September 8, 2017

The Honorable Thomas E. Price, MD
Secretary
U.S. Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Price,

Created in 2014, the Partnership for Part D Access ("the Partnership") is a coalition of healthcare stakeholders committed to maintaining access to medications under the Medicare Part D program. The Partnership and its members work with a broad range of organizations to ensure the continued protection of the categories and classes of drugs identified for unique patient access under the Social Security Act (the "protected classes"). These medications are vital to the treatment of: (1) epilepsy; (2) mental illness; (3) cancer; (4) HIV-AIDS; and (5) organ transplants. The Partnership and other concerned stakeholders are writing to urge the Department of Health and Human Services to take steps to assure and maintain access to medications under Medicare Part D's protected classes policy, a central patient protection for Medicare beneficiaries.

The Partnership was founded to combat efforts to undermine consumer access to appropriate treatment by increasing policymaker awareness of the vulnerability of patients with conditions within these protected classes and the potential impact of delayed or denied care. The Partnership's membership currently includes a variety of patient advocacy organizations, such as the National Council for Behavioral Health, Transplant Recipients International Organization (TRIO), The AIDS Institute, Epilepsy Foundation, Cancer Support Community, National Alliance on Mental Illness (NAMI), and the National Kidney Foundation, as well as representatives of industry stakeholders.

The Protected Classes Are Critically Important to Vulnerable Patients

The protected classes policy is essential for maintaining access to proper treatment for Medicare beneficiaries. Patients with a condition in one of the protected classes have very complicated medical needs, and many of these patients must attempt a variety of therapies before coming to a decision with their physicians about what is the most appropriate treatment. For example, patients often have significant co-morbidities, requiring nuanced treatment regimens.

Patients with mental health conditions often have high rates of diabetes and heart disease, which may be exacerbated by untreated mental illness.[1] Additionally, one in four individuals with cancer has clinical depression.[2] The protected classes policy shields them from arbitrary restrictions and limitations that may hinder access to important medications.

While the protected classes policy protects patients, Part D plans have a number of tools that they use to control costs through utilization management and rebate negotiation. For example, under current guidance issued by the Centers for Medicare and Medicaid Services (CMS), for drugs other than those relating to HIV, Part D plans may use prior authorization and step therapy to manage therapies for any beneficiary beginning treatment on a protected class drug.[3] In addition, Part D plans may utilize formulary tiering to steer patients toward lower cost drugs. These tools give Part D plans considerable flexibility to manage more expensive medications, as well as leverage to negotiate rebates with manufacturers.

The Protected Classes Lower Medicare Spending and Promote Adherence

An August 2016 study from researchers at Northwestern University's Kellogg School of Management and the University of Texas at Austin highlights how "profit-maximizing" Part D plans are incentivized to limit benefits or increase certain costs for which Part D plans are not responsible under Medicare (e.g., hospitalizations).[4] As detailed in the study, Part D plans are explicitly encouraged to reduce drug spending without bearing financial responsibility for the holistic health of the patient. The authors conclude that in covering drugs less generously, Part D plans end up costing traditional Medicare $475 million per year.[5] The study reinforces the importance of Medicare's six protected classes in limiting future medical complications, hospitalizations, and additional costs to the Medicare program.

Further, a March 2016 literature review conducted by Avalere Health suggests little evidence exists to show that limiting formulary access leads to meaningful cost savings.[6] The authors observed that while formulary restrictions often lead to lower drug spending, they were accompanied by increases to inpatient and outpatient medical care that outweighed savings achieved on prescription drugs.[7] They also found evidence to suggest that formulary restrictions led to increased rates of non-adherence, especially among older beneficiaries.[8] The authors further noted that studies indicate

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[1] Smith, Kenneth J. et. al. (February 2013), *Cost-Effectiveness of Medicare Drug Plans in Schizophrenia and Bipolar Disorder*, 19:2 American Journal of Managed Care 55.
[2] American Cancer Society website, accessed Aug. 14, 2017, Available at: https://www.cancer.org/treatment/treatments-and-side-effects/physical-side-effects/changes-in-mood-or-thinking/depression.html.
[3] Medicare Prescription Drug Benefit Manual, Ch. 6, § 30.2.5.
[4] Starc, A., and Town, R.J. (August 2016). *Externalities and Benefit Design in Health Insurance*. Available at: https://kelley.iu.edu/BEPP/documents/starc_town_fall2016.pdf.
[5] *Ibid*.
[6] Avalere Health (March 2016), *Impact of Formulary Restrictions on Adherence, Utilization, and Costs of Care*.
[7] *Ibid*.
[8] *Ibid*.

patients who were less adherent or who switched their therapies had higher hospitalization rates with longer stays.

History of Support for the Protected Classes

When Congress passed the Medicare Modernization Act of 2003 (MMA), it sought to ensure that all individuals would have access to robust prescription drug benefits, regardless of their clinical conditions.[9] To that end, the MMA forbade an approved prescription drug plan (PDP) from having a design and formulary that was "likely to substantially discourage enrollment" by certain classes of patients.[10] Furthermore, in a Senate colloquy just before the enactment of the MMA, Senators repeatedly emphasized the importance of safeguards, including the protected classes, available to beneficiaries who need "exactly the right medicine for them."[11]

To implement the MMA statutory requirements, CMS issued subregulatory guidance in 2005, specifying that plans cover "all or substantially all" of the drugs in six categories: antidepressants, antipsychotics, anticonvulsants, antineoplastics, antiretrovirals and immunosuppressants. These categories became known as the classes of "clinical concern" or "six protected classes." CMS stated that it had a responsibility to ensure Medicare beneficiaries received clinically appropriate medications and had "uninterrupted access" to all drugs in these classes.[12] For beneficiaries already stabilized on a drug in these categories, CMS' expectation was that plans would not use formulary management techniques, such as prior authorization or step therapy, absent "extraordinary circumstances."[13]

In 2008, Congress passed the Medicare Improvements for Patients and Providers Act (MIPPA), which included language affecting the six protected classes.[14] Section 176 of MIPPA required the Secretary of Health and Human Services (HHS) to establish a process for determining the appropriate categories and classes of protected drugs, beginning with plan year 2010. MIPPA replaced CMS' "substantially all" standard, instead requiring that "all" drugs in the protected classes be covered.[15]

When the Affordable Care Act (ACA)[16] was enacted in 2010, again there were provisions related to the six protected classes. Section 3307 of the ACA required the HHS Secretary to identify categories and classes of drugs that are of clinical concern through the promulgation of regulations, including a notice and comment period. In addition, for the first time, the existing six protected

[9] Public Law 108-173 (December 8, 2003).
[10] 42 U.S.C. § 1395w-111(e)(2)(D)(i).
[11] 149 Cong. Rec. S5882-03.
[12] Centers for Medicare & Medicaid Services. (2005). *Why is CMS Requiring "All or Substantially All" of the Drugs in the Antidepressant, Antipsychotic, Anticonvulsant, Anticancer, Immunosuppressant, and HIV/AIDS Categories?* Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/FormularyGuidanceAllorSubAll.pdf.
[13] *Ibid*.
[14] Public Law 110-275 (July 15, 2008).
[15] 42 U.S.C. §1395w-104(b)(3)(G)(ii).
[16] Public Law 111-148 (March 23, 2010).

classes were recognized in statute. Also of importance, the ACA reiterated that PDP sponsors must cover *all* drugs within the protected classes.[17]

In early 2014, CMS proposed sweeping changes to the protected classes requirements within a proposed rule that made policy and technical changes to the Medicare Advantage (MA) and prescription drug benefit programs for calendar year 2015.[18] Under the proposed rule, CMS would keep only three categories of drugs as protected classes: antiretrovirals, antineoplastics, and anticonvulsants. It proposed to remove immunosuppressants and antidepressants from the classes of clinical concern in 2015, but to keep antipsychotics for that year only.

The proposed regulation was met with extraordinary opposition by Congress, patient groups and others concerned with access to medications for Medicare beneficiaries. All members of the Senate Finance Committee wrote to HHS opposing the proposed redefinition of the protected classes and said they were unconvinced that cost savings would materialize.[19] Fifty bipartisan members of the House Ways & Means and Energy & Commerce Committees wrote to oppose the proposal, saying it would "place harmful limits on Medicare beneficiaries' access to necessary medications that would otherwise be covered."[20] Well over 1,400 comments were submitted by patient organizations, medical guilds, and other patient-focused groups to CMS opposing the change.

Ultimately, CMS did not finalize the proposed rule, stating it "did not strike the balance among beneficiary access, quality assurance, cost containment and patient welfare" that it had hoped to achieve.[21] Instead, in its final rule CMS stated that categories and classes of drugs of clinical concern would continue to be the six enumerated in the ACA until such time as the agency could undertake rulemaking to establish new criteria.[22]

As represented by the diversity of organizations signing this letter, the Part D program has been both popular among Medicare beneficiaries and successful in providing affordable drug coverage to them. We ask HHS to support retaining the six protected classes in their present form as the Department examines ways to address drug pricing and benefit design. Further, members of the Partnership would welcome the opportunity to meet with you in person to discuss this important issue.

Sincerely,

ADAP Advocacy Association
Advocates for Responsible Care
AIDS Action Baltimore
AIDS Foundation of Chicago

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[17] *Ibid*.
[18] 79 Fed. Reg. 1917 (January 10, 2014).
[19] Letter to HHS by Senate Finance Committee, February 2014, available here.
[20] Letter to HHS by House W&M and E&C Committee Members, available here.
[21] 79 Fed. Reg. 29865 (May 23, 2014).
[22] 79 Fed. Reg. 29844 (May 23, 2014).

AIDS Research Consortium of Atlanta
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 Dance Therapy Association
American Foundation for Suicide Prevention
American Psychological Association
American Urological Association
American Society of Consultant Pharmacists
American Society of Transplantation
Association for Ambulatory Behavioral Healthcare
Association of Northern California Oncologists
Brain and Behavior Research Foundation
California Access Coalition
California Chronic Care Coalition
California Council for the Advancement of Pharmacy
California Hepatitis C Task Force
California Psychiatric Association
Cancer*Care*
Cancer Support Community
CaringKind
Clinical Social Work Association
Coalition for Healthy Communities
Community Access National Network
Depression and Bipolar Support Alliance
Epilepsy California
Epilepsy Foundation
Epilepsy Foundation Central & South Texas
Epilepsy Foundation of Connecticut
Epilepsy Foundation of Delaware
Epilepsy Foundation Eastern Pennsylvania
Epilepsy Foundation of Greater Chicago
Epilepsy Foundation Heart of Wisconsin
Epilepsy Foundation of Indiana
Epilepsy Foundation of Kentuckiana
Epilepsy Foundation of Long Island
Epilepsy Foundation of Louisiana
Epilepsy Foundation of Metropolitan New York
Epilepsy Foundation of Missouri & Kansas

Epilepsy Foundation of Nevada
Epilepsy Foundation New England
Epilepsy Foundation of Northeastern New York
Epilepsy Foundation Northwest
Epilepsy Foundation of North Central Illinois, Iowa, Nebraska
Epilepsy Foundation of Oklahoma
Epilepsy Foundation Texas - Houston/Dallas-Fort Worth/West Texas
Epilepsy Foundation of Vermont
Epilepsy Foundation of Utah
Epilepsy Foundation of Western/Central Pennsylvania
Families for Depression Awareness
Georgia AIDS Coalition
Global Alliance for Behavioral Health and Social Justice
HealthHIV
Hemophilia Council of California
HIV Medicine Association
Lakeshore Foundation
Leukemia Lymphoma Society
Los Angeles LGBT Center
Lupus Foundation of America
Medical Oncology Association of Southern California, Inc.
Men's Health Network
Mental Health America
Mental Health America of California
Mental Health America of Franklin County
Minnesota AIDS Project
National Alliance on Mental Illness
National Alliance on Mental Illness of California
National Alliance on Mental Illness of New York City
National Association of Social Workers
National Association of State and Territorial AIDS Directors
National Coalition for LGBT Health
National Coalition for Maternal Mental Health
National Council for Behavioral Health
National Disability Rights Network
National Federation of Families for Children’s Mental Health
National Kidney Foundation
National Leiomyosarcoma Foundation
National Oncology Society Network
National Organization for Rare Disorders
National Patient Advocate Foundation
National Register of Health Service Psychologists
NHMH- No Health Without Mental Health

NMAC
Prevent Cancer Foundation
Project Inform
Prostate Health Education Network
San Francisco AIDS Foundation
Southern AIDS Coalition
Southern HIV/AIDS Strategy Initiative
Transplant Recipients International Organization
Transplant Support Organization
Treatment Communities of America
The AIDS Institute
The Mental Health Association of New York City
The Michael J Fox Foundation for Parkinson's Research
The National Association of County Behavioral Health and Developmental Disability Directors
The National Association for Rural Mental Health
United States People Living with HIV Caucus
U.S. Pain Foundation
US TOO International Prostate Cancer Education and Support
VillageCare
Village Family Services
Whitman-Walker Health
ZERO-The End of Prostate Cancer