Published on *The National Law Review* https://natlawreview.com

DEA Proposes Limited Post-PHE Telemedicine Prescription of Controlled Substances

Article By:

Amanda Enyeart

Marshall E. Jackson, Jr.

Lisa Schmitz Mazur

Grayson I. Dimick

Jayda Greco

On February 24, 2023, the US Drug Enforcement Administration (DEA) issued two proposed rules (the Telemedicine Controlled Substance Proposed Rule and the Telemedicine Buprenorphine Proposed Rule) that would establish additional potential pathways for the prescription of certain controlled substances in limited quantities via telehealth without an initial in-person medical examination. Currently, this practice is allowed during the COVID-19 public health emergency (PHE), which is slated to end on May 11, 2023. The DEA issued a press release, a chart on practitioner rules, frequently asked questions regarding how the proposed rules may impact practitioners and patients, a flow chart explaining the proposed rules and a handout describing whether a prescription is a controlled substance. Stakeholders have 30 days to comment after publication of the proposed rules in the *Federal Register*.

IN DEPTH

Key Takeaways

Telehealth providers would no longer be able to prescribe Schedule II controlled substances or narcotics without an in-person evaluation.

Telehealth providers would be able to prescribe a 30-day supply of Schedule III–V controlled substances or buprenorphine as medication for opioid use disorder *without* an in-person evaluation, but an in-person evaluation (further explained below) would be required for any renewal of such prescriptions.

An exception for provider-patient relationships formed via telehealth during the COVID-19 PHE would allow telehealth providers to continue prescribing Schedule II–V controlled medications through November 7, 2023. After that, an in-person evaluation would be required to continue prescribing.

An in-person evaluation may be conducted by the prescribing telehealth provider, by another DEA-registered provider who participates in a real-time audio-visual telehealth consultation with the patient and the prescribing provider, or by another DEA-registered provider who has performed an in-person evaluation of the patient and refers the patient to the prescribing provider.

The need for an in-person evaluation would make it more challenging for patients who face significant barriers to accessing care without telehealth to continue receiving the controlled medications they need.

Background

The Ryan Haight Online Pharmacy Consumer Protection Act of 2008 requires a telemedicine provider to perform an in-person medical evaluation of a patient prior to prescribing a controlled substance to that patient, unless an exception applies (21 U.S.C. § 829(e)(1)). The act includes a broad exemption to the in-person medical evaluation requirement for the delivery, distribution or dispensing of a controlled substance by a practitioner engaged in the "practice of telemedicine" (21 U.S.C. § 829(e)(3)). However, despite the apparent flexibilities for providers that are delivering services via telemedicine, the "practice of telemedicine" is defined quite narrowly. Specifically, it is defined as an encounter that is provided through a "telecommunications system" (currently defined under 42 CFR § 410.78(a)(3) to require a live audio-visual encounter except with respect to certain mental health treatment under special circumstances, although there is no statutory definition) in one of the following seven circumstances:

A. The patient is being treated in and is physically located in a hospital or clinic.

B. The patient is being treated by and in the physical presence of another practitioner.

C. The patient is being treated by a provider employed by the Indian Health Services.

D. The treatment is occurring during a PHE declared by the secretary of the US Department of Health and Human Services (HHS) involving locations and controlled substances designated by the Secretary and the US Attorney General.

E. The patient is being treated by a practitioner who holds a special registration, requirements for which are set forth at 21 U.S.C. § 831(h).

F. There is a medical emergency and the patient is being treated by an employee of the Veterans Health administration (provided that certain additional requirements are met).

G. The patient is being treated under other circumstances as set forth in regulation as determined jointly by the HHS Secretary and the US Attorney General to be consistent with effective controls against diversion and otherwise consistent with the public health and safety (21 U.S.C. § 802(54)).

The controlled substance prescribing flexibilities invoked in January 2020 in response to the COVID-19 PHE under subparagraph D were set to end with the termination of the PHE on May 11, 2023. Providers and others have long been awaiting the development of the "special registration"

process described in subparagraph E, which would require the DEA to establish the circumstances and procedures under which a special registration could be issued under the Ryan Haight Act. In the 14 years since the act's passage, the DEA has failed to implement such a process, even though Congress imposed a deadline of October 2019 in the 2018 SUPPORT for Patients and Communities Act for the promulgation of final regulations. In the proposed rules, the DEA opted not to implement the registration process and instead invoked its authority under subparagraph G.

Summary of the Rules

Telemedicine Prescribing of Controlled Substances Without Prior In-Person Evaluation

The Telemedicine Controlled Substance Proposed Rule would amend 21 CFR parts 1300, 1304 and 1305 to establish circumstances under which healthcare practitioners may prescribe certain controlled medications via telemedicine encounters. The proposed rule would only be applicable to telemedicine encounters authorized under 21 U.S.C. § 802(54)(G), and would not be applicable to telemedicine encounters pursuant to 21 U.S.C. §§ 802(54)(A)-(G).

Definitions

The Telemedicine Controlled Substance Proposed Rule proposes to amend 21 CFR § 1300.04 to modify the definition of the "practice of telemedicine" to require that telemedicine take place "using an interactive telecommunications system referred to in 42 CFR 410.78(a)(3)." This would not be a substantive change to the DEA's regulations, but merely a clarification of the existing requirements under 42 CFR 410.78(a)(3)—that interactive telecommunications systems include audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site practitioner, and for certain mental health services, real-time audio-only communication technology. The Telemedicine Controlled Substance Proposed Rule also proposes to amend 21 CFR § 1300.04 to add the following definitions:

- "Qualifying Telemedicine Referral" would mean a referral by a practitioner who has conducted at least one in-person exam of a patient to another practitioner who conducts a telemedicine exam of such patient. This definition would clarify the nature of the medical evaluation relationship that is required for the referral to enable the prescribing practitioner to issue prescriptions in excess of the 30-day limit as described in the proposed 42 CFR § 1306.3 l(c)(2).

- "Telemedicine Encounter" would mean a communication between a practitioner and a patient using an interactive telecommunications system referred to in 42 CFR 410.78(a)(3), while the practitioner is engaged in the practice of telemedicine.

- "Telemedicine Prescription" would mean a prescription issued by a physician or a mid-level practitioner (21 CFR 1300.0l(b)) engaging in the practice of telemedicine.

- "Telemedicine Relationship Established During the COVID-19 Public Health Emergency" would mean a relationship that was not conducted as an in-person medical evaluation of the patient, but rather a telemedicine encounter during the nationwide PHE declared by the HHS Secretary on January 31, 2020 as a result of the Coronavirus Disease 2019 and pursuant to the designation pursuant to that PHE on March 16, 2020, by the HHS Secretary, with concurrence of the Acting DEA Administrator.

Finally, the Telemedicine Controlled Substance Proposed Rule proposes a technical amendment to remove from the DEA's regulations the "[t]emporary definition of the practice of telemedicine" in 21 CFR 1300.04(j).

Prescriptions

The Telemedicine Controlled Substance Proposed Rule proposes to amend 21 CFR § 1304.06 to allow practitioners to prescribe non-narcotic Schedule III-V controlled substances when certain circumstances are met. The proposed rule would provide several requirements, to be set forth in 21 CFR §1306.31, that a practitioner must satisfy in order to prescribe a controlled substance via a telemedicine encounter:

- Controlled substances may only be prescribed if issued during a telemedicine encounter for legitimate medical purposes by practitioners acting in the usual course of professional practice.
- The prescribing practitioner must be located in the United States or a territory of the United States (*e.g.*, Puerto Rico).
- The prescribing practitioner must be authorized to prescribe controlled substances under applicable state controlled substance prescribing registrations where the practitioner is located *and* where the patient is located.
- The practitioner must review the prescription drug monitoring program (PDMP) in the state in which the patient is located for the past year (or for Veterans Affairs (VA) practitioners, the VA's centralized health information system).
- The practitioner must include a notation—either on the face of the prescription or within the prescription order if prescribed electronically—that the prescription has been issued via a telemedicine encounter.

The commentary to the Telemedicine Controlled Substance Proposed Rule specifically notes that the third item above would require that a practitioner using telemedicine to prescribe a controlled substance be authorized to prescribe that basic class of controlled substance under DEA registrations in both the state where the practitioner is located and the state where the patient is located.

The Telemedicine Controlled Substance Proposed Rule would allow a practitioner to prescribe non-narcotic Schedule III-V controlled substances, and would exclude the prescription of Schedule II controlled substances via telemedicine encounters. To combat diversion of controlled substances, the Telemedicine Controlled Substance Proposed Rule proposes that prescriptions for controlled substances be time-limited for each patient (unless conducted by VA practitioners). Under the proposed rule, practitioners could prescribe controlled substances to a patient using telemedicine only for a 30-day supply, and could only continue prescribing beyond the 30-day window if the practitioner would have to see the patient in-person, the practitioner performs a synchronous audio-video telemedicine encounter with the patient while the patient is located in the physical presence of another DEA registered practitioner, or the practitioner receives a qualifying telemedicine referral from a DEA registered practitioner who has conducted an in-person exam of the patient. Once any of

these criteria is satisfied, the Telemedicine Controlled Substance Proposed Rule would allow a practitioner to continue prescribing a controlled medication to a patient without additional evaluations, unless otherwise required by law.

The Telemedicine Controlled Substance Proposed Rule would require practitioners review the PDMP in the state in which the patient is located for the past year (or for VA practitioners, the VA's centralized health information system). If the PDMP is nonoperational and therefore a practitioner is unable to review a patient's prior prescription history, then the practitioner may only prescribe a seven-day prescription of controlled substances, which can only be refilled upon the practitioner s successful review of the PDMP, which must occur within seven days of the telemedicine encounter. During time period in which the practitioner is not able to access the PDMP, she must annotate in the prescription the dates and times she attempted to access the PDMP, the reason why she could not gain access to the PDMP, and any follow-up attempts to gain access to the PDMP. Once able to access the PDMP, the practitioner may refill the prescription for the controlled substance; however, together with the initial seven-day prescription, the refill may not exceed a 30-day supply.

Record Keeping

Pursuant to the Telemedicine Controlled Substance Proposed Rule, the DEA proposes to amend 21 CFR § 1304.04 to require practitioners to keep detailed records regarding prescriptions issued as a result of a telemedicine encounter at the registered location identified in the practitioner's DEA registration (21 CFR § 1301.13.), in digital or paper form that is readily accessible. As part of the practitioner's records for each prescription a practitioner issues pursuant to a telemedicine encounter, the practitioner must maintain a record of the following:

- Date the prescription was issued
- Full name and address of the patient
- Drug name, strength, dosage form, quantity prescribed and directions for use
- Address at which the practitioner is located during the telemedicine encounter, 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 (with a copy of the referral and any communications shared pursuant to 21 CFR § 1306.3
- All efforts to comply with the requirement of accessing the PDMP system.

The Telemedicine Controlled Substance Proposed Rule would also require practitioners to maintain copies of all qualifying referrals they issue. The rule also proposes to set requirements for practitioners to maintain records related to medical evaluations conducted with the patient and another DEA practitioner physically together at the other end of an audio-video link. Both the prescribing practitioner and the DEA-registered healthcare worker physically present with the patient must maintain, for each medical evaluation, the following:

- 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
- The address at which the DEA-registered healthcare worker is physically present with the patient during the medical evaluation.

The commentary to the Telemedicine Controlled Substance Proposed Rule acknowledges that practitioners may practice telemedicine in multiple states (*e.g.*, where the patient is located). To avoid the confusion (and the burden) of requiring practitioners to maintain medical records in each state in which they provide telemedicine encounters, and to allow the DEA to readily locate records when necessary, practitioners need only maintain such records at the location identified in their DEA registration (21 CFR § 1301.13).

Expansion of Induction of Buprenorphine via Telemedicine Encounter

The Telemedicine Buprenorphine Proposed Rule would expand the circumstances under which practitioners are authorized to prescribe buprenorphine for use in the maintenance or detoxification treatment of opioid-use disorder via a telemedicine encounter, including an audio-only telemedicine encounter that meets the standard of 42 CFR 410.78(a)(3), provided certain requirements and conditions are met. In addition to the requirements proposed under the Telemedicine Controlled Substance Proposed Rule (the expanded and amended definitions, the record keeping requirements and the prescribing requirements including supply limitations, as outlined above), the Telemedicine Buprenorphine Proposed Rule would amend 21 CFR §1306 to provide the following:

- The Telemedicine Buprenorphine Proposed Rule would clarify that buprenorphine may only be prescribed if “issued for maintenance or detoxification treatment” and not for any other purpose.
- The Telemedicine Buprenorphine Proposed Rule would add a new section 1306.34, setting forth the circumstances in which practitioners are authorized to use the expanded authorities to prescribe buprenorphine:
    - A practitioner must obtain and maintain a DEA registration in the state where the practitioner is located. *See* 21 U.S.C. 823(g) and 21 CFR 1301.13(e)(l)(iv).
    - A practitioner must be authorized by state law, or not otherwise prohibited by state law, from practicing telemedicine in the state in which the patient is located *and* the state in which the practitioner is located. This means, for example, that practitioners may not prescribe buprenorphine in states where state law prohibits the prescription of a controlled substance based solely on an audio-only evaluation.
    - Prescription must comply with the provisions of the relevant Controlled Substances Act and DEA regulations that govern dispensing for maintenance and detoxification treatment.
    - A practitioner must be technically capable of using audio and video equipment permitting two-way, real-time interactive communication with the patient at the time of the telemedicine encounter.

- All prescriptions issued based on a telemedicine encounter under the authority of the rule must be issued for a Schedule III, IV or V narcotic drug approved by the US Food and Drug Administration specifically for use in maintenance or detoxification treatment and must be issued pursuant to 21 CFR 1306.04.

- Practitioners must review and consider relevant PDMP data in the state where the patient is located prior to prescribing buprenorphine.

Analysis

Although the new rules would expand the use of telemedicine for prescribing controlled substances beyond what was allowed before the COVID-19 PHE, they would re-establish the barriers many patients face in accessing in-person care, and the barriers that telehealth providers that do not have physical locations face in providing care, by requiring at least one in-person visit. Even though the DEA did not decide to establish a special registration process, explaining that doing so would be too burdensome for both prospective telemedicine providers and patients, not establishing a telehealth-only pathway to treatment is also burdensome.

What Works

- The new rules would allow telehealth providers who have formed a provider-patient relationship with patients during the COVID-19 PHE to continue prescribing controlled medications through November 7, 2023, allowing them six months from the end of the PHE to re-evaluate their business model in order to fall under one of the three pathways permitted to conduct an in-person evaluation.

- Providers with a hybrid model of providing care (via telehealth and in person) may continue to benefit from the expansion of telemedicine with controlled medications because they have a physical location to accommodate at least one in-person visit per patient.

What's Missing/What Doesn't Work

- Patients who were unable to get the controlled medications they needed before the COVID-19 PHE flexibilities went into effect would face the same challenges because the barriers they previously faced in accessing in-person care, whether geographical or socioeconomic, are likely still present.

- Telehealth providers that do not have physical locations, especially those who currently treat patients in all 51 jurisdictions, would need to rely on other providers to conduct an in-person evaluation to establish a physical presence to continue care for their patients. It is unclear whether this reliance on other providers would pose issues, such as liability issues or unwillingness by other providers to provide a referral.

- The proposed rules would not create a special telemedicine registration process, which was a process contemplated in the telemedicine exceptions to the Ryan Haight Act and the subject of a congressional directive to the DEA under the 2018 SUPPORT for Patients and Communities Act.

State Law Still Matters

Although the Ryan Haight Act is often the focus of telemedicine remote prescribing compliance, in reality remote prescribing regulation is largely left to the states. Remote prescribing restrictions can be commonly found in telemedicine-specific statutes or regulations, pharmacy practice acts and medical practice acts, and in controlled substances acts themselves. Some states may still require an in-person encounter prior to prescribing controlled substances to treat a patient. While many states introduced flexibilities for the prescribing of controlled substances in light of COVID-19, many flexibilities have expired or will expire soon, reverting to the pre-COVID-19 landscape at the state level. As a result, the effect of the DEA's new position could be limited within a particular state by the application of state laws that are more stringent.

Rachel Stauffer also contributed to this article.

National Law Review, Volume XIII, Number 62