



January 25, 2018

**Submitted electronically via [CompetitionRFI@hhs.gov](mailto:CompetitionRFI@hhs.gov)**

The Honorable John R. Graham  
Acting Assistant Secretary for Planning and Evaluation  
U.S. Department of Health & Human Services  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

**RE: U.S. Department of Health and Human Services Request for Information – Promoting Healthcare Choice and Competition Across the United States, Released Dec. 26, 2017**

Dear Acting Assistant Secretary Graham,

The Partnership for Part D Access (the Partnership) would like to take this opportunity to respond to The Department of Health and Human Services' (HHS) Request for Information (RFI) issued on December 26, 2017 seeking information from stakeholders about the Medicare program. We respectfully are providing information about an important policy that ensures the Medicare Part D program functions effectively, especially for patients with complicated disease cases and multiple conditions. The six classes of clinical concern, also known as protected classes, is a vital policy that ensures patients with high-risk complicated conditions receive access to the most appropriate medication. As you evaluate the program, we urge you to retain this policy.

The Partnership is a coalition of healthcare stakeholders committed to maintaining access to 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 classes of medications — (1) anticonvulsants; (2) antidepressants; (3) antineoplastics; (4) antipsychotics; (5) antiretrovirals; and (6) immunosuppressants — provide important treatments for individuals who have epilepsy, mental illness, cancer, HIV-AIDS, and organ transplant. The Partnership was founded to combat efforts to undermine consumer access to appropriate treatment by increasing awareness of the vulnerability of patients with these conditions and the potential impact and cost resulting from delayed or denied care. The Partnership's membership currently includes a variety of patient advocacy organizations, such as the National Council for Behavioral Health (National Council), the National Alliance on Mental Illness (NAMI), the Leukemia and Lymphoma Society, Mental Health

America (MHA), The Michael J. Fox Foundation, The AIDS Institute, the Epilepsy Foundation, and the National Kidney Foundation (NKF), as well as industry representatives.

### **The Protected Classes Are Critically Important to Vulnerable Patients**

The protected classes policy is essential for maintaining access to the most appropriate treatment for Medicare beneficiaries. Patients with a condition requiring medication from one of the protected classes typically 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 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 protects patients from arbitrary restrictions and limitations that may negatively impact their health and well-being.

While the protected classes policy ensures patient access to needed medications, 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 needed to negotiate rebates with manufacturers.

### **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

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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.

under Medicare (e.g., hospitalizations).<sup>4</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>5</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>6</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>7</sup> They also found evidence to suggest that formulary restrictions led to increased rates of non-adherence, especially among older beneficiaries.<sup>8</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**

Federal policymakers — both in Congress and the most recent Republican administration — have a long history of support for Medicare's six 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.<sup>9</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>10</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>11</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>12</sup> For beneficiaries already

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<sup>4</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>5</sup> *Ibid.*

<sup>6</sup> Avalere Health (March 2016), *Impact of Formulary Restrictions on Adherence, Utilization, and Costs of Care*.

<sup>7</sup> *Ibid.*

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

<sup>9</sup> Public Law 108-173 (December 8, 2003).

<sup>10</sup> 42 U.S.C. § 1395w-111(e)(2)(D)(i).

<sup>11</sup> 149 Cong. Rec. S5882-03.

<sup>12</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*

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>13</sup>

However, in time, it became clear that CMS' guidance was being interpreted unevenly among plans. Therefore, Congress pursued legislative action to codify the protected classes. In 2008, Congress passed the Medicare Improvements for Patients and Providers Act (MIPPA),<sup>14</sup> which 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 (Section 176). MIPPA replaced CMS' "substantially all" standard, instead requiring that "all" drugs in the protected classes be covered.<sup>15</sup>

Looking to build on the success of the protected classes, Congress again addressed the policy as part of the Affordable Care Act (ACA)<sup>16</sup> in 2010. 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 Part D plan sponsors must cover *all* drugs within the protected classes.<sup>17</sup>

While the clear intent of Congress had been to expand on the popular six protected classes policy, in early 2014, CMS proposed sweeping changes to the protected classes requirements based on their regulatory authority provided under the ACA. Under a proposed rule that made policy and technical changes to the Medicare Advantage (MA) and prescription drug benefit programs for calendar year 2015,<sup>18</sup> CMS proposed keeping 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, and to remove antipsychotics the following year.

The proposed regulation was met with extraordinary opposition from Congress, patient groups, and others concerned with access to medications for Medicare beneficiaries. Indeed, every member of the Senate Finance Committee wrote to HHS opposing the proposed redefinition of the protected classes and said they were unconvinced that any cost savings would materialize.<sup>19</sup> Additionally, 50 bipartisan members of the House Ways & Means and Energy & Commerce Committees wrote to oppose the proposal, saying it would "place harmful limits on Medicare

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*Categories?* Available at: <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/FormularyGuidanceAllorSubAll.pdf>.

<sup>13</sup> *Ibid.*

<sup>14</sup> Public Law 110-275 (July 15, 2008).

<sup>15</sup> 42 U.S.C. §1395w-104(b)(3)(G)(ii).

<sup>16</sup> Public Law 111-148 (March 23, 2010).

<sup>17</sup> *Ibid.*

<sup>18</sup> 79 Fed. Reg. 1917 (January 10, 2014).

<sup>19</sup> Letter to HHS by Senate Finance Committee, February 2014, available [here](#).

beneficiaries' access to necessary medications that would otherwise be covered."<sup>20</sup> Further, well over 1,400 comments were submitted to CMS by patient organizations, medical guilds, and other patient-focused groups 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>21</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>22</sup>

## **Conclusion**

The overwhelming success of the Medicare Part D program and its significantly lower than expected cost are for many beneficiaries a result of the protected classes policy. This policy has provided access to certain medications for the most complex patients — the frail, disabled and those with multiple chronic conditions. As the Department considers ways to improve the Medicare program, the protected classes policy should be retained. The Partnership's members stand ready to work with you and other leaders at HHS to pursue policies that protect patients access to medications, result in better health outcomes.

Sincerely,

A handwritten signature in black ink that reads "Charles Ingoglia". The signature is written in a cursive, flowing style.

Chuck Ingoglia  
National Council for Behavioral Health  
Executive Director, Partnership for Part D Access

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<sup>20</sup> Letter to HHS by House W&M and E&C Committee Members, available [here](#).

<sup>21</sup> 79 Fed. Reg. 29865 (May 23, 2014).

<sup>22</sup> 79 Fed. Reg. 29844 (May 23, 2014).