January 25, 2019

The Honorable Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Administrator Verma,

The undersigned organizations represent millions of seniors, individuals with disabilities, and beneficiaries dually eligible for Medicare and Medicaid who depend on Medicare Part D to cover critical therapies within the protected categories and classes of drugs. We strongly oppose sections of the Centers for Medicare and Medicaid Services' (CMS) Proposed Rule: Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce, which would establish broad exceptions to Part D's protected classes policy.

We want to acknowledge that CMS is working to address the affordability of prescription drugs for all patients, including Medicare beneficiaries. We support reasonable efforts to address the affordability of prescription drugs, but the changes to the protected classes policy advanced in this proposed rule threaten the well-being of Medicare beneficiaries with chronic conditions, cognitive impairments, and limitations in their activities of daily living.

Currently, Part D plans are statutorily required, with limited exceptions, to include all drugs of these six classes on their formularies: (1) anticonvulsants, (2) antidepressants, (3) antineoplastics, (4) antipsychotics, (5) antiretrovirals, and (6) immunosuppressants. Under the proposed rule, CMS seeks to advance a much more extensive set of exceptions to the protected classes policy than Congress has previously allowed or that an extensive body of literature and data analysis would support. We disagree with CMS' statement that an open coverage policy substantially limits Part D sponsors' ability to negotiate price concessions in exchange for formulary placement of drugs in the protected categories or classes of drugs.

We believe that CMS' assertion that providing plans more expansive negotiating tools in order to lower costs for Medicare and chronically ill beneficiaries is flawed and raises significant concerns. A November 2018 analysis conducted by Avalere and using CMS' own data shows plans aggressively utilize their existing authority to protect patient health and safety and promote cost effective options within the protected classes. Specifically, Part D plans already limit coverage to only 67% of all drugs in the protected classes. Plans combine these access limits with extensive use of utilization management such as prior authorization, step therapy, and formulary tiers to promote cost effective treatments. The Avalere analysis also finds that 75 percent of all protected class drugs are classified

as either non-preferred or specialty, and only a small number of beneficiaries – less than one percent – filled scripts for specialty drugs in the protected classes. Additionally, the vast majority of prescriptions filled for protected class medications are for low-cost generic drugs, not for brand name drugs.

We remain concerned that broader authority for plans to use utilization management tools and prior authorization, in which doctors must obtain approval from a patient's Part D plan to prescribe a given medication, would add new barriers for patients seeking lifesaving treatments. This proposal also would, for the first time, allow plans to implement prior authorization and step therapy for antiretrovirals to treat HIV, subverting Congress's intent to establish protections specific to patients who need these lifesaving treatments.

Subjecting vulnerable Part D enrollees to more restrictive and disruptive utilization management practices heightens their chance of using medications that do not work well or have adverse side effects. Patients with complex conditions often use multiple medications, and they must work closely with their doctors to find the best treatment regimen, which may need to be changed over time or updated to assess the effectiveness of innovative therapies that are introduced into the marketplace. Medications can also become ineffective or produce complications over time, specifically in the case of enrollees using antiretrovirals to treat HIV. Patients facing medical issues that the protected classes were meant to help treat must be able to access the full range of treatment options.

Concerningly, the proposal would allow for prior authorization and step therapy for enrollees stabilized on a particular treatment in addition to enrollees initiating a treatment. As plans revise their drug designs, the significantly more expansive approach to utilization management could result in disruption in access to treatment for a patient already stabilized on a treatment within the protected classes. As a result of the rule, patients doing well with a particular treatment may be forced to newly justify their treatment regime or could be placed on a different treatment regimen that may be less effective. Taking patients off of highly effective treatment regimens in favor of other medications can undermine adherence, resulting in hospital visits and other interventions that could have been avoided.

Finally, CMS's proposal to allow Part D plans to add significant new restrictions on the protected categories and classes of drugs is short-sighted with respect to the effect on costs. CMS justifies its misguided proposal to weaken the protected classes by stating that the protected class policy contributes to high drug prices. However, potential savings CMS could realize from allowing plans to add new, more expansive restrictions on access to drugs in the protected classes would be reversed by increases in costs in other areas of Medicare and lead to undesirable patient outcomes. CMS's analysis overlooks the importance of the costs that could be incurred from disrupting treatment for stabilized patients and restricting access for those patients starting treatment. Delayed or improper treatment leads to increased costs for Medicare Parts A and B and Medicaid and worse outcomes for patients.

As discussed previously we have significant concerns with the proposed changes to the protected classes policy, which could actually make it harder for vulnerable Medicare Part D enrollees to access and maintain the right treatment regime for their situation. We urge CMS to maintain beneficiaries' access to protected class drugs to ensure timely, quality care and to prevent the total cost of care in Medicare from rising due to avoidable complications. We ask that you continue to collaborate with

patient groups and other stakeholders to ensure Medicare provides ongoing access to critical medications.

Sincerely,

ADAP Advocacy Association
Advocates for Responsible Care
AIDS Foundation of Chicago
AIDS United
Alameda Council of Community Mental Health Agencies
Alliance for Patient Access
American Academy of Family Physicians
American Academy of HIV Medicine
American Association for Psychoanalysis in Clinical Social Work
American Association on Health and Disability
American Brain Coalition
American Cancer Society Cancer Action Network
American Foundation for Suicide Prevention
American Kidney Fund
American Psychological Association
American Society of Consultant Pharmacists
Association for Behavioral Healthcare (Massachusetts)
Association of Northern California Oncologists
Association of Nurses in AIDS Care
Association of University Centers on Disabilities
Autistic Self Advocacy Network
California Association of Social Rehabilitation Agencies
California Council for the Advancement of Pharmacy
California Council of Community Behavioral Health Agencies
California Hepatitis C Task Force
Cancer Support Community
Caregiver Action Network
Caregiver Voices United
Center for Health Law and Policy Innovation
Child Care Advocates of Kentucky
Coalition for Whole Health
College of Psychiatric and Neurologic Pharmacists
Colorado Organizations and Individuals Responding to HIV/AIDS
Community Access National Network (CANN)
Consumers for Quality Care
Depression and Bipolar Support Alliance
District of Columbia Behavioral Health Association
EPIC Long Island
Epilepsy Foundation
Epilepsy Foundation Alabama
Epilepsy Foundation Alaska
Epilepsy Foundation Central & South Texas

Epilepsy Foundation Heart of Wisconsin
Epilepsy Foundation Maryland
Epilepsy Foundation Metropolitan Washington
Epilepsy Foundation New England
Epilepsy Foundation of Arizona
Epilepsy Foundation of Colorado
Epilepsy Foundation of Connecticut
Epilepsy Foundation of Delaware
Epilepsy Foundation of Florida
Epilepsy Foundation of Greater Chicago
Epilepsy Foundation of Greater Los Angeles
Epilepsy Foundation of Greater Southern Illinois
Epilepsy Foundation of Hawaii
Epilepsy Foundation of Indiana
Epilepsy Foundation of Iowa
Epilepsy Foundation of Kentuckiana
Epilepsy Foundation of Long Island
Epilepsy Foundation of Metropolitan New York
Epilepsy Foundation of Michigan
Epilepsy Foundation of Middle and West Tennessee
Epilepsy Foundation of Minnesota
Epilepsy Foundation of Mississippi
Epilepsy Foundation of Missouri and Kansas
Epilepsy Foundation of Nebraska
Epilepsy Foundation of Nevada
Epilepsy Foundation of Northeastern New York, Inc.
Epilepsy Foundation of Northern California
Epilepsy Foundation of Oklahoma
Epilepsy Foundation of Utah
Epilepsy Foundation of Vermont
Epilepsy Foundation Ohio
Epilepsy Foundation Oregon
Epilepsy Foundation Texas-Houston/Dallas-Fort Worth/West Texas
Epilepsy Foundation Washington
Epilepsy Foundation West Virginia
FAIR Foundation
Families for Depression Awareness
Florida Keys HIV Community Planning Partnership
Georgia AIDS Coalition
Georgia Equality
GLMA: Health Professionals Advancing LGBTQ Equality
HealthHIV
Hematology/Oncology Pharmacy Association
HIV Medicine Association
Human Rights Campaign
International Foundation for Autoimmune & Autoinflammatory Arthritis
Iowa Association of Community Providers

John Snow, Inc. (JSI)
Lakeshore Foundation
Legal Action Center
LUNGevity Foundation
Lupus and Allied Diseases Association, Inc.
Lupus Foundation of America
Medical Oncology Association of Southern California, Inc.
Mental Health America
Mental Health America of California
Mental Health America of Franklin County
Mental Health Liaison Group
Montana Community Services, Inc.
National Alliance on Mental Illness
National Alliance on Mental Illness of New York City
National Association of Nutrition and Aging Services Programs
National Black Justice Coalition
National Coalition for LGBT Health
National Council for Behavioral Health
National Disability Rights Network
National Health Law Program
National Kidney Foundation
National Patient Advocate Foundation
National Register of Health Service Psychologists
New Jersey Association of Mental Health and Addiction Agencies, Inc.
NMAC
No Health without Mental Health
Oklahoma Behavioral Health Association
Patient Advocate Foundation
Patients Rising Now
Positive Coalition Project, South Carolina
Prostate Health Education Network, Inc.
Ryan White Medical Providers Coalition
San Francisco AIDS Foundation
Schizophrenia and Related Disorders Alliance of America
Southern AIDS Coalition
The AIDS Institute
The American Society of Transplant Surgeons
The American Society of Transplantation
The Center for HIV Law & Policy
The Michael J. Fox Foundation for Parkinson's Research
The National Association for Rural Mental Health
The National Association of County Behavioral Health and Developmental Disability Directors
The Village Family Services
Thresholds
Tourette Association of America
Transplant Recipients International Organization (TRIO)
Transplant Recipients International Organization (TRIO) - Manhattan Chapter

Transplant Support Organization
Treatment Communities of America
United Spinal Association
United States People Living with HIV Caucus
Us TOO International Prostate Cancer Education & Support
Washington Council for Behavioral Health
ZERO - The End of Prostate Cancer