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National Advocacy

Epilepsy Advocates and Partners Successfully Preserve Medicare’s Six Protected Classes Policy

On May 16, the Centers for Medicare & Medicaid Services (CMS) announced that it would not move forward with implementing proposed changes to Medicare Part D’s Six Protected Classes policy – codifying and affirming the policy’s importance for people with complex acute and chronic health conditions, including epilepsy. CMS established the Six Protected Classes policy to ensure that Medicare Part D beneficiaries living with serious and complex health care needs — such as epilepsy, HIV, mental illness, cancer, and organ transplants — have meaningful and timely access to the full range of approved
medications necessary to manage their conditions and maintain their quality of life. Last November, however, CMS proposed changes that would have weakened the policy by allowing health insurance plans to impose more prior authorization and step therapy (or “fail-first”) even for those currently stable on their medication. Plans would have also been able to exclude drugs from its formulary under certain circumstances.

Since the proposed rule was issued, the Foundation engaged in a multi-faceted advocacy campaign to educate the public, lawmakers, and members of the Administration about the importance of preserving the original intent of the policy. Epilepsy advocates submitted more than 870 comments to the Department of Health and Human Services on the proposed rule and sent 3,671 letters to their U.S. Representatives and Senators asking Congress to help stop the rule. This is an incredible victory for the 1.1 million Medicare beneficiaries living with epilepsy and the Foundation is incredibly grateful for the persistent engagement of the epilepsy community, our coalition partners, members of Congress who spoke up and the Administration for heeding our concerns.

Learn more about Medicare’s Six Protected Classes policy at advocacy.epilepsy.com/ProtectedClasses.

Foundation Testifies at FDA Public Hearing on Medical Cannabis and Cannabis-Derived Products

On behalf of the Foundation, Jacqueline French, M.D., chief medical and innovation officer of the Epilepsy Foundation and professor of neurology at NYU Langone Health's Comprehensive Epilepsy Center, testified at a U.S. Food & Drug Administration (FDA) public hearing about the importance of allowing CBD products to remain on the market and the need for robust regulations to ensure consistency and safety in available products. The hearing was the FDA’s first step toward developing a framework to regulate CBD products after legislation was enacted to federally legalize hemp including hemp-derived CBD with 0.3% or less THC by dry weight in late 2018.

Currently, more than one-third of people living with epilepsy do not achieve seizure control with available medications. There are also many people living with significant side-effects from their current treatment. The Foundation believes that more research is needed to understand the effectiveness of CBD in treating epilepsy and seizures, however if individuals –in consultation with their healthcare team – feel that the potential benefits of CBD outweigh the risks, those individuals should have access to safe, consistent and regulated CBD products.

The Foundation will also be submitting comments to the FDA and will continue to monitor the FDA’s decisions and regulations regarding CBD products which are expected to take awhile.

Read more about medical cannabis and CBD at advocacy.epilepsy.com/medical-cannabis.

Foundation Comments on Congressional Proposals to Improve Medicare Prescription Drug Coverage and Lowering Health Care Costs
Health care costs, including drug pricing, continues to be top of mind in Congress and among the public. Various health committees have begun holding hearings and proposing legislation to address these concerns. Earlier this month, the Foundation submitted comments to the House Committees on Ways & Means and Energy & Commerce regarding their draft legislation to improve prescription drug coverage under Medicare Part D, which would affect approximately 11 million Medicare beneficiaries living with epilepsy. The Foundation expressed strong support for capping out-of-pocket costs in Part D while addressing additional concerns about the erosion of access, supporting the Six Protected Classes, and reiterating the need to place patient-centered care at the forefront of any decisions.

The Foundation also provided input on the Lower Health Care Costs Act of 2019, a bipartisan bill package drafted by the Senate Health Education Labor and Pensions (HELP) Committee. The legislation aims to tackle topics including surprise medical billing, reducing the prices of prescription drugs, improving transparency in health care, and improving public health. The Foundation supports the committee’s approach in addressing numerous issues in the draft bill such as surprise medical billing, removing gag clauses, and increasing transparency of health care spending and costs. However, the letter expresses concerns over issues not addressed by the draft bill like consumer protections for high cost sharing, the need to include the voices of people with chronic conditions and disabilities in transparency efforts and provides ideas for the committee to take into consideration as it moves forward.

Foundation & National Patient Groups Endorse Bills that Would Improve Health Care Access

On May 15, 2019, the Foundation joined with over 20 national patient and consumer partners in endorsing three pieces of legislation aimed at improving access to affordable and high-quality health care coverage. The first, H.R. 987, Marketing and Outreach Restoration to Empower (MORE) Health Education Act of 2019, would require the Department of Health and Human Services (HHS) to resume activities related to outreach and education for open enrollment in the Marketplace so that consumers are aware of the open enrollment period and their healthcare coverage options.

The coalition also endorsed H.R. 1386, Expand Navigator’s Resources for Outreach, Learning, and Longevity (ENROLL) Act of 2019 and H.R. 1010 – both of which are now included as a provision within H.R. 987. The ENROLL Act would help preserve and guarantee funding for navigator programs while H.R. 1010 would rescind the final rule on Short-Term Limited Duration Insurance (STLDI). Previously, short term plans were available to fill a temporary gap in coverage, such as gaps in employment. However, since the rule was finalized, the growth and availability of these products threatens people with pre-existing conditions because these plans have insufficient benefits to meet their complex needs and they are also expected to increase costs for people with pre-existing conditions.

Read more about the Foundation’s efforts to protect individuals with pre-existing conditions at advocacy.epilepsy.com/ACA.

Over 30 Patient and Disability Rights Groups Send Strong Message to ICER
On June 10, 2019, 38 patient and disability rights organizations, including the Foundation, signed on to a letter to the Institute for Clinical Economic Review (ICER) highlighting concerns with its 2020 Value Assessment Framework. The letter calls on ICER to abandon its use of the quality-adjusted-life-years (QALY) metric, as well as other metrics that discriminate against patients and people with disabilities. The letter emphasizes that ICER must put patients and people with disabilities at the center of their assessments and develop novel measures of value to account for patient differences and priorities. The groups call on ICER to create models that are open-source, transparent, and available to all patients and researchers.

QALYs are a one-size-fits-all measurement of health outcomes based on the overall population. As such, they ignore the important differences in individual needs and preferences, and value individuals in "perfect health" more highly than those with a chronic condition or disability in a discriminatory manner.

ICYMI: TSA Updates Guidelines on Flying Across State Lines with CBD

In late May, the Transportation Security Administration (TSA) updated its guidelines on traveling with cannabidiol (CBD) products. When you fly domestically, TSA has clarified that you can now carry on or pack in checked baggage products/medications that contain hemp-derived CBD (with less than 0.3% THC) or are approved by the FDA, such as Epidiolex®. This is in line with the farm bill which was signed into law in December 2018.

While the carry-on quantity of liquids is less than 3.4 ounces/100mL, TSA allows larger amounts of medically necessary liquids in reasonable quantities for your trip. However, you must declare that you have medically necessary liquids and supplies at the security checkpoint. In checked baggage, liquid medications are allowed without packing requirements, quantity limitations, or notification requirements. Learn more here.
On June 11, 2019, Sam’s Law (HB 684) was signed into law by Governor Greg Abbott (seated at desk). Back row from left to right: Representative Travis Clardy, Barbara Watkins, Sindi Rosales, Senator Bryan Hughes, and Shari Dudo.

STATE ADVOCACY

Seizure Safe Schools Legislation Signed into Law in Texas

On June 11, 2019, Governor Greg Abbott signed Sam’s Law (HB 684) into law making Texas the third state in the nation to enact Seizure Safe Schools legislation. Spearheaded by Epilepsy Foundation Texas-Houston/Dallas-Fort Worth/West Texas and Epilepsy Foundation Central & South Texas, the bill includes the Foundation's Seizure Safe Schools language, which will help improve the care of over 49,000 students living with epilepsy and seizure disorders in Texas. Under the law, public schools in the state will mandate training of school personnel on seizure detection and first aid; require that Seizure Action Plans be on file for every student diagnosed with epilepsy or a seizure disorder and available to all personnel responsible for the student; and ensure the administration of Food and Drug Administration (FDA)-approved seizure rescue medications or medication prescribed by the student’s health care provider.

Learn more about the Seizure Safe Schools initiative at advocacy.epilepsy.com/seizuresafeschools.

Step Therapy Reform Bills Pass in Maine and Delaware

On June 13, 2019, Governor Janet Mills signed LD 1009, An Act to Provide Protections for Maine Patients Facing Step Therapy, into law. The Epilepsy Foundation New England worked diligently behind the scenes to help pass step therapy reform in the state. On June 18, 2019, HB 1005 was signed into law by Delaware Governor John Carney. Maine and Delaware join four other states this legislative session which have enacted step therapy or “fail-first” protocol reform.

Learn more about step therapy at advocacy.epilepsy.com/StepTherapy.

Stay up to date with the legislation in your state by visiting advocacy.epilepsy.com/states.
We encourage you to invite others to join our Speak Up, Speak Out! advocacy network. Members receive the monthly Capitol Circuit 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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