

July 24, 2024

The Honorable Anne Milgram
U.S. Drug Enforcement Administration 8701 Morrisette Drive
Springfield, VA 22152
RE: E.O. 12866 RIN:1117-AB40

Re: Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have not had a Prior In-Person Medical Evaluation

Dear Administrator Milgram,

We appreciate the opportunity to comment on the Drug Enforcement Administration's proposed rule on telemedicine prescribing of controlled substances, as well as highlight the importance of prioritizing safe, accessible and quality ADHD care and treatment in a virtual environment. There is currently a major risk to the disruption of care, yet there are solutions actively being used to address some of the concerns around monitoring treatment via telehealth that should be considered. We urge the DEA to consider the negative impact of restricting access to virtual care and prescribing Schedule IIN (non-narcotic) medications, specifically for patients presenting with ADHD. We support the letters and supportive data sent to Administrator Milgram earlier this Spring by ACAP, et. al., ATA and others, around the inclusion of Schedule IIN and agree that these should not be excluded from the Special Registration process.

With nearly half of all Americans living in areas with a shortage of mental health professionals,¹ virtual care is indispensable for providing comprehensive care for mental health conditions. Recent data² revealed that mental health conditions accounted for the top telehealth diagnostic category across the United States, with ADHD being the fourth most common mental health diagnosis. If this access is disrupted, tens of thousands of individuals across the country will be left without care or will be forced to seek care from providers without adequate training due to the national provider shortage. ADHD is one of the most addressable behavioral health conditions and is commonly co-occurring with other mental health conditions, making it imperative to prioritize not only its management, but access to treatment.

Pediatric patients should not be left out of this discussion. Data shows that there are only 758 Developmental and Behavioral Pediatricians qualified to treat the estimated 19 million children with developmental disabilities nationwide.³ Telehealth flexibilities have allowed these clinicians to care for more patients and provide support to non-specialists. With the increased prevalence of ADHD and Autism Spectrum Disorders, access to specialized providers is essential to allowing families to receive care in a timely manner; patients should not have to wait months if not a year for an appointment.

Thus, we advocate for access through an extension with required safeguards in place to ensure that access is guaranteed while ensuring the highest level of quality. Incorporating evidence-based, regulated, and innovative technology that enables thorough and objective diagnostic evaluations should be a requirement for all ADHD virtual care visits, leading to safe, effective, and accessible care. The DEA can expand on current flexibilities to pioneer safe, innovative methods that allow patients to receive necessary treatment.

When evaluating a patient for ADHD, safety must always be of the utmost priority. Even if a special registration process is put in place, this does not decrease the necessity for safeguards that prevent misuse. FDA-cleared, objective testing tools that have been validated for use at diagnosis and when monitoring treatment, increase provider confidence⁴ and capture treatment effects within hours of administration.⁵ A

1 <https://bhw.hrsa.gov/sites/default/files/bureau-health-workforce/Behavioral-Health-Workforce-Brief-2023.pdf>

2 <https://www.fairhealth.org/press-release/fair-health-s-monthly-telehealth-regional-tracker-enters-fifth-year>

3 <https://pubmed.ncbi.nlm.nih.gov/36170013/>

4 <https://acamh.onlinelibrary.wiley.com/doi/full/10.1111/jcpp.12921#:~:text=QbTest%20reduced%20appointment%20length%20by,no%20difference%20in%20diagnostic%20accuracy>

5 <https://pubmed.ncbi.nlm.nih.gov/38164455/>

6 <https://www.nice.org.uk/news/articles/nice-recommends-digital-technology-to-help-diagnose-adhd-in-children-and-young-people>

recent NICE recommendation stated that QbTest can improve wait times without sacrificing accuracy.⁶ When combined with a proper diagnostic evaluation, objective data provides a necessary safeguard to ensure the highest level of ADHD care and can help prevent possible misuse.

As members of the ADHD community, we intimately understand the nuances of this condition and the impact of the decisions that are under your thoughtful consideration. We thank you for your review of these recommendations and your mindfulness to keep patients at the forefront. Without safeguards in place, any temporary or permanent solution could continue to lead to poor outcomes for both individual patients and the community at large.

While we recognize that short-term and permanent solutions require thoughtful guidance and constructive approaches, we advocate for an extension with a process to evaluate mandatory safeguards until the special registration process as required by Ryan Haight is put in place. We believe that leveraging FDA-cleared technology to provide safe, accessible care should be part of the permanent rule put forth by the DEA and would be the most responsible and measured solution regarding the prescribing of controlled substances for those practitioners who are registered with the DEA. We would welcome the opportunity to assist in developing a proposed special registration process.

Sincerely,

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