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March 31, 2023

The Honorable Anne Milgram
Administrator
United States Drug Enforcement Administration
DPW
800 K Street NW, Suite 500
Washington, D.C. 20001

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

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Submitted electronically via: www.regulations.gov

Dear Administrator Milgram:

The American Academy of Sleep Medicine (AASM) appreciates the opportunity to comment on the proposed rules, published by the United States Drug Enforcement Administration (DEA), which directly address telemedicine and the prescription of controlled substances under the Ryan Haight Online Pharmacy Consumer Protection Act of 2008. The proposals included in these rules will directly impact the care provided by AASM members to patients with sleep disorders. The AASM is dedicated to advancing sleep care and enhancing sleep health to improve lives, and the comments included in this response reflect the needs of more than 10,000 individual AASM members and 2,500 AASM-accredited sleep facilities, providing sleep medicine services to the Medicare population.

Steve Van Hout
Executive Director

Throughout the public health emergency (PHE), providers and patients have benefitted from the flexibility of patients being prescribed certain controlled substances without having to meet the requirement of an in-person visit. This policy modification has allowed for greater access to care as well as the establishment of provider-patient relationships in instances where this may not have been possible, given the limited number of providers in certain geographical areas. As the PHE comes to an end, the Agency is now proposing to limit prescriptions for schedule III – V controlled medications to a 30-day supply, requiring an in-person visit after the 30 days. This policy seems unnecessarily restrictive and may potentially, once again, limit access to care. The AASM strongly urges the Agency to instead consider requiring an audio-visual visit after the first 30 days for the majority of patients, which will allow providers to evaluate the patient remotely. As we understand the primary concern is for patients being treated for opioid use disorders

(OUDs) we recommend that if the Agency decide to move forward with this proposal, that exceptions be established for patients treated with controlled substances, with no history of OUD and whom the provider designates low risk for OUD.

Sleep medicine patients are commonly treated with controlled substances for sleep disorders including parasomnias, insomnias, hypersomnias, sleep-related rhythmic movement disorders, and sleep-disordered breathing (i.e., obstructive sleep apnea). For those sleep patients with no history of OUD, we believe these patients should continue be treated via telemedicine. Removal of the current flexibility may prevent some of these patients from being able to receive the required care, given limited access to sleep medicine providers and sleep facilities, in some areas. Continuity of care is also extremely important in treating sleep disorders and we hope the Agency will consider the potential negative impact on patient outcomes, if patients are suddenly no longer able to receive necessary medications.

Thank you for your consideration of these comments. The AASM appreciates the DEA's efforts to protect patient safety, particularly for patients with OUD, as the public health emergency comes to an end. We encourage the Agency to consider the feedback summarized in this letter, which will hopefully assist in the appropriate management of prescription of controlled substances using telehealth as an alternative to in-person visits, when appropriate. Please feel free to contact Diedra Gray, AASM Director of Health Policy, at dgray@aasm.org or 630-737-9700, for additional information or clarifications.

Sincerely,

Jennifer Martin, PhD