

DEA SOLICITING INPUT FOR DEVELOPMENT OF TELEPHARMACY PRACTICE REGULATIONS

On November 17, 2021, the Drug Enforcement Administration (“DEA”) issued an **advanced notice of proposed rulemaking (“ANPR”)** with the goal of obtaining further information regarding the practice of telepharmacy. The DEA is seeking input as it considers promulgating new telepharmacy regulatory requirements. Interested stakeholders have until January 18, 2022 at 11:59 PM EST to submit their comments to DEA.

Currently, the term “telepharmacy” is not actually defined in the Controlled Substances Act (“CSA”) or DEA regulations. This has led to uncertainty related to telepharmacy practice and the dispensing of controlled substances. In turn, this uncertainty has served as a headwind to the adoption of remote care modalities that have become increasingly important during the COVID-19 pandemic.

Of course, telepharmacy is practically considered to include the remote, technology-enabled provision of pharmacist care to patients located at a dispensing site. State standards governing telepharmacy vary widely and address (in a myriad of ways) standards related to dispensing, drug utilization review, patient counseling and drug therapy monitoring.

Given the expansion of telepharmacy modalities that have facilitated non-controlled drug dispensing in recent years, DEA is seeking to revisit its guidance in this space, presumably with an emphasis toward facilitating access to pharmacy care. Of course, access to pharmacist services must be balanced against diversion risks unique to telehealth services which fundamentally differ from more traditional pharmacy settings with in-person monitoring.

Comments that interested stakeholders might address include facilitation of models under current federal law related to “online pharmacies” under the Ryan Haight Online Pharmacy Consumer Protection Act (the “Ryan Haight Act”). While the Ryan Haight Act allows for the use of telepharmacy services after DEA has issued a modified online pharmacy registration, or where the telepharmacy falls within one of ten Ryan Haight Act exceptions, to date there are no online pharmacy registrations with DEA.

Accordingly, DEA is soliciting information from state regulatory authorities, national and professional associations, industry, telepharmacy vendors and servicers and the general public so that DEA may better understand telepharmacy and how it is currently functioning from both the prescribing and dispensing standpoint. This is an opportunity for interested stakeholders to explain how modern pharmacies operate and offer reasonable recommendations for telepharmacy dispensing of controlled substances.

Interested stakeholders have until Tuesday, January 18, 2022 to submit their comments. Electronic comments may be submitted through [this link](#) by following the online instructions at that site for submitting comments. Paper comments may be directed to the address listed in the ANPR.

PRACTICAL TAKEAWAYS

- Considering the lack of standardized regulations addressing the practice of telepharmacy and the considerable growth of telehealth services nationwide, DEA is seeking input from a wide variety of stakeholders regarding how telepharmacy should function, particularly in the context of controlled substance dispensing.
- Interested stakeholders should submit their comments relating to modern pharmacy operation and reasonable oversight proposals to help shape future DEA rulemaking in the telepharmacy space.

If you have questions regarding DEA’s ANPR or would like assistance submitting a comment to DEA, please contact:

- **Todd Nova** at (414) 721-0464 or tnova@hallrender.com;
- Your primary Hall Render contact.

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