AMERICAN ACADEMY OF NEUROLOGY®

201 Chicago Avenue
Minneapolis, Minnesota 55415

Tel: (612) 928-6100
Fax: (612) 454-2744

AAN.com

March 22, 2023

Anne Milgram
Administrator
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, VA 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]

Dear Administrator Milgram,

The American Academy of Neurology (AAN) is the world's largest neurology specialty society representing more than 40,000 neurologists and clinical neuroscience professionals. The AAN is dedicated to promoting the highest quality patient-centered neurologic care. A neurologist is a physician with specialized training in diagnosing, treating, and managing disorders of the brain and nervous system. These disorders affect one in six people and include conditions such as multiple sclerosis (MS), Alzheimer's disease (AD), Parkinson's disease, stroke, migraine, epilepsy, traumatic brain injury, ALS, and spinal muscular atrophy.

The AAN appreciates the opportunity to comment on the proposed rule on "Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient have Not Had a Prior In-Person Medical Evaluation."[1] There is consensus among AAN members that adoption of telehealth and continued use over the past three years has had many benefits for patient care. We note that evidence supports the effectiveness of telehealth in inpatient and outpatient settings, for acute evaluation and routine assessment and for multiple neurologic subspecialties.[2] Throughout the Covid-19 Public Health Emergency (PHE), the expanded availability of telehealth services and additional administrative flexibilities have allowed AAN members to mitigate infection risk and continue to provide care to patients who otherwise would have missed critical appointments with serious potential consequences. Expanded access to telehealth services has also allowed patients with cognitive and mobility impairments to more easily receive care and has reduced travel time for patients and numerous burdens for caregivers. Telehealth is also associated with lower rates of no-show

[1] 88 Fed. Reg. at 12875
[2] Hatcher-Martin, Jaime M., et al. "American Academy of Neurology Telehealth Position Statement." Neurology, American Academy of Neurology, 17 Aug. 2021, https://n.neurology.org/content/97/7/334.

appointments and is widely viewed by neurology patients as a convenient and appropriate alternative to in-person care.[3][4] The AAN strongly supports policies that ease unnecessary restrictions to virtual care, support long-term sustainability of care delivery, and promote high-quality, patient-centered care.

We appreciate that the Drug Enforcement Administration (DEA) recognizes the importance of telemedicine in current medical practice and intends to allow physicians to prescribe medically necessary controlled medications via telehealth in certain circumstances after the end of the PHE. The AAN particularly appreciates that the DEA, in concert with the Department of Health and Human Services (HHS), is working to provide updates about the requirements and limitations on such prescribing before the PHE expires to give providers much needed clarity and time to prepare for these critical policy changes.

To avoid confusion and maintain access to care as medical practitioners transition out of the PHE, the AAN strongly recommends that the DEA and HHS continue existing flexibilities and make the effective date of the proposed regulations January 1, 2025, to align with the extension of the COVID-19 Medicare telehealth flexibilities provided by Section 4113 of the Consolidated Appropriations Act, 2023 (CAA, 2023). We also ask that the DEA and HHS develop additional materials to educate practitioners about the new requirements, particularly those related to documentation and to qualifying telemedicine referrals. We describe these recommendations in greater detail below.

A. DEA Regulations Should be Aligned with the Extension of Telehealth Flexibilities Under the CAA, 2023.

In the proposed rule, the DEA states: "This rule is designed to ensure that patients do not experience lapses in care. It is also deigned to ensure continuity of care under the current telehealth flexibilities in place as a result of the COVID–19 public health emergency."[5] The AAN believes this is a critical consideration for neurology patients, as patients with a wide variety of neurologic conditions including immobility, seizure disorders, sleep disturbances, Parkinson's disease, disorders of arousal, and traumatic brain injury rely on telehealth to maintain access to care. The AAN strongly believes that the transition from the PHE must not disrupt ongoing care, nor serve to create new barriers to accessing telehealth service.

Congress also recognized the need to ensure continuity of care and to provide a transition from the flexibilities in effect during the PHE to the post-PHE period. In Section 4113 of the CAA 2023, Congress extended until December 31, 2024, numerous flexibilities related to the provision of services to Medicare beneficiaries through telehealth, including covering and paying for audio-only services. The DEA should align the effective date of these regulations with that extension and make these regulations effective January 1, 2025. An effective date of January 1, 2025, will also provide substantial time for the DEA, HHS, and other groups,

[3] Muppavarapu, Kalyan, et al. "Study of Impact of Telehealth Use on Clinic 'No Show' Rates at an Academic Practice." The Psychiatric Quarterly, U.S. National Library of Medicine, June 2022, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9004215/.
[4] Olszewski, Carly, et al. "A Comparison of Telemedicine and in-Person Neurology Visits: What Are the Factors That Patients Consider When Selecting Future Visit Type?" Journal of Neurology, U.S. National Library of Medicine, Sept. 2022, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9068349/.
[5] 88 Fed. Reg. at 12882.

including specialty societies such as the AAN, to educate practitioners about the requirements and better ensure compliance.

As noted in the proposed rule, "the Ryan Haight Act generally requires an in-person medical evaluation prior to the prescription of controlled substances. Section 829(e), however, also provides an exception to this in-person medical evaluation requirement where the practitioner is 'engaged in the practice of telemedicine." To fall within this definition, a practice must use a telecommunications system. The DEA relies on Medicare regulations for the definition of key concepts including, importantly, the definition of an "interactive telecommunications system." To avoid confusion, the DEA regulations should align with the Medicare payment policy in effect at the same time. The CAA, 2023 requires that Medicare continue to cover and pay for services through audio-only telecommunications systems through December 31, 2024. The DEA should explicitly acknowledge that it will include audio-only services in its definition of "practice of telemedicine" for the same duration.

However, if the DEA does not make the regulations as a whole effective January 1, 2025, we strongly recommend that the DEA revise the provisions at 21 CFR 1300.04(o) regarding a telemedicine relationship established during the COVID-19 PHE to recognize the extension of the flexibilities under the CAA, 2023. For telemedicine relationships established during the PHE, the proposed rule maintains current telehealth flexibilities in place during the COVID-19 public health emergency and applies to all schedule II-V controlled substances for an additional 180 days from the end of the emergency declaration. As proposed, such a relationship would end the latter of 180 days from the end of the PHE, or the effective date of the final rule. This 180-day period is arbitrary and could result in changes that take effect at an unexpected time (i.e., 180-days after the expected end of the PHE on May 11, 2023 is November 7, 2023). DEA should not finalize the provision at 1300.04(o)(3) and should instead finalize a provision that states "the date is on or before December 31, 2024." This would make the definition of a telemedicine relationship established during the COVID-19 public health emergency consistent with the length of time Medicare must continue applicable telehealth flexibilities. Aligning the relationship period with the extension of the Medicare telehealth flexibilities will minimize confusion and the need to track multiple effective dates to comply with changing authorities. Alternatively, the relationship period should be extended to the end of the calendar year in which the PHE expires. This will cause less confusion, be easier for practitioners to remember, and most importantly, minimize the risk of inadvertent non-compliance.

B. DEA and HHS Should Provide Additional Guidance on Compliance

The proposed regulations are an expansion of prescribing ability via telemedicine compared to the period before the PHE but represent a restriction of the flexibilities available during the PHE. The AAN appreciates that the DEA has defined the term "qualifying telemedicine referral" to mean a referral "that is predicated on a medical relationship that exists between a referring practitioner and a patient where the referring practitioner has conducted at least one medical evaluation in the physical presence of the patient, without regard to whether portions of the evaluation are conducted by other practitioners, and has made the referral for a legitimate medical purpose in the ordinary course of their professional practice."[6] The AAN

[6] 88 Fed. Reg. at 12888

also appreciates that the agency is interpreting the Ryan Haight Act to allow the requirement for an in-person medical evaluation to be met by a qualifying telemedicine referral.

Under the proposed rule, "practitioners could prescribe controlled medications to a patient using telemedicine only for a period of 30 days before a medical evaluation… would be required, starting from the date of issuance of the first prescription pursuant to a telemedicine encounter."[7] The AAN notes that this flexibility only applies to prescribing of Schedule III-V non-narcotic controlled substances. To continue prescribing beyond the 30-day allowance period, a provider would either need to receive a qualifying telemedicine referral or simultaneously participate via telemedicine in a visit in which a DEA registered practitioner is providing an in-person examination to the patient. There is no similar flexibility available for the prescribing of Schedule II and/or narcotic controlled medications. The AAN appreciates the establishment of this 30-day grace period but notes that for patients with mobility challenges or other physical or cognitive impairments it may be difficult or impossible to access timely in-person care. The AAN recommends establishing an exception process to allow for prescribing beyond the 30-day allowance period for patients who were unable to be seen in-person during that timeframe due to a mobility challenge or other physical or mental impairment, until they are able to access in-person care to receive a qualifying telemedicine referral.

Although the AAN understands and supports the critical need for guardrails to combat diversion and ensure appropriate and medically necessary prescribing, this is a complex and potentially confusing schema that may lead to inadvertent non-compliance without significant efforts to educate providers on these new requirements. As such, we recommend that the DEA clarify in the final rule and in any subregulatory guidance, how the timing of a qualifying telemedicine referral will impact prescribing authority and provide additional examples of how this authority operates procedurally. We also request that the DEA clarify the obligations of prescribing practitioners to ensure that the referral qualifies under the new regulations, including requirements for prescribing providers to confirm that that the referral source is a DEA-registered practitioner and that the referring practitioner performed an in-person examination.

C. DEA Should Provide Adequate Support and Time to Develop Materials to Support Appropriate Documentation

Additionally, the proposed documentation requirements are a substantial increase from the current requirements. This proposed rule would require a practitioner to maintain a written or electronic log for each prescription issued pursuant to a telemedicine encounter indicating:

- the date the prescription was issued
- the full name and address of the patient
- the drug name, strength, dosage form, quantity prescribed, and directions for use
- the address at which the practitioner, and the city and State in which the patient, are located during the telemedicine encounter

[7] 88 Fed. Reg. at 12881

- if issued through a qualifying telemedicine referral, the name and NPI of the referring practitioner
- a copy of the referral and any communications shared pursuant to § 1306.31(d)(3)(i)–(iii) and all efforts to comply to access the Prescription Drug Monitoring Program system (and, if employed by the Department of Veterans Affairs, Department of Veterans Affairs internal prescription database)[8]

These requirements are very burdensome and will require medical specialty societies such as the AAN to provide substantial education and support to its members who prescribe controlled substances. It will take time for the AAN and others to develop these resources. Aligning the effective date of the changes to coincide with the extension of Medicare telehealth flexibilities under the CAA, 2023, as recommended above, would also allow DEA and HHS sufficient time to develop guidance materials to ensure that practitioners understand these requirements and how to comply with them. We strongly urge the DEA to prepare such materials as soon as possible. The AAN intends to conduct outreach to ensure our members are aware of the new requirements once they are finalized. Official guidance documents will facilitate that process and minimize the potential for confusion.

Thank you for the opportunity to submit these comments. We appreciate the DEA providing much-needed clarity as providers work to transition out of the Covid-19 PHE. Please contact Matt Kerschner, the AAN's Director, Regulatory Affairs and Policy at mkerschner@aan.com with any questions or requests for additional information.

Sincerely,

Orly Avitzur, MD, MBA, FAAN
President, American Academy of Neurology

[8] 88 Fed. Reg. at 12879