April 24, 2017

Seema Verma
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

RE: 2017 Transformation Ideas

Dear Administrator Verma:

The Partnership for Part D Access (the Partnership), appreciates the opportunity to provide the Centers for Medicare and Medicaid Services (CMS) comments in response to the Request for Information (RFI) that was included in the "Announcement of Calendar Year (CY) 2018 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter and Request for Information" (CY 2018 Call Letter). As you consider recommendations from stakeholders to transform the Part D program and simplify rules for Medicare beneficiaries, providers and plans, we ask that you do not adopt new policies that would undermine access to critical and life-saving medications for Medicare beneficiaries, as discussed in detail below.

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 at section 1860D-4(b)(3)(G)(iv) of 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 these conditions 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, The 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 industry representatives.

History of the Protected Classes

When Congress passed the Medicare Modernization Act of 2003 (MMA)[1], it sought to ensure that all individuals would have access to a robust prescription drug benefit, regardless of their clinical conditions. To that end, the MMA required that a prescription drug plan (PDP) be approved only if it was determined that the plan's design and formulary were not "likely to substantially discourage enrollment" by certain classes of patients.[2]

To implement this statutory requirement, the Centers for Medicare and Medicaid Services (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 that Medicare beneficiaries received clinically appropriate medications and had "uninterrupted access" to all drugs in the classes.[3] 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."[4]

In 2008, Congress passed the Medicare Improvements for Patients and Providers Act (MIPPA)[5], which included language regarding the six protected classes. Section 176 of MIPPA required that the Secretary of Health and Human Services (HHS) establish a process for determining the appropriate categories and classes of protected drugs, beginning with plan year 2010. MIPPA replaced CMS' "substantially all" standard, requiring that "all" drugs in the protected classes be covered.[6]

When the Affordable Care Act (ACA)[7] 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 the 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 cover *all* drugs within the protected classes.

In early 2014, CMS proposed sweeping changes to the protected classes policy within a proposed rule for policy and technical changes to the Medicare Advantage (MA) and prescription drug benefit programs for calendar year 2015.[8] In the proposed rule, CMS proposed to keep only three categories of drugs as protected classes: antiretrovirals, antineoplastics and anticonvulsants.

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[1] Public Law 108-173 (December 8, 2003).
[2] 42 U.S.C. § 1395w-111(e)(2)(D)(i).
[3] https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/FormularyGuidanceAllorSubAll.pdf
[4] *Ibid*.
[5] Public Law 110-275 (July 15, 2008).
[6] 42 U.S.C. §1395w-104(b)(3)(G)(ii).
[7] Public Law 111-148 (March 23, 2010).
[8] 79 Fed. Reg. 1917 (January 10, 2014).

It proposed to remove immunosuppressants and antidepressants from the classes of clinical concern in 2015, but to continue to treat antipsychotics as a class of clinical concern for that year.

As the result of extraordinary opposition by patient groups and others concerned with access to medications for Medicare beneficiaries, CMS did not finalize the proposed changes. Instead, in its final rule, CMS stated that categories and classes of drugs of clinical concern would be the six enumerated in the ACA until such time as the agency would undertake rulemaking to establish new criteria.[9] CMS said that it wasn't finalizing its proposal it "did not strike the balance among beneficiary access, quality assurance, cost containment and patient welfare" that it had been hoping to achieve.[10] The Partnership applauds CMS for making the decision to continue to protect the interests of vulnerable Medicare beneficiaries.

Support the Continuation of the Protected Classes

As CMS considers recommendations from stakeholders to make changes to the Medicare Part D program, we ask you to support the continuation of the six protected classes. This policy is essential for Medicare beneficiaries, who generally have more complex health needs and does not result in higher drug prices. In addition, Part D plans already have strong cost control measures at their disposal.

Patients with a condition in one of the protected classes have very complicated medical needs. Many of these patients must attempt a variety of therapies before they come to a decision with their physicians about the most appropriate treatment. The protected classes policy shields them from arbitrary restrictions and limitations intended to hinder access to important medications.

According to independent research performed in 2016 by Avalere Health, little evidence exists to suggest meaningful cost savings from limiting formulary access. In fact, the opposite impact often is found. Increases in inpatient and outpatient medical care outweighed any savings on prescription drugs from formulary restrictions. In addition, the Medicare Payment Advisory Commission (MedPAC) found that from 2006-2013, prices for protected-class drugs rose more slowly than Part D prices overall.[11] Cumulative Part D price growth from 2006-2013 was 47 percent overall and 38 percent for protected class drugs; after accounting for generic substitution, cumulative prices decreased by 16 percent for protected-class drugs and increased by two percent for all Part D drugs.[12]

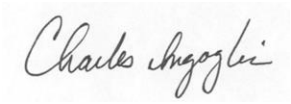
Finally, while it sometimes is asserted that Part D plans have less opportunity to negotiate drug prices for protected classes, plans already have a number of tools to manage the utilization of drugs in these classes and negotiate rebates. Under current CMS guidance, for drugs other than those relating 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, allowing Part D Plans

[9] 79 Fed. Reg. 29844 (May 23, 2014).
[10] 79 Fed. Reg. 29865 (May 23, 2014).
[11] MedPAC, March 2016 Report to Congress, Medicare Payment Policy, at 392.
[12] *Ibid*.

considerable flexibility to limit access to more expensive drugs and leverage to negotiate rebates with manufacturers.[13] In addition, Part D Plans may utilize formulary tiering to steer patients toward lower cost drugs.

The Part D program has been both popular among Medicare beneficiaries and successful in providing affordable drug coverage to them. We ask that as CMS considers responses to the RFI, that you support retaining the six protected classes as they exist today. We would welcome the opportunity to meet with you in person to discuss this important issue and are happy to answer any questions you may have.

Sincerely,



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[13] Medicare Prescription Drug Benefit Manual, Ch. 6, § 30.2.5.