



**END EPILEPSY**



# FISCAL YEAR 2020 LABOR, HHS, AND EDUCATION APPROPRIATIONS BILL

Centers for Disease Control and Prevention | Chronic Disease Prevention and Health Promotion

## Recommendation

Appropriate \$11,500,000 within the Centers for Disease Control and Prevention (CDC)'s National Center for Chronic Disease Prevention and Health Promotion's Epilepsy program to direct and support activities that improve quality of life and care for people affected by epilepsy.

**BACKGROUND:** The Institute of Medicine's (IOM) report on epilepsy, *Epilepsy Across the Spectrum: Promoting Health and Understanding*, identifies the Epilepsy Foundation and the CDC as leaders in addressing many of its national recommendations. The Department of Health and Human Services initiative, *Healthy People 2020*, includes the goal to "increase the proportion of people with epilepsy and uncontrolled seizures who receive appropriate medical care." Continued and increased funding for the CDC epilepsy program is critical to meeting this goal—as it is the only public health program specifically related to epilepsy that offers a national scope and local community programs. The Epilepsy Foundation, supported by a cooperative agreement with CDC, has:

- Provided education and/or direct training on epilepsy to more than **81,487** law enforcement and first responders, **57,511** school nurses and **407,649** students and teachers;
- Delivered evidence-based self-management training to people with epilepsy so that they can take control of their health, better cope with day-to-day challenges and reduce healthcare utilization and healthcare costs;
- Reached underserved populations through:
  - Project ECHO, a tele-mentoring process between an epilepsy specialist and primary care providers, in Ohio, Indiana, West Virginia and Kentucky;
  - An advanced practice provider model with family nurse practitioners and physicians assistants;
  - Delivery of signature programs through local Epilepsy Foundation offices;
  - Training community health workers in Texas and Illinois; and
  - Outreach to behavioral health professionals in rural settings.

## ABOUT EPILEPSY

Epilepsy is a disease or disorder of the brain which causes reoccurring seizures. Epilepsy is made up of many different types of seizures or syndromes, affects people throughout the lifespan, and can have many different causes and associated conditions.

3.4 million Americans live with active epilepsy. While some are able to gain seizure control, 30-40% of people with epilepsy live with uncontrolled seizures despite available treatments. Delayed recognition of seizures and inadequate treatment increase a person's risk of subsequent seizures, brain damage, disability, and death. Epilepsy imposes an annual economic burden of \$19.4 billion on the country.

FY 2019

**\$8,500,000**

FY 2020 ADMINISTRATION

**\$0\***

FY 2020 REQUEST

**\$11,500,000**

\* The Administration proposes an America's Health Block Grant that would eliminate the Epilepsy program

## FOR MORE INFORMATION, CONTACT:

**LAURA WEIDNER** Vice President, Government Relations & Advocacy, Epilepsy Foundation | 301.918.3766 lweidner@efa.org or **AMY SOUDERS** Principal & Director, Cornerstone Government Affairs | 202.448.9500 asouders@cgagroup.com

# REFORM STEP THERAPY PROTOCOLS

## Recommendation

Pass the Safe Step Act (H.R. 2279), which would amend the Employee Retirement Income Security Act of 1974 (ERISA) to streamline step therapy protocols and require exceptions to step therapy requirements so that people with epilepsy can access the most effective medications in a timely manner.

## BACKGROUND

Step therapy, or fail first, is a process that requires individuals who have been prescribed a medication by their healthcare provider to try and fail one or more medication(s) preferred by the insurer before receiving the originally prescribed drug.

There is no “one size fits all” treatment option for epilepsy, and the response to epilepsy medications can be different for each person. People with epilepsy who are forced to fail on one or more medications other than those prescribed by their physician by step therapy requirements are at a higher risk for developing breakthrough seizures and related complications, including death.

The Safe Step Act does not ban the use of step therapy, but instead requires exemptions from step therapy protocols for people who are currently stable on their medication regime, who have already failed or had an adverse reaction to the treatment, or for whom the step is contraindicated. The legislation will also give healthcare providers and people with epilepsy a transparent and standardized process to appeal step therapy requirements when a particular treatment is needed.

## ABOUT EPILEPSY

Epilepsy is a disease or disorder of the brain which causes reoccurring seizures. Epilepsy is made up of many different types of seizures or syndromes, affects people throughout the lifespan, and can have many different causes and associated conditions.

3.4 million Americans live with active epilepsy. While some are able to gain seizure control, 30-40% of people with epilepsy live with uncontrolled seizures despite available treatments. Delayed recognition of seizures and inadequate treatment increase a person's risk of subsequent seizures, brain damage, disability, and death. Epilepsy imposes an annual economic burden of \$19.4 billion on the country.

**More than 20**

states have instituted step therapy protocol reform

**12 states**

have introduced step therapy reform legislation in 2019

**Up to 10x**

higher health care costs per year for patients with uncontrolled epilepsy

## FOR MORE INFORMATION, CONTACT:

**RACHEL PATTERSON** Senior Director, Government Relations & Advocacy, Epilepsy Foundation | 301.918.3791  
rpatterson@efa.org



**END EPILEPSY**



# PRESERVE MEDICARE PART D'S SIX PROTECTED CLASSES

## Recommendation

Express opposition to the Administration's proposed changes that weaken the Six Protected Classes policy in Medicare. If the proposal is finalized and still creates access barriers, block implementation of the final rule.

## BACKGROUND

The Centers for Medicare and Medicaid Services (CMS) established and Congress has since confirmed the Six Protected Classes policy to ensure that Medicare Part D beneficiaries living with serious and complex health needs, like epilepsy, have access to the full range of approved medications. The classes include treatments for epilepsy, cancer, mental health conditions, organ transplants, and HIV/AIDS.

CMS issued a proposed rule in November 2018 that would allow increased utilization management practices in the Six Protected Classes. Under the administration's proposal, Part D plans would be able to institute broader use of prior authorization and step therapy, including for people who are currently stable on their medications. The proposal would also allow plans to exclude medications from the formulary in certain instances.

Epilepsy medications are not interchangeable. People living with epilepsy need meaningful access to the full range of approved anticonvulsants. When people living with epilepsy are forced to switch medications, or alter their treatment plan, this can lead to breakthrough seizures, associated complications and costs, or even death.

## ABOUT EPILEPSY

Epilepsy is a disease or disorder of the brain which causes reoccurring seizures. Epilepsy is made up of many different types of seizures or syndromes, affects people throughout the lifespan, and can have many different causes and associated conditions.

3.4 million Americans live with active epilepsy. While some are able to gain seizure control, 30-40% of people with epilepsy live with uncontrolled seizures despite available treatments. Delayed recognition of seizures and inadequate treatment increase a person's risk of subsequent seizures, brain damage, disability, and death. Epilepsy imposes an annual economic burden of \$19.4 billion on the country.

**1.1 million**

Medicare beneficiaries live with epilepsy

**870 comments**

submitted to CMS by the epilepsy community

**16.7% rate**

of seizure reoccurrence if someone who is stable on an anticonvulsant is forced to switch

## FOR MORE INFORMATION, CONTACT:

**RACHEL PATTERSON** Senior Director, Government Relations & Advocacy, Epilepsy Foundation | 301.918.3791  
rpatterson@efa.org



# SAFE & LEGAL ACCESS TO MEDICAL CANNABIS AND CANNABIDIOL (CBD)

## Recommendation

Pass legislation like the Strengthening the Tenth Amendment Through Entrusting States (STATES) Act (H.R. 2093/S.1028) and the Compassionate Access, Research Expansion, and Respect States (CARERS) Act of 2019 (H.R. 127) to improve access to medical cannabis programs, expand medical and scientific research into therapeutic uses for cannabis, and remove the threat of federal prosecution for those lawfully acting in accordance with state law.

**BACKGROUND:** There is no “one size fits all” treatment for epilepsy, and around 30 – 40 percent of individuals living with epilepsy suffer from uncontrolled or intractable seizures, despite available treatments. Some people living with epilepsy and seizures and their providers have reported beneficial effects and reduced seizure activity when using medical cannabis or cannabidiol (CBD) and therefore turn to it when other treatments have failed. As with any other treatment regimen, it is critical that physicians have the ability to consult and closely monitor individuals using cannabis and/or CBD, and physicians must have the ability to legally do so.

Currently, the use of cannabis is legal in 33 states and the District of Columbia. However, without safeguards in place, individuals who legally use medical cannabis and/or CBD under state law are at a continual risk of federal prosecution. Federal protections for lawful state-level medical cannabis activities would help ensure safe and reliable access to medical cannabis through state-regulated programs.

Despite some evidence that cannabis and CBD help reduce seizure activity in some individuals, it is currently difficult and expensive to conduct further, more robust research into this connection. There are significant obstacles for scientists and researchers to organize clinical trials involving cannabis due to its Schedule I designation, and only the National Institute for Drug Abuse (NIDA) can cultivate cannabis for medical research. There are also additional costs and infrastructure requirements due to the Schedule I designation that further limit innovation and investment into medical benefit research.

## ABOUT EPILEPSY

Epilepsy is a disease or disorder of the brain which causes reoccurring seizures. Epilepsy is made up of many different types of seizures or syndromes, affects people throughout the lifespan, and can have many different causes and associated conditions.

3.4 million Americans live with active epilepsy. While some are able to gain seizure control, 30-40% of people with epilepsy live with uncontrolled seizures despite available treatments. Delayed recognition of seizures and inadequate treatment increase a person’s risk of subsequent seizures, brain damage, disability, and death. Epilepsy imposes an annual economic burden of \$19.4 billion on the country.

## 33 states & DC

have passed comprehensive medical cannabis laws

## 30 - 40%

of individuals diagnosed with epilepsy have uncontrolled seizures

## 1 FDA approved

therapy derived from cannabis for the treatment of seizures associated with two rare forms of epilepsy

## FOR MORE INFORMATION, CONTACT:

**ABBEY ROUDEBUSH** Senior Manager, Government Affairs & Advocacy, Epilepsy Foundation | 301.918.3784  
aroudebush@efa.org