

## **AHIP Response & Feedback to Ways & Means and Energy & Commerce Committees on the Part D Reform – June 6, 2019**

As the association representing health insurance providers who cover millions of Americans eligible for Medicare, we thank the Ways and Means and Energy and Commerce Committees for their commitment to reducing the impact of out-of-control drug prices on seniors and taxpayers. America's Health Insurance Plans (AHIP) and its members share this commitment and appreciate the opportunity to comment on draft legislation to reform the Medicare Part D program, which would implement a maximum out-of-pocket limit (MOOP) for all Medicare Part D enrollees while reducing federal reinsurance payments.

**Seniors should be able to get the medications they need at a cost they can afford. That is why health insurance providers support eliminating Part D enrollees' cost sharing when they reach the catastrophic phase.**

Nearly ten percent of Part D enrollees reach the Part D drug spending threshold for the year (\$6,350 in 2020) and enter the catastrophic phase of the Part D benefit. In this phase, they are responsible for paying five<sup>1</sup> percent of their prescription drug costs for the rest of the year. When Part D launched in 2006, given typical drug costs and spending for seniors at that time, some modest percentage of beneficiary co-insurance represented a rational level of cost sharing. But as drug prices have skyrocketed year after year since Part D's inception, with an increasing number of drugs exceeding a price tag of tens or even hundreds of thousands of dollars, even a five percent cost sharing requirement creates significant financial strain for these individuals.

While we support the implementation of a Part D MOOP to protect beneficiaries with high prescription spending, it is important for policymakers to consider the entire package of Part D reforms and the combined impact on Part D enrollee cost sharing, Part D premiums, and government costs. **Without other changes the draft legislation's approach of pairing a MOOP only with lower federal reinsurance payments will result in substantially higher government costs and higher premiums that are paid by all seniors.**

According to a new study, the implementation of a MOOP would increase government costs by \$84.7 billion and enrollee premiums by \$20.0 billion over the next ten years (2021 to 2030). Reducing federal reinsurance subsidies would raise costs even more – increasing government costs by an additional \$6.9 billion and increase member premiums by another \$5.9 billion over the same period.<sup>2</sup> In total, higher costs attributable to increased premiums and government spending would be \$117.5 billion. By contrast, implementing a MOOP would clearly help the subset of Part D enrollees with drug spending above the catastrophic threshold by reducing their cost sharing—an estimated \$59.3 billion—but that figure is only about half the amount of the total increase in Part D costs attributable to higher premiums and higher government spending.

This raises significant concerns about the long-term sustainability of the Part D program because of the much greater financial burdens placed on seniors through higher premiums and the impact on taxpayers through much higher government costs. There is a better way. **Drug makers should share the costs**

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<sup>1</sup> Part D Payment System. MedPAC. Available online at: [http://medpac.gov/docs/default-source/payment-basics/medpac\\_payment\\_basics\\_18\\_partd\\_final\\_sec.pdf](http://medpac.gov/docs/default-source/payment-basics/medpac_payment_basics_18_partd_final_sec.pdf)

<sup>2</sup> Giese, G., Conway, B., Sober, J. Part D catastrophic coverage – Financial implications of restructuring liability. Oliver Wyman. May 2019. Available online at: <https://www.ahip.org/wp-content/uploads/Restructuring-the-CMS-Federal-Reinsurance-Program.pdf>

**incurred for the purchase of their products in the catastrophic phase, where they currently have no liability—for example, by extending manufacturer liability in the Medicare Coverage Gap Discount Program into the catastrophic phase. By forcing them to have more “skin in the game,” drug makers would be more accountable for the high prices they alone set and increase year after year.**

There is no question that drug prices are out of control. The Medicare Payment Advisory Commission found that between 2007 and 2017, list prices for a small number of single-source brand drugs lacking cheaper alternatives increased by 195 percent.<sup>3</sup> This past January, using their monopoly-like power, drug makers increased hundreds of drug prices by an average of 6.3 percent – well above the rate of inflation.<sup>4</sup>

We commend the Committees for their work on this issue. With the changes proposed here, Congress could ensure that all enrollees and taxpayers receive greater financial protection and protect the Part D program against increasingly higher drug costs, both now and into the future.

## **Reducing Federal Reinsurance Subsidies Increases Premiums and Government Costs**

As currently drafted, this legislation would add a MOOP and reduce federal reinsurance payments over several years. By reducing out-of-pocket costs for seniors and other Part D enrollees, the MOOP significantly raises the cost of covering drugs under the Part D benefit.

However, a new study by the actuarial firm Oliver Wyman demonstrates that **reducing reinsurance payments would not “pay” for the higher costs associated with the MOOP**. Instead, it would effectively shift costs from one subsidy, the federal reinsurance subsidy, to another, the federal direct subsidy – **while raising premiums** for all seniors and other Part D enrollees. Oliver Wyman also found that there would be significant plan costs to mitigate the additional financial risk they carry in the catastrophic phase. This would be reflected in Part D plan bids, further driving up program costs.

While the Congressional Budget Office (CBO) has scored the President’s Budget proposal that closely mirrors the draft legislation as saving \$1.7 billion over ten years, it is unclear what assumptions CBO used and whether other Part D reform proposals had an impact on the score. In fact, **the Office of Management and Budget scored the same proposal as costing over \$14 billion**, which is directionally similar to the Oliver Wyman analysis.

Finally, to the extent CBO assumes the restructuring would somehow lead to larger discounts obtained from drug makers, CBO may be expecting Part D plans to impose sudden restrictions on access to drugs that may not be appropriate or feasible within Part D. The CBO analysis also may not consider the limits of plan leverage for negotiating lower costs for high-priced drugs that are not subject to material market competition. Moreover, the CBO score does not reflect the fact that beneficiary premiums would be higher. In the sections below, our discussion references data and evidence to show why such assumptions are incorrect.

## **Lack of Competition Reduces Plan Leverage and Leads to Higher Costs for Everyone (Except Drug Makers)**

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<sup>3</sup> Medicare Payment Advisory Commission, Report to the Congress: Medicare payment policy, March 2019.

<sup>4</sup> See, e.g., Reuters article from January 2, 2019: “Drug companies greet 2019 with U.S. price hikes.” Accessed at: <https://www.reuters.com/article/us-usa-drugpricing/drug-companies-greet-2019-with-u-s-price-hikes-idUSKCN1OWIGA>

**Contrary to assumptions by some analysts, Part D plans are already fully incentivized to negotiate lower prices for consumers**, as they lead to lower premiums for seniors and increased market share for plans. Over the past decade, plans have utilized private market tools for drugs subject to robust market competition, including significantly increasing the use of therapeutically equivalent, less expensive generics. This has generated significant savings for Part D enrollees and taxpayers. It has provided Medicare beneficiaries with access to prescription drug benefits with **consistently low and stable premiums and high satisfaction rates – all at a cost far below what CBO estimated when the program was created**.

However, over time, an increasing number of extremely expensive Part D drugs with extraordinarily high list prices have been approved, protected by patents and/or periods of market exclusivity, and most lack any meaningful competition. **These drug maker monopolies create a broken market where drug makers are empowered to set high list prices, demand higher prices year after year, and plans have little leverage to negotiate lower net prices.** The Part D program further restricts plan leverage to negotiate lower costs by limiting the ability to use well-established formulary management tools for drugs in the six “protected” classes. In fact, CMS recently stated that “Part D sponsors obtain substantially smaller rebates for protected class drugs than they do for non-protected class drugs.”<sup>5</sup>

As further discussed below, **a small number of high-priced drugs have a disproportionate effect on total spending, out-of-pocket costs, and federal reinsurance payment levels.** This impact is amplified by the fact that most of these highly priced drugs lack meaningful competition, are protected by CMS policies that prevent meaningful negotiation from occurring, or both. For example, less than 0.6 percent of Part D enrollees were prescribed the top ten Part D drugs in 2017 as ranked by estimated reinsurance spend<sup>6</sup>, but **these ten drugs accounted for 11.3 percent of total Part D spending.** It is no coincidence that all ten drugs lacked generic alternatives and that the majority were also protected by CMS policies<sup>7</sup> that effectively limit plan leverage to negotiate lower net prices.

Accordingly, even if one assumed that restructuring the catastrophic phase of the Part D benefit would provide additional incentives for lowering Part D drug costs beyond the incentives that exist today, there would be little that plan sponsors could do to achieve material savings for the drugs that are primarily driving up Part D costs in the catastrophic phase. **Part D plans cannot fix the broken market and overcome drug maker monopolies with absolutely no additional tools or leverage.**

AHIP strongly supports policies that would increase competition, including patent reforms to limit games that drug makers play to reduce new entrants into the market and increasing the availability of biosimilars and generics. However, unless or until such reforms are successfully implemented, we all must fully and seriously consider the realities of a broken market.

**As such, we encourage the Committees to increase drug maker liability in the catastrophic phase for the prices that they alone set and increase without justification.** Drug makers currently hold zero liability for costs incurred during the catastrophic phase. This creates a perverse incentive for manufacturers to launch their drugs at ever higher prices, increase them year-over-year, or both. In fact, implementing a MOOP without any additional and meaningful drug maker liability in the catastrophic

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<sup>5</sup> CMS proposed rule: “Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses” pp.20 – 21. Accessed at <https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-25945.pdf>

<sup>6</sup> See footnote 15.

<sup>7</sup> The “six protected classes” and the “two drug per class” CMS policies.

phase would remove any weak remaining limits on their pricing behaviors, giving them even less incentives to provide seniors and other Part D enrollees with reasonable prices.

## **Background on the Drug Industry: The Problem is the Price – Especially in Medicare**

Drug makers' practice of setting high launch prices and increasing them year after year without any justification have driven up – and will continue to drive up – Part D costs. In fact, drug makers have used this intentional, continuous, and persistent strategy to their benefit by increasing their revenue and profits for decades at the expense of patients, payers and taxpayers.<sup>8</sup>

### **Recent studies of price increases in cancer drugs indicate the increases are not generally warranted.**

For example, one study found that few cancer drugs approved via the accelerated Food and Drug Administration (FDA) approval pathway had verified benefits based on reported improvements in survival.<sup>9</sup> **The fact is that more must be done to hold drug makers accountable.** Another study<sup>10</sup> found that though many cancer drugs are approved by the FDA based on numerically low or modest response rates, some of these could undergo more robust clinical trials before they are marketed.

**Part D has not been immune to drug price increases.** A recent study published in *JAMA*<sup>11</sup> analyzed drug prices for oral anticancer drugs covered by Part D between 2010 and 2018. The researchers found that the 13 drugs in this class covered by Part D in 2010 had an average prescription price of \$7,438, while the average prescription price for the 54 drugs covered by Part D in 2018 was \$13,992, **an increase of 88 percent.**

This means that, as a direct result of drug makers increasing prices for higher profits, seniors and individuals with disabilities who are fighting cancer were forced to bear additional out-of-pocket costs by 88 percent – up to \$3,498 on average in 2018.<sup>12</sup> Further, oral anticancer drugs are one of the six protected classes in Part D, of which Part D plans must cover “all or substantially all” drugs in each of the six protected classes. This significantly reduces negotiating leverage and has led to much lower average rebates compared to other drug classes.

Consider the case of Revlimid, an anticancer drug with a per-prescription price tag of \$7,333.<sup>13</sup> How would a prescription for Revlimid impact Mary, a hypothetical 70-year old senior with multiple myeloma who is enrolled in a Part D plan and fills her first script for Revlimid in January? **Just by filling one script for Revlimid, she instantly enters the catastrophic phase of the Part D benefit,** going through the deductible, initial coverage limit, and the coverage gap phases all at once.<sup>14</sup> This means that she remains in the catastrophic phase for the rest of the year, where she likely pays 5 percent cost sharing and where federal reinsurance subsidies pay for 80 percent of the cost of every subsequent prescription. Alternatively, if Mary were to fill a prescription with a price tag of \$13,992 – the average for a Part D covered oral

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<sup>8</sup> See pp. 8-9 of AHIP comments in response to “HHS Blueprint to Lower Drug Prices and Reduce Out of Pocket Costs.” Accessed at <https://www.ahip.org/wp-content/uploads/2018/07/AHIP-Letter-to-Secretary-Azar-and-Detailed-Comments-RE-FR-Doc.-201810435-HHS-Blueprint-to-Lower-Drug-Prices-and-Reduce-Out-of-Pocket-Costs-FIN.pdf>

<sup>9</sup> <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2733561>

<sup>10</sup> <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2733563>

<sup>11</sup> <https://jamanetwork.com/journals/jama/fullarticle/2734308>

<sup>12</sup> Out-of-pocket costs derived assuming a 25% coinsurance.

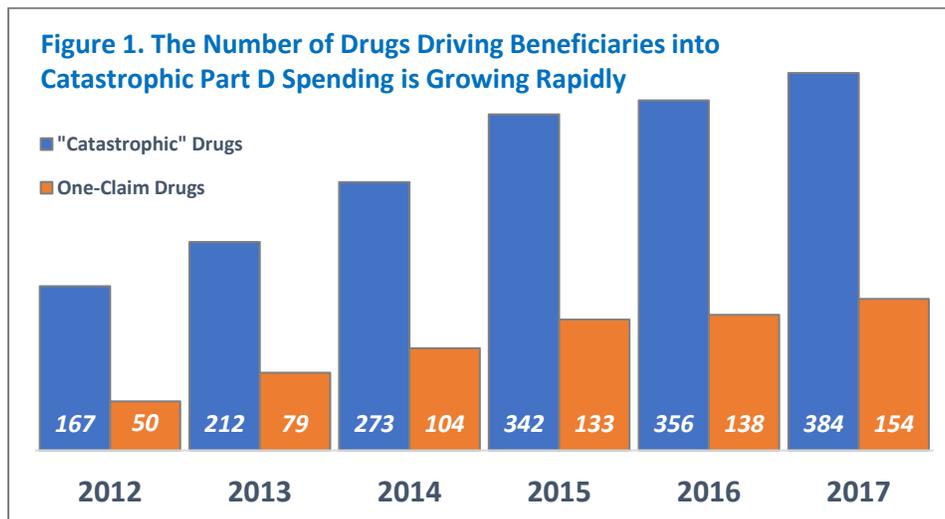
<sup>13</sup> Revlimid cost based average costs for Part D beneficiaries in 2017.

<sup>14</sup> Based on CMS published thresholds for coverage years 2019 and 2020

anticancer medication in 2018 – she would still enter the catastrophic phase in January, but every subsequent claim would increase her costs and catastrophic spending by nearly twice as much as a prescription for Revlimid.

As shown in the example above, as the price of a Part D drug goes higher, seniors and other Part D enrollees must take on more burdens with higher out-of-pocket costs and premiums while taxpayers subsidize increased Part D spending through higher government reinsurance payments. Unfortunately, this is not simply a hypothetical situation. AHIP’s analyses of the Centers for Medicare & Medicaid Services (CMS) Medicare Part D Drug Spending Dashboard<sup>15</sup> paint a bleak picture of how this drug pricing problem in Part D is worsening over time.

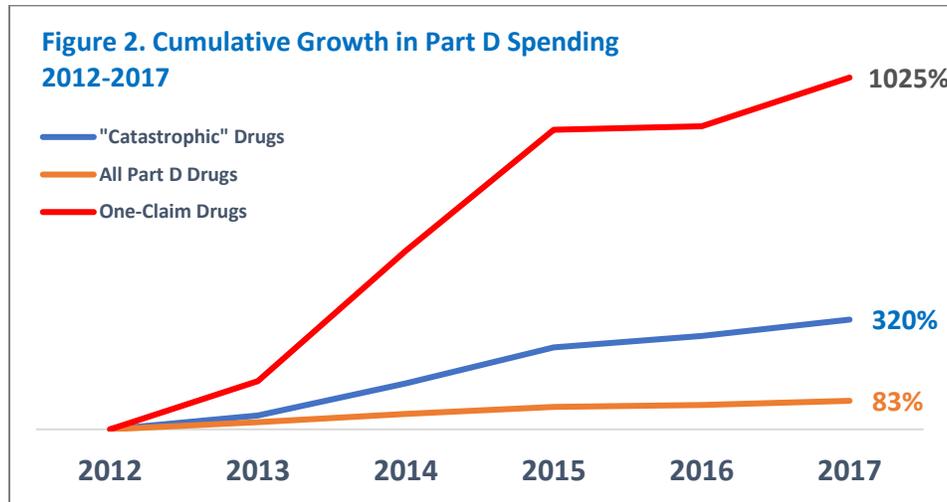
For example, the number of drugs, by itself, that would guarantee a Part D enrollee’s entry into catastrophic phase **by the end of the year** (“catastrophic drugs”) **more than doubled over five years** – from 167 drugs in 2012 to 384 drugs in 2017 (see Figure 1). Even worse, the number of drugs that would guarantee entry into the catastrophic phase **with just one claim** (“one-claim catastrophic drugs”) **more than tripled over the same period** – from 50 drugs in 2012 to 154 drugs in 2017.<sup>16</sup> **The data clearly show that the number of “catastrophic drugs” is increasing dramatically, including the number of “one-claim catastrophic” drugs that carry the highest price tags.**



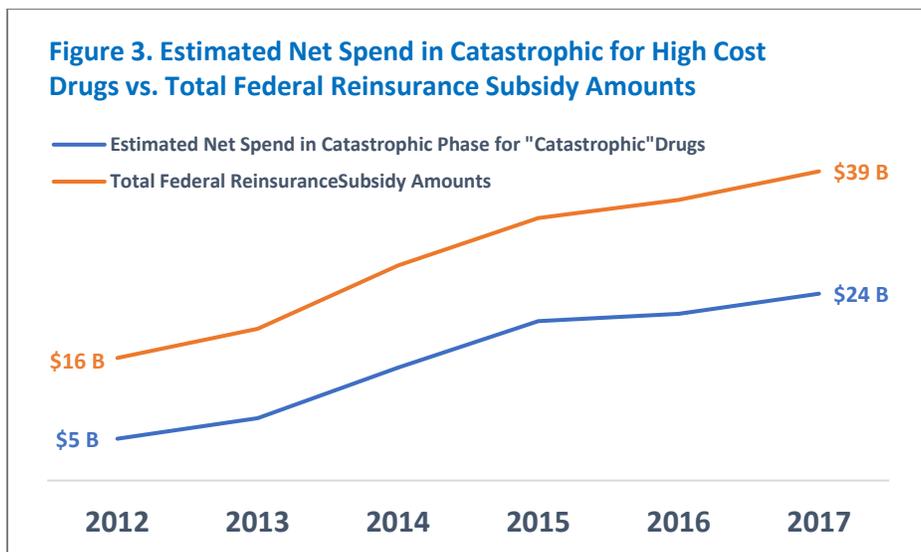
AHIP also analyzed and compared the average cumulative increase in spending between 2012 and 2017 for all Part D drugs, “catastrophic drugs”, and “one-claim catastrophic drugs” (see Figure 2). Though the increase in spending for all Part D drugs was significant — rising 83 percent over the five-year period — “catastrophic drug” spending rose an **astronomical 320 percent** over the same period. However, these figures are both dwarfed by **the 1,025 percent increase** in spending for “one-claim catastrophic drugs.” **This is why spending in the catastrophic phase is rising.**

<sup>15</sup> <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePartD.html>

<sup>16</sup> We derived the estimated catastrophic spend by assuming that an enrollee would only take that one drug and determined whether, under that scenario and based on CMS thresholds for each given year, the enrollee would enter the catastrophic phase by end of year. We then estimated the cost incurred in the catastrophic phase, which would be an underestimation as high cost enrollees typically take multiple drugs. We then conducted the same analysis to determine which drugs would cause catastrophic phase entry with just one claim and their estimated catastrophic spend.



The increase in federal reinsurance subsidies is being driven by the increase in spending for the highest cost drugs. To show this, we examined the trend in federal reinsurance subsidies between 2012 and 2017, estimated the minimum spend in the catastrophic phase for high cost drugs in each year,<sup>17</sup> and compared them with each other (see Figure 3). We found that federal reinsurance subsidies increased by 144 percent and that the estimated net spending for high cost drugs in the catastrophic phase increased by 380 percent.



As the data indicate, the high-priced drugs, especially the ones with the highest price tags, are becoming more prevalent and are driving increases in Part D spending, particularly through higher federal reinsurance subsidies. AHIP urges the Committees to pursue solutions that eliminate the perverse incentives that, without justification, allow drug makers to expose seniors and other Part D enrollees to ever higher launch prices and price increases.

<sup>17</sup> After deriving the estimated catastrophic spend (see footnote 15), we applied each year's average rebate percentage based on the Medicare Trustee's Report figures.

## AHIP Recommendations and Alternative Policies for Improving Medicare Part D

Below we provide policy recommendations that, when taken together, would prevent premium and government cost increases, hold drug makers accountable for the prices they alone set and increase without justification, and prevent drug maker gaming of rebates.

### *Implement a Part D MOOP Without Significantly Increasing Premiums or Government Costs*

- **AHIP supports a Part D MOOP** and believes that seniors and other Part D enrollees deserve some relief from drug makers' egregious pricing practices.
- However, **we firmly oppose any additional policy that increases premiums and government costs**. Rather, we recommend that the Committees **significantly increase drug maker liability in the Part D catastrophic phase**.

### *Hold Drug Makers Accountable*

- **Significantly increase the zero liability that drug makers currently have in the catastrophic phase**. For example, Congress could extend the existing coverage gap discount program into the catastrophic phase.
- **Empower an independent assessor of value** (e.g., Institute for Clinical and Economic Review) to gain **early access to FDA clinical data and results** and to **publicly report on the drug's economic value before market-entry** if its launch price exceeds an established cost- or budget-based threshold.
- **Consider other approaches to limit drug prices**. For example, Congress could apply an **inflationary measure** based on both the drug's **list price and net cost** after rebates to prevent industry gaming by increasing list prices, reducing rebates, or both. Addressing both list and net prices would ensure no cross-industry effects would occur and prevent increases in Part D premiums and government costs.

### *Stop Gaming of Rebates*

- Prevent drug makers from introducing and setting the list price of their **"authorized generics" at amounts higher than the net price of their brand product**, and work with insurance providers to **limit other drug maker activities that increase premiums and government costs**.

### *Do Not Make Changes to Part D for 2020*

- **Do not implement any changes to Part D for 2020**. By law, Part D bids must be finalized and submitted to CMS, for their review and approval, on the first Monday of the June before the start of each Part D plan year. For the 2020 plan year, plans finalized and submitted their bids on June 3, 2019.
- **If Congress makes any change to the 2020 benefit now, it would create new and significant threats to the Part D benefit for which over 45 million enrollees depend for access to prescription drugs**.

Again, we thank the Committees for their work to protect seniors and people with disabilities from the harmful effects of out-of-control drug prices. We look forward to working with you on solutions that will work to both protect seniors' access to the medications they need, and ensure those medications are available at an affordable cost for all Americans.

*AHIP is the national association whose members provide coverage for health care and related services for millions of Americans. Our members provide prescription drug coverage to more than 45 million seniors and persons with disabilities who have chosen to enroll in Part D to help them afford their prescription drugs. They include almost 20 million in Medicare Advantage (MA) plans that integrate Part D coverage and more than 25 million in standalone Part D plans.*