FOLEY & LARDNER LLP

DEA Extends Telemedicine Flexibilities for Prescribing of Controlled Medications

Nathan A. Beaver, Nathaniel M. Lacktman, Thomas B. Ferrante, Rachel B. Goodman, Kyle Y. Faget
10 May 2023

Health Care Law Today
Updated on May 11, 2023

On May 10, 2023, the Drug Enforcement Agency (DEA) released a new regulation – "Temporary Extension of COVID-19 Telemedicine Flexibilities for Prescription of Controlled Medications" – temporarily extending the "full set" of DEA's COVID-19 waivers for prescribing controlled substances via telemedicine. Those waivers, which have been in place since March 2020, are now extended through November 11, 2023. In addition, for any practitioner-patient relationships created during the waiver period, the waivers will continue to apply through November 11, 2024. Put another way, if a patient and practitioner establish a telemedicine relationship by November 11, 2023, the same flexibilities that governed the prescribing will continue to apply through November 11, 2024.

While this is just a temporary extension of COVID flexibilities, it can be considered a win for patients and clinicians using telemedicine. The credit goes to the public at large for making their voices heard (loudly) through the submission of a record-breaking 38,369 public comments to the proposed telemedicine rule. These public comments were a significant reason for this extension. Our gratitude also goes out to the Administration and the leadership at DEA and Substance Abuse and Mental Health Services Administration (SAMHSA) for listening to those voices. Finally, a thank you to our clients and the stakeholder professional associations, including the American Telemedicine Association (ATA), for their tireless advocacy in pursuit of patient care.

Key Provisions Under the DEA's Temporary Rule

1. What is the Ryan Haight Act?

The statutory basis for the DEA's rule is the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (Ryan Haight Act), which prohibits the distributing, dispensing or delivery of controlled substances via the Internet without a valid prescription. It applies only in limited circumstances where the practitioner wishes to prescribe a controlled substance via telemedicine and has never conducted an in-person medical exam of the patient.

The Ryan Haight Act requires a practitioner to conduct at least one in-person medical evaluation of the

patient before prescribing a controlled substance by means of the "Internet" (a broadly-defined term that includes telemedicine). Once the practitioner has conducted this in-person medical evaluation, the Ryan Haight Act does not set an expiration period or requirement for subsequent annual exams. Failure to conduct this in-person medical evaluation can constitute a *per se* violation of the Controlled Substances Act and result in civil and criminal penalties.

The Ryan Haight Act was designed to combat the proliferation of so-called "rogue Internet sites" that unlawfully dispensed controlled substances by means of the Internet, including online pharmacies offering controlled substances without a valid doctor-patient relationship. Yet the broad language of the Ryan Haight Act applies not only to pharmacies, but also to legitimate practitioners who prescribe controlled substances via telemedicine.

In the years since it was enacted, the DEA has used the Ryan Haight Act to regulate the marketplace, sanctioning practitioners and pharmacies whose unethical and substandard prescribing practices violated the law.

2. Is this rule issued pursuant to one of the "practice of telemedicine" exceptions under the Ryan Haight Act?

Yes. The Ryan Haight Act contains seven "practice of telemedicine" exceptions to the in-person medical evaluation requirement. These are seven distinct categories Congress determined were appropriate to allow for telemedicine prescribing of controlled substances despite the practitioner never having examined the patient in person. The rule creates the temporary extension under exception #7, a flexible catch-all exception ("The practice of telemedicine is being conducted under any other circumstances that the [DEA] Administrator and the Secretary of Health and Human Services have jointly, by regulation, determined to be consistent with effective controls against diversion and otherwise consistent with the public health and safety."). The rule is issued pursuant to 21 U.S.C. § 802(54)(G) and amends 21 C.F.R. Part 1307 and 42 C.F.R. Part 12.

3. What is this rule intended to accomplish?

According to the DEA, the rule is designed to extend the COVID-19 telemedicine flexibilities in place to ensure patients do not experience lapses in care, and to ensure continuity of care under the current telehealth flexibilities in place as a result of the COVID-PHE. It is also intended to facilitate continuity of care for telemedicine relationships established via telemedicine during the COVID-19 PHE and address the urgent public health need for continued access to the initiation of buprenorphine as medication for opioid use disorder. Other stated purposes are:

- Allow patients, practitioners, pharmacists, service providers, and other stakeholders sufficient time to prepare for the implementation of any future regulations that apply to prescribing of controlled medications via telemedicine;

- Enable DEA, jointly with SAMHSA, to thoroughly review and respond to the 38,369 comments they received in response to the two notices of proposed rulemaking; and

- Enable DEA, jointly with SAMHSA, to conduct a thorough evaluation of regulatory alternatives in order to promulgate regulations that most effectively expand access to telemedicine encounters in a manner that is consistent with public health and safety, while maintaining effective controls against diversion.
  Note: This final purpose (conduct a "thorough evaluation of regulatory alternatives") potentially hints the DEA is open to consider another alternative, such as publishing a Telemedicine Special Registration rule. A Telemedicine Special Registration rule is an excellent vehicle to solve for many of the concerns about balancing access to care while limiting and identifying unscrupulous prescribing patterns and illegal diversion.

4. What time period does this rule cover?

The rule extends the COVID-19 PHE DEA telemedicine flexibilities through November 11, 2023. For any practitioner-patient relationships established via telemedicine encounters on or before that date, the rule also extends the COVID-19 PHE telemedicine flexibilities through November 11, 2024.

- The full set of telemedicine flexibilities regarding prescription of controlled medications as were in place during the COVID-19 PHE will remain in place through November 11, 2023.

- For practitioner-patient telemedicine relationships established on or before November 11, 2023, the full set of telemedicine flexibilities regarding prescription of controlled medications as were in place during the COVID-19 PHE will continue to be permitted via a one-year grace period through November 11, 2024. In other words, if a patient and a practitioner have established a telemedicine relationship on or before November 11, 2023, the same telemedicine flexibilities that have governed the relationship to that point are permitted until November 11, 2024.

5. Which DEA waivers are extended under this rule?

DEA said it is extending the "full set" of telemedicine flexibilities regarding the prescription of controlled medications, referencing the two DEA letters that authorized telemedicine waivers.

- A March 25, 2020 "Dear Registrant" letter signed by William T. McDermott, DEA's then-Assistant Administrator, Diversion Control Division.

- A March 31, 2020 "Dear Registrant" letter signed by Thomas W. Prevoznik DEA's then-Deputy Assistant Administrator, Diversion Control Division.

The March 25 letter addressed two waiver exceptions: one related to DEA registrations in individual states; and one related to the in-person evaluation requirement. It stated, in relevant part:

- DEA-registered practitioners are not required to obtain additional registration(s) with DEA in the additional state(s) where the dispensing (including prescribing and administering) occurs, for the duration of the public health emergency declared on January 31, 2020, if authorized to dispense controlled substances by both the state in which a practitioner is registered with DEA and the state in which the dispensing occurs. Practitioners, in other words, must be registered with DEA in at least one state and have permission under state law to practice using controlled substances in the state where the dispensing occurs.

- Under the Controlled Substances Act (CSA), a prescription for a controlled substance issued by means of the Internet must generally be predicated on an in-person medical evaluation. See 21 U.S.C. § 829(e)(1). This requirement does not apply, however, when a practitioner is practicing telemedicine as defined by the CSA. The CSA's definition of the practice of telemedicine includes multiple different categories of telemedicine. For several of these categories, the CSA specifically requires a practitioner to have a DEA registration in the state in which the patient is located. See, e.g., 21 U.S.C. § 802(54)(A), (B). But the practice of telemedicine during a public health emergency pursuant to 21 U.S.C. § 802(54)(D) does not include this requirement. On March 16, 2020, the Secretary of the United States Department of Health & Human Services, with concurrence of the Acting DEA Administrator, designated that the telemedicine allowance under section 802(54)(D) applies to all schedule II-V controlled substances in all areas of the United States.

The March 31 letter extended waivers with respect to prescribing of buprenorphine. It stated, in relevant part:

- DEA notes that practitioners have further flexibility during the nationwide public health emergency to prescribe buprenorphine to new and existing patients with opioid use disorder (OUD) via telephone by otherwise authorized practitioners without requiring such practitioners to first conduct an examination of the patient in person or via telemedicine.

The currently-prevailing interpretation is this newly-released rule extends the waivers in both the March 25 letter (registration and in-person exam) and March 31 letter (buprenorphine), together constituting the "full set" of telemedicine flexibilities. Foley has reached out to DEA for confirmation that the registration requirements are being extended and will update this blog when we receive a response.

6. What is the definition of "telemedicine relationship established via COVID-19 telemedicine prescribing flexibilities"?

Under the rule, "telemedicine relationship established via COVID-19 telemedicine prescribing flexibilities" means:

1. The practitioner has not conducted an in-person medical evaluation of the patient; and

2. The practitioner has prescribed one or more controlled substances to the patient during the period May 12, 2023 through November 11, 2023 *and* the following conditions are met:

    a. The prescription is issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice;
    b. The prescription is issued pursuant to a communication between a practitioner and a patient using an interactive telecommunications system referred to in 42 C.F.R. § 410.78(a)(3);
    c. The practitioner is:
        i. Authorized under their registration under 21 C.F.R. § 1301.13(e)(1)(iv) to prescribe the basic class of controlled substance specified on the prescription; or
        ii. Exempt from obtaining a registration to dispense controlled substances under 21 U.S.C. § 822(d); and
    d. The prescription is consistent with all other requirements of 21 C.F.R. Part 1306.

On May 11, 2023, Foley received confirmation from the DEA's Section Chief of its Diversion Regulatory Draft and Policy Support Section (Scott Brinks) that the registration policy outlined in the March 25, 2020 letter is being extended. Thus, the policy on single-state DEA registrations in place during the PHE will continue during the duration of the flexibilities as outlined in the temporary rule.

7. Does this rule shed any light on how DEA views telemedicine and telemedicine companies generally?

Yes. In the rule, DEA stated "SAMHSA and DEA strongly support policies that promote access to effective and safe treatment for opioid use disorder, including through telemedicine platforms, and ensuring continued access to necessary controlled medications past the COVID-PHE." DEA also stressed:

> While certain telemedicine companies may engage in problematic behavior, many telemedicine companies are engaged in good faith, patient-centered prescribing practices. DEA looks forward to working with them – and future companies in this space – to further enhance patient access to needed medications when telemedicine prescriptions are appropriate and issued in the usual course of professional practice following bona fide medical evaluations.

Despite the bullishness severally, DEA remains concerned about "problematic prescribing practices" and wants to "disincentivize the creation of telemedicine companies that may seek to engage in problematic prescribing practices." In the meantime, DEA stated it is actively investigating certain telemedicine companies DEA believes may have engaged in problematic prescribing practices.

8. What comes next after this rule?

According to DEA, the "goal of this temporary rule is to ensure a smooth transition for patients and practitioners that have come to rely on the availability of telemedicine for controlled medication prescriptions, as well as allowing adequate time for providers to come into compliance with any new

standards or safeguards that DEA and/or SAMHSA promulgate in one or more final rules."

DEA said it plans to issue "one or more final rules … based on the two proposed rules published on March 1, 2023". DEA anticipates such final rule(s) will "extend[] certain telemedicine flexibilities on a permanent basis" to permit "the practice of telemedicine under circumstances that are consistent with public health and safety, while maintaining effective controls against diversion."

Conclusion

This rule only temporary extends the telemedicine flexibilities for patients seen prior to November 11, 2023. Telemedicine companies must remain focused on preparation for care after this date. Based on the timeframe of the extension, it is probable the DEA will issue a new telemedicine final rule (based on the March proposed rule) prior to November 11, 2023. We will continue to monitor for updates.

Want to Learn More?

- *2023 Telemedicine and Digital Health Trends*
- *Brainwaves: A Foley Forward Experience*
- *PHE Ends May 11: What Telemedicine Companies Need to Know*

We'd like to thank Jennifer Walsh, Director of Public Affairs for her contribution to this blog post.

Foley is here to help you address the short- and long-term impacts in the wake of regulatory changes.For more information on telemedicine, telehealth, virtual care, remote patient monitoring, digital health, and other health innovations, including the team, publications, and representative experience, visit Foley's Telemedicine & Digital Health Industry Team or our Health Care Practice Group.