COUNCIL FOR AFFORDABLE
HEALTH COVERAGE

440 1st St. NW, Suite 430 Washington, DC 20001
o: 202.808.8850 w: CAHC.NET

June 6, 2019

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

Congressman Frank Pallone, Jr.
Chairman, Energy & Commerce Committee
2125 Rayburn House Office Building
Washington, DC 20515

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

Congressman Greg Walden
Ranking Member, Energy & Commerce Committee
2322 Rayburn House Office Building
Washington, DC 20515

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 share our thoughts on the bipartisan draft legislation to create a beneficiary out-of-pocket maximum for prescription drug spending in the Part D program. The Council for Affordable Health Coverage (CAHC) is a broad-based alliance with a single focus: bringing down the cost of health care for all Americans. Our membership represents a broad range of interests—organizations representing small and large employers, manufacturers, retailers, insurers, patient groups, and physician organizations. As a result, these comments reflect the positions of CAHC, but may not necessarily reflect the individual views of all members.

CAHC supports your efforts to cap beneficiary out-of-pocket spending on prescription drugs in the Medicare Part D program. We suggest the Committees implement a policy that is at least budget neutral and also does not raise premiums for plan enrollees.

Background

Under current law, beneficiaries are responsible for five (5) percent of spending above the Catastrophic Threshold ($5,100 in 2019), while plans are responsible for 15 percent and taxpayers pay 80 percent.

Congress created this shared liability structure to ensure that: 1) plans would participate in Part D by limiting their risk above a threshold; and 2) beneficiaries would retain “skin in the game” above the threshold. While these policies made sense in 2003, we now have the benefit of 13 years of Part D experience: 1) 901 plans currently participate in Part D; and 2) the five percent cost sharing is resulting in disease progression by causing many to forgo treatment due to cost. The rationale for the five percent contribution no longer makes sense as it has a disproportionate impact on the sickest beneficiaries who need expensive but extraordinarily valuable drug

therapies. Furthermore, the current Part D structure does not align with private sector coverage, where 99 percent have an out-of-pocket maximum.[1]

Medicare's spending above the catastrophic became the largest and fastest growing component of program spending in 2014, rising at an average annual rate of nearly 18 percent between 2007 and 2016.[2] High cost enrollees make up more than 57 percent of Part D program costs.

Comments on the Committee Draft Legislation

The bipartisan draft legislation creates an out-of-pocket maximum limit on prescription drug spending for Part D beneficiaries at the current catastrophic threshold, after which beneficiaries would have zero cost sharing. The draft language also reduces the current taxpayer reinsurance payment from today's 80 percent to 20 percent, phasing down over 4 years. The bill would also increase plan liability from 15 percent to 80 percent in the catastrophic phase.

While CAHC is supportive of an out-of-pocket cap, we are concerned that merely dialing down taxpayer liability and dialing up insurer liability will have a significant effect on Part D premiums. To avoid raising premiums, we suggest additional reforms to lower costs that can then be transmitted into direct subsidies to hold Medicare beneficiaries harmless.

Additional Part D Reforms

Lower the Catastrophic Threshold

The catastrophic threshold is currently defined in terms of the "true out-of-pocket" (TrOOP) costs that enrollees face. But the discount payments that drug manufacturers make for non-LIS enrollees for drugs purchased in the doughnut hole count towards that total. The catastrophic threshold is projected to be $6,350 in TrOOP costs in 2020. Factoring out the average amount of discount payments received in the coverage gap, an enrollee would incur about $2,750 in their own out-of-pocket costs, on average, to reach that threshold. The OOP cap could be set at $2,750 in 2020 and would no longer take into account coverage gap discounts—thus providing a better indication of what enrollees would actually be expected to pay to reach the catastrophic threshold. Congress might also raise the initial coverage limit to approach or meet the catastrophic limit, thus reducing price distortions within the coverage gap that tend to increase costs.

Congress could lower the OOP threshold and increase the initial coverage limit to eliminate incentives within the coverage gap portion of the benefit for manufacturers to increase costs (due to significant rebate liability) and for plans to lightly manage benefits (due to minimal plan liability) in that phase.

Allow beneficiaries to pay their Part D cost sharing over time.

[1] Add KFF cite

[2] MedPAC March 2018 Report to the Congress. Chapter 14: The Medicare prescription drug program (Part D) Status Report. http://www.medpac.gov/docs/default-source/reports/mar18_medpac_ch14_sec.pdf

Some beneficiaries who do not qualify for low income assistance still face difficulties meeting their deductible and cost-sharing obligations from month to month. Deductible amounts reset every year, creating an affordability challenge every January for some beneficiaries. Combined with co-payments and co-insurance, these financial obligations create access barriers for some beneficiaries.

Congress should allow lower income beneficiaries to access plans that cap monthly cost sharing without impacting their premiums or plans' bids. Beneficiaries with incomes between the LIS threshold and 250 percent of poverty could apply for added help.

Incentives to Lower Costs

As liability is shifted to plans above the catastrophic, plans should be granted additional tools to manage costs above the threshold. In many cases, expenditures for high-cost enrollees may not be suitable for further management, as they reflect a need for expensive but crucial medications that do not have close substitutes, including many specialty medications. For example, placing a very high cost drug on the specialty tier will be unlikely to change clinical demand for the product. In these cases, we suggest the Committee include policies that allow plans and manufacturers to enter pay-for-value arrangements that allow coordination around process, clinical, quality, and efficiency targets while allowing price discounts without triggering additional rebate liability. This would allow lower prices and costs across a mix of products that prove ineffective at improving outcomes.

We estimate that encouraging VBAs to address high cost drugs would substantially increase the share of drugs under these arrangements over the next ten years. On balance, additional VBAs would foster greater access to and utilization of prescription drugs but at lower costs per dose or treatment. Thus, the overall health system costs for prescriptions under VBAs would be mostly unaffected, as higher utilization would be offset by lower consumer prices. However, the broader and better targeted use of drugs under VBAs would lead to savings in other "downstream" health costs—particularly hospital and physician costs—due to improved outcomes for patients. We estimate that there would be overall annual health system savings of almost $40 billion dollars, which would be coupled with significant gains in access to treatments. If these proposals prove to be transformative savings and access could increase.

We estimate that VBAs will account for an additional 12 percent of private health insurance prescription drug spending in 2020, growing to more than 20 percent by 2025. As such Congress would have to enact a range of reforms designed to allow plans to better manage prices of the high cost products that will tend to cause more beneficiaries to reach the catastrophic threshold.[3] These changes include:

- **Establishing clear exceptions to Medicaid best price and Average Manufacturer Price reporting.** Manufacturers and payers are reluctant to enter into value-based arrangements, in

[3] Council for Affordable Health Coverage, "Prescriptions for Competition, Value and Innovation", May 2017. Accessed at https://static1.squarespace.com/static/58bf2243d482e99321a69178/t/59136add1e5b6cf9cea0713e/1494444780319/CAHC+Prescriptions+for+CVI+v7.3.pdf

part, because of the challenge of squaring such innovative approaches with the inflexible complexities of rebate liabilities under Medicaid's "best price" reporting requirements. As manufacturers lower prices, they must pay more to state Medicaid programs, creating a powerful disincentive to discount. Since the law was enacted in 1990, discounts have decreased significantly. Additionally, other drug reporting programs hinge reimbursement on sales prices, which compounds the chilling effect on value-based systems by setting artificial pricing floors. The result is that many innovative, lower cost arrangements simply are not pursued.

Congress should provide clear exceptions to Medicaid best price and Average Manufacturer Price reporting for value-based arrangements, coupled with clear guidance to reduce current ambiguity about how to capture value-based pricing for reporting purposes.

- **Reforming Anti-Kickback and Stark restrictions.** Value based arrangements are growing in prominence in the commercial markets. They rely on coordination between payers, providers, drug makers, and patients. The Anti-Kickback Statute (AKS) and Stark laws prevent such collaboration around value in federal programs in drug pricing and outcomes. These laws are intended to prevent fraudulent and abusive practices by prohibiting arrangements where organizations, individuals, and physicians could receive inappropriate payments for referring a product or service that would be paid for by federal health programs. Although the laws have historically been effective in capturing true misconduct, their broad and relatively inflexible approach has also had the unintended effect of hampering the adoption of innovative arrangements and patient engagement efforts that can truly benefit consumers and the health care system. Congress created exceptions that allow physicians and hospitals to collaborate in Medicare as part of Accountable Care Organizations. Congress should also allow payers, drug manufacturers, providers, and patients to collaborate on value-based payment efforts in federal programs.

  Value-based and care coordination arrangements should have a clear safe harbor from AKS and Stark to allow payers, providers, drug makers, and patients to enter into these arrangements.

- **Improving and Encouraging Data Infrastructure, Sharing, and Availability.** Value-based arrangements rely on information about consumers' health and treatment efficacy so that value can be evaluated appropriately, and the arrangement can be implemented effectively. This includes clinical and claims data, and, increasingly, real-world evidence from surveys, registry information, and other sources. Without quality, accurate information at the individual and population levels, such arrangements are less effective. Incentives to use health information technology, share data appropriately and securely, and protect privacy are all critical elements of a successful value-based arrangements. Unfortunately, most clinical data is inconsistently reported and frequently locked away in silos. Standards that encourage and improve data and its exchange across providers and systems are needed to promote value-based arrangements and precision medicine. Incentives to include all providers and other relevant entities in information-sharing arrangements are necessary to ensure success.

- **Proposal: Laws, programs, and operating standards should be updated to improve data and foster its use in value-based arrangements.**

    - **Congress should establish a safe harbor to allow manufacturers and payers to share or donate technology (both hardware and software) that is necessary to monitor, track patient progress, and automatically report outcomes to facilitate payments in value-based arrangements.**

    - **Congress and HHS do not need to build value-based programs from whole cloth. Examples of successful programs abound in commercial markets. Congress should direct the Government Accountability Office (GAO) to conduct a study documenting measures of patient outcomes, identifying gaps in measures, and reporting on examples of existing commercial programs' successes. GAO should evaluate these programs and report to Congress within 12 months on what makes them successful.**

Conclusion

While there are many ways to structure an out of pocket cap in Part D, we encourage Congress not to get hung up on one approach versus another. We encourage you to follow several principles in crafting an out of pocket limit, including ensuring the reform is at least budget neutral and that is has no impact on beneficiary premiums.

CAHC believes the policies presented here will dramatically improve the operations and finances of the Part D benefit while adding significant value for consumers. As a group of united and diverse stakeholders, we stand ready and willing to serve policy makers in their search for solutions to the complex challenges facing our health system today.

Sincerely,

Joel C. White
President