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DEA and HHS Extend Telemedicine Flexibilities for Controlled Substance Prescriptions Through 2024

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On October 6, 2023, the Drug Enforcement Agency (DEA) and the Department of Health and Human Services (HHS) announced they would further extend the COVID-19 flexibilities allowing for telemedicine prescription of controlled medications without a prior in-person evaluation through December 31, 2024. This article highlights the background on this Second Temporary Rule, the noteworthy provisions of the Rule, and key takeaways for providers and entities to which the Rule applies.

The Second Temporary Rule goes into effect on November 11, 2023, and ensures that flexibilities remain in place through the end of 2024 while proposals for permanent policies related to prescribing controlled medications via telemedicine remain under consideration. Key provisions of the Second Temporary Rule and pending proposed rules are summarized in more detail below.

I. Telehealth Flexibilities During the COVID-19 PHE

The Ryan Haight Online Pharmacy Consumer Act of 2008 (Ryan Haight Act) generally requires a practitioner to establish a provider-patient relationship by conducting an in-person assessment before prescribing certain controlled medications to that patient. The DEA and HHS suspended this in-person evaluation requirement in response to the COVID-19 Public Health Emergency (PHE) on January 31, 2020. This exception permitted practitioners to prescribe controlled medications through telemedicine, even if the practitioner had not evaluated the patient in person. Consequently, during the COVID-19 PHE, practitioners could prescribe schedule II-V controlled medications through audio-visual telemedicine, so long as the prescriptions complied with DEA regulations and guidance and applicable state and federal laws. At the end of the COVID-19 PHE on May 11, 2023, these flexibilities were set to expire absent a permanent or temporary extension.

II. Initial Extension of Temporary Flexibilities Through November 11, 2023

On May 11, 2023, the COVID-19 PHE expired. To prevent lapses in care for patients, the DEA and HHS extended the temporary COVID-19 PHE flexibilities. On May 10, 2023, after reviewing the ensuing comments, the agencies issued their First Temporary Rule extending the full set of telemedicine flexibilities related to the prescribing of controlled medications until November 11, 2023. The First Temporary Rule also included a one-year grace period (through November 11, 2024), that would allow practitioners to prescribe controlled substances via telemedicine, without a prior in-person evaluation, provided the practitioner and patient had established a telemedicine relationship by November 11, 2023. In other words, flexibilities would be extended for telemedicine relationships existing on or before November 11, 2023, but any *new* practitioner-patient relationships established via telemedicine after that date would require an in-person evaluation before the practitioner could prescribe controlled medications.

The DEA hosted Telemedicine Listening Sessions on September 12 and 13, 2023, to gather feedback as it considered revisions to proposed rules explained in further detail below. As the November 11, 2023, expiration approached, a further extension was needed to grant the DEA and HHS more time to consider their proposed permanent policies based on feedback from stakeholders expressed during the Listening Sessions and in written comments.

III. Second Temporary Rule Extending Flexibilities Through December 31, 2024

The DEA and HHS announced a Second Temporary Rule on October 6, 2023, extending the COVID-19 PHE flexibilities through December 31, 2024. This Rule authorizes DEA-registered practitioners to prescribe schedule II-V controlled medications via telemedicine through the end of 2024, regardless of whether the patient and practitioner established a telemedicine relationship on or before November 11, 2023. In other words, in lieu of the grace period provided in the First Temporary Rule, the Second Temporary Rule continues the extension of the current flexibilities for *all* practitioner-patient relationships – including *new* practitioner-patient relationships established through telemedicine after November 11, 2023 – until the end of 2024.

This Second Temporary Rule provides the DEA and HHS additional time to consider input collected through the Listening Sessions, while also allowing practitioners and patients to transition to the new standards or safeguards after nearly four years of experiencing these COVID-19 flexibilities regarding controlled medication prescriptions.

IV. Proposed Permanent Flexibilities Under Consideration

On March 1, 2023, (before there was a pressing need for a temporary extension), the DEA and HHS published two proposed rules (the Proposed Rules) – found here and here – concerning how controlled medications can be prescribed via telemedicine after the COVID-19 PHE ended. The Proposed Rules would permit a medical practitioner to prescribe an initial 30-day supply of Schedule III, IV and V non-narcotic controlled medications, or a 30-day supply of buprenorphine for the treatment of opioid use disorder, without an in-person examination or referral from a medical practitioner that has conducted an in-person evaluation if:

- The controlled substance being prescribed is issued during a telemedicine encounter for a legitimate medical purpose by practitioners acting in the usual course of professional practice;
- The prescribing practitioner is located within the United States;
- The prescribing practitioner is authorized to prescribe controlled substances under applicable federal and state laws; and
- The prescribing practitioner includes a notation on the prescription that the prescription was issued via a telemedicine encounter.

Thus, the Proposed Rules would allow a practitioner to prescribe non-narcotic schedule III-V controlled medications, up to an initial 30-day supply, via telemedicine encounters. However, for the renewals of such prescriptions beyond the initial 30 days, the practitioner would be required to: (a) examine the patient in person; (b) perform a synchronous audio-video telemedicine encounter with the patient while the patient is located in the physical presence of another DEA-registered practitioner; or (c) receive a qualifying telemedicine referral from a DEA-registered practitioner who has conducted an in-person examination of the patient.

These Proposed Rules have received over 38,000 comments and are still under agency consideration.

V. Takeaways

The DEA and HHS have clarified their intention to promulgate final telemedicine prescription rules by Fall 2024. The long rulemaking period, extensive public comments, and listening sessions indicate that the final rules may include greater flexibilities than what has been proposed. As practitioners await finality from the agencies, they can continue to prescribe controlled medications via telemedicine through December 31, 2024, without a prior in-person examination (unless the prescribing practitioner determines it clinically necessary).

For more information, please contact Allison M. Cohen, Alex S. Lewis, McKenna S. Cloud, or any member of Baker Donelson's Telehealth Group.