CLIENT ALERTS & INSIGHTS

DEA Permits Continuation of Telemedicine Controlled Substances Prescribing: A Temporary Pause of the Proposed Rules or a Fundamental Change?

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Earlier this year in late February, the Drug Enforcement Administration (DEA) announced proposed rules attempting to change the rules for tele-prescribing controlled drugs that were permitted during the COVID-19 Public Health Emergency (PHE). The PHE is set to expire on May 11, 2023. These new proposed rules, which were developed with the U.S. Department of Health and Human Services (HHS), would have brought back the prior in-person consultation requirements for tele-prescribing.

The comment period for the proposed rules ended on March 31, 2023, and according to DEA Administrator Anne Milgram, the DEA received a record 38,000 comments criticizing the proposed rules.[1] Industry groups criticized the rules as being too restrictive. The American Hospital Association called the rules "burdensome restrictions" with "additional administrative requirements" and expressed concern that the rules "will adversely impact patient access to medically necessary treatments."[2] The Association of American Medical Colleges expressed concern that the burdensome requirements would limit access to care.[3]

Other commenters were surprised that the proposed rules failed to develop a special registration process for telehealth-only prescribers as required by the Ryan Haight Act.[4] In the comments, the DEA explained that upon consideration, it determined that such a special registration would be too burdensome for telemedicine providers and patients.[5]

In response to the record number of comments received and negative industry concerns reflected in such comments, DEA Administrator Milgram, in conjunction with HHS, submitted a draft Temporary Rule to the Office of Management and Budget.[6] The details of this Temporary Rule will be publicly available once published in the Federal Register, expected this week. It remains yet to be seen whether the extension serves only as a temporary extension and refinement for implementation of the proposed rules on telemedicine prescribing as originally proposed-or whether the extension indicates that the DEA and HHS intend to fundamentally alter the rules to reflect such concerns.

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[1] Statement from the DEA Administrator Anne Milgram on COVID-19 Telemedicine Flexibilities for Prescription of Controlled Medications

[2] AHA Comment Letter to DEA on Telemedicine Prescribing of Controlled Substances Proposed Rule

[3] AAMC Submits Comments to DEA on Telemedicine Prescribing Controlled Substances

[4] Ryan Haight Online Pharmacy Consumer Protection Act of 2008, National Council for Mental Wellbeing

[5] 88 FR 12883

[6] Temporary Extension of COVID-19 Telemedicine Flexibilities for Prescription of Controlled Medications Statement from the DEA Administrator Anne Milgram on COVID-19 Telemedicine Flexibilities for Prescription of Controlled Medications