

DEA AND HHS ANNOUNCE THIRD EXTENSION OF COVID-ERA TELEMEDICINE FLEXIBILITIES FOR CONTROLLED SUBSTANCE PRESCRIBING

On Friday, November 15, 2024, the Drug Enforcement Administration (“DEA”) and the Department of Health and Human Services (“HHS,” and together with the DEA, the “Agencies”) issued a **third temporary rule** (the “Third Temporary Rule”) extending the COVID-19 Telemedicine Flexibilities for Prescription of Controlled Medications (“telemedicine flexibilities”). As a result of both Congressional and health care stakeholder pressure, this is the third extension of the effective period of these telemedicine flexibilities since the end of the federal Public Health Emergency. Therefore, practitioners will be permitted to continue relying on the telemedicine flexibilities to prescribe certain controlled medications through telemedicine, without conducting an in-person examination, for all patient encounters through **December 31, 2025**. Specifically, those telemedicine flexibilities permit DEA-registered practitioners to issue prescriptions for controlled medications to patients for whom they have not conducted an in-person medical evaluation, provided:

- The prescription is issued for a legitimate medical purpose by a practitioner acting in the usual course of his/her professional practice;
- The telemedicine communication is conducted using an audio-visual, real-time, two-way interactive communications system; and
- The practitioner is acting in accordance with applicable federal and state law.

These telemedicine flexibilities were first extended by a **May 2023 temporary rule** (the “First Temporary Rule”) at the end of the PHE, while the Agencies considered the more than 38,000 public comments received in response to **proposed rules for telemedicine prescribing of controlled substances published in early 2023**, which differed considerably from the Agencies’ current telemedicine flexibilities (the “Proposed Final Rules”). Six months later, the Agencies **published a second temporary rule** (the “Second Temporary Rule”), which extended the telemedicine flexibilities again through December 2024, while they worked to finalize permanent telemedicine regulations to allow sufficient time to thoroughly consider the multitude of public comments received both in response to the Proposed Final Rules and during the Agencies’ September 2023 **Telemedicine Listening Sessions**.

At the time of the Second Temporary Rule’s issuance, the Agencies were expected to promulgate final telemedicine regulations by the fall of 2024. However, in the intervening 13 months, the DEA developed a new draft telemedicine notice of proposed rulemaking entitled, **“Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have not had a Prior In-Person Medical Evaluation,”** which was transmitted to the Office of Management and Budget (“OMB”) for review in June 2024, and is still sitting at OMB pending final review. Although this new proposed rule has not been released publicly, many stakeholders have expressed concerns about the substantial limitations on controlled medications telemedicine prescribing practices that would take effect if its proposals were finalized.

Thus, with the December 31, 2024, deadline and expiration of the telemedicine flexibilities under the Second Temporary Rule quickly approaching, the Agencies issued this Third Temporary Rule to ensure a smooth transition for practitioners and patients who have come to rely on the availability of telemedicine for controlled medications prescriptions. The Agencies anticipate that this additional time will allow them to issue proposed and final regulations that take into account the extensive public comments received in prior rulemaking and listening sessions. Given that future DEA proposals are in the hands of a new Administration, stakeholders should clarify their positions as the regulations take shape.

PRACTICAL TAKEAWAYS

- The Third Temporary Rule should bring a welcome sigh of relief for practitioners and patients bracing for the impending expiration of the telemedicine flexibilities and the impact it may have on care continuity. However, practitioners should note that the extension of these federal telemedicine flexibilities does not negate any state or payor-specific requirements that may otherwise apply to remote prescribing and/or require in-person examination. Indeed, it is critical that practitioners ensure their prescribing practices conform not only to applicable DEA rules but to all other applicable state and payor requirements.
- This subsequent extension of telemedicine flexibilities should also allow for adequate time for those practitioners to come into compliance with any new standards or safeguards established under final regulations that the Agencies eventually adopt.

- Now that the DEA has finalized this extension, there is one less thing on Congress' to-do list for policies expiring at the end of the year. Congress is still expected to pass some type of year-end package that will extend Medicare telehealth flexibilities.
- Though the Agencies have committed to working on finalizing a permanent solution, this will be a difficult lift to do in one year, as both the DEA and HHS will have to staff up in the new Administration and start the process of issuing a permanent solution. It has been announced that both the Department of Justice (which oversees the DEA) and HHS will be led by controversial nominees who will have to go through the confirmation process starting in January 2025. Thus, it is to be determined where this will fall on the Agencies' priority list. Stakeholders, including Hall Render, will engage with policymakers to communicate priorities for future proposed regulations in the new Administration. Hall Render will continue to monitor the Agencies' rulemaking activity for updates.

For more information regarding the DEA and HHS proposed rules or other considerations related to telehealth prescriptions, please contact:

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