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 longstanding 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.”

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.”

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. 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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1 149 Cong. Rec. S5887-88.
3 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
ACCSES - The Voice of Disability Service Providers
ADAP Advocacy Association
AIDS Alabama
AIDS Alliance for Women, Infants, Children, Youth & Families
AIDS Foundation Chicago
AIDS United
Alliance for Aging Research
American Academy of Family Physicians
American Academy of Neurology
American Association for Psychoanalysis in Clinical Social Work
American Association on Health and Disability
American Autoimmune Related Diseases Association
American Brain Coalition
American Cancer Society Cancer Action Network, Inc
American Kidney Fund
American Society of Consultant Pharmacists
American Society of Transplant Surgeons
Association for Ambulatory Behavioral Healthcare
Brain Injury Association of America
Cancer Support Community
CancerCare
Charlie Foundation
Child Neurology Foundation
Chronic Care Policy Alliance
College of Psychiatric and Neurologic Pharmacists
Community Access National Network
Danny Did Foundation
Depression and Bipolar Support Alliance
Dravet Syndrome Foundation
Epilepsy Foundation
Epilepsy Foundation Alabama
Epilepsy Foundation Alaska
Epilepsy Foundation Arizona
Epilepsy Foundation Arkansas
Epilepsy Foundation Central & South Texas
Epilepsy Foundation of Colorado
Epilepsy Foundation of Delaware
Epilepsy Foundation of East Tennessee
Epilepsy Foundation Florida
Epilepsy Foundation of Greater Chicago
Epilepsy Foundation of Greater Southern Illinois
Epilepsy Foundation of Hawaii
Epilepsy Foundation Indiana
Epilepsy Foundation Iowa
Epilepsy Foundation of Long Island
Epilepsy Foundation Louisiana
Epilepsy Foundation Maryland
Epilepsy Foundation Metro D.C.
Epilepsy Foundation of Michigan
Epilepsy Foundation Mississippi
Epilepsy Foundation of Minnesota
Epilepsy Foundation Montana
Epilepsy Foundation Nebraska
Epilepsy Foundation Nevada
Epilepsy Foundation New Jersey
Epilepsy Foundation New Mexico
Epilepsy Foundation North Carolina
Epilepsy Foundation North Dakota
Epilepsy Foundation of Northeastern New York
Epilepsy Foundation Ohio
Epilepsy Foundation Oklahoma
Epilepsy Foundation Orange County and Riverside
Epilepsy Foundation Oregon
Epilepsy Foundation of San Diego County
Epilepsy Foundation South Carolina
Epilepsy Foundation South Dakota
Epilepsy Foundation Texas - Houston/Dallas-Fort Worth/West Texas
Epilepsy Foundation Utah
Epilepsy Foundation of Vermont
Epilepsy Foundation of Virginia
Epilepsy Foundation Washington
Epilepsy Foundation West Virginia
Epilepsy Foundation Wyoming
Epilepsy Leadership Council
Families for Depression Awareness
Georgia AIDS Coalition
Global Liver Institute
Health Hats
Hepatitis C Mentor & Support Group, Inc.
HIV+Hepatitis Policy Institute
Hope for the Day
Hope for ULD
Illinois Psychiatric Society
International Foundation for Autoimmune & Autoinflammatory Arthritis
International OCD Foundation
International Society for Psychiatric Mental Health Nurse
Iowa Association of Community Providers
CC: Liz Richter, Acting Administrator, Centers for Medicare and Medicaid Services