



June 6, 2019

The Honorable Richard Neal
Chairman
House Committee on Ways & Means
1102 Longworth House Office Building
Washington, DC 20515

The Honorable Frank Pallone
Chairman
House Committee on Energy & Commerce
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Kevin Brady
Ranking Member
House Committee on Ways & Means
1139 Longworth House Office Building
Washington, DC 20515

The Honorable Greg Walden
Ranking Member
House Committee on Energy & Commerce
232 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Neal, Chairman Pallone, Ranking Member Brady & Ranking Member Walden:

On behalf of the more than 1.3 million Americans living with a blood cancer diagnosis, The Leukemia & Lymphoma Society (LLS) appreciates the opportunity to provide our perspective on the draft legislation you released to address Medicare Part D beneficiary out-of-pocket costs and the liability in the program's catastrophic benefit. Thank you for your leadership in reaching across party lines to offer a pair of solutions that LLS considers essential to the goal of providing Medicare beneficiaries with meaningful protection against the financial burden associated with a diagnosis like cancer.

As an organization at the forefront of the fight to cure cancer, LLS knows that the cost of care associated with a blood cancer diagnosis continues to rise and have a significant impact on all stakeholders in the healthcare system, particularly patients. Such spending growth is simply unsustainable, and the direct impact on patients poses a threat to their ability to access their treatments. In response to cost growth in recent years, payers and policymakers have often passed the cost burden to patients in the form of increased cost-sharing and changes that erode the quality of the care accessible to cancer patients.

We truly appreciate the opportunity to offer our perspective on the impact of the current benefit design and the potential for these policies to significantly improve the Part D benefit for current and future enrollees. Our comments on the draft legislation are below.

Establishing an out-of-pocket cap

LLS is deeply concerned about unsustainably-rising patient out-of-pocket costs in the Medicare Part D program. The combination of escalating list prices and the Part D program's benefit design leads patients who rely on costly medications to face enormous cost-sharing in January and February of each plan year, requiring the beneficiary to pay thousands of dollars for their first prescription of the year.¹ Increasingly, patients reliant on costly drugs continue to experience burdensome cost-sharing throughout the year, as the five percent cost-sharing required under the catastrophic phase of the Part D benefit can still require hundreds of dollars each month in out-of-pocket costs.

¹ Doshi, J; Li, P; Pettit, A.R.; Dougherty, J.S.; Flint, A; and Ladage, V. (2017). Reducing Out-of-Pocket Cost Barriers to Specialty Drug Use Under Medicare Part D: Addressing the Problem of "Too Much Too Soon." *American Journal of Managed Care*.

These costs have a real and dangerous impact on treatment adherence.² A recent study published in the *Journal of Clinical Oncology* found that high out-of-pocket costs significantly limit access to novel oral cancer medications.³ Specifically, the study found that nearly half of cancer patients whose Medicare Part D out-of-pocket costs were more than \$2,000 failed to pick up their new prescription for an oral cancer medication. By comparison, only 10 percent of patients who were required to pay less than \$10 at the time of purchase did not pick up their medications. In addition to treatment abandonment, delays in picking up prescriptions were also more frequent among patients facing higher out-of-pocket costs.

Unfortunately, more seniors every year are paying these burdensome costs. In 2010, 380,000 enrollees without low-income subsidies (LIS) entered the catastrophic phase of the Part D program. Six years later, that number had grown to 1,044,000 enrollees.⁴ In fact, in 2016, 10 times more enrollees entered the catastrophic benefit simply by filling a single costly prescription than in 2010.

Many blood cancer patients find themselves in just this situation, as new oncology drugs entering the market in 2018 had a median price of \$12,417 per month.⁵ Patients who need to access therapies at or above this price will enter the catastrophic phase when filling their first prescription of the year. Unfortunately, these beneficiaries still find themselves facing hundreds of dollars in cost-sharing for every prescription they need for the rest of the year. As a result, many blood cancer patients with self-administered prescription therapies must pay over \$10,000 each year simply to maintain access to the treatment most effective in fighting their cancer.⁶ While patients and clinicians have cheered the introduction of therapies that turn certain diagnoses from a 'death sentence' into a chronic condition, these therapies often demand daily adherence for the rest of the patient's life—requiring potentially hundreds of thousands of dollars in cost-sharing at a time when the average annual income for Americans over 65 years of age, inclusive of Social Security benefits, is only slightly over \$26,000.

Cancer patients with other types of insurance coverage—employer health plans, individual health plans, Medicaid, and Medicare Advantage—often depend on their annual out-of-pocket cap to provide some limit to the amount they must pay for life-saving care. Extending this essential patient protection to the Medicare Part D program would dramatically lower enrollee cost-sharing for costly and often lifesaving drugs. An out-of-pocket cap would provide meaningful benefits to the more than one million non-LIS beneficiaries whose drug costs push them into the catastrophic phase. Typical plans require patients to pay costs as high as \$16,000 out-of-pocket each year for their cancer drugs.⁷ In the face of this burdensome cost-sharing, these enrollees will benefit immediately from the establishment of a limit to their financial exposure.

An out-of-pocket maximum also provides meaningful peace of mind to Part D enrollees who are not currently taking costly medications. These beneficiaries often hear out-of-pocket horror stories from spouses, siblings,

² Doshi, J; Li, P; Huo, H; Pettit, A.R.; Kumar, R; Weiss, B.M.; and Huntington, S.F. (2016). High Cost Sharing and Specialty Drug Initiation Under Medicare Part D: A Case Study in Patients With Newly Diagnosed Chronic Myeloid Leukemia. *American Journal of Managed Care*.

³ Doshi, J; Li, P; Huo, H; Pettit, A.R.; Armstrong, K. (2018). Association of Patient Out-of-Pocket Costs With Prescription Abandonment and Delay in Fills of Novel Oral Anticancer Agents. *Journal of Clinical Oncology* 36, no. 5.

⁴ MedPAC (2019). Report to the Congress: Medicare Payment Policy.

⁵ Nass, D. and Simorellis, A. (2019). Global Oncology Trends 2019: Therapeutics, Clinical Development and Health System Implications. *IQVIA Institute for Human Data Science*. Accessed at https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/global-oncology-trends-2019.pdf?_id=1559845114841

⁶ Cubanski, J. Neuman, T. Orgera, K. (2017). No Limit: Medicare Part D Enrollees Exposed to High Out-of-Pocket Drug Costs Without a Hard Cap on Spending. *Kaiser Family Foundation*. Accessed at <https://www.kff.org/report-section/no-limit-medicare-part-d-enrollees-exposed-to-high-out-of-pocket-drug-costs-without-a-hard-cap-on-spending-issue-brief/>

⁷ Cubanski, J. Koma, W. Neuman, T. (2019). The Out-of-Pocket Cost Burden for Specialty Drugs in Medicare Part D in 2019. *Kaiser Family Foundation*. Accessed at <https://www.kff.org/medicare/issue-brief/the-out-of-pocket-cost-burden-for-specialty-drugs-in-medicare-part-d-in-2019/>

friends, and neighbors, and they understand that one positive medical test result is all that stands between them and the extraordinary financial burden of the current Part D benefit design. With this perspective in mind, these enrollees will benefit from having the reassurance that their Part D coverage will provide meaningful protection against financial ruin in the case of an unforeseen diagnosis.

Given the need for an out-of-pocket maximum demonstrated above, LLS strongly supports the provision in your draft legislation to establish this crucial patient protection for Medicare Part D enrollees, as this policy will improve the lives of countless patients with blood cancer. As noted above, patients diagnosed with blood cancer often rely on Part D to access the most appropriate treatment for their cancer. In fact, 42 percent of prescription therapies approved by the Food and Drug Administration (FDA) with blood cancer indications since 2000 are self-administered treatments and are therefore accessed through the Part D benefit. In many cases, these prescription therapies represent the current standard of care, and the maximum out-of-pocket established in the bill will promote access to these potentially life-saving treatments for patients with cancer.

LLS endorses your decision in the draft legislation to set the maximum out-of-pocket at the entry point to the catastrophic phase, while maintaining the current benefit's treatment of drug manufacturer discount program payments. LLS urges you to continue to maintain this accounting of total out-of-pocket costs (or "TrOOP"). If you consider changes to TrOOP accounting—particularly changes that would exclude manufacturer discounts from the calculation or by shifting manufacturer contributions from the coverage gap phase to another phase—it is essential that Congress hold beneficiaries harmless and not force patients to pay even more out-of-pocket to reach an annual cap than under the current calculation.

Solving the "first script" access crisis

Although an annual limit on enrollee cost-sharing is clearly a valuable protection for many beneficiaries, LLS urges you to consider how to incorporate a limit on the cost-sharing required for a given month or for a single prescription. Due to the progression of the Part D benefit design, many enrollees will not experience the benefit of an annual out-of-pocket cap without first providing thousands of dollars out-of-pocket—often for a single prescription following a new diagnosis or in January of a new plan year. The evidence clearly demonstrates that this outsized "first-script" payment is the most significant financial barrier for patients trying to afford their cancer treatment in Part D. Enrollees seeking to fill a cancer medication are *five times* more likely to abandon their therapy when facing cost-sharing over \$2,000.⁸

An annual maximum that does not address the extraordinary cost of filling the first prescription will not fix the crisis of low- and middle-income enrollees being unable to access their cancer treatments. As we noted above, this is a crisis that keeps nearly half of cancer patients prescribed self-administered therapies from accessing their treatment, and LLS believes that Congress must stand up for these patients and fix this problem.

We urge you to incorporate into your legislation a mechanism that limits the out-of-pocket costs required of enrollees to fill their first prescription. There have been proposals to enact a per-prescription cap, a "smoothed" annual cap with monthly or quarterly limits, and a strict monthly cap. Several states—including California, Colorado, Delaware, Louisiana, Maine, Maryland, Montana, and Vermont—require that state-regulated commercial plans incorporate formulary designs with coinsurance that is capped at a reasonable level.⁹ Given the experience that Part D plan sponsors have in managing these caps in the commercial

⁸ Doshi, J; Li, P; Huo, H; Pettit, A.R.; Armstrong, K. (2018). Association of Patient Out-of-Pocket Costs With Prescription Abandonment and Delay in Fills of Novel Oral Anticancer Agents. *Journal of Clinical Oncology* 36, no. 5.

⁹ Pyenson, B.; Dieguez, G.; Simon, K.; Bochner, A. (2018). Small Changes or Big Ones? The Case of Limits on Prescription Drug Copayments in California. *Managed Care Magazine*. Accessed at <https://www.managedcaremag.com/archives/2018/7/small-changes-or-big-ones-case-limits-prescription-drug-copayments-california>

market, plans should already have the tools at their disposal to replicate a similar patient protection for Part D enrollees. In fact, an executive from one of the largest pharmacy benefit managers in the United States market has offered a cap on Part D copays as a solution that PBMs, drug makers, and beneficiaries could support.¹⁰ Given the enormous benefit of a per-prescription/monthly out-of-pocket cap to Part D enrollees with cancer and other serious medical conditions, LLS urges you to work with stakeholders to incorporate this policy into your legislation.

Restructuring liability in the catastrophic phase

The current Medicare Part D catastrophic benefit design provides insufficient incentives for plans to negotiate for lower patient and government spending on certain drugs. In fact, the current Part D benefit and subsidy structure financially rewards Part D plans that have higher utilization of prescription drugs with a high list price, as long as the drug manufacturer also provides the plan with a high rebate. A 2016 study conducted by the actuarial firm Milliman put this dynamic in stark relief.¹¹ As you can see in the report's table below (emphasis added), a Part D plan can game the system to *make* money by covering a drug with a high list-price combined with a high rebate: Although the plan's choice would increase costs to the patient by \$2,500 and taxpayers by over \$20,000, the plan itself would save more than \$22,600 in comparison to the cost to the plan of covering a drug with the exact same net price but no rebate.

Item	Cost Type	Formula	\$50,000 No Rebate	\$100,000 With Rebate	Difference
A	Medication Cost	N/A	50,000	100,000	50,000
B	Beneficiary Cost-Sharing	N/A	4,886	7,386	2,500
C	CGDP	N/A	1,817	1,817	0
D	Reinsurance Before Rebates	N/A	34,445	74,445	40,000
E	Net Plan Liability Before Rebates	A – B – C – D	8,852	16,352	7,500
F	Total Rebates	N/A	0	50,000	50,000
G	Rebates for Federal Reinsurance	F * (D / A) ¹	0	19,879	19,879
H	Rebates for Plan Sponsor	F – G	0	30,121	30,121
I	Net Plan Sponsor Liability	E – H	8,852	-13,769	-22,621
Total Paid by Payer²					
	Pharma	C + F – A	-48,183	-48,183	0
	Beneficiary	B	4,886	7,386	2,500
	Federal Reinsurance	D – G	34,445	54,566	20,393
	Plan Sponsor	I	8,852	-13,769	-22,621

¹ Uses the ratio of federal reinsurance to medication cost for the overall plan from Table 2 with an adjustment for the impact of the brand medication on the overall plan's ratio. This reflects the rebates for federal reinsurance for the brand medication net of the impact of the brand medication on retained rebates for all other drugs covered by the plan.

² Total Paid by Payer represents revenue for Pharma, and costs for the other payers.

This structure creates a significant incentive for Part D plans to maximize rebates, even if the list prices of the rebated drugs increase substantially. Although Part D plans and drug manufacturers can benefit from

¹⁰ *Inside Health Policy*. (2018). Express Scripts Tries Beating Back Pharma Campaign Against PBMs. Accessed at: <https://insidehealthpolicy.com/inside-drug-pricing-daily-news/express-scripts-tries-beating-back-pharma-campaign-against-pbms>

¹¹ Milliman. (2016). The AIDS Institute, Financial Incentives in Medicare Part D. Accessed at www.theaidsinstitute.org/sites/default/files/attachments/Milliman%20Report%20-%20Final.pdf

this structure, patients and taxpayers end up paying more.¹² As demonstrated in the Milliman study's table above, the current Part D structure's rewards for high list prices lead patients to pay even more out-of-pocket, since specialty drug cost-sharing is typically based on a percentage of the drug's list price. At the same time, these incentives have ballooned taxpayer subsidies provided under the Part D program's reinsurance phase,¹³ from \$8 billion per year in 2007 to \$37.4 billion in 2018. Moreover, these incentives have encouraged the use of anti-competitive rebating practices that inhibit beneficial formulary placement for lower cost generic and biosimilar products.¹⁴

These perverse incentives are unsustainable, and it is past time to enact reforms that promote contracting practices that effectively constrain costs for patients and the government. To this end, LLS continues to call upon Congress to restructure the catastrophic benefit phase of the program by increasing the proportion of catastrophic spending for which payers are liable, and we commend you for including this important reform in your draft legislation.

As you have noted, similar proposals have been included in the President's Fiscal Year 2019 and 2020 budget proposals¹⁵ and the June 2016 MedPAC Report to Congress,¹⁶ while the Center for Medicare & Medicaid Innovation (CMMI) has highlighted this liability shift as an opportunity for program savings in its discussions surrounding the initiation of a related demonstration project.¹⁷ We believe that a catastrophic liability restructuring along the lines of what you have proposed in this draft legislation has the potential to promote lower out-of-pocket costs for patients and constraining government spending by better aligning plan incentives with those of beneficiaries and taxpayers.

Navigating impact on Part D premiums

Your draft legislation's provisions to establish an out-of-pocket maximum to protect Part D enrollees and restructure the catastrophic phase's incentives represent important and valuable improvements to Part D for current and future enrollees. Of course, it is important for Congress to ensure that any such improvements are implemented in a way that limits any negative impact on Part D premiums, and we encourage Congress to consider various approaches to mitigating any increases associated with new patient protections or shifts in plan liability.

With respect to an out-of-pocket cap, analysts project that an annual cap at the threshold outlined in your draft legislation could cost as little as 40 cents per member per month.¹⁸ Given the affordable premiums currently available among Part D plan options, LLS believes enrollees will be able to absorb a relatively small premium increase in order to receive the concrete protection of an out-of-pocket maximum.

¹² Dusetzina SB, Conti RM, Yu NL, Bach PB.(2017) Association of Prescription Drug Price Rebates in Medicare Part D With Patient Out-of-Pocket and Federal Spending. *JAMA Intern Med.* 2017;177(8):1185–1188.

doi:10.1001/jamainternmed.1885

¹³ Hayes, T. (2018). Redesigning Medicare Part D to Realign Incentives. American Action Forum. Accessed at: <https://www.americanactionforum.org/research/redesigning-medicare-part-d-realign-incentives-1/>

¹⁴ Narasimham, Vas. (2018) *Forbes*. "Novartis CEO: How To Create Cheaper Alternatives To The Most Expensive Drugs."

¹⁵ HHS. (2018). Putting America's Health First, FY 2019 President's Budget for HHS.

¹⁶ MedPAC (2016) Chapter 6: Improving Medicare Part D. *Report to Congress: Medicare and the Healthcare Delivery System*.

¹⁷ CMS. (2019) Part D Payment Modernization Model Fact Sheet. Accessed at <https://www.cms.gov/newsroom/fact-sheets/part-d-payment-modernization-model-fact-sheet>

¹⁸ Dusetzina SB, Huskamp HA, Keating NL. (2019). Research Letter: Specialty Drug Pricing and Out-of-Pocket Spending on Orally Administered Anticancer Drugs in Medicare Part D, 2010 to 2019. *JAMA* 2019;321(20):2025-2027



To the extent that Congress needs to incorporate other policy components in order to both mitigate any impact on premiums and constrain the government spending associated with these benefit changes, LLS urges you to consider the following options:

1. Drug manufacturer contributions – Drug manufacturer discount payments in the coverage gap represent an important component of Part D financing today, and your proposals to improve the program merit additional manufacturer contributions. We anticipate that the program improvements outlined in your draft legislation would expand access to prescription therapies, and we encourage drug manufacturers to come to the table with thoughtful mechanisms for increased manufacturer contributions that help facilitate this expanded patient access. For example, additional manufacturer contributions in the catastrophic phase could be designed both to help offset anticipated plan and programs costs and also provide a new incentive against increases in drug list prices.
2. Transition period for shifts in plan liability – Your draft legislation's catastrophic liability reform provision envisions a gradual increase in plan liability over four years. It is possible that plans would respond to a longer implementation period in a fashion that is less likely to increase plan premiums, and we encourage you to consider the relative value of a longer implementation period versus better aligned program incentives. Importantly, LLS urges you to reject efforts to delay the implementation of an out-of-pocket maximum. Part D enrollees have waited for far too long for this reform, and it is crucial to provide this benefit as soon as possible.
3. Focusing relief on non-LIS beneficiaries – The over one million beneficiaries without LIS financial assistance are most acutely affected by the lack of a limit on out-of-pocket exposure in Medicare Part D. Congress could consider the trade-offs in terms of patient access to treatment for approaches that apply the out-of-pocket maximum to all beneficiaries or to only non-LIS beneficiaries.

These are only a small selection of options that could be considered in your efforts to ensure premium stability for all Part D enrollees. It is clear that there are ample policy tools that hold beneficiaries harmless while addressing potential premium impacts of the policies included in your draft legislation, and Congress must not allow the essential reforms you have proposed to stall due to addressable concerns.

Conclusion

On behalf of the 1.3 million Americans living with a blood cancer diagnosis, we are proud to support the policies you have proposed in this draft legislation. We are thankful for your work in demonstrating the bipartisan support for an out-of-pocket cap for Part D beneficiaries. We know that not easy to work across the aisle, and we greatly appreciate your leadership in elevating this critical issue above partisan politics in order to take a big step forward for Medicare beneficiaries across the country. Your achievements on this issue will make a lasting impact for patients affected by blood cancers and many other chronic and life-threatening conditions.

If you have any questions about our comments or other areas in which we can provide the patient perspective, please contact Brian Connell, LLS Executive Director of Federal Affairs, at brian.connell@lls.org. We look forward to working with you on this and other issues in order to make a positive difference for the patients, survivors, and caregivers we represent.

Sincerely,

A handwritten signature in black ink that reads "Bernadette O'Donoghue".

Bernadette O'Donoghue
Vice President
Office of Public Policy



Office of Public Policy
10 G Street NE
Suite 400
Washington, DC 20002
main 202.969.1800
www.LLS.org

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