June 6, 2019

Submitted electronically via email to ***PartDImprovements@mail.house.gov***

The Honorable Richard Neal
Chairman
Ways and Means Committee
U.S. House of Representatives
1102 Longworth House Office Building
Washington, DC 20515

The Honorable Kevin Brady
Ranking Member
Ways and Means Committee
U.S. House of Representatives
1102 Longworth House Office Building
Washington, DC 20515

The Honorable Frank Pallone, Jr.
Chairman
Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Greg Walden
Ranking Member
Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

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

PCMA appreciates the opportunity to comment on draft legislation to reform and update Medicare Part D. After more than a decade of experience with the Part D program and more than 15 years after its enactment, Congress rightly should consider whether or not the program requires updates in order to enhance its quality and affordability.

PCMA is the trade association for the nation's pharmacy benefit managers or PBMs, which are largely responsible for administering the Medicare Part D program. PBMs negotiate price concessions from manufacturers and pharmacies on behalf of stand-alone Part D, MAPD, and employer group waiver plans and the 44.9 million beneficiaries they serve. As you may know, PBMs recommend formularies to Part D plans and are responsible for the real-time claims adjudication that occurs when prescription drugs are dispensed.

The Part D bidding model—unprecedented and untried until enacted in the Medicare Modernization Act of 2003—has been an overwhelming success since its 2006 implementation. Part D has performed better than initially forecast by the Congressional Budget Office (CBO), with stable premiums and satisfied beneficiaries. According to MedPAC, "More than 8 in 10 Part D enrollees report they are satisfied with the program."[1] Indeed, a March 2019 PCMA poll found that 83 percent of elderly

[1] "Report to the Congress: Medicare Payment Policy," Medicare Payment Advisory Commission (MedPAC), http://medpac.gov/docs/default-source/reports/mar19_medpac_entirereport_sec.pdf?sfvrsn=0, March 2019.

Pharmaceutical Care Management Association
325 7th Street, NW, 9th Floor
Washington, DC 20004
www.pcmanet.org

beneficiaries are satisfied with their Part D plan, 92 percent found it convenient to use, and 90 percent were satisfied with the number of pharmacies included.[2] In recent years, the Medicare Trustees Report has attributed the slow growth in Part D program costs to the success of PBMs in negotiating rebates to lower drug costs.[3]

Part D plans, working with PBMs, have structured their benefits and cost sharing so that Medicare beneficiaries have an incentive to take generic medications and preferred brand drugs that are the most cost-effective for beneficiaries and for the Part D program overall. In addition, responding to beneficiary demand for lower-premium plans, PBMs and Part D plans have worked to keep premiums low, including in part by innovating preferred pharmacy networks that reward efficient pharmacies that perform well on quality metrics.

The recent unprecedented and unforeseen rise in manufacturer launch prices and semi-annual price increases year-over-year of brand drugs, however, has resulted in a Part D benefit that is stretched and is leaving beneficiaries who need high-cost drugs with increasingly high cost sharing. Indeed, our recent poll found lower satisfaction with out-of-pocket costs in Part D.[4] Any changes to the program should reinforce Part D's success in delivering the prescription drugs its enrollees need, with the economy taxpayers demand.

The key question for the Committees now is how best to structure Medicare Part D to minimize manufacturer incentives to price ever higher and to maximize insurers' and PBMs' incentives—and tools—to negotiate aggressively on behalf of beneficiaries and taxpayers in order to achieve the lowest net drug cost possible.

PCMA will assess support for bills to revise Medicare Part D based on whether they meet the following principles:

- Provide relief to beneficiaries with very high cost sharing, while keeping premiums affordable for all.
- Place more responsibility on manufacturers for high costs in the catastrophic phase of the benefit where a growing share of federal program costs are.
- Retain the market-based bidding structure that has delivered high enrollee satisfaction and spending far below initial estimates, since the program began in 2006.

[2] "National Survey of Seniors Regarding the Medicare Part D Prescription Drug Benefit, March 6-11, 2019." North Star Opinion Research, commissioned by PCMA, March 2019.
[3] "2019 Annual report of the boards of trustees of the federal hospital insurance and federal supplementary medical insurance trust funds," Office of the Actuary (OACT) Centers for Medicare and Medicaid Services (CMS), April 22, 2019. pp. 32, 99.
[4] "National Survey of Seniors," North Star Opinion Research.

- Allow plans greater leverage to manage the benefit, while retaining beneficiary access to needed drugs.
- Encourage continued innovation, improvement, and transparency in service delivery in, and administration of, the Part D benefit.

In general, the bipartisan Committees' draft bill retains Part D's bidding structure and relieves those with very high cost sharing by implementing a maximum out-of-pocket cap. We understand that given the increase in the number, users, and prices of very high-cost drugs, the government's responsibility for reinsurance costs needs to be lessened to ensure sustainability of the Part D program and mitigate the trend toward negative direct subsidy payments. We believe plans currently have strong incentives to negotiate and manage high-cost drugs. Moreover, medical loss ratio penalties and CMS Office of the Actuary (OACT) bid review tests strongly regulate plan profit.

While the four-year phase-in of increased plan liability in the reinsurance phase of the benefit should help smooth premium impact and potential disruption, changing plan reinsurance liability without adding additional tools to manage the benefit will not in and of itself reduce program costs. Indeed, MedPAC, in its original proposal, recommended that additional tools to expand plan and PBM negotiating power accompany changes to reinsurance. As MedPAC noted, "collectively, the recommendations make up a package of interrelated steps."[5] These interrelated tools are not included in the Committees' bill. We respectfully urge the Committees to include these tools, which include ending protected class status for several classes, as well as additional flexibility for both formulary changes and drug utilization management protocols. These additional tools put critical teeth into PBMs' negotiations with manufacturers.

Value-based purchasing could help Part D plans conserve beneficiary and taxpayer dollars by reducing reimbursement when prescription drugs fail to work as intended. We recommend that the Committees consider ways to facilitate better value-based purchasing, including ways to allow multi-year contracting designed to permit Part D plans to assess a given product's effectiveness over time in given patients or populations.

We recommend that the Committees also consider how best to incentivize brand drug manufacturers not to price stratospherically high, which we think would be achieved through policies that place significant liability on drug manufacturers in the benefit's catastrophic phase. Such liability could be indexed and phased up as prices increased. A number of the economists who testified before the Committees recommended such an approach.

[5] "Report to the Congress: Medicare and the Health Care Delivery System," Medicare Payment Advisory Commission (MedPAC). June 2016. p. 158.

As the Committees consider how best to update Part D, we recommend that you take into account the likely disruption to beneficiaries and the Part D program that would result from a finalized rebate safe harbor rule. Should a rule be finalized for plan year 2020, the premium impact of the change would likely hit for plan year 2021 and subsequent years, as plans adjusted to a new contracting environment with manufacturers. Imposing significant new liability on plans during that period would increase uncertainty and likely result in additional premium impact – on top of the CMS OACT's estimated 25 percent increase for the rebate rule – as plans accounted for the added risk.

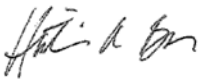
We understand that Congress and HHS do not coordinate actions, but nonetheless caution the Committees to be especially cognizant of imposing increased plan liability right when a final rebate rule may require PBMs to renegotiate agreements with manufacturers and alter their Part D administrative infrastructure. Simultaneous major Part D program changes will lead to disruption and increased beneficiary premiums and cost sharing that could be minimized with more staggered timing.

With Low-Income Subsidy (LIS) beneficiaries more likely to use brand prescription drugs than are non-LIS beneficiaries, MedPAC has recommended changes to LIS cost sharing to encourage more use of generics. PCMA supports efforts to increase incentives for LIS beneficiaries to use generics instead of brand drugs, including reducing LIS beneficiary cost sharing for generics. Shifting from brand to generic drugs will save money for both beneficiaries and taxpayers.

PCMA appreciates the opportunity to comment on the Committees' draft bill updating Medicare Part D and stands ready to help with technical assistance and to answer any questions the Committees may have.

If you need additional information, please contact me at 202.756.5730 or by email at kbass@pcmanet.org.

Sincerely,



Kristin Bass
Chief Policy and External Affairs Officer