their comments to the DEA this month. We will publish another update when the final rule is issued.

About the author

Jeremy Sherer is a partner in **Hooper, Lundy & Bookman**'s Boston office. He is widely recognized as a digital health thought leader and counsels health care providers and suppliers, including hospital systems, national telehealth platforms, investors and digital health startups, on issues involving regulatory compliance, transactions and innovative business arrangements. He can be reached at jsherer@hooperlundy.com. This article was originally published March 2, 2023, on the firm's website. Republished with permission.

This article was published on Westlaw Today on March 20, 2023.