



Highlights from the Hill

July 2018

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National Advocacy

U.S. Food and Drug Administration Approves Epidiolex®

The U.S. Food & Drug Administration (FDA) [approved Epidiolex®, an oral solution of cannabidiol \(CBD\)](#), on June 25, 2018. Epidiolex® is the first FDA-approved medication that contains a purified substance derived from cannabis. The therapy is currently only approved for the treatment of Dravet and Lennox-Gastaut syndromes (LGS) in individuals two years of age and older.

The Drug Enforcement Agency (DEA) must now take action to schedule the medication because CBD, a derivative of cannabis, is a Schedule I substance. The DEA has 90 days from the FDA-approval date to take action. However, scheduling by the DEA does not override state controlled substance laws. If a state considers cannabis a Schedule I substance under its laws, Epidiolex®

cannot be prescribed until it is rescheduled in that state. The Epilepsy Foundation will continue to advocate in states to create a pathway for therapies derived from CBD.

[Read some frequently asked questions regarding FDA-approved therapies derived from CBD.](#)

Learn more about our advocacy efforts on state rescheduling for FDA-approved therapies derived from CBD at advocacy.epilepsy.com/statefdapathway.

Epilepsy Foundation Submits Comments in Response to Administration’s Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs

On July 16, 2018, the Epilepsy Foundation submitted comments to Alex Azar, Secretary of the Department of Health and Human Services (HHS), in response to the Administration’s Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs, announced in mid-May. We also joined with several coalitions to submit comments, including the I Am Essential coalition and the MAPRx coalition.

The Epilepsy Foundation is concerned about several proposals being considered that would be harmful to the epilepsy community, including proposed changes to the six protected classes under Medicare Part D, changes to the formulary, and indication based pricing. However, there are various proposals that we support that would help lift the burden of high prescription drug prices such as prohibiting pharmacy gag clauses, applying manufacturer rebates at the point-of-sale, and capping out-of-pocket costs for Part D beneficiaries.

Read the Epilepsy Foundation’s comment and learn more at advocacy.epilepsy.com/Medicare.

Administration Announces Freeze of Risk Adjustment Payments and Cuts to the Navigator Program

Seema Verma, Administrator of the Centers for Medicare & Medicaid Services (CMS) announced on July 7, 2018 that the Affordable Care Act’s (ACA) risk adjustment payment program would be on hold. The program provides payments to insurers who enrolled higher-risk patients from some insurers who enrolled healthier patients. The risk adjustment program helps to stabilize the individual marketplace and prevent insurers from cherry-picking the healthiest people.

The Epilepsy Foundation joined 13 other patient advocacy groups in a [statement](#) expressing concern over the frozen risk adjustment payments and urging the Administration to resume payments as quickly as possible.

Additionally, the Administration announced on July 10, 2018 a decision to drastically reduce funding for the navigator program to \$10 million from \$36 million last year, which was a 41 percent cut from 2016. Navigators are local groups and organizations that receive funding from the federal government to provide education and outreach to the public regarding health insurance options and to assist with enrollment.

The reduced investment in outreach and enrollment support has been linked to a decline in enrollment through the federally run marketplaces, resulting in higher premiums for beneficiaries. The Epilepsy Foundation will be joining many patient advocacy groups in a letter to Secretary Alex Azar and Administrator Seema Verma expressing deep concern over the cuts and the efforts to undermine access to quality, affordable health care.

Read more about our efforts on the ACA and protecting patients with pre-existing conditions at advocacy.epilepsy.com/ACA.

28th Anniversary of the Americans with Disabilities Act

July 26, 2018 will mark the 28th anniversary of the signing of the Americans with Disabilities Act (ADA). The ADA was originally signed by President H.W. Bush on July 26, 1990. The ADA is a civil rights law that prohibits discrimination against individuals with disabilities in all areas of public life and guarantees equal opportunity in public accommodations, employment, transportation, public entities, and telecommunications.

The Epilepsy Foundation has been a staunch supporter of the ADA since its introduction in Congress in 1988 and we continue to fight the stigma surrounding epilepsy that fuels discrimination and isolation of the epilepsy community. We are committed to defending and expanding civil rights laws that ensure protections for people with epilepsy.

Check out our recent advocacy efforts on discrimination and disability rights at advocacy.epilepsy.com/ADA.

STATE ADVOCACY

California Creates Pathway for FDA-approved Therapies Derived from CBD

On July 9, 2018, Governor Brown of California signed Assembly Bill 710 into law. California is now the fourth state during the 2018 legislative session to create a pathway for FDA-approved therapies derived from CBD. With the recent approval of Epidiolex®, it will become very important for states that require rescheduling of therapies derived from CBD legislatively to act.

advocacy.epilepsy.com/statefdapathway.

Preserving Open Access to Anticonvulsant Medications in Colorado

On July 10, 2018, the Pharmacy and Therapeutics (P&T) Committee of Colorado reviewed their open access policy for various drug classes, including anticonvulsants. The Epilepsy Foundation strongly opposes any formulary changes that would restrict access and any policies that would require multiple failures or prior authorization before a non-preferred medication can be secured. Failure to have access to the appropriate medication can result in increased or

breakthrough seizures, injury, accidents, additional medical and hospitalization costs, loss of earnings, and can even cause an unexpected death.

The Epilepsy Foundation and the Epilepsy Foundation of Colorado sent a [letter to the P&T Committee](#) prior to the July meeting to urge them to maintain open access to the anticonvulsant medications. Sarah Klein, Executive Director of the Epilepsy Foundation of Colorado, spearheaded the effort with the Epilepsy Foundation of Colorado's Professional Advisory Board (PAB) members to send additional letters to committee, opposing any restrictions to the anticonvulsant class.

At the hearing, Sarah and three PAB members testified on behalf of people living with epilepsy and urged the committee to retain their policy of open access to anti-epileptic drugs (AED) medications. After thoughtful discussion, the committee did indeed vote to recommend no restrictions on the class for people with an epilepsy diagnosis. It was a big win for the epilepsy community in Colorado.

Find out what's going on in your state at advocacy.epilepsy.com/states.



We encourage you to invite others to join our [Speak Up, Speak Out!](#) advocacy network. Members receive the monthly *Highlights from the Hill* newsletter and alerts about opportunities to advocate for the epilepsy community throughout the year. Growing our advocacy network is critical to achieving our public policy goals as we move through busy state and federal legislative sessions. Make a difference today by sharing our Speak Up, Speak Out! Network on [Facebook](#) and [Twitter](#).

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