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DEA Telemedicine Flexibilities Extended: What it Means for Providers

Background

On November 19, the Department of Health and Human Services (HHS) and the Drug Enforcement Administration (DEA) jointly finalized their highly anticipated temporary extension of the *COVID-19 Telemedicine Flexibilities for Prescription of Controlled Medication* (the Temporary Rule). This is the third extension of the Temporary Rule, that was originally introduced during the 2020 COVID-19 pandemic, highlighting another delay by HHS and the DEA in finalizing a permanent telemedicine policy.

Under the *Ryan Haight Online Pharmacy Consumer Protection Act of 2008*, a prescribing practitioner is required to conduct an in-person evaluation prior to prescribing a controlled substance to any patient. In response to COVID-19, the DEA granted temporary exceptions to the Ryan Haight Act to allow for continuity of care via telehealth during the pandemic.

Nearly three years later, the surge in telemedicine services continues throughout the United States, and this has prompted HHS and the DEA to extend certain exceptions for a third time with an effective date of **January 1, 2025**, and extending **through December 31, 2025**.

The Third Extension

The Temporary Rule did not introduce any substantive changes from the second extension and merely cleaned up language regarding a "telemedicine relationship," which in the second extension had eliminated the requirement for a prior in-person visit for prescription services. The existing criteria for prescribing via telehealth remain unchanged. In particular, the third extension requires the same "communication between a practitioner and a patient using an interactive telecommunications system referred to in 42 CFR 410.78(a)(3)." For purposes of the Temporary Rule, "interactive telecommunications system" means multimedia communications that include, at a minimum, two-way audiovisual equipment permitting two-way, real-time interactive communication between a patient and a provider. This means common technologies such as videoconferencing platforms like Zoom, Microsoft Teams or Doxy.me, which allow patients and providers to communicate face-to-face in real time, comply with the requirements defined in 42 CFR 410.78.

Mental health service providers should note that for services offered to a patient in their home for the purposes of diagnosis, evaluation or treatment of a mental health disorder, two-way, real-time **audio-only** communication technology is permitted if the patient either is not capable of or does not consent to the use of video technology. For this exception to apply, the provider must still be capable of engaging in audiovisual services at all times, and the reason for using audio only for a visit should be documented in the patient's chart.

Additionally, the proposed joint comprehensive telemedicine regulations titled *Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation* are referenced several times in the Temporary Rule. The DEA notes that this third extension will give additional time to the DEA and HHS to promulgate proposed and final comprehensive regulations relating to telemedicine, and allow adequate time for providers to comply with any new standards or safeguards eventually adopted in a final set of regulations.

A set of proposed, comprehensive telemedicine regulations have been submitted to the Office of Information and Regulatory Affairs and are currently pending review. Day Pitney is monitoring these proposed regulations and will provide updates going forward.

Takeaways

- Providers may continue to prescribe controlled substances to patients without an initial in-person visit but should continue to be aware of the recurring criteria found in the Temporary Rule, including the proper technology associated with an interactive telecommunications system.
- Mental health service providers have a limited exception to the two-way audiovisual communication requirement. However, to maintain compliance with the Temporary Rule, they must continue to use technologies with audiovisual capabilities for all telemedicine prescribing activities, only disengaging video capabilities if the patient either does not consent to video or does not have video capability.
- Given the quantity of references to the impending comprehensive telemedicine regulations, providers may expect to see movement in this area, and perhaps a final set of rules, during 2025.

If you have questions about prescribing via telehealth or the third extension of the *COVID-19 Telemedicine Flexibilities for Prescription of Controlled Medication*, please contact a member of Day Pitney's Healthcare, Life Sciences, and Technology Practice Group.

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