



April 9, 2018

The Honorable Alex Azar  
Secretary  
U.S. Department of Health & Human Services  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

Dear Secretary Azar,

Congratulations on your recent confirmation to lead the Department of Health and Human Services. The Partnership for Part D Access (“the Partnership”) has been pleased to learn of your commitment to policies that will help bring down the cost of treatments for patients without reducing access. We recognize the depth of expertise that you bring to the multifaceted discussions on prescription drug issues, and we are hopeful this will allow the Partnership and other concerned stakeholders to engage with you around innovative ideas that continue to safeguard the breadth of patients’ treatment needs.

As you begin to engage your staff around a wide range of policy options, we are writing to make you aware of the access issues particular to Medicare Part D’s protected classes policy. Created in 2014, 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 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.

## **New Budget Proposals Threaten Access to Treatment**

We reviewed with interest the drug pricing and payment proposals in the Administration's Fiscal Year 2019 budget plan. We appreciate that since the budget proposals were finalized prior to your confirmation, you will review the proposals with fresh eyes and prioritize feasible solutions. As you do so, we urge you to consider the Partnership's longstanding views and well-regarded work around Medicare Part D's protected classes and proposals impacting prescription drug formularies.

We welcome new ideas to address drug costs and we have a record of supporting appropriate tools that have effectively helped to manage access to prescription drug therapies for Medicare Part D beneficiaries. However, for the reasons we discuss in more detail below, policymakers must balance the current drive for affordability with a person-centered approach to treatment. Managing access, rather than restricting it, allows Medicare beneficiaries to continue to avail themselves of therapies within each of Medicare Part D's six protected classes. Overemphasizing affordability ultimately could compromise patient health and well-being and drive up overall health care costs for certain patient populations.

## **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.<sup>1</sup> Additionally, one in four individuals with cancer has clinical depression.<sup>2</sup> 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.<sup>3</sup> 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. Furthermore, it is worth noting that plans are utilizing the existing

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<sup>1</sup> 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.

<sup>2</sup> 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>.

<sup>3</sup> Medicare Prescription Drug Benefit Manual, Ch. 6, § 30.2.5.

flexibility and this has ensured that generic dispensing rates (GDR) within the protected classes are on par with other therapeutic classes.<sup>4</sup>

### **The Protected Classes Lower Medicare Spending and Promote Adherence**

While proponents of changes to the six protected classes argue that removing certain drugs from protected class status could reduce costs, their analysis consistently fails to recognize the significant tangential costs associated with austere formulary management. Limiting beneficiary access to vital medications will drive higher costs in Medicare Part A and Part B and Medicaid by increasing the need for inpatient care and emergency department visits due to the destabilization of patients' conditions. The costs associated with this care often is not born by the Part D plan, but would increase overall costs to Medicare and Medicaid.

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).<sup>5</sup> 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.<sup>6</sup> 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.<sup>7</sup> 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.<sup>8</sup> They also found evidence to suggest that formulary restrictions led to increased rates of nonadherence, especially among older beneficiaries.<sup>9</sup> The authors further noted that studies indicate 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

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<sup>4</sup> Medicare Payment Advisory Commission, "Data Book: Health Care Spending and the Medicare Program: Chapter 10—Prescription Drugs," June 2013, p. 24, <http://www.medpac.gov/chapters/Jun13DataBookSec10.pdf>.

<sup>5</sup> 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](https://kelley.iu.edu/BEPP/documents/starc_town_fall2016.pdf).

<sup>6</sup> *Ibid.*

<sup>7</sup> Avalere Health (March 2016), Impact of Formulary Restrictions on Adherence, Utilization, and Costs of Care.

<sup>8</sup> *Ibid.*

<sup>9</sup> *Ibid.*

conditions.<sup>10</sup> 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.<sup>11</sup> 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.”<sup>12</sup>

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.<sup>13</sup> 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.”<sup>14</sup>

In 2008, Congress passed the Medicare Improvements for Patients and Providers Act (MIPPA), which included language affecting the six protected classes.<sup>15</sup> 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.<sup>16</sup>

When the Affordable Care Act (ACA)<sup>17</sup> 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 classes were recognized in statute. Also of importance, the ACA reiterated that PDP sponsors must cover all drugs within the protected classes.<sup>18</sup>

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

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<sup>10</sup> Public Law 108-173 (December 8, 2003).

<sup>11</sup> 42 U.S.C. § 1395w-111(e)(2)(D)(i).

<sup>12</sup> 149 Cong. Rec. S5882-03

<sup>13</sup> 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-DrugCoverage/PrescriptionDrugCovContra/downloads/FormularyGuidanceAllorSubAll.pdf>.

<sup>14</sup> *Ibid.*

<sup>15</sup> Public Law 110-275 (July 15, 2008)

<sup>16</sup> 42 U.S.C. §1395w-104(b)(3)(G)(ii).

<sup>17</sup> Public Law 111-148 (March 23, 2010).

<sup>18</sup> *Ibid.*

prescription drug benefit programs for calendar year 2015.<sup>19</sup> 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.<sup>20</sup> 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.”<sup>21</sup> 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.<sup>22</sup> 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.<sup>23</sup>

## **Conclusion**

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, the organizations represented on this letter welcome the opportunity to meet with you in person to discuss this important issue.

Sincerely,  
ADAP Advocacy Association  
AIDS Action - Baltimore  
AIDS Research Consortium of Atlanta  
AIDS United  
Advocates for Responsible Care  
Alameda Council of Community Mental Health Agencies  
Alliance for Patient Access  
Alliance for Patient Care

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<sup>19</sup> 79 Fed. Reg. 1917 (January 10, 2014).

<sup>20</sup> Letter to HHS by Senate Finance Committee, February 2014, available [here](#).

<sup>21</sup> Letter to HHS by House W&M and E&C Committee Members, available [here](#).

<sup>22</sup> 79 Fed. Reg. 29865 (May 23, 2014).

<sup>23</sup> 79 Fed. Reg. 29844 (May 23, 2014).

American Academy of HIV Medicine  
American Association for Psychoanalysis in Clinical Social Work  
American Association on Health and Disability  
American Cancer Society Cancer Action Network  
American Dance Therapy Association  
American Foundation for Suicide Prevention  
American Psychological Association  
American Society of Consultant Pharmacists  
American Society of Transplantation  
American Society of Transplant Surgeons  
Association for Ambulatory Behavioral Healthcare  
Anxiety and Depression Association of America  
Association of Northern California Oncologists  
Bailey House, Inc.  
California Chronic Care Coalition  
California Council for the Advancement of Pharmacy  
California Hepatitis C Task Force  
CancerCare  
Cancer Support Community  
Caregiver Action Network  
Clinical Social Work Association  
College of Psychiatric and Neurologic Pharmacists  
Colorado Organizations and Individuals Living with HIV/AIDS  
Community Access National Network  
Depression and Bipolar Support Alliance  
Epilepsy Foundation  
Epilepsy Foundation of Alabama  
Epilepsy Foundation of Arizona  
Epilepsy Foundation of California  
Epilepsy Foundation of Colorado  
Epilepsy Foundation of Florida  
Epilepsy Foundation Greater Dayton Region  
Epilepsy Foundation of Hawaii  
Epilepsy Foundation of Indiana  
Epilepsy Foundation Iowa  
Epilepsy Foundation of Kentuckiana  
Epilepsy Foundation of Long Island  
Epilepsy Foundation Metropolitan Washington  
Epilepsy Foundation of Michigan  
Epilepsy Foundation of Middle and West Tennessee  
Epilepsy Foundation of Minnesota  
Epilepsy Foundation of Mississippi  
Epilepsy Foundation of Nevada

Epilepsy Foundation New England  
Epilepsy Foundation Northwest  
Epilepsy Foundation North/Central Illinois  
Epilepsy Foundation of Oklahoma  
Epilepsy Foundation Texas-Houston/Dallas-Fort Worth/West  
Epilepsy Foundation of Utah  
Epilepsy Foundation of Vermont  
Epilepsy Foundation of Virginia  
FAIR Foundation  
Families for Depression Awareness  
Georgia AIDS Coalition  
Global Alliance for Behavioral Health and Social Justice  
International Association of Hepatitis Task Forces  
International Foundation for Autoimmune & Autoinflammatory Arthritis  
International Myeloma Foundation  
Lakeshore Foundation  
Leukemia and Lymphoma Society  
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 American of Franklin County  
National Alliance of State and Territorial AIDS Directors  
National Alliance on Mental Illness  
National Alliance on Mental Illness of New York City  
National Association of Social Workers  
National Council for Behavioral Health  
National Disability Rights Network  
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  
Prostate Health Education Network, Inc.  
San Francisco AIDS Foundation  
Transplant Recipients International Organization  
Transplant Support Organization  
Treatment Communities of America  
The AIDS Institute  
The Empowerment Program

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

The Prevent Cancer Foundation

United States People Living with HIV Caucus

Us TOO International Prostate Cancer Education and Support

Village Family Services

Whitman-Walker Health

ZERO - The End of Prostate Cancer