



July 13, 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,

The Partnership for Part D Access appreciates the opportunity to comment on the draft proposals contained in the President's "American Patients First" blueprint and the corresponding May 16, 2018, Request for Information (RFI) issued by the Department of Health and Human Services (HHS). 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. Given our mission, the Partnership will limit its comments to this specific issue within the RFI.

We commend you for putting forward a robust set of ideas and taking a thoughtful approach to address the cost challenge which threatens to limit patient access to prescription medications. The Partnership believes that barriers to prescription medications for Medicare patients with chronic conditions are particularly detrimental, as they can undermine adherence to highly effective medication regimens and drive up medical costs across the program.

While the goals articulated in the blueprint and corresponding RFI are laudable, we are concerned that the Department's focus on tackling cost drivers for prescription drugs does not allow for appropriate recognition of the complicated treatment needs of the most vulnerable Medicare patients, many of whom have a condition requiring medication in one of the six protected classes. Additionally, we believe that any policy that might have the effect of reducing beneficiary access to the right medicines carries significant costs that may outweigh any potential savings. The ability for patients to access their prescription medications is one of several important factors that determine whether patients are receiving the treatment they need. Because patients with these serious illnesses react differently to different medicines, their availability to the full range of effective medications, as determined by their physician, is a crucial component of successful treatment and recovery.

The Partnership for Part D Access believes that any viable proposal must ensure patients can access the course of treatment that best meets their needs, including treatment regimens in Medicare's six protected classes. Congress has repeatedly affirmed such a policy in strong bipartisan

fashion, and over time has further clarified its intent to ensure Medicare patients are afforded timely access to medications in the six protected classes.

As you continue to evaluate administrative options available to the Department to address prescription drug pricing, we request that you preserve the existing policies which safeguard Medicare beneficiaries' access to a wide range of treatment options in the protected classes. We further urge you to consider the potential impact that changes to the protected classes could have on Medicare beneficiaries as well as the robust body of research which demonstrates that restrictive access leads to higher costs for the Medicare program, upon which we elaborate below. Patients with these serious health conditions often require physicians and patients to fine-tune medications to achieve clinically necessary treatment outcomes. Finally, we note for your consideration that compared to Medicare beneficiaries generally, enrollees with the most vulnerable health conditions could be disproportionately harmed should the Administration also impose new utilization and access restrictions across the Part D program.

OVERVIEW

The President's blueprint asserts that Medicare Part D sponsors do not have full flexibility to manage high cost drugs that do not provide the plan with rebates or negotiated fixed prices, including in the protected classes. The document also suggests that a change in the protected classes policy could allow Part D plans to use the tools available to private payers outside of the Medicare program to better negotiate for these drugs.

We believe, however, that these suggestions misrepresent the scope of existing authority to restrict and manage access to medications. In doing so, the Administration's explicit recommendation to reform the six protected classes policy likely overestimates the potential for savings. There are a number of studies and guidance discussed below which demonstrate the flaws in policies that undermine the existing protected classes policy.

PROTECTED CLASSES ARE SUBJECT TO UTILIZATION MANAGEMENT COMPARABLE TO COMMERCIAL PLANS

Under current guidance issued by the Centers for Medicare & Medicaid Services (CMS), Part D plans are generally required to cover brand-name drugs in a protected class when no generic equivalent is available, but they may exclude brand-name drugs from coverage when a generic equivalent is available. The plans may also exclude extended-release formulations if an immediate-release formulation is available, and multiple formulations with the same route of administration are not required.

Guidance issued by CMS also permits, other than for drugs relating to HIV, Part D plans to use prior authorization and step therapy to manage therapies for any beneficiary beginning treatment on a protected class drug.¹ For HIV drugs, consistent with HHS Treatment Guidelines, utilization management tools such as prior authorization and step therapy are generally not employed. However, for all of the protected classes, Part D plans may utilize formulary tiering to steer patients

¹ Medicare Prescription Drug Benefit Manual, Ch. 6, § 30.2.5.

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.

As an example of how this flexibility is applied, as recently as June 2018, a study published in the *American Journal of Managed Care* found that antipsychotic drugs – one of the six protected classes – is among the most likely classes of drugs to have step therapy imposed upon formulary placement. The study authors also reported that antipsychotics along with antiepileptics are among the most likely drug classes to require prior authorization upon formulary placement.²

A separate detailed analysis of one of the protected classes, anticonvulsants, adds to the body of evidence demonstrating that protected classes do *not* prevent Part D plans from effectively managing formularies — as is typical among commercial plans.^{3,4,5} In fact, this analysis finds that Part D plans have *more* restrictive formularies for this class of therapy than commercial health insurance plans. In 2013, commercial plans covered 80 percent of unique formulations in the class (including both brand and generic formulations), while Part D plans covered only 62 percent. This study also found that while both insurer types covered nearly all generic formulations, commercial plans covered 76 percent of branded drugs, compared with only 46 percent coverage by Part D plans, demonstrating that these plans frequently use their ability to exclude branded drugs when a generic is available. This study found that Part D plans also place anticonvulsants on higher tiers than do commercial plans.

Further, a substantial body of evidence demonstrates that the existing flexibility for Medicare Part D plans to manage utilization has ensured that generic dispensing rates (GDR) within the protected classes are on par with other therapeutic classes.^{6,7} In fact, one analysis of CMS’ 2015 Medicare Drug Spending Data shows that protected classes currently have a higher overall rate of generic utilization than other drug classes (92 percent and 84 percent of prescriptions, respectively). Additionally, generic uptake has affected prices for these therapies. According to the Medicare Payment Advisory Commission (MedPAC), prices for protected-class drugs have increased at the same rate as all Part D drugs, and cumulative prices decreased by 16 percent between 2006 and 2013

² Stuart, Bruce C., PhD and Tom, Sarah E., PhD., *The American Journal of Managed Care*. “Placement of Selected New FDA-Approved Drugs in Medicare Part D Formularies, 2009-2013”, June 2018.

³ The Pew Charitable Trusts, “Policy Proposal: Revising Medicare’s Protected Classes Policy,” March 2018, <http://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2018/03/policy-proposal-revising-medicare-protected-classes-policy>

⁴ Brantley, Kelly, Wingfield, Jacqueline, and Washington, Bonnie, Avalere, “An Analysis of Access to Anticonvulsants in Medicare Part D and Commercial Health Insurance Plans,” June 2013, http://avalere.com/research/docs/Anticonvulsants_in_Part_D_and_Commercial_Health_Insurance.pdf

⁵ QuintilesIMS Institute. “Estimate of Medicare Part D Costs After Accounting for Manufacturer Rebates A Study of Original Branded Products in the U.S.,” October 2016, <https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/estimate-of-medicare-part-d-costs-after-accounting-for-manufacturer-rebates.pdf?la=en&hash=C2AE92B591D0E059BDC9D90FE526E23E73493F84>

⁶ 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>.

⁷ QuintilesIMS Institute, “Estimate of Medicare Part D Costs After Accounting for Manufacturer Rebates A Study of Original Branded Products in the U.S.,” October 2016, <https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/estimate-of-medicare-part-d-costs-after-accounting-for-manufacturer-rebates.pdf?la=en&hash=C2AE92B591D0E059BDC9D90FE526E23E73493F84>

due to generic substitution.⁸ The current high rates of generic use within the protected classes strongly suggest there is limited potential for savings from changes to the protected classes policy.

PROTECTED CLASSES ELICIT REBATES COMPARABLE ACROSS ALL PART D PRODUCTS

While the proposals in the blueprint argue that Medicare Part D plans are currently unable to negotiate lower prices for high cost drugs without competition, there is ample evidence to the contrary.

As one example, analysis of Part D data from 2014 found that plans received on average a 17.5 percent rebate on all Part D brand-name drugs. Among 40 drugs identified by Medicare as having high total spending, high per-user spending, or large price increases in 2014, the average rebate was 17.8 percent. Of these 40 drugs, about a third (13) were in protected classes and accounted for roughly one-third (30 percent) of the spending on those 40 drugs. As the rebates on these 40 drugs were already consistent with rebates across all Part D brand-name drugs, this offers strong evidence to suggest that rebates on protected-class drugs are consistent with other brand-name drugs.⁹

Additionally, for antidepressants – one of the protected classes – Part D plans have achieved significant rebates of approximately 70 percent.¹⁰ This is further evidence that the protected classes policy does not present a barrier to negotiating meaningful discounts and rebates.

PROTECTED CLASSES ARE CRITICALLY IMPORTANT TO THE MOST VULNERABLE PATIENTS

The protected classes policy is essential for maintaining access to proper treatment for Medicare beneficiaries. Patients with a prescribed medication 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 the medications they take to treat their mental illness.¹¹ Additionally, one in four individuals with cancer has clinical depression.¹² The protected classes policy may help mitigate barriers to access these important medications.

⁸ 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>.

⁹ The Pew Charitable Trusts. “Policy Proposal: Revising Medicare’s Protected Classes Policy,” March 2018, <http://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2018/03/policy-proposal-revising-medicare-protected-classes-policy>

¹⁰ QuintilesIMS Institute, “Estimate of Medicare Part D Costs After Accounting for Manufacturer Rebates A Study of Original Branded Products in the U.S.,” October 2016, <https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/estimate-of-medicare-part-d-costs-after-accounting-for-manufacturer-rebates.pdf?la=en&hash=C2AE92B591D0E059BDC9D90FE526E23E73493F84>

¹¹ 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.

¹² 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>.

Due to the unique and variable ways in which patients respond to different drugs, and the complicated interplay of co-morbidities and drug interactions, it has been widely recognized that doctors need to have complete discretion to prescribe the most appropriate medicines for patients with these and other conditions addressed by the protected classes. The diversity in treatment needs in depressed patients serves as an illustrative example of the necessity of the protected classes policy. Under the American Psychiatric Association's Diagnostic and Statistical Manual V, major depressive disorder (MDD) is diagnosed based on the individual having five out of nine listed symptoms associated with clinically significant distress or impairment in social, occupational or other areas of functioning.¹³ This means that there are over 200 different variations of major depression that someone could present with and one would not look like the other. Given the heterogeneity of the patient population and multi-factorial nature (e.g., age, gender, sex, socioeconomic status, childhood history of sexual abuse, and recent stressful life events) of this disease in patients' response to therapy, it seems inconceivable that availability of one, two or even 20 medications is enough. Further, people with mental illness who may relapse, not respond to, or frequently experience varying side effects to medications.

Additionally, it is well established that MDD is significantly associated with a wide variety of chronic physical disorders, including arthritis, asthma, cancer, cardiovascular disease, diabetes, hypertension, chronic respiratory disorders, and a variety of chronic pain conditions.^{14,15,16,17,18} The strong link between depression and various comorbid medical conditions suggest that management of all conditions are needed for optimal patient care. Comorbidities can limit the type of antidepressants a person can tolerate -- thus heightening the need for a broad range of antidepressant choices, as a drug's tolerability may affect adherence to the prescribed treatment regimen.^{19,20} Delays in receiving the correct depression medication and/or patient lack of adherence (e.g., because coverage restrictions bar access to an antidepressant with fewer side effects) can adversely affect both the patient's mental health and the treatment of the patient's medical comorbidity and overall health -- with all the associated expenses necessary to treat both the MDD and the comorbid condition after these problems have grown worse.²¹ These circumstances will cause Medicare to pay for avoidable hospitalizations, emergency department visits, physician visits,

¹³ The nine DSM criteria for depression are as follows and a combination of any five criteria supports a diagnosis of MDD where at least one of the symptoms is either depressed mood or loss of interest or pleasure: (1) Depressed mood; (2) Decreased interest or pleasure; (3) Significant weight change; (4) Insomnia; (5) agitation or psychomotor retardation noticed by others; (6) Fatigue or loss of energy; (7) Guilt/worthlessness; (8) Diminished concentration; (9) Recurrent thoughts of death.

¹⁴ RJ Anderson et al., The Prevalence of Comorbid Depression in Adults with Diabetes: A Meta-Analysis, 24 *Diabetes Care* 1069, 1069–78 (2001)

¹⁵ M.A. Buist-Bouwman MA et al., Comorbidity of Physical and Mental Disorders and the Effect on Work-Loss Days, 111 *Acta Psychiatrica Scandinavica* 436, 436–43 (2005).

¹⁶ Daniel P. Chapman et al., The Vital Link Between Chronic Disease and Depressive Disorders, 1 *Preventing Chronic Disease Pub. Health Res., Prac. and Pol'y* A14 (2005).

¹⁷ L.R. Derogatis et al., The prevalence of psychiatric disorders among cancer patients, 249 *JAMA* 751, 751–57 (1983).

¹⁸ C.B. Nemeroff et al., Depression and Cardiac Disease: A Review, 19 *Cardiology in Review* 130, 130-142 (2011).

¹⁹ Goethe JW. et al. *J Clin Psychopharmacol.* 2007;27(5):451-458.

²⁰ Bull SA. et al. *Ann Pharmacother.* 2002;36(4):578-584.

²¹ Dan V. Iosifescu, et. al., The Impact of Medical Comorbidity on Acute Treatment in Major Depressive Disorder. *Am. J. Psychiatry*; 160:2122-2127.

and other interventions that would not have been necessary if the patient had ready access to the right antidepressant.

A second example demonstrating the necessity of the existing structure for protected classes can be found with immunosuppressive medications. These medications are not interchangeable but rather are prescribed in combinations tailored to meet the unique needs of the individual transplant recipient to achieve sufficient immunosuppression while minimizing the toxicity associated with individual agents. Physicians prescribe the most appropriate combination for the individual patient to achieve sufficient immunosuppression while minimizing the adverse side effects. Often the first combination doesn't work and the physician must revise the regimen, further underscoring the need to have all drugs available. Restrictive formularies limit physicians' ability to prescribe the right combination of medications.

Further, for patients with HIV, the advent of antiretroviral medications in the late '90s turned the disease from a near certain death to a manageable prognosis if patients have access to quality care and medications. Not all medications are the same, and each person may react differently to a particular medication. Together, doctors and patients make careful treatment decisions about which therapies are most appropriate on a case by case basis. Some individuals may develop side-effects to a particular drug, while another person may need a certain therapy to avoid a harmful interaction with a drug being taken for another health condition. Additionally, for people living with HIV, drug resistance can occur, and they must have the ability to switch to another drug without interruption.

The protected classes policy is particularly significant for the approximately 11.7 million individuals who are simultaneously enrolled in the Medicare and Medicaid programs. Among these dually eligible beneficiaries are poor seniors with and without chronic medical conditions, younger individuals with disabilities, and individuals with serious mental illness. As a group, these Medicare-Medicaid enrollees experience high rates of chronic illness, with many having multiple chronic conditions and/or long-term care needs. CMS data shows that 41 percent of dually eligible beneficiaries have at least one mental health diagnosis, while 68 percent have three or more chronic conditions, including, but not limited to, diabetes, pulmonary disease, stroke, Alzheimer's disease, and mental illness.²² Dual eligible beneficiaries require access to a wide variety of medicines to meet their complex health needs; this cohort, in particular, may be susceptible to any treatment disruptions and would likely be disproportionately impacted by a change to weaken or otherwise modify the current six protected classes.

PROTECTED CLASSES LOWER MEDICARE SPENDING AND PROMOTE ADHERENCE

While proponents of changes to the protected classes argue that removing certain drugs from their 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'

²² Medicare-Medicaid Coordination Office, Centers for Medicare & Medicaid Services, "Fiscal Year 2017 Report To Congress" https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/RTC_MMCO_FY2017_06072018.pdf

conditions. The costs associated with this care often is not borne by the Part D plan, but would increase overall costs to Medicare and Medicaid.

A study issued in 2015 and updated in April 2018 by 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).²³ 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.²⁴ Another study found that formulary restrictions within the Medicaid program appear to lead to worse outcomes for patients with major depressive disorder and increased the probability of an MDD-related hospitalization by nearly 17 percent with no significant reductions to pharmacy or total spending. Importantly, there was no evidence that these restrictions resulted in any net savings for Medicaid.²⁵

Similarly, a June 2016 Working Paper published by the National Bureau of Economic Research (NBER) examines policies which may incentivize some Medicare Advantage plans to use drug formulary design to encourage enrollment by patients with medical conditions that are more profitable under traditional Medicare.²⁶ The researchers also find evidence that these plans more generously cover drugs that are likely to minimize health care costs, compared to standalone Part D plans. These studies reinforce 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.²⁷ 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.²⁸ They also found evidence to suggest that formulary restrictions led to increased rates of nonadherence, especially among older beneficiaries.²⁹ The authors further noted that studies indicate patients who were less adherent or who switched their therapies had higher hospitalization rates with longer stays. These findings are consistent with a recent report from the Pew Charitable Trusts, which concludes that "lack of adequate access to medications can in some

²³ Starc, A., and Town, R.J. National Bureau of Economic Research, Working Paper No. 21783. Externalities and Benefit Design in Health Insurance, Issued December 2015, revised April 2018, <http://www.nber.org/papers/w21783.pdf>

²⁴ *Ibid.*

²⁵ Seabury, Seth, Lakdawalla, Darius, Walter, Deborah et al., "Patient Outcomes and Cost Effects of Medicaid Formulary Restrictions on Antidepressants," *Forum for Health Economics and Policy*, Volume 17, Issue 2, Pages 153–168, 2014.

²⁶ Lavetti K, Simon K. National Bureau of Economic Research, Working Paper No. 22338, "Formulary design in Medicare Part D plans," June 2016, [nber.org/papers/w22338](http://www.nber.org/papers/w22338). Published. Accessed May 15, 2017.

²⁷ Avalere Health Impact of Formulary Restrictions on Adherence, Utilization, and Costs of Care, March 2016.

²⁸ *Ibid.*

²⁹ *Ibid.*

circumstances increase costs to other Medicare programs through increased hospitalizations from complications or increased physician visits to manage medications.”³⁰

CONGRESSIONAL INTENT AND HISTORY OF ONGOING 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.³¹ To that end, the MMA forbade an approved Medicare prescription drug plan (PDP) from having a design and formulary that was “likely to substantially discourage enrollment” by certain classes of patients.³² 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.”³³

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.³⁴ 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.”³⁵

In 2008, Congress passed the Medicare Improvements for Patients and Providers Act (MIPPA), which included language affecting the six protected classes.³⁶ 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.³⁷

When the Affordable Care Act (ACA)³⁸ 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,

³⁰ The Pew Charitable Trusts. “Policy Proposal: Revising Medicare’s Protected Classes Policy,” March 2018, <http://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2018/03/policy-proposal-revising-medicare-protected-classes-policy>

³¹ Public Law 108-173 (December 8, 2003).

³² 42 U.S.C. § 1395w-111(e)(2)(D)(i).

³³ 149 Cong. Rec. S5882-03

³⁴ 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>.

³⁵ *Ibid.*

³⁶ Public Law 110-275 (July 15, 2008)

³⁷ 42 U.S.C. §1395w-104(b)(3)(G)(ii).

³⁸ Public Law 111-148 (March 23, 2010).

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.³⁹

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 2015.⁴⁰ 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.⁴¹ 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.”⁴² Additionally, 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.⁴³ 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.⁴⁴

CONCLUSION

We understand this RFI is the beginning of an ongoing conversation and look forward to continuing to work with you to ensure that patient access to needed medications is not undermined in the process. Given the relatively high rate of utilization management that already occurs in the protected classes, patients with the most vulnerable health conditions already often face barriers in accessing the medications that might work best for them. Moreover, Part D plans have demonstrated that they have substantial tools at their disposal to elicit rebates for medications in the protected classes that are comparable to other drugs covered under Part D, and there is little question that access to the right therapies can help reduce costs related to hospitalization. As vulnerable patients rely on these medications to manage their particularly complex health conditions, we hope the Department will consider the longstanding sentiment of Congress in supporting this policy that effectively reduces other unnecessary health complications.

³⁹ *Ibid.*

⁴⁰ 79 Fed. Reg. 1917 (January 10, 2014).

⁴¹ Letter to HHS by Senate Finance Committee, February 2014, available [here](#).

⁴² Letter to HHS by House W&M and E&C Committee Members, available [here](#).

⁴³ 79 Fed. Reg. 29865 (May 23, 2014).

⁴⁴ 79 Fed. Reg. 29844 (May 23, 2014).

The member organizations of The Partnership and I look forward to continuing our dialogue with you about the best ways to improve Part D. Should you have questions or wish to meet with us, please do not hesitate to contact me at 202-684-3749 ext. 249 or chucki@thenationalcouncil.org.

Sincerely,

A handwritten signature in black ink that reads "Charles Ingoglia". The signature is written in a cursive style with a large initial "C".

Chuck Ingoglia, MSW

Executive Director, The Partnership for Part D Access

Sr. Vice President, Public Policy & Practice Improvement, The National Council