



February 25, 2021

The Honorable Xavier Becerra  
Secretary-designate  
U.S. Department of Health and Human Services  
200 Independence Ave, S.W.  
Washington, D.C. 20201

Dear Secretary-designee Becerra:

The following organizations are writing to express our opposition to a proposal announced on the Trump Administration's final day in office through the Centers for Medicare and Medicaid Services (CMS) that would undermine key patient protections in Medicare's prescription drug program. Namely, on January 19, 2021, the Center for Medicare and Medicaid Innovation (CMMI) announced the opportunity for new "formulary flexibilities" for Medicare Part D plans that participate in its Part D Payment Modernization (PDM) Model. Under the proposal, participating plans can choose to limit the drugs they cover, including denying patient access to medications used to manage complex conditions such as cancer, mental illness, HIV/AIDS, epilepsy, Parkinson's, and organ transplantation.

On behalf of the patients who we serve in our various communities, we call upon the Biden Administration to exercise its authority to immediately eliminate this policy proposal, which would undermine the protected classes policy, either via the so-called midnight rule moratorium, or the authority provided within the model to change its criteria or eliminate it entirely at any time. The protected classes policy has been a cornerstone of Part D's success: helping to ensure that Part D formularies serve the needs of all Medicare beneficiaries, including the most vulnerable patients with the greatest need for drug coverage. This has made Part D an integral part of Medicare by making plans compete based on quality and efficiency instead of seeking to reduce costs by driving away people with serious illnesses.

Our groups represent a broad, diverse coalition of health care stakeholders, patient advocates, and health care professionals committed to maintaining access to critically important medications under Medicare Part D — especially the categories and classes of drugs identified for unique patient protections in section 1860D-4(b)(3)(G)(iv) (the protected classes). These medications are vital, and often are not interchangeable, to the treatment of certain complex chronic conditions. For years, our organizations have collaborated to combat efforts to undermine consumer access to appropriate treatment by increasing policymaker awareness of the vulnerability of patients with these conditions and the potential impact of delayed or denied care.

The Trump Administration's formulary flexibility proposal is contrary to bipartisan congressional consensus, as expressed numerous times in recent years, and undermines long-standing and congressionally directed protections that guarantee access to life-saving drugs for patients with the most severe health conditions. Indeed, Congress has repeatedly expressed strong bipartisan support for the protected classes policy and has chosen to strengthen, rather than weaken it, over time. In a Senate colloquy just before the enactment of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA), Senators repeatedly emphasized the role of protections, including the protected classes, available to beneficiaries who need "exactly the right medicine for them."<sup>1</sup>

Congress reaffirmed the importance of the original protected classes in Section 3307 the Affordable Care Act (ACA), which codified in law the six protected classes and categories by name, and expanded coverage to include "all" drugs within these six classes. Additionally, every Member of the [Senate Finance Committee](#) opposed CMS' 2014 proposed rescission of protected-class protections, echoed in a separate letter from [50 Members](#) of the House Energy and Commerce and the Ways and Means Committees. More recently, in 2019, the Trump Administration attempted to roll back these important patient protections and were again rebuffed with significant opposition from Congress. Indeed, Secretary Azar was repeatedly challenged about the merits of this proposal both through several congressional letters as well as during his appearances before Congress. Ultimately, the policy suggesting changes to the six protected classes was withdrawn.

In addition to its obviously deleterious impact on patients' health, we think it is self-evident that the Trump administration's most recent proposal is short-sighted with respect to the effect on costs. Any potential savings CMS might realize from allowing plans to severely restrict access to drugs in the protected classes would be countered by increases in costs in other areas of Medicare and lead to undesirable patient outcomes. As The Pew Charitable Trusts concluded in a recent report, "Lack of adequate access to medications can in some circumstances increase costs to other Medicare programs through increased hospitalizations from complications or increased physician visits to manage medications."<sup>2</sup> Further, a study performed by researchers at Northwestern University and the University of Texas found that in covering drugs less generously, Part D plans end up costing traditional Medicare \$475 million per year.<sup>3</sup> Finally, it is clear that the Trump administration's most recent proposal was issued in a rush and without any meaningful patient or stakeholder input. Accordingly, we implore you to reverse this policy immediately.

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<sup>1</sup> 149 Cong. Rec. S5887-88.

<sup>2</sup> The Pew Charitable Trusts (2018). *Policy Proposal: Revising Medicare's Protected Classes Policy*. Access February 9, 2021: [https://www.pewtrusts.org/-/media/assets/2018/03/dsri\\_policy\\_proposal\\_revising\\_medicare\\_protected\\_classes\\_policy.pdf](https://www.pewtrusts.org/-/media/assets/2018/03/dsri_policy_proposal_revising_medicare_protected_classes_policy.pdf)

<sup>3</sup> Amanda Starc, Kellogg School of Management, Northwestern University, and NBER Robert J. Town, University of Texas - Austin and NBER (2016). *Externalities and Benefit Design in Health Insurance*

Please do not hesitate to contact Chuck Ingoglia, President and CEO of the National Council for Behavioral Health, who serves as executive director of the Partnership for Part D Access, and is this letter's lead signatory, if you have any questions regarding these comments or attachments or if he can provide additional information.

Signed on behalf of the following organizations,

The National Council for Behavioral Health	Epilepsy Foundation Iowa
ACCSES - The Voice of Disability Service Providers	Epilepsy Foundation of Long Island
ADAP Advocacy Association	Epilepsy Foundation Louisiana
AIDS Alabama	Epilepsy Foundation Maryland
AIDS Alliance for Women, Infants, Children, Youth & Families	Epilepsy Foundation Metro D.C.
AIDS Foundation Chicago	Epilepsy Foundation of Michigan
AIDS United	Epilepsy Foundation Mississippi
Alliance for Aging Research	Epilepsy Foundation of Minnesota
American Academy of Family Physicians	Epilepsy Foundation Montana
American Academy of Neurology	Epilepsy Foundation Nebraska
American Association for Psychoanalysis in Clinical Social Work	Epilepsy Foundation Nevada
American Association on Health and Disability	Epilepsy Foundation New Jersey
American Autoimmune Related Diseases Association	Epilepsy Foundation New Mexico
American Brain Coalition	Epilepsy Foundation North Carolina
American Cancer Society Cancer Action Network, Inc	Epilepsy Foundation North Dakota
American Kidney Fund	Epilepsy Foundation of Northeastern New York
American Society of Consultant Pharmacists	Epilepsy Foundation Ohio
American Society of Transplant Surgeons	Epilepsy Foundation Oklahoma
Association for Ambulatory Behavioral Healthcare	Epilepsy Foundation Orange County and Riverside
Brain Injury Association of America	Epilepsy Foundation Oregon
Cancer Support Community	Epilepsy Foundation of San Diego County
CancerCare	Epilepsy Foundation South Carolina
Charlie Foundation	Epilepsy Foundation South Dakota
Child Neurology Foundation	Epilepsy Foundation Texas - Houston/Dallas-Fort Worth/West Texas
Chronic Care Policy Alliance	Epilepsy Foundation Utah
College of Psychiatric and Neurologic Pharmacists	Epilepsy Foundation of Vermont
Community Access National Network	Epilepsy Foundation of Virginia
Danny Did Foundation	Epilepsy Foundation Washington
Depression and Bipolar Support Alliance	Epilepsy Foundation West Virginia
Dravet Syndrome Foundation	Epilepsy Foundation Wyoming
Epilepsy Foundation	Epilepsy Leadership Council
Epilepsy Foundation Alabama	Families for Depression Awareness
Epilepsy Foundation Alaska	Georgia AIDS Coalition
Epilepsy Foundation Arizona	Global Liver Institute
Epilepsy Foundation Arkansas	Health Hats
Epilepsy Foundation Central & South Texas	Hepatitis C Mentor & Support Group, Inc.
Epilepsy Foundation of Colorado	HIV+Hepatitis Policy Institute
Epilepsy Foundation of Delaware	Hope for the Day
Epilepsy Foundation of East Tennessee	Hope for ULD
Epilepsy Foundation Florida	Illinois Psychiatric Society
Epilepsy Foundation of Greater Chicago	International Foundation for Autoimmune & Autoinflammatory Arthritis
Epilepsy Foundation of Greater Southern Illinois	International OCD Foundation
Epilepsy Foundation of Hawaii	International Society for Psychiatric Mental Health Nurse
Epilepsy Foundation Indiana	Iowa Association of Community Providers

Iowa Behavioral Health Association  
 Lakeshore Foundation  
 Lennnon-Gastaut Syndrome (LGS) Foundation  
 Leukemia & Lymphoma Society  
 Lupus and Allied Diseases Association, Inc  
 Lupus Foundation of America  
 Medical Oncology Association of Southern California  
 Medicare Rights Center  
 Mental Health America  
 Mental Health America of California  
 Mental Health America of Illinois  
 Mental Health America of Ohio  
 Mental Health Association in Michigan  
 Mental Health Association in NYS, Inc.  
 Mental Health Summit  
 Michael J. Fox Foundation for Parkinson's Research  
 National Alliance of State & Territorial AIDS Directors  
 National Alliance on Mental Illness  
 National Alliance on Mental Illness - NYS  
 National Alliance on Mental Illness Chicago  
 National Alliance on Mental Illness Illinois  
 National Alliance on Mental Illness Mass  
 National Alliance on Mental Illness Metro Suburban  
 National Alliance on Mental Illness of NYC  
 National Association for Rural Mental Health  
 National Association of Behavioral Health and  
 Developmental Disability Directors

National Association of Nutrition and Aging Services  
 Programs  
 National Association of Social Workers  
 National Kidney Foundation  
 National Register of Health Service Psychologists  
 New Jersey Association of Mental Health and Addiction  
 Agencies  
 Oncology State Societies at ACCC  
 Phelan-McDermid Syndrome Foundation  
 Psychiatric Physicians Alliance of California  
 Ring14 USA  
 Schizophrenia and Related Disorders Alliance of America  
 STXBP1 Foundation  
 The AIDS Institute  
 The Coelho Center for Disability Law, Policy &  
 Innovation  
 The Kennedy Forum  
 The Multiple Sclerosis Foundation  
 Tourette Association of America  
 Transplant Recipients International Organization (TRIO)  
 TRIO - Oklahoma  
 TRIO - Manhattan Chapter  
 Transplant Support Organization  
 Tuberous Sclerosis Alliance  
 Whitman-Walker Institute  
 Wishes for Elliott/DEE-P Connections

CC: Liz Richter, Acting Administrator, Centers for Medicare and Medicaid Services