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DEA Extends Pandemic Telehealth Prescribing Flexibilities For Up To 18 Months

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On May 9, 2023, the Drug Enforcement Administration (DEA) issued a <u>temporary rule</u> that extends pandemic-era flexibilities allowing prescribing of controlled substances based on a telehealth relationship, after receiving in excess of 38,000 comments on its March 1, 2023, proposed rules (previously discussed <u>here</u>) to extend certain of those flexibilities but allow others to end upon expiration of the COVID-19 public health emergency on May 11, 2023. The Temporary Rule provides the DEA with additional time to assess feedback on its proposed rules for post-pandemic tele-prescribing, and provides practitioners and patients with additional time to utilize pandemic-era flexibilities and to transition away from such flexibilities once final rules are issued.

The Temporary Rule extends all pandemic-era flexibilities related to controlled substance prescribing based on a telemedicine relationship through November 11, 2023, and further establishes a "one-year grace period" thereafter allowing practitioners and patients who established a telemedicine relationship prior to November 11, 2023, to continue to utilize the flexibilities in connection with prescribing until November 11, 2024. The Temporary Rule does so by establishing new regulations effective May 12, 2023, which in pertinent part define a practitioner-patient "telemedicine relationship established via COVID-19 telemedicine prescribing flexibilities" as existing if the practitioner prescribed a controlled medication for the patient pursuant to telemedicine flexibilities in place until November 11, 2023. The Temporary Rule regulations reiterate the continued requirements for controlled substance prescribing via a telemedicine relationship, including that:

- The prescription must be issued for a legitimate medical purpose, by a practitioner acting in the usual course of professional practice, with a DEA registration covering the class of prescribed medication(s);
- The prescription must be issued pursuant to a practitioner-patient communication via an interactive telecommunications system with audio and video (or audio-only for certain mental health (including buprenorphine) prescribing if the patient doesn't consent to video); and
- The prescription must otherwise be consistent with all DEA regulatory requirements for prescriptions of controlled substances.

As a reminder, the COVID-19 telemedicine prescribing flexibilities allow practitioners to prescribe Schedule II-V controlled medications, including FDA-approved Schedule III-V controlled medications for maintenance and withdrawal management treatment for opioid use disorder, without an in-person medical evaluation, provided certain criteria are met.

The DEA continues to "carefully evaluate" all comments received on its proposed rules, and determined the need to issue this Temporary Rule to enable a transition once final rules are promulgated. The DEA acknowledged receipt of many comments proposing a grace period for extension of the telemedicine flexibilities, as well as some opposing any extension on the basis that the pandemic-era telemedicine flexibilities had led to increased diversion and overprescribing (particularly related to certain telemedicine arrangements involving prescribing

without conducting a bona fide medical evaluation of the patient).

Interestingly, aside from comments related to the extension and grace period the DEA has ultimately established under the Temporary Rule, the DEA did not describe other comments regarding the substance of the proposed rules, and in particular the DEA's proposals concerning Schedule II controlled substances. It therefore remains to be seen how the DEA will address inclusion or exclusion of Schedule II controlled substances and other substantive matters that have been raised by industry stakeholders since issuance of the proposed rules in early March.

If you have any questions, please contact any member of Robinson+Cole's<u>Health Law Group</u>.

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