March 31, 2023

The Honorable Anne Milgram
Administrator, Drug Enforcement Agency
8701 Morrissette Drive
Springfield, VA 22152

Re: Docket No. DEA-407

Administrator Milgram:

Thank you for the opportunity to comment on the Drug Enforcement Administration (DEA) proposed rule regarding telemedicine prescribing of controlled substances when the practitioner and the patient have not had a prior in-person medical evaluation. The undersigned organizations represent people living with the epilepsies and providers that provide specialized epilepsy care. Many anti-seizure medications are controlled substances under Schedules III, IV, and V. Any limitations on access to prescribed medications for epilepsy could be extremely dangerous to people with the epilepsies.

Our comments focus on two provisions of the rule:

1. When a patient has not been seen in a face-to-face visit, we suggest extending the limitation on the prescription by telehealth from a 30-day supply to a 90-day supply for prescriptions for the treatment of epilepsy. It is not always feasible to schedule an in-person visit within 30 days due to the limited number of epilepsy specialists in the U.S. and transportation being a significant issue for the many adults living with epilepsy, who cannot drive due to the frequency of their seizures.
2. We do not support any limitation on the issuance of prescriptions for controlled medications to the FDA-approved indications for patients with epilepsy. Off-label prescriptions for epilepsy, especially children living with epilepsy, are common and critically important to the treatment of this disorder.

For people living with the epilepsies, timely access to appropriate, physician-directed care, including epilepsy medications, is a critical concern. Epilepsy medications are the most common and cost-effective treatment for controlling and/or reducing seizures. To delay, change, limit, or deny access to medications could be extremely dangerous. Many anti-seizure medications are controlled substances under Schedules III, IV, and V. Epilepsy medications are scheduled due to their potential for abuse, but this potential is limited. Human abuse potential studies analyze the abuse potential in a population of recreational drug users and may not correlate with the likelihood of abuse in a population using the medication therapeutically.[i]

During the COVID-19 pandemic and public health emergency (PHE), many flexibilities were put in place to ensure that people—including people living with the epilepsies—could continue to access health care and needed health care services. With the HHS COVID-19 PHE expected to expire in May 2023, many of these flexibilities have gone away or are in process of being pulled back. The epilepsy community greatly benefited from accessing needed health care services including prescription refills via telehealth. This is the case for many reasons, but especially for the following reasons. First, one third of adults with epilepsy cannot hold driver's licenses because their seizures are not entirely controlled by medications. Second, in many parts of the U.S., the closest epilepsy specialist or epilepsy center – the doctor or site most effectively able to treat individuals with drug resistant epilepsy – is far away often requiring hours of travel. Third, because of the shortage of epilepsy specialists in many parts of the U.S., wait times for appointments are often long and wait times of several months are common. Finally, while having epilepsy alone does not make someone immunocompromised, people with epilepsy may have other health conditions and/or take medications that make them immunocompromised—making telehealth appointments the far safer option.

As the PHE ends and rules related to telehealth and controlled substances are determined moving forward, it is essential that people with the epilepsies are able to access their anti-seizure medications in a timely manner. Delays or interruptions in obtaining anti-seizure medications increase the risk of breakthrough seizures with related complications including injury or even death. We appreciate that the DEA has sought to balance the need for access to medications with effective controls against diversion while keeping in line with the underlying statute. To ensure the safety and wellbeing of people with the epilepsies, we urge the DEA to consider the needs of people with the epilepsies by providing a longer initial supply and not limiting prescription to FDA-approved indications.

30-Day Supply Limitation
Instead of limiting initial prescribing to a 30-day supply, the DEA should allow for at least a 90-day supply for prescriptions of controlled substances used to treat patients with a diagnosis of epilepsy or seizures. In many parts of the U.S., providers specializing in the care of individuals with epilepsy are in high demand. Telehealth appointments have been extremely beneficial for people with the epilepsies and enabled providers to see more patients in need. Telehealth visits have reduced obstacles to patient access and allowed epilepsy specialists to spend less time traveling between offices and more time with patients.

In addition, it is very dangerous for a person with epilepsy to miss or skip doses of anti-seizure medications once a regime has been established. Abrupt disruption of epilepsy medications can cause breakthrough seizures (new, prolonged, and often repeated seizures after a period of seizure freedom) and result in hospitalizations or death. Studies have linked nonadherence to medications and risk for Sudden

Unexpected Death in Epilepsy (SUDEP).[ii] People with epilepsy should never to stop their anti-seizure medications without discussing with their health care provider.[iii] We work also against procedural reasons that cause people with epilepsy to miss doses. For these reasons, we urge DEA to allow a longer initial prescribing period of 90 days.

Off-Label Prescribing
The DEA requests comment on whether the rule should limit the issuance of prescriptions for controlled medications to the FDA-approved indications. We urge the DEA not to take this action. Epilepsy is not one disease, but hundreds.[iv] It would be impossible to conduct clinical trials on every seizure type and syndrome. Instead, anti-seizure medications are approved to treat one type of seizure but are found, and documented in the literature, to be effective treating other seizure types and syndromes. It therefore is very common for anti-seizure medications to be prescribed off-label.

For example, clobazam is a Schedule IV drug approved by the FDA in 2011 for the treatment of Lennox-Gastaut syndrome in 2011. Since then, it has been used effectively for the treatment of many different seizure types and epilepsy syndromes. Researchers at the University of Pennsylvania conducted a specific study into off-label use and found efficacy with no statistically significant difference between seizure types.[v]

Limiting initial prescribing to only on-label indications would significantly hinder effective care and would be dangerous for people with epilepsy. We urge the DEA not to move forward with this limitation.

Thank you for the opportunity to comment on this rulemaking. We urge you to implement our recommendations to ensure that people with the epilepsies can access their anti-seizure medications in a timely manner and remain safe. For more information contact Laura Weidner, Vice President of Government Relations & Advocacy at lweidner@efa.org.

Sincerely,

American Epilepsy Society (AES)
CACNA1A Foundation
Child Neurology Foundation
Coalition to Cure CHD2
CURE Epilepsy
CureSHANK
Cute Syndrome Foundation
Danny Did Foundation
Developmental and Epileptic Encephalopathies Project (DEE-P Connections)
Dravet Syndrome Foundation

Dup15q Alliance
Epilepsy Information Service of Wake Forest School of Medicine
Epilepsies Action Network
Epilepsy Alliance America
Epilepsy Foundation
Epilepsy Leadership Council
FAM177A1 Research Fund
FamilieSCN2A Foundation
Glut1 Deficiency Foundation
Hope for Hypothalamic Hamartomas
International Foundation for CDKL5 Research
International SCN8A Alliance
KCNQ2 Cure Alliance
National Association of Epilepsy Centers (NAEC)
NORSE Institute
NR2F1 Foundation
Paul's Purple Warriors
PCDH19 Alliance
Pediatric Epilepsy Research Consortium
Pediatric Epilepsy Surgery Alliance
Phelan-McDermid Syndrome Foundation
Project 8p
Rare Epilepsy Network
Ring14 USA
SNAP25 Foundation
STXBP1 Foundation
SynGAP Research Fund
SYNGAP1 Foundation
TSC Alliance

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[i] Kelsey L. Hawkins, Barry E. Gidal PharmD. When adverse effects are seen as desirable: Abuse potential of the newer generation antiepileptic drugs. Epilepsy & Behavior 77 (2017) 62-72. https://doi.org/10.1016/j.yebeh.2017.10.007

[ii] Olafur Sveinsson, MD, PhD, Tomas Andersson, BSc, Peter Mattsson, MD, PhD, Sofia Carlsson, PhD, and Torbjorn Tomson, MD, PhD. Pharmacologic treatment and SUDEP risk: A nationwide, population-based, case-control study. Neurology 2020;95:e2509-e2518. doi:10.1212/WNL.0000000000010874

[iii] https://www.epilepsy.com/what-is-epilepsy/seizure-triggers/missed-medicines

[iv] https://www.rareepilepsynetwork.org/

[v] Levinson N, Jami A, Kjankjanian P, Hill C, Davis K. Efficacy and Tolerability of Clobazam in Adult Drug-Refractory Epilepsy. Presented at: AAN Annual Meeting; May 5-9, 2019; Philadelphia, PA. P1.5-035.