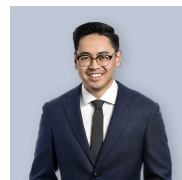


DEA Extends COVID-19 Telemedicine Flexibilities for Controlled Substance Prescribing

Insights

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On October 10, 2023, the US Drug Enforcement Administration (DEA) and the Substance Abuse and Mental Health Services Administration (SAMHSA) published a [temporary rule](#) – “*Second Temporary Extension of COVID-19 Telemedicine Flexibilities for Prescription of Controlled Medications*” (Second Temporary Rule) – further extending telemedicine flexibilities for prescribing controlled substances.

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BACKGROUND

Under the Controlled Substances Act as amended by the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (Ryan Haight Act), prescribing practitioners generally must conduct an in-person evaluation of a patient before prescribing a controlled substance via the internet, unless one of a number of narrow exceptions applies. The Ryan Haight Act further requires providers to hold a DEA-issued registration in any state where the practitioner is prescribing controlled substances, and such registrations must generally be tied to a brick-and-mortar practice location.

Originally intended to address the threat of “rogue” online pharmacies distributing opioids and other controlled substances, the Ryan Haight Act presents a sizable hurdle to the operation of legitimate telemedicine providers seeking to improve access to care. Importantly, as adopted by Congress in 2008, the Ryan Haight Act expressly calls for the DEA to establish a special telemedicine registration process to allow providers to prescribe medically necessary controlled medications to patients via telehealth. Despite exhaustive lobbying from the healthcare industry and repeated calls for the DEA to establish the registration, including in the SUPPORT Act of 2018 by then President Trump, no such registration has been established.

Early in the COVID-19 public health emergency (PHE), DEA and SAMHSA took quick action to waive the Ryan Haight Act’s in-person exam requirement and the state-specific DEA registration requirement for the duration of the PHE. These important flexibilities allowed providers to establish patient-provider relationships via telemedicine and to prescribe medically necessary medication to patients in the safety of their home.

On March 1, 2023, DEA and SAMHSA issued two proposed rules which would have created modest flexibilities with respect to the prescription of controlled substances via telemedicine post-PHE. The proposed rules, which generated enormous public interest, resulting in over 38,000 public comments,

provided that with limited exceptions patients would still need to arrange for in-person examinations to receive treatment involving controlled substances under federal law. We summarized these proposed rules in a prior alert, available [here](#). Notably, the DEA declined to establish a telemedicine registration process in those proposed rules, to the bewilderment of industry.

To avoid lapses in patient care while the proposed rules were being considered, DEA and SAMHSA released a [temporary rule](#) on May 10, 2023, extending the COVID-19 PHE telemedicine flexibilities for the prescription of controlled medications (the First Temporary Rule). Under the First Temporary Rule, the telemedicine flexibilities that had been in place since March 2020 for prescribing controlled substances via telemedicine were:

- For **new and existing** patients, extended through November 11, 2023.
- For **existing** patients (i.e., practitioner-patient relationships established via telemedicine encounters on or before November 11, 2023), extended through November 11, 2024.

Meanwhile, the proposed rules from March 1, 2023, continue to undergo review and DEA and SAMHSA have not issued final rules. The two agencies recently held “[Telemedicine Listening Sessions](#)” on September 12 and 13, 2023 to receive additional input from the public regarding the proposed rules, telemedicine, and the prescription of controlled substances.

THE NEW TEMPORARY RULE: FURTHER EXTENDING TELEMEDICINE FLEXIBILITIES

DEA and SAMHSA issued this Second Temporary Rule following the deluge of public comments to the March 2023 proposed rules and the presentations at the recent Telemedicine Listening Sessions. The Second Temporary Rule is intended 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.”

The Second Temporary Rule allows all DEA-registered practitioners to prescribe schedule II-V controlled medications via telemedicine through December 31, 2024. This new extension differs from the First Temporary Rule in two ways: (1) the flexibilities are extended through the end of 2024, whereas the First Temporary Rule only extended flexibilities through November 11, 2024; and (2) the flexibilities are extended to all practitioner-patient relationships – not just those telemedicine relationships which were established on or before November 11, 2023.

WHAT HAPPENS NEXT

DEA has stated its aim to promulgate new standards or safeguards by fall 2024. While DEA and SAMHSA have not disclosed specifics about the pending final rules, the elongated rulemaking period and extensive public comments and listening sessions all suggest the final rules will include greater flexibilities than the modest ones found in the March 2023 proposed rules (summarized by us [here](#)), potentially including a special telemedicine registration for providers leveraging this technology moving forward.

In the meantime, telemedicine providers who had been worried about transitioning operations for new patients within the next month to adhere to the previously set November deadline can breathe a sigh of relief. Providers can continue to prescribe medically necessary controlled substances via telemedicine through December 31, 2024 – with no need for an initial in-person examination (except as deemed clinically necessary by the prescribing practitioner).

The anticipated timing of these final rules places these pivotal updates to the Ryan Haight Act alongside critical changes to the Medicare program and its coverage and reimbursement of telehealth services. [As we wrote earlier this year](#), the Centers for Medicare & Medicaid Services (CMS) extended most pandemic flexibilities involving Medicare telehealth services until the end of calendar year 2024. As a result, 2024 is shaping up to be a “make or break” year for the telehealth industry.

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