June 6, 2019

United States House of Representatives
Ways and Means and Energy and Commerce Committees
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 provide feedback on the Committees' bipartisan draft legislation to improve the structure of the Medicare Part D program. Arnold Ventures is a philanthropy dedicated to addressing some of the most pressing problems in the United States. We invest in sustainable change based on a strong foundation of evidence. We drive public conversation, craft policy, and inspire action through education and advocacy. Our objective in health care is to lower cost while maintaining and enhancing access to needed, high-quality care. We focus on four areas where we see the greatest problems and opportunities. These four areas are 1) reducing hospital and physician prices and costs, 2) rationalizing prescription drug prices and purchasing approaches, 3) identifying and avoiding low-value and/or unsafe care, and 4) managing the care for Americans with complex health conditions and needs.

Arnold Ventures commends the Committees for proposing important reforms to the Part D program that would give plans greater financial incentives and stronger tools to manage the benefit, while also protecting Medicare beneficiaries with high drug spending. However, legislation addressing issues in the Part D program needs to be more comprehensive. In addition to providing comments on the draft legislation, we outline additional Part D policies that we encourage the Committees to consider.

**Shifting Risk from the Taxpayer to Plans and Manufacturers**

Arnold Ventures strongly supports shifting financial risk away from the federal government and from beneficiaries above the catastrophic threshold. Shifting more risk to Part D plans would generate significant savings to taxpayers by (1) reducing the amount the government pays for high cost beneficiaries through reinsurance payments, and (2) correcting misaligned financial incentives that encourage higher drug prices and formulary decisions that do not always steer people to the lowest cost alternative.

We stated in our testimony before the Senate Finance Committee, the Ways and Means Committee, and the Health Subcommittee of the Energy and Commerce Committee that Congress should consider proposals that mirror the Committees' draft legislation to increase plan liability to 80 percent, eliminate cost-sharing for beneficiaries with high prescription drug costs, and decrease the federal government's liability to 20 percent. The Congressional Budget Office estimates that these proposals generate about $2 billion in savings to taxpayers after taking into account the significant cost associated with eliminating cost-sharing for beneficiaries with drug costs above the catastrophic threshold.[i]

However, we strongly suggest that the Committees modify this proposal to require both Part D plans and brand pharmaceutical manufacturers to finance all catastrophic spending. A potential high level approach to this type of policy is to:

- Eliminate the manufacturer discount in the coverage gap;
- Require that plans pay 75% of costs until the catastrophic threshold; and

- Require manufacturers pay a level of discount above the catastrophic threshold that has them contributing, at a minimum, the same amount to the Part D program under the proposal as they do under current law. Plans would pay any remaining amount.
    - This could be designed by establishing the appropriate discount level using the current catastrophic threshold or by establishing the discount level relative to a lower catastrophic threshold amount.

The balance of plan and manufacturer liability is one that needs to be thought through carefully as there are many considerations that generate both costs and savings to the taxpayer and to the beneficiary.[ii] The larger the plan liability above the catastrophic threshold, the:

- Higher Part D benefit costs and premiums become;
- Stronger the incentive will be for plans to manage spending;
- Higher rebates potentially will be in competitive classes; and
- More limited the ability of plans to negotiate price concessions for therapies with limited competition.

The larger the manufacturer liability above the catastrophic threshold, the:

- Lower Part D benefit costs and premiums become;
- Weaker plan incentives to manage spending become; and
- Higher discounts would be on therapies with limited competition.

The proportions allocated to the plan versus the manufacturer should facilitate both slowed price growth and stronger incentives for plans to manage spending.

**Additional Benefit Redesign and Plan Flexibility Considerations**

In addition to changing the risk structure of the Part D benefit, MedPAC also recommended additional modifications to the Part D program that we support and ask the Committees to consider.[iii] These include:

1. Excluding manufacturers' discounts in the coverage gap from enrollees' true out-of-pocket spending (relevant only if the risk redesign does not modify manufacturer contributions in this portion of the benefit).
2. Providing plans with additional leverage to lower prices paid for drugs by removing at least the antidepressant and immunosuppressant drug classes from protected status and by considering recent administrative proposals that give plans additional tools to manage the six protected classes.[iv] To protect the beneficiary, these policies must be coupled with expeditious, well-functioning exceptions and appeals processes.
3. Streamlining the process for formulary changes.
4. Requiring prescribers to provide supporting justifications with more clinical rigor when applying for exceptions.
5. Permitting plan sponsors to use selected tools to manage specialty drug benefits while maintaining appropriate access to needed medications.

**Giving Part D More Tools to Manage Specialty Drug Spending**

Part D was constructed to rely on Pharmacy Benefit Managers (PBMs) managing the benefit on behalf of taxpayers and beneficiaries. It assumes that the PBMs can effectively use various tools to leverage significant price concessions from manufacturers. However, these tools only lower prices when drugs

have competition. PBMs cannot do their jobs and extract price concessions from manufacturers of high cost specialty drugs that do not have competition.

There are two sets of policies that could address this issue:

1. *Reference pricing.* The program could use the following external prices when setting reimbursement rates for certain high cost drugs:
    a. Prices paid by a subset of foreign countries similar to the idea proposed by the Administration in its Part B demonstration.
    b. Prices based on the clinical value of the drug to the patient.
    c. Prices based on independently developed research and development costs for a given therapeutic class.
    d. Prices paid for similar drugs with competition or other drugs within a similar therapeutic class.

2. *Introducing Negotiation.* Before Medicare covers certain high cost drugs, the Secretary of Health and Human Services and pharmaceutical manufacturers would negotiate a price. We recognize that there are a number of complex design issues that need to be worked through. As mentioned, this would be restricted to a small subset of high cost drugs with limited competition so it is administratively feasible. This concept of program-level negotiation may be foreign to Medicare, but it is important to keep in mind that the Department of Veterans Affairs engages in negotiation for drugs it purchases on behalf of their patients.

You can combine these two ideas and have reference prices built into the negotiation process in order to guide the bids that are offered.

In both of these policies, once there are a sufficient number of competitors on the market, price negotiation would return to Part D's standard negotiation process.

**Penalizing Excessive Price Growth**

Once launched, drug prices continue to escalate year-over-year, while clinical efficacy stays the same. In order to address this issue, brand manufacturers should be required to pay a rebate to the SMI Trust Fund for drugs purchased by Medicare Part D if the drug's average manufacturer price rises faster than inflation. The inflation penalty would be a transaction that occurs between the manufacturer and the federal government. It would not affect the negotiation process between Part D plans and manufacturers.

Manufacturers are required to pay this type of rebate to the Medicaid program. It is a key reason brand-name drugs are significantly less expensive in Medicaid when compared with Medicare Part D.[v] Additionally, the Congressional Budget Office estimated $1.5 billion in savings by applying an inflation rebate to drugs covered under Medicare Part B, which was proposed in the last two President's Budgets.[vi] The savings generated from an inflation rebate in Part D could be used to provide greater protections to Part D beneficiaries by lowering the burden of their out-of-pocket costs in some capacity.

**Modifying the Low-Income Subsidy Co-Payment Structure to Encourage Use of Lower Cost Drugs**

Part D plans have limited tools available to them to encourage lower cost drug use by individuals enrolled in the Low-Income Subsidy (LIS) program. Currently, most LIS enrollees pay no more than $3.40 for generic drugs (and brand drugs with generic equivalents) and $8.50 for brand drugs without generic equivalents.[vii] These co-payment amounts are set in statute and plans have limited flexibility to modify their structure to ensure the use of the most effective, least costly drugs.

Both MedPAC and the President's Budget in Fiscal Years 2016 and 2017 proposed reducing the LIS generic co-payment and increasing the brand co-payment amount.[viii] The Secretary would be able to (1) target particular classes where this structure would be most effective and (2) exclude brand drugs from the policy in classes where there are few lower cost generic alternatives. CBO estimated that this proposal would reduce Part D spending by over $18 billion over 10 years.[ix] This policy should include requirements to ensure access to streamlined prior authorization and appeals processes in cases where therapeutic substitution was not clinically appropriate.[x]

We strongly encourage the Committees to broaden their approach to fixing the Part D program in order to lower taxpayer and beneficiary spending. Taken together, the proposals discussed in this letter would significantly reduce the amount that taxpayers pay to provide the Part D drug benefit to its 44 million beneficiaries. However, some of these policies would increase cost-sharing for certain beneficiaries. In turn, the Committees should consider using a share of the savings generated by these policies to reduce beneficiary out-of-pocket spending.

Thank you for your consideration of our comments. We look forward to working with you and your staff on developing these proposals. If you have any questions about these comments, please contact me at MMiller@arnoldventures.org.

Sincerely,

Mark E. Miller, PhD
Executive Vice President of Health Care
Arnold Ventures
1776 I (Eye) Street, NW
Suite 850
Washington, DC 20006

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[i] https://www.cbo.gov/system/files/2019-05/55210-medicare.pdf
[ii] http://www.medpac.gov/docs/default-source/default-document-library/options-to-increase-the-affordability-of-specialty-drugs-in-pt-d---final.pdf?sfvrsn=0
[iii] http://www.medpac.gov/docs/default-source/reports/chapter-6-improving-medicare-part-d-june-2016-report-.pdf
[iv] http://www.medpac.gov/docs/default-source/comment-letters/01162019_partd_4180_p_medpac_comment-letter_v2_sec.pdf?sfvrsn=0
[v] https://www.cbo.gov/sites/default/files/113th-congress-2013-2014/reports/45552-PartD.pdf
[vi] https://www.cbo.gov/system/files/115th-congress-2017-2018/dataandtechnicalinformation/53906-medicare.pdf
[vii] https://secure.ssa.gov/poms.nsf/links/0603001005
[viii] http://www.medpac.gov/docs/default-source/reports/chapter-6-improving-medicare-part-d-june-2016-report-.pdf
[ix] https://www.cbo.gov/system/files/2018-09/51431-HealthPolicy.pdf
[x] http://www.medpac.gov/docs/default-source/reports/chapter-6-improving-medicare-part-d-june-2016-report-.pdf