



Alliance for Connected Care

Summary: “Expansion of Induction of Buprenorphine via Telemedicine Encounter (RIN: 1117-AB78)” Drug Enforcement Administration (DEA) Notice of Proposed Rulemaking

Public comments due after publication in the Federal Register (March 31, 2023)

The Drug Enforcement Administration (DEA) [released](#) its Notice of Proposed Rulemaking ([NPRM](#)) on buprenorphine via telemedicine encounter, a [summary](#), and [highlights](#) for medical practitioners.

The proposed rule amends the DEA’s regulations, in concert with the Department of Health and Human Services (HHS), on the circumstances under which individual practitioners are authorized to prescribe schedule III-V controlled substances which are approved for treating opioid use disorder, either as medication maintenance or treatment for withdrawal management, referred to as maintenance or detoxification treatment via a telemedicine encounter, including an audio-only telemedicine encounter.

Specifically, the proposed rule provides requirements to check the Prescription Drug Monitoring Program (PDMP) prior to issuance of a prescription, 30-day limitations, in-person requirements for follow-up appointments, and more detailed requirements for record-keeping are expected to minimize the diversion of buprenorphine via telemedicine, including audio-only telemedicine.

Summary of Proposed Rule

Unmet Need to Facilitate Patient Access to Treatment for Opioid Use Disorder

DEA is proposing regulations that would address the unmet need to increase patient access to treatment for opioid use disorder (OUD). This would enable patients who, prior to being able to access treatment under the circumstances newly authorized, did not wish to, or did not possess the means to, be inducted for the OUD treatment.

This includes expanding the circumstances under which practitioners are authorized to prescribe via telemedicine encounters, including audio-only encounters, for those individuals with OUD who may not want to seek treatment, or are unable to see treatment, due to various economic, geographical, sociological, and logistical reasons.

Increased Access Must Be Consistent with Effective Controls Against Diversion and Public Health and Safety

DEA is proposing to require a thorough review of PDMP data prior to prescribing, a medication evaluation of the patient meeting certain conditions within 30 days, as well as comprehensive recordkeeping requirements.

DEA believes there are diversion risks associated with the expanding access to narcotics over the phone. DEA emphasizes draft regulations need to be consistent with public health and safety.

Prescription Drug Monitoring Program Review



DEA is proposing to require a practitioner to review and consider PDMP data prior to prescribing buprenorphine under the authority the regulations would grant. The review would allow the practitioners to:

- Make informed clinical decisions and identify and counsel the patient regarding higher risks;
- Identify patients who may have obtained a buprenorphine or another recent prescription from another source;
- Monitor for practitioners deliberately misprescribing buprenorphine; and
- Prevent the diversion of such drugs through practitioners' lack of awareness that the patient on the other end of the line does not have an actual medical need or requires a more careful examination.

DEA believes that without requiring practitioners to review and consider PDMP data, different practitioners could prescribe multiple 30-day supplies, or subsequent 30-day supplies indefinitely, to patients without realizing that they are doing so.

DEA believes a PDMP review requirement for prescribers, prior to writing a prescription, would balance the states' interest in regulating the practice of medicine with the overarching interest in mitigating the high risk of diversion for prescriptions which do not require face-to-face interaction with the prescribing physician.

Requirement of Medical Evaluation in Person or in Presence of Another DEA Registrant within 30 Days

DEA is proposing to require the patient receiving buprenorphine under the expanded authority of these regulations to receive a medical evaluation meeting certain requirements within 30 days of being prescribed buprenorphine for the induction of OUD treatment to obtain an additional supply of buprenorphine. The requirement can be satisfied when the prescribing practitioner receives a qualifying telemedicine referral for medical-assisted treatment (MAT) for OUD from a DEA-registered practitioner prior to issuing a prescription for controlled substances.

DEA believes this requirement is necessary because without this provision, practitioners could theoretically prescribe buprenorphine without ever conducting a thorough medical evaluation of the patient.

DEA is also proposing, for supplies after the 30 days, to require a medical evaluation on the safety and appropriateness of a buprenorphine prescription for the patient to prescribe a supply in excess of 30 days. DEA believes this will assist in the investigation and persecution of malicious practitioners and to ensure the public health and safety of patients.

Recordkeeping

DEA is proposing to require practitioners to keep comprehensive records establishing the nature of the encounter, the patient's proffered reason for the audio-only encounter (if the patient requests the telemedicine encounter be audio-only rather than audio-video), and all efforts to comply with PDMP checks.



Prescribing Buprenorphine for the Induction of Medication for the Treatment of Opioid Use Disorder

DEA is proposing that the induction of buprenorphine via a telemedicine encounter simply for the treatment for OUD for patients and does not seek to circumvent or replace the individualized treatment protocols present in the usual course of treating an individual with OUD.

Request for Comments

DEA invites comments:

- Concerning whether any clarifications or other regulatory provisions are warranted to ensure appropriate access to care, are consistent with effective controls against diversion and other consistent with the public health and safety;
- On the proposed practitioner recordkeeping obligations;
- About additional safeguards or flexibilities that should be considered with respect to this rule; and
- Whether the [Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation](#) should be combined with this rulemaking when publishing the Final Rule.