DEA Proposes Rule for Post-PHE Telemedicine

While subject to change, the proposed rule extends the waiver of the required in-person medical evaluation by 180 days **By Arushi Pandya, JD, and Sara Shanti, JD**

ON FEBRUARY 24, 2023, the Drug Enforcement Agency (DEA) announced a new proposed rule, which provides some much-anticipated guidance related to the implications of telemedicine prescribing under the Ryan Haight Act of 2008 (RHA) after the COVID-19 Public Health Emergency (PHE) terminates on May 11, 2023. The proposed rule extends certain flexibilities beyond the PHE and proposes to make permanent certain scenarios, in which a practitioner may prescribe controlled substances without a prior in-person medical evaluation.

The comment period for the proposed rule ends on March 31, 2023.

Background

The RHA generally requires a prescribing practitioner to have conducted at least one in-person medical evaluation of a patient prior to prescribing controlled substances via telemedicine. The RHA was enacted to prevent the unlawful distribution of controlled substances through unregulated websites. During the PHE, the DEA waived the in-person evaluation requirement, provided certain conditions were met. Since then, the exponential expansion of telemedicine during the PHE has grown along with increased DEA enforcement, intending to counter over-prescribing and fraudulent arrangements. These concerns, as well as recent news of low inventory of certain medications, appear to be considered by the DEA in the rulemaking.

Notable Provisions of the Proposed Rule

1. Extension of Flexibilities Under the PHE Waiver

The proposed rule extends, by 180 days after the termination of the PHE, the waiver of RHA's required in-person medical evaluation. Notably, the in-person medical evaluation will apply to both new and existing patients after the 180-day period, unless the patient meets a proposed exception (e.g., a "qualifying telemedicine referral" or an "initial 30-day prescription," detailed below). For instance, if a telemedicine provider began a patient relationship, involving the prescribing of a controlled substance, during the PHE and without an in-person evaluation having first occurred, such an evaluation must be conducted by December 2023 to continue the prescribing.

2. New "Qualifying Telemedicine Referral" Exception

The proposed rule allows a practitioner to prescribe Schedule II-V narcotic and non-narcotic controlled substances by telemedicine, when the prescribing practitioner has received a "qualifying telemedicine referral" from a referring practitioner who has conducted the prior in-person medical evaluation.

3. New Permissible Prescribing Without an In-Person Evaluation

The proposed rule allows a practitioner to prescribe up to a 30-day initial prescription for a Schedule III-V controlled substance via telemedicine without a prior in-person medical evaluation or qualifying telemedicine referral from a referring practitioner. To issue more than a 30-day supply and to issue additional prescriptions, an in-person medical evaluation is required. This exception does not extend to Schedule II and/or narcotic controlled substances prescribing, which still requires an in-person medical evaluation or a qualifying telemedicine referral.

Industry Reaction and State Restrictions

DEA's proposed rule has begun generating industry reactions. The American Telemedicine Association, for example, recently released a statement outlining its opposition and citing the proposed rule as "overly restrictive." Additionally, states are active in addressing telemedicine prescribing post-PHE. For example, prior to the announcement of the DEA rules, New York published guidance indicating the reinstatement of RHA requirements for an in-person medical evaluation post-PHE.

Looking Ahead

Although the PHE is set to draw to a close soon, telemedicine is here to stay. The termination of the PHE will require providers to carefully navigate state and federal law, especially as the proposed rule is subject to change. Sheppard Mullin will continue to monitor developments and provide updates as they arise.

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The proposed rule extends, by 180 days after the termination of the PHE, the waiver of the Ryan Haight Act-required in-person medical evaluation.