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January 18, 2022

Anne Milgram
Administrator
Drug Enforcement Administration
Department of Justice
8701 Morrisette Drive
Springfield, VA 22152

RE: Regulation of Telepharmacy Practice Advanced Notice of Proposed Rulemaking (RIN 1117–AB74)

Submitted electronically on regulations.gov

Dear Administrator Milgram,

Thank you for the opportunity to comment on this advanced notice of proposed rulemaking. The Drug Enforcement Administration (DEA) is requesting more information about current state regulatory authorities around the practice of telepharmacy, unofficially defined as the provision of pharmacist care by a remote pharmacist, through the use of telecommunications and other technologies, to a patient located at a dispensing site. More specifically, DEA outlines two scenarios considered to be telepharmacy. The first is where a non-pharmacist employee at a brick-and-mortar facility, such as a pharmacy technician, is remotely supervised by a pharmacist in a different location. The second is a self-served, automated machine, or kiosk, that can dispense patient prescriptions without the physical presence of a pharmacist or other employee.

As the only organization completely focused on advancing telehealth, the ATA is committed to ensuring that everyone has access to safe, affordable and appropriate care when and where they need it, enabling the system to do more good for more people. The ATA commends the DEA for carefully considering how to regulate the practice of telepharmacy. With consistent health care workforce shortages only exacerbated by the COVID-19 pandemic, the use of remote clinicians can add efficiency and greatly enhance access to care. Thus, the ATA supports the DEA regulating telepharmacy in such a way that allows it to occur when clinically appropriate and safe.

The DEA distinguishes between the practice of telepharmacy and the use of the internet to dispense controlled substances, the latter of which falls under the jurisdiction of the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (Ryan Haight Act). The remainder of these comments provide the ATA's position on the use of telemedicine under the Ryan Haight Act.

The ATA appreciates the DEA's role in combatting rogue internet sites illegally selling and dispensing controlled substances. The ATA also appreciates the Ryan Haight Act and the DEA's recognition that the internet *can* be used to dispense controlled substances for legitimate medical purposes via telemedicine. The Act requires a DEA-registered practitioner to conduct at least one in-person exam of a patient before prescribing a controlled substance by means of the internet including through telemedicine except in a few limited cases. Prior to the COVID-19 pandemic, those exceptions to the prior in-person requirement were very limited and did not allow for the patient to receive telemedicine services while located in their home.

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During the COVID-19 Public Health Emergency (PHE), the DEA has used the Ryan Haight Act's "public emergency" exception to temporarily remove the in-person exam requirement, eliminating all restrictions on the location of the patient. Experience during the pandemic has not indicated that the flexibility on the location of the patient has resulted in an increase in illegal drug diversion, inappropriate prescribing, or the prevalence of opioid dependency. On the contrary, having easier access to critical care is helping to combat the spikes in mental health and substance use.

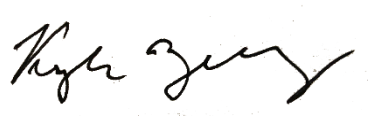
The Ryan Haight Act's pre-pandemic restriction on the location of the patient during a telemedicine visit is a needless barrier to critical clinically necessary treatments from legitimate health care providers and does not do much to prevent illegal online drug sales by illegitimate actors. The ATA believes the ultimate choice about a patient's care plan, including the modality of care and clinical appropriateness of services, should be the decision of an empowered patient and their provider in accordance with the standard of care. As such, the ATA strongly recommends policymakers ensure patients continue to have access to controlled substances for legitimate medical purposes via telemedicine once the PHE ends. **The ATA recommends maintaining appropriate oversight of the remote prescriber while lifting restrictions on the location of the patient receiving telemedicine services.**

The ATA recognizes that some controlled substances, including schedules I and II, pose an increased risk of dependency and illegal diversion. As such, permanent policy should focus on ensuring patients have access to schedule II (stimulants only), controlled substances under schedules III and IV, and certain medications for treatments for substance use and opioid use disorders (suboxone, naloxone, buprenorphine). For certain schedule II stimulants, the ATA believes the policy should ensure that patients treated via clinically valid telepsychiatry have access to medications, including stimulants, necessary to treat their medical and mental health needs.

The DEA should work with Congress to ensure statutes and regulations are updated to expand access to care without sacrificing safety and supply chain security. Absent updated congressional action, the ATA also encourages the DEA to complete the Special Registration for telemedicine regulations previously required by Congress.

Thank you very much for the opportunity to provide our feedback on this advanced notice of proposed rulemaking. If you have any questions or would like to further discuss our recommendations, please contact Kyle Zebley, Vice President, Public Policy at kzebley@americantelemed.org.

Kind regards,



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