

June 6, 2019

The Honorable Richard E. Neal  
Chairman, Ways and Means Committee  
2309 Rayburn House Office Building  
Washington DC 20515

The Honorable Frank Pallone, Jr.  
Chairman, Energy and Commerce Committee  
2107 Rayburn House Office Building  
Washington, DC 20515

The Honorable Kevin Brady  
Ranking Member, Ways and Means Committee  
1011 Longworth House Office Building  
Washington, DC 20515

The Honorable Greg Walden  
Ranking Member, Energy and Commerce  
2185 Rayburn House Office Building  
Washington, DC 20515

**Re: Solicitation for feedback on draft Medicare Part D legislation**

National Patient Advocate Foundation (NPAF) appreciates your bipartisan leadership and the opportunity to provide comments on the Committees' draft legislation improving the Medicare Part D prescription drug program.

NPAF represents the voices of millions of adults, children and families coping with serious and chronic illness nationwide as the advocacy affiliate of Patient Advocate Foundation (PAF). PAF provides direct case management, financial support and educational services to tens of thousands of primarily low-income patients and caregivers each year who are experiencing distressing financial, employment, insurance coverage or household material hardships because of their health conditions. In 2017, 41 percent of all patients seeking PAF case management assistance listed Medicare as their primary insurance;<sup>1</sup> this number rose to approximately 45 percent in 2018.<sup>2</sup>

Our case managers consistently report that medication affordability challenges as well as household material hardships including housing, energy and transportation insecurities remain the top issues in patients seeking PAF assistance. NPAF is encouraged by the Committees' attention to helping millions of seniors and people with disabilities access treatment to improve their quality of life at an affordable out-of-pocket (OOP) cost. We offer the following recommendations to protect the financial and emotional well-being of Medicare beneficiaries coping with serious and chronic illness.

**Introducing an annual and monthly OOP cap**

NPAF and the advocacy community have long advocated for an OOP cap in Medicare Part D as there is currently no way for beneficiaries to limit spending for medications at the pharmacy counter. Beneficiaries receiving high-cost specialty drugs subject to coinsurance are particularly vulnerable for financial distress and medical debt. Fortunately, those who qualify for low-income subsidies (LIS) are protected from catastrophic level spending once they reach the \$5,100 threshold, however, those who

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<sup>1</sup> Patient Advocate Foundation. Annual Impact Report. 2017. Available at: [https://www.patientadvocate.org/wp-content/uploads/2017\\_AnnualImpactReport.pdf](https://www.patientadvocate.org/wp-content/uploads/2017_AnnualImpactReport.pdf)

<sup>2</sup> Patient Advocate Foundation. Internal Case Management Data (Pre-publication). 2018.

do not qualify may face costs up to \$16,551 for a single medication. Additionally, those not eligible for LIS are subject to even higher OOP expenses as much as \$145,769 for drugs not covered under the plan.<sup>3</sup>

While enrollment in the Part D program continues to grow, the proportion of people receiving LIS is unfortunately dwindling because eligibility thresholds are exceptionally low. Implementing an annual OOP limit will be increasingly important as more non-LIS beneficiaries confront catastrophic costs.<sup>4</sup>

In the broader context of reducing health care costs, we urge Congress and the Administration to examine the patient experience throughout the health care year. Research illustrates that OOP costs due to a variety of cancer types showed a strong seasonal effect, peaking significantly each January when patients face new plan year deductibles and immediately upon diagnosis.<sup>5</sup> In Part D, patients and their families currently bear 100 percent of drug costs until their deductible is reached followed by coinsurance ranging from 25 to 33 percent of costs in the initial coverage phase and coverage gap followed by five percent coinsurance in the catastrophic phase. Most families (67 percent) who receive assistance from PAF earn less than \$36,000 per year and are unable to pay the up-front costs for prescription drugs, especially layered upon other household expenses and non-medical costs related to their illness.

NPAF recommends for Congress enact a smoothing policy that would create a monthly OOP cap to address the seasonality of health costs. We believe a monthly OOP cap would have the greatest impact on patient affordability and would enable patients to better budget for drug costs throughout the year.

### **Modernizing the Part D benefit design**

In addition to creating an annual and monthly OOP cap, we recommend that Congress consider policies to modernize and simplify the Part D benefit design. Patients are often confused about the various cost-sharing levels: deductible, initial coverage, coverage gap and catastrophic. Studies have shown that the Part D coverage gap or “donut hole” affects adherence to treatment, and those without financial assistance in the gap were more likely to discontinue treatment.<sup>6</sup>

The Affordable Care Act and the Bipartisan Budget Act introduced important reforms to close the coverage gap and reduce patients’ cost-sharing obligations during this period. Yet patients largely remain unaware of how their financial responsibility changes at any given point during the plan year based on which medications, brand or generic, they receive. Congress should consider eliminating the distinction between the initial coverage phase and the coverage gap if the cost-sharing amounts are equivalent at 25 percent cost-sharing. We strongly support eliminating the coverage gap altogether.

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<sup>3</sup> Kaiser Family Foundation. The Out-of-Pocket Cost Burden for Specialty Drugs in Medicare Part D in 2019. Issue Brief. February 2019. Available at: <https://www.kff.org/medicare/issue-brief/the-out-of-pocket-cost-burden-for-specialty-drugs-in-medicare-part-d-in-2019/>

<sup>4</sup> Trish E, Xu J and G Joyce. Growing number of unsubsidized Part D beneficiaries with catastrophic spending suggests need for an out of pocket cap. *Health Affairs*. 2018. 37(7):1048–1056. Available at: <https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2018.0006>

<sup>5</sup> Milliman Research Report. A multi-year look at the cost burden of cancer care. April 11, 2017. Available at: <http://us.milliman.com/uploadedFiles/insight/2017/cost-burden-cancer-care.pdf>

<sup>6</sup> Park YJ and Martin EG. Medicare Part D’s effects on drug utilization and out-of-pocket costs: A systematic review. *Health Serv Res*. 2017 Oct; 52(5):1685-1728.

Additionally, simplifying the benefit design by removing the five percent cost-sharing requirement when patients reach the catastrophic coverage phase while eliminating the coverage gap would provide clarity for both low- and moderate-income patients in Part D. This policy in conjunction with an OOP cap represents a person-centered solution that affords patients significant relief from high OOP costs and has also been recommended by the National Academies of Science Engineering and Medicine.<sup>7</sup>

Any improvements to the Part D benefit design should be outlined in the explanation of benefits (EOB) that beneficiaries receive so that EOBs delineate more clearly patients' financial responsibility in terms of copayment, coinsurance and deductible distinct from their insurance premiums. NPAF has suggested that the Centers for Medicare and Medicaid Services (CMS) could enhance usability and simplify existing transparency tools such as Medicare Plan Finder to better assist patients and families with anticipating OOP costs and making health care decisions.

## Conclusion

As the Part D program evolves, maintaining availability of personalized therapeutic choices will be increasingly critical to realize the full return on our national investment in human genome research and precision medicine. These investments have delivered an array of highly targeted therapies that offer improved outcomes. Affordability issues may derail this progress and the promise of using this research to optimize treatments based on patients' particular profiles and preferences.

Concurrently, access challenges in Part D persist with narrowing formularies and increased utilization management, such as prior authorization and step therapy. As Congress seeks to strengthen Part D, we urge Congress to require CMS to develop and execute contemporaneous evaluative processes alongside new reforms to ensure these policies do not interfere with patients' equitable access to effective medication, personalized care or health outcomes.

NPAF appreciates the opportunity to reinforce our strong support for an annual and monthly OOP maximum and respectfully requests that Congress work closely with the Administration to introduce this feature. We believe these reforms will have a significant impact on affordability for Part D beneficiaries. NPAF stands ready to provide feedback from patient, caregiver and family perspectives. Please contact Nicole Braccio, policy director at [Nicole.Braccio@npaf.org](mailto:Nicole.Braccio@npaf.org) if NPAF can provide further assistance.

Respectfully submitted,



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EVP Health Care Quality and Value

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<sup>7</sup> National Academies of Science Engineering and Medicine. Recommendation. Making Medicines Affordable: A National Imperative. November 2017. Available at: <https://www.nap.edu/resource/24946/11302017AffordableDrugsRecs.pdf>