



March 31, 2023

Administrator Anne Milgram
Attn: DEA Federal Register Representative/DPW
The Drug Enforcement Administration
8701 Morrisette Drive
Springfield, Virginia 22152

RE: Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation (Docket No. DEA-407, RIN 1117-AB40)

Submitted electronically via regulations.gov

Dear Administrator Milgram:

The Center for Telehealth and e-Health Law (CTeL) commends your continued commitment to addressing diversion, while also proposing to permanently expand access to medically necessary controlled substances through telehealth. The Drug Enforcement Administration's (DEA) notice of proposed rulemaking (RIN 1117-AB40) makes historic steps to better align prescribing guidelines with advancements in high quality virtual care.

For 28 years, CTeL has been the leading source of legal, regulatory, and policy intelligence for the telehealth community. CTeL is a 501(c)3 nonprofit, apolitical, and vendor-agnostic telehealth research institute. CTeL and its members are advocates of high quality health care, regardless of whether it is administered in-person or in a virtual environment. We are cognizant of the DEA's role in developing effective safeguards to deter diversion for both in-person and telemedicine prescribing. While the proposed rule is well intentioned, we want to highlight certain ways in which it could severely hinder patient access, resulting in unintended consequences for patients, providers, and the health care community as a whole. These consequences include increased patient reliance on black-market drugs, significant appointment wait-times for patients, exacerbation of the clinician workforce crisis, and, most alarming, needless SUD/fentanyl deaths.

Existing laws and recent Department of Justice (DOJ) enforcement actions have been effective in investigating and deterring telemedicine actors suspected of inappropriate prescribing practices. We applaud DOJ's efforts in investigating these entities while protecting patients' access to legitimate, quality virtual care services.

The telehealth community has long awaited DEA's promulgation of rules for a "special telemedicine registration" exception as set forth in the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 and mandated under the SUPPORT for Patients and Communities Act of 2018. While we understand that the DEA elected not to pursue a "special telemedicine registration" citing concerns about potential burdens for patients and providers, we believe the DEA's proposed "referral pathway" can be improved to ensure patients can continue to receive medically necessary controlled substances through telemedicine, while also safeguarding against diversion.

CTeL recommends that DEA consider the following modifications as it works to finalize the proposed rule:

6-Month (180-Day) Flexibility for “Telemedicine Relationships Established During the COVID-19 Pandemic Public Health Emergency.”

1. **In-Person Exclusion for Provider-Patient Relationships Established During PHE.** CTel recommends that DEA consider establishing an exclusion to the in-person requirement for all telemedicine providers and patients who have formed a practitioner-patient relationship during the COVID-19 public health emergency (PHE). The language of the rule as proposed would require that patients and providers that have established such a relationship already, including the prescribing of controlled substances, would need to participate in an in-person encounter to continue their existing relationship. This results in unnecessary medical visits that are burdensome for patients and providers alike, who have utilized telehealth effectively and without diversion since March of 2020. In many cases, telemedicine prescribers may not be in the same geographic area as their patients, making an in-person evaluation practically impossible. This results in fractured care, with patients being forced to find new providers despite having an effective and established relationship. The difficulties imposed by travel and other obligations will disrupt valuable therapies, perhaps permanently, with resulting increases in morbidity and mortality.
2. **Extend 180-day transition period to a minimum of 1 year.** If DEA elects not to adopt public recommendations to exclude telemedicine relationships established during the PHE from the in-person evaluation requirement, CTel recommends DEA extend the 180-day flexibility to a minimum of one year. The proposed 180-day transition period, simply put, is not enough time for telemedicine providers to build a network of in-person providers to see each patient, especially where, as is not uncommonly the case, provider and patient are geographically distant. This challenge is exacerbated by factors including limited or non-existent primary care providers in close proximity to the patient’s home, particularly in rural areas. The 180-day timeframe will worsen the clinician workforce shortage and put at risk many patients, especially those receiving mental and behavioral health services through virtual means.

In-Person Medical Evaluation Requirement for Schedule II - V Controlled Substances.

1. **In-Person Medical Examination Impractical During National Provider Shortage.** This requirement will have a pernicious impact on patients’ ability to receive needed care timely from a specialist at a distance.

Given our Nation’s ongoing national provider shortage crisis, the DEA’s proposed referral pathways will be difficult for telemedicine providers to utilize. According to the Health Resources Services Administration, an estimated 98,827,276 million Americans (nearly 1/3rd of the U.S. population) reside in federally designated primary care shortage areas and an estimated 159,792,634 million Americans (nearly half) reside in mental health professional shortage areas. If implemented as proposed, the new requirement will negatively impact millions of patients facing serious obstacles to seeing providers in-person, regardless if telehealth is a later option. Telehealth is known for bridging the patient-provider gap. Requiring a prior in-person exam, however, will result in an unnecessary barrier to care, particularly where the vast majority of health care providers are conscientiously prescribing controlled substances already.

2. **In-Person Requirement Restricts Access to Care and Increases Unintended Consequences.** There is little evidence that the proposed rule’s referral pathways will deter bad actors from

violating the law, the applicable standards of care, or medical ethics. CTeL encourages DEA to consider unintended consequences of the proposed rule that have a potential of causing serious harm to patients and providers:

- a) **Schedule II - V Controlled Substances.** Under the proposed rule, patients will be restricted from obtaining medically necessary medications prescribed via clinically appropriate telemedicine which will likely result in patients pursuing black-market alternatives. For instance, students who have been appropriately prescribed and have relied on Schedule II stimulants for attention-deficit/hyperactivity disorder may turn to black-market suppliers of the medication if their telehealth provider can no longer continue to treat the patient. This would have the unintended consequences of increasing patient diversion and exposing patients to substances that not only lack efficacy but could well be contaminated with harmful foreign matter. Self-prescribing and self-dispensing pose significant risks, with the Centers for Disease Controls reporting a 56% increase in fentanyl deaths from 2019 to 2020.

- b) **Schedule III-V Controlled Substances.** Given the proposed 30-day supply limit for schedule III-V controlled substances before patients must be seen in-person by a qualified medical practitioner, patients may attempt to see a new telemedicine provider once the 30-day medication supply runs out (in order to perpetually avoid the in-person evaluation). This will lead to fractured care and physician shopping, especially for patients that may already be predisposed to drug-seeking behavior. States' Prescription Drug Monitoring Programs (PDMP) were created to track controlled substance prescriptions and prevent this type of misuse. Ideally, PDMPs can help identify patients who pose diversion risks. At the same time, there are several challenges hindering effective use of PDMPs, including lag time, state-to-state variability in information sharing, and important privacy concerns. The 30-day requirement may create off-market medication seeking behavior by patients who are unable to see their providers in-person within that 30-day window.

Conclusion.

As you and your colleagues review public comments on the proposed rule for RIN 1117-AB40, CTeL would like to share the following comments and recommendations that we have received from the telehealth community in the forthcoming pages. We would like to note that the following comments do not necessarily reflect CTeL's position on the proposed rules; however, we collated and gathered feedback for the benefit of DEA.

For questions or comments on CTeL's research or the comments shared below, please contact CTeL's Director of Policy and External Affairs, Ben Steinhafel, at Ben@CTeL.org.

Very truly yours,

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