June 5, 2019
United States House of Representatives
Ways and Means and Energy and Commerce Committees
Washington, DC 20510-6400

RE: Solicitation for Feedback on Draft Medicare Part D Legislation

Dear Chairmen Neal and Pallone, and Ranking Members Brady, and Walden:

Thank you for the opportunity to respond to your draft Medicare Part D legislation released on May 23, 2019. I am an Associate Professor of Health Policy at Vanderbilt University School of Medicine and an expert on prescription drug prices and policies, including Medicare Part D. My research informs many of your questions related to reducing reinsurance subsidies and eliminating beneficiary out-of-pocket costs above the Medicare Part D catastrophic threshold. The following comments are my own and not on behalf of Vanderbilt University. Specifically, I would like to contribute evidence related to the limitations of the current Part D benefit for beneficiaries, the problems caused by the current branded manufacturer discount paid in the coverage gap, and affordability concerns for beneficiaries enrolled in the Extra Help program. I also provide suggestions for ways to address these problems.

I have responded to the questions below and would be happy to engage with your committees in the future on these topics. Several of the findings mentioned below are from papers that are under review or forthcoming. I have included links to published work and I would be happy to share papers that are under review if requested.

***Committee Question: How is the Part D program addressing the problem of high cost drugs? How could it do better?***

For Medicare beneficiaries receiving Part D, the two-thirds of beneficiaries that do not receive full low-income subsidies can face substantial out-of-pocket costs for prescriptions, particularly when using expensive specialty drugs or multiple higher-cost brand-name drugs.[1-7] Today, beneficiaries using specialty drugs have higher out-of-pocket spending in the catastrophic phase of Part D than in the other benefit phases combined.[1,5,6] This is due to the high list prices of many of these products, where patients may reach catastrophic spending on their first medication fill.

One of the original goals of allowing private plans to manage the Part D benefit was to provide beneficiaries with plan choices that met their specific needs. Unfortunately, plans uniformly provide poor coverage for high-priced / specialty tiered drugs.[2] This is not a problem Beneficiaries can solve themselves by shopping for health plans.

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For context, my colleagues and I recently published a paper[1] demonstrating that price increases for anticancer drugs on Part D have eliminated expected savings from closing the Part D coverage gap for beneficiaries who use these medications. Today a beneficiary needing an orally-administered anticancer drug would pay, on average, approximately $10,000 out-of-pocket annually for these drugs. This is $1,700 more than they would have paid for the same drugs in 2010, before the coverage gap closed. The same is likely true for beneficiaries needing other high cost drugs for complex diseases.

We also observed that the prices for anticancer drugs available in both 2010 and 2018 increased by 8% per year on average above inflation (mean prices per fill were $7,438 in 2010 and $12,883 in 2018). Such trends in both prices at initial market entry[1,8] and over time are concerning. Therefore, modifications to the Part D benefit should include both patient and Medicare program spending in mind, as is the case in the Committees' draft bill.

Another concern that is less readily apparent is related to out-of-pocket costs beneficiaries pay when prescribed generic options for high priced specialty products. In a forthcoming paper in Health Affairs (Dusetzina et al, July 2019) we find that Part D beneficiaries who elect to take a generic specialty drug (or who take multiple lower priced drugs) may find themselves paying more out-of-pocket for generic drugs than their branded counterparts. This occurs for beneficiaries with high drug spending due to the current coverage gap discount program for branded drugs. This program currently requires drug manufacturers to offer a 70% discount off the branded drug price for products filled in the coverage gap, while there is no corresponding discount program for generic drugs. Branded drug discounts are then counted as beneficiary out-of-pocket spending, helping beneficiaries reach the catastrophic phase of coverage faster than they would using generic products. For example, in 2019 branded drug users who enter the coverage gap would reach catastrophic coverage after spending $982 out-of-pocket versus $3,730 for generic drug users (who receive no such discount) (From: Dusetzina et al. Forthcoming, Health Affairs). This problem will be exacerbated due to the "Part D cliff" where out-of-pocket spending limits to reach the catastrophic coverage phase are expected to increase from $5,100 to $6,350 in 2020. The Chairmen already proposed a bill related to this issue in July 2018 (the "Lower Out-of-Pocket Costs for Seniors Act").

The Committee should consider modifying the Part D benefit to remove incentives for plans to use branded drugs when generics are available. Importantly, this should be done while trying to limit the burden on beneficiaries. Recent proposals (the President's Blueprint / proposed budgets and from MedPAC) suggest removing branded manufacturer discounts from the calculation of patient true out-of-pocket spending for the purposes of determining entrance to the catastrophic region of the benefit. This is in addition to adding an out-of-pocket cap on the benefit. Under these proposals, patients using branded drugs in the coverage gap would have to spend more out-of-pocket to reach the catastrophic spending limit than they do today, although some of the highest spenders would still benefit from this proposals' out-of-pocket spending cap.

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However, even with a cap, beneficiaries will face very high costs to initiate their treatments (paying thousands of dollars for their first fill). If the opportunity arises, it may be preferable to consider ways to combine an annual out-of-pocket maximum with a monthly out-of-pocket maximum (e.g., $3,000 per year and no more than $250 per month). This could serve two purposes: help to avoid prescription drug abandonment at the pharmacy for first fills and ensuring that patients do not overuse medications after the out-of-pocket maximum is reached (and the out-of-pocket price is $0). This type of limit could also make treatment costs more predictable for beneficiaries month-to-month.

An annual out-of-pocket maximum could reduce beneficiary incentives to control drug expenditures each month (particularly if out-of-pocket prices were $0 after the cap is reached) and would not discourage manufacturers from increasing drug prices under the current system. In addition, an annual cap may increase premiums to the extent that plans take on greater financial responsibility. Prior surveys have shown that beneficiaries are willing to accept tradeoffs of small premium increases in order to have greater protection for anticancer treatments and other high priced drugs.

To my knowledge, the impact of a monthly cap in addition to an annual out-of-pocket cap on out-of-pocket spending on Part D has not been estimated. Our team is beginning work on this topic to quantify these impacts.

***Question: Should Congress consider changing or eliminating the distinction between the initial coverage phase and the coverage gap discount program?***

Yes. Under the 2019/2020 benefit the standard benefit design will require patients to pay 25% coinsurance for both the initial phase and in the former "coverage gap" for both branded and generic drugs. The transition between phases is no longer disruptive to beneficiaries due to the similar cost sharing between phases. However, the coverage gap discount program shifts responsibility on drug spending to manufacturers during the coverage gap phase (for branded drugs and biosimilars only). This creates incentives for beneficiaries to use branded drugs instead of generic drugs in the coverage gap. I believe that the coverage gap discount rules should be revised (suggestions below) to address these incentives.

***Question: What share of costs should be attributed to the beneficiary, Part D plans, and manufacturers under the current system and how should this share change if the liability were shifted for the manufacturer from the current coverage gap discount program to the catastrophic phase of the Part D benefit?***

The American Action Forum has an intriguing analysis of a benefit redesign that the Committee should consider. https://www.americanactionforum.org/research/redesigning-medicare-part-d-realign-incentives-1/

The American Action Forum proposed model tests several different beneficiary out-of-pocket maximums that are lower than those under the MedPAC redesign. It also removes the

coverage gap discount paid by manufacturers of branded drugs and require a smaller, but uncapped, discount from manufacturers in the catastrophic phase of the benefit. To my knowledge, this proposal has not been evaluated by organizations such as MedPAC or the CBO but the goals of this approach in terms of asking manufacturers and plans to take on more responsibility in the catastrophic phase of the benefit is intriguing. Given the prior concerns mentioned related to incentives for patients to use branded drugs over generics in the current benefit design, a redesign is needed.

***Question: What improvements should the Committees consider with respect to low-to-moderate income Part D beneficiaries and out-of-pocket costs below the catastrophic level?***

Medicare beneficiaries without full low-income subsidies face significant out-of-pocket spending for their medications on Part D (see Table), particularly for specialty drugs. For individuals without subsidies, specialty drugs typically require 25% coinsurance for fills until they reach the catastrophic spending limit. This can result in paying thousands of dollars for the first medication fill.

**Medicare Part D Benefit Design in 2019 by Subsidy Eligibility Status**

| Part D subsidy | Qualifying income (% FPL) | Cost-sharing prior to catastrophic threshold | Annual OOP spending prior to catastrophic threshold | Cost-sharing after catastrophic threshold |
|---|---|---|---|---|
| Full Subsidy | ≤134 | $8.50 copay/fill (brand-name) | N/A | N/A |
| Partial Subsidy | 135-149 | 15% coinsurance[a] | $5,100 | $8.50 copay/fill (brand-name) |
| Unsubsidized | ≥150 | 25% coinsurance[b,c] | $5,100 | 5% coinsurance |

**a:** after $85 annual deductible. **b:** after $415 annual deductible. **c:** prior to 2019, beneficiaries had >25% coinsurance while in the "coverage gap" between $3,820 and $5,100 out-of-pocket. FPL, federal poverty level; OOP, out-of-pocket.

Individuals with partial subsidies (also called "Extra Help" under Part D) are also required to pay a percentage of the drug's list price when filling prescriptions prior to the catastrophic phase of the benefit. While their percentage-based coinsurance is lower than the unsubsidized group (15% versus 25%), they have low incomes and fewer assets and may not be able to afford the out-of-pocket spending required for their drugs. For example, across the 54 orally-administered anticancer drugs now offered on Part D, the average list price for a month of treatment is approximately $14,000. This would result in thousands of dollars in out-of-pocket spending for partially-subsidized and unsubsidized individuals with their first fill alone.

In a project led by my former PhD trainee (currently undergoing peer review), we found that Medicare beneficiaries with lung cancer who had partial subsidy were less likely to start an orally-administered anticancer drug offered on Part D than those with either full subsidies or no subsidies. Only 7.4% of those with partial subsidies started a Part D drug versus 11.4% with full subsidies and 9.9% without subsidies. In contrast, uptake of Part B covered drugs among these same groups showed those with partial subsidies had higher use of Part B drugs than full subsidies (40.6% versus 35.0%) but lower use than those with no subsidies (51.6%). Since many

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patients have supplemental insurance to cover out-of-pocket spending on Part B, we believe differences could be attributed to affordability of Part D treatments for those without full subsidies.

Senator Bob Casey introduced a bill in March 2019, S.691 (the Medicare Extra Rx HELP Act of 2019) to address this topic. Specifically, the bill expands the eligibility criteria for subsidies under the Extra Help program. The Committees should consider expanding eligibility and improving the benefit by requiring plans to use a more predictable and lower copayment (flat fee) instead of a percentage-based cost sharing arrangement. This would likely provide substantially improved access for those in the Extra Help program today.

Thank you to the Committees for considering an out-of-pocket cap on Part D and ways to redesign the program to better meet the needs of individuals using high-priced drugs. This is an important step towards improving access to specialty drugs for all beneficiaries of the program.

I appreciate the opportunity to respond to this draft House bill. I would be happy to engage with the Committees on this and other solutions aimed at reducing Medicare Part D reinsurance subsidies and eliminating beneficiary out-of-pocket costs above the Part D catastrophic threshold.

Sincerely,

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**Citations:**

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