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June 6, 2019

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

The Honorable Kevin Brady
Ranking Member
U.S. House Committee on Ways and Means
1139 Longworth House Office Building
United States House of Representatives
Washington, DC 20515

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

The Honorable Greg Walden
Ranking Member
U.S. House Committee on Energy and Commerce
2322 Rayburn House Office Building
United States House of Representatives
Washington, DC 20515

Re: Part D Discussion Draft and Related Questions

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

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to comment on the discussion draft and related questions released by the Ways and Means Committee and Energy and Commerce Committee on May 23, 2019. PhRMA represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. Since 2000, PhRMA member companies have invested more than $600 billion in the search for new treatments and cures, including an estimated $71.4 billion in 2017 alone.

PhRMA applauds the Committees' interest in Medicare Part D and looks forward to working with the Committees to strengthen this vital program. For more than a decade, Medicare Part D has successfully provided seniors and people with disabilities with comprehensive prescription drug coverage through its unique market-based structure that has kept overall program costs far below initial projections. By embracing broad consumer choice and competition, private sector efficiencies, and innovation, Part D successfully balances the need to provide broad access to medicines with sustainable costs. With the multitude of changes that have taken place in the insurance and pharmaceutical markets over the past 10 years, it makes sense to now consider whether Part D can be strengthened to improve the benefit for patients.

The Committees' discussion draft released on May 23, 2019 (the discussion draft) takes an important step towards strengthening the benefit by including an out-of-pocket cap for beneficiaries. This is a critical component needed to address a significant problem for Medicare beneficiaries enrolled in the Part D program—the growing burden of out-of-pocket costs for prescription medicines.

In addition, we urge the Committees to consider other reforms to address cost sharing challenges for patients who have not yet reached the catastrophic phase of the benefit, and we are encouraged that the Committees asked questions about this topic. Medicare Part D patients that do not qualify for low-income subsidies can face $2,750 in cost sharing before they reach the catastrophic threshold—sometimes in the first month or two in the year. This often leads to crucial medicines being abandoned when the cost sharing simply is not affordable.

Our responses to the specific questions posed by the Committees and our feedback on the discussion draft itself are below. PhRMA looks forward to engaging with the Committees on potential changes to the program. We emphasize that any structural changes contemplated by the Committees should be paired with affordability gains for patients. Further, we encourage the Committees and the Centers for Medicare & Medicaid Services (CMS) to ensure that robust patient protections are in place so that patients can gain coverage of the medicines they need as they consider any changes that could increase Part D plans' incentives to limit access to medicines.

1) *Feedback on how the Part D program is addressing the problem of high cost drugs and how the program could better address the costs of these drugs. Specifically, whether or not Congress should consider changing or eliminating the distinction between the initial coverage phase and the coverage gap discount program.*

Out-of-pocket costs in Part D are creating challenges for many patients and the pharmaceutical industry wants to be at the table to help shape solutions that strengthen the Part D program. Beneficiaries typically have higher and more unpredictable out-of-pocket costs for their medicines in Medicare Part D than for the hospital and physician services they receive coverage for through Parts A and B.[1] In part, this is because those enrolled in fee-for-service Medicare have the option of purchasing supplemental Medigap coverage to limit their Parts A and B out-of-pocket costs, and Medicare Advantage (MA) enrollees have the added benefit of an annual out-of-pocket spending limit for A and B services. These options are not available in the Part D program and beneficiaries have no such safeguards against high out-of-pocket costs.

[1] Frankel M. "Here's the Average American's Annual Medicare Bill." The Motley Fool. 5 February 2017. Available: https://www.fool.com/retirement/2017/02/05/heres-the-average-americans-annual-medicare-bill.aspx

Part D and prescription drug cost trends:

Any discussion of how Part D should address high drug costs needs to be grounded in an understanding of trends for drug pricing and Part D spending. The Medicare actuaries report that the average plan bid in Part D — the amount plans project an average enrollee will cost — is actually lower today than in the first year of Part D's operation.[2] According to the 2018 Medicare Trustees Report, over the past 10 years, Part D benefit payments have increased by an annual rate of just 3.8 percent on a per enrollee basis. From a budgetary perspective, the Medicare Part D program is succeeding beyond all expectations, delivering needed prescription drugs to Medicare beneficiaries at a far lower cost than expected, due to strong competition among health plans to keep costs low and negotiate with biopharmaceutical companies for savings. Part D's market-based approach is so successful that CBO reports that the "rebates negotiated by Part D plans on preferred brands appear to make the net prices approach the lowest prices obtained in the private sector."[3]

Both in Part D and the overall private market for prescription medicines, fierce market competition among medicines results in sizable discounts from brand manufacturers and shifts utilization from brand medicines to generics and biosimilars.[4] As a result of these forces:

- In 2017, total net drug spending grew just 0.6 percent, even as many new treatments reached patients.[5] In 2018, prices for brand-name medicines increased just 1.5 percent after discounts and rebates, lower than the rate of inflation.[6]

- In 7 of the last 10 years, net retail prescription drug costs grew more slowly than total health care costs—and, on average, spending for retail prescription medicines has grown

[2] 2018 Annual Report of the Board of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Fund. June 5, 2018.
[3] CBO, "Costs under Medicare's Prescription Drug Benefit and a Comparison with the Cost of Drugs under Medicaid Fee-for-Service," as presented by Anna Cook, Health, Retirement, and Long-term Analysis Division, at Academy Health, June 23, 2013.
[4] Generics and biosimilars are a form of cost containment that applies only to the biopharma sector. For instance, the price of one widely used statin dropped by about 92 percent from 2005 to 2013 when generic versions came to market. Over the same period, the average charge for percutaneous transluminal coronary angioplasty, a surgical procedure to treat cardiovascular disease, increased by almost 66 percent. (Invoice price data for atorvastatin 10mg from IQVIA National Sales Perspectives data for 2005 (branded Lipitor) and 2015 (generic). https://www.iqvia.com/locations/united-states/commercial-operations/essential-information/sales-information. Accessed May 2018.; Average hospital charge data from Healthcare Cost and Utilization Project Hospital Charge Database 2005, 2013, and 2015. https://www.ahrq.gov/research/data/hcup/index.html. Accessed May 2018.)
[5] IQVIA. 2017 Medicine Use and Spending in the U.S.: A Review of 2017 and Outlook to 2022. April 2018. Available at: https://www.iqvia.com/institute/reports/medicine-use-and-spending-in-the-us-review-of-2017-outlook-to-2022.
[6] IQVIA. The Global Use of Medicine in 2019 and Outlook to 2023. January 2019. Available at: https://www.iqvia.com/institute/reports/the-global-use-of-medicine-in-2019-and-outlook-to-2023.

more slowly than growth for other major types of care, and more slowly than total health expenditures.[7]

- In 2018, nearly 90 percent of all prescriptions filled in Medicare Part D were generics[8], up from 61 percent in 2007.[9] IQVIA projects total U.S. brand sales will be reduced by $95 billion due to competition from generics and biosimilars between 2019 and 2023.[10] There is no similar type of built-in cost containment for other health care services.

Affordability challenges in Part D:

Even though market forces are working to hold down prices and spending for medicines, Medicare Part D beneficiaries who are not eligible for low-income subsidies (LIS) face multiple affordability challenges today due, in part, to the way the benefit is structured and how cost sharing is calculated. These challenges include high cost sharing, the lack of an out-of-pocket maximum, and an uneven distribution of out-of-pocket costs throughout the year. We discuss policy approaches to address these challenges later in our letter.

- *High Coinsurance Based on List Prices:* Financial barriers to drug treatment are particularly acute for Part D beneficiaries whose medicines are subject to coinsurance (cost sharing set as a percentage of the medicine's cost), particularly when those drugs are covered on a plan's non-preferred or specialty drug tiers. Most Part D plan sponsors impose up to 33 percent coinsurance for medicines on the specialty tier and coinsurance for non-preferred tier medicines can be as high as 40 to 50 percent.[11] What's more, the coinsurance percentage is typically applied to a medicine's undiscounted "list price," even if the Part D sponsor or their pharmacy benefit manager (PBM) has negotiated a substantial rebate for the product. This means that effectively a patient could be paying more than half of the net cost of a medicine even if the assigned coinsurance is 20 or 30 percent.

- *Lack of an Out-of-Pocket Cap:* Analysis by the Kaiser Family Foundation shows that more than one million non-LIS beneficiaries incurred out-of-pocket spending high

[7] PhRMA analysis of CMS 2016 National Health Care Expenditure Accounts. December 2017.
[8] MedPAC. Report to the Congress: Medicare Payment Policy. Chapter 14: The Medicare prescription drug program (Part D): Status report. March 2019.
[9] MedPAC. Report to the Congress: Medicare and the Health Care Delivery System. Chapter 6: Improving Medicare Part D. June 2016.
[10] IQVIA. The Global Use of Medicine in 2019 and Outlook to 2023. January 2019. Available at: https://www.iqvia.com/institute/reports/the-global-use-of-medicine-in-2019-and-outlook-to-2023.
[11] Cubanski J, Damico A, Neuman T. Medicare Part D in 2018: The Latest on Enrollment, Premiums and Cost-Sharing. Kaiser Family Foundation. May 2018.

enough to reach catastrophic coverage in 2015, more than twice the number in 2007.[12] Annual out-of-pocket expenses for these patients were significant—more than $3,000, on average—and exceeded $5,200 for one in 10 beneficiaries. On average, these beneficiaries filled 99 prescriptions per year.[13] Such high out-of-pocket expenses are persistent from year-to-year for patients with complex health care needs: Medicare Payment Advisory Commission (MedPAC) analysis indicates that 70 percent of beneficiaries who reached catastrophic coverage in one year reached it in the following year as well.[14]

- *Uneven Distribution of Out-of-Pocket Costs:* Expenses for beneficiaries with high annual out-of-pocket costs are heavily concentrated at the beginning of each calendar year. Patients with a serious illness or multiple chronic conditions can rapidly progress through the deductible, initial coverage phase, and the coverage gap within a month or two, resulting in a large upfront cost burden. For example, one study found that Part D beneficiaries with rheumatoid arthritis (RA), multiple sclerosis, or chronic myeloid leukemia (CML)—whose average annual out-of-pocket spending ranged from $3,900 to $6,300—incurred 25 to 40 percent of these costs in January alone and between 54 and 66 percent of these costs in the first three months of the year.[15] According to the authors, the average out-of-pocket cost for the first prescription filled during the calendar year "nearly equaled or exceeded the average monthly Social Security benefit" for two of these three conditions.

The increased use of complex, multi-tiered formularies and growing prevalence of coinsurance expose patients to a disproportionately high share of the cost of their medicines. Today, the vast majority (95 percent) of Prescription Drug Plans (PDPs) use formularies with five coverage tiers, and 5 percent are now using a sixth tier.[16] Relative to the fixed-dollar copays commonly applied to medicines on the preferred drug tier, the increased use of coinsurance-based non-preferred and specialty tiers results in higher and less predictable cost sharing for beneficiaries who rely on brand medicines.

Research consistently shows that patients facing high cost sharing are less likely to initiate or adhere to their prescribed medication regimens. For example, analysis by Amundsen Consulting

[12] Cubanski J, Neuman T, Orgera K, et al. No Limit: Medicare Part D Enrollees Exposed to High Out-of-Pocket Drug Costs Without a Hard Cap on Spending. Kaiser Family Foundation. November 2017.
[13] Id.
[14] MedPAC. Report to the Congress: Medicare and the Health Care Delivery System. Chapter 6: Improving Medicare Part D. June 2016.
[15] Doshi JA, Pengxiang L, Pettit AR, et al. Reducing Out-of-Pocket Cost Barriers to Specialty Drug Use Under Medicare Part D: Addressing the Problem of "Too Much Too Soon." *American Journal of Managed Care*. 2017;23(3 Suppl):S39-S45.
[16] Avalere Health. 2018 Medicare Part D Formularies: An Initial Analysis. November 2017.

shows that 38 percent of all new specialty prescriptions filled by Part D beneficiaries beginning therapy for the first time were abandoned at the pharmacy in 2016, and that the likelihood of abandonment was strongly associated with out-of-pocket cost.[17] When beneficiary cost sharing exceeded $250, 71 percent of new specialty prescriptions were abandoned. This level of cost sharing was not uncommon, as nearly 40 percent of all new Part D prescriptions for specialty medicines had cost sharing of more than $250. Even among patients with debilitating or life-threatening illnesses, abandonment rates were alarmingly high. For example, more than 6 out of 10 new oncology prescriptions and more than 7 out of 10 new antipsychotic and multiple sclerosis prescriptions were abandoned at the pharmacy counter when their cost sharing exceeded $250.

Improved medication adherence can improve clinical outcomes and, by preventing the need for expensive hospital, emergency, or long-term care, reduce the growth in health care spending.[18] Based on a large body of research showing that better use of medicines can reduce spending on other medical services, the Congressional Budget Office (CBO) now credits Medicare policies that increase use of medicines with savings on other Medicare costs. According to CBO, every 1 percent increase in the utilization of prescription medicines decreases Medicare spending in Parts A and B by 0.20 percent.[19]

Simplifying the Part D benefit:

The Committee specifically solicits comments on Part D reforms that could change or eliminate the difference between the initial coverage phase and the coverage gap discount program. The coverage gap discount program was designed to eliminate the so-called 'donut hole' that left non-LIS patients paying 100 percent of costs in the coverage gap (compared to 25 percent of costs in the initial coverage phase). Effective with the 2019 plan year, the coverage gap is "closed" and patients are responsible for 25 percent of the cost (on average) of their drugs in both the initial coverage phase and the coverage gap. However, patient cost sharing often changes as patients move from the initial coverage phase, which has different levels of cost sharing assigned by formulary tier, to the coverage gap, where patients pay 25 percent of the cost of all brand prescriptions. This change in cost sharing may cause confusion and a lack of predictability for patients. We look forward to engaging on changes that would simplify this structure, and we encourage the Committees to ensure that those efforts move patients towards having more manageable and predictable cost-sharing and continue to preserve the program's market-based structure.

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[17] Amundsen Consulting. Medicare Part D Abandonment: Deep Dive into Branded Product Abandonment. November 2017.
[18] Boswell KA, Cook CL, Burch SP, et al. Associating Medication Adherence with Improved Outcomes: A Systematic Literature Review. *American Journal of Managed Care*. 2012;4(4):e97-e108.
[19] CBO. Offsetting Effects of Prescription Drug Use on Medicare's Spending for Medical Services. November 2012.

Any simplification of the Part D benefit should also seek to address the current low level of plan liability in the coverage gap. The Bipartisan Budget Act passed by Congress in February 2018 reduced plan liability in the coverage gap from 25 percent to just 5 percent for brand medicines. This reduction in plan liability has weakened Part D's successful market-based structure by substantially scaling back plan liability and potentially crowding out privately-negotiated rebates with statutorily-mandated price controls. As part of any Part D simplification effort, Congress should work to ensure that the problematic incentives that exist in the coverage gap today are not extended to other parts of the Part D benefit. As MedPAC has noted, "When competing plans bear risk, they have an incentive to strike a balance between offering benefits that are attractive to beneficiaries and managing their enrollees' drug spending so that plans' premiums will be affordable." To avoid upsetting this balance, potential changes to the benefit should be examined carefully, with an eye towards fully understanding how such changes could impact the competitive incentives built into the Part D program.[20] Specifically, the current coverage gap discounts provided by brand manufacturers, at 70 percent, should not be extended to other phases of the benefit.

Negotiated price:

Another change that would complement the Committees' efforts to simplify Part D would be adopting a statutory definition of "negotiated price" (the basis for determining Part D coinsurance) that applies across all phases of the benefit, and defining the term as the price paid to the dispensing pharmacy for a drug (including the dispensing fee) net of price concessions received by the plan sponsor or its pharmacy benefit manager. These changes would simplify the benefit (which currently has a statutory definition of negotiated price that only applies in the coverage gap, and a different regulatory definition of the term) while promoting affordability for enrollees and encouraging their utilization of drugs with lower net prices. This would ensure that patients are receiving the benefit of negotiated price concessions, as well as compliance with the HHS Office of Inspector General's proposed anti-kickback safe harbor rule assuming the rule is finalized.

2) *What share of costs should be attributed to the beneficiary, Part D plans, and manufacturers under the current system and how this share should 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?*

As discussed above, PhRMA is concerned about the multiple affordability challenges non-LIS Part D beneficiaries face, including high cost sharing for brand prescriptions, the lack of an out-

[20] MedPAC. Report to the Congress: Medicare and the Health Care Delivery System. Chapter 6: Sharing Risk in Medicare Part D. June 2015.

of-pocket maximum, and the uneven distribution of out-of-pocket costs throughout the year. We encourage the Committees to focus on improving patient affordability as part of any changes to the Part D benefit.

The role of Part D plan liability:

Medicare Part D has a unique structure in which the government, instead of providing health coverage directly, oversees a market of private options. Patients have the freedom to choose among dozens of competing private health plans, who take on the financial risk of managing Part D costs and compete for enrollment based on premiums, coverage, quality and service. By embracing broad consumer choice and competition, private sector efficiencies, and innovation, Part D successfully balances the need to provide broad access to medicines with sustainable costs.

Requiring private Part D plans to bear risk provides incentives for them to manage benefit spending. As the Medicare Payment Advisory Commission (MedPAC) has noted, "Plan sponsors bear insurance risk for the benefit spending of their enrollees. When competing plans bear risk, they have incentives to offer benefits that are attractive to beneficiaries and yet manage spending so that premiums remain affordable." MedPAC has also noted that "evidence suggests that sponsors have been less successful at cost containment when they were at less risk for benefit spending."[21]

The current low plan liability in the catastrophic phase of the benefit also appears to be contributing to plans underbidding. This behavior allows plan sponsors to suppress growth in premiums, while still receiving reimbursement for a large share of their actual incurred catastrophic coverage costs through additional reinsurance payments made during reconciliation. Since retrospective reconciliation payments are not reflected in plan sponsors' bids, this allows plans with high reinsurance costs to continue offering low premiums. A higher share of Part D payments in 2016 were made through retrospective reconciliation, rather than the prospective risk-based capitation system, which suggests that plan sponsors' liability for managing the benefit may be shrinking.[22]

Recent changes to the Part D benefit have moved in the wrong direction, reducing plan liability to just 5 percent of costs in the coverage gap. CMS notes that it is "concerned about the impact these changes will have on drug costs under Part D in 2019 and future years, particularly as plan liability in the gap significantly decreases for brand name drugs beginning in 2019."[23]

[21] MedPAC. Report to the Congress: Medicare and the Health Care Delivery System. June 2015.
[22] MedPAC. Report to the Congress: Medicare Payment Policy. Chapter 14: The Medicare Prescription Drug Program (Part D): Status Report. March 2018.
[23] CMS. Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter, April 2, 2018

However, another key factor in the success of the Part D program, in addition to the appropriate level of plan benefit risk, is that the risk must be well-balanced with beneficiary access protections. Thus, as the Committees consider changes that increase plan liability in the catastrophic phase of the benefit, it will be critical to make sure that balance of patient protections is maintained. For example, ensuring robust patient protections would be consistent with CMS' recent decision to not finalize proposed changes to the six protected classes.[24]

In fact, we encourage the Committees to consider adopting additional safeguards for beneficiaries to ensure access is not comprised for the sake of costs under any Part D reform effort. For example, Congress could enact policies to protect against non-medical switching and to bolster a beneficiary's right to appeal coverage and tiering decisions for all medicines. Such changes will ensure that Medicare beneficiaries continue to have access to a broad and appropriate range of treatment options. They will also protect patients who are already stable on a medication from disruptions in treatment that could threaten their health and increase overall Medicare costs.

CMS should also step up monitoring to ensure that formularies are appropriately broad and do not use overly restrictive utilization management. Prescription drug utilization is often more predictable than spending on other types of health care services, making formularies particularly vulnerable to discriminatory benefit designs that seek to avoid certain high-cost patients. Currently, CMS checks each "formulary to ensure inclusion of a range of drugs in a broad distribution of therapeutic categories and classes, in order to satisfy the Medicare Modernization Act (MMA) requirement that a sponsor's categorization system does not substantially discourage enrollment by any group of beneficiaries."[25] But these reviews rely in part on identifying formularies that are outliers.[26] However, it is entirely possible that most plans could have discriminatory formulary designs and under such a scenario these plans would not be identified in an outlier analysis. We saw this pattern in the early years of the Affordable Care Act, when many marketplace plans put all medicines to treat HIV—including generic drugs—on the highest formulary tier.[27]

Manufacturer contributions:

Beginning in 2011, brand manufacturers took on responsibility for a share of Part D program costs as part of the Coverage Gap Discount Program to close the donut hole for non-LIS beneficiaries, and this year began paying 70 percent of brand medicine costs in the coverage gap,

[24] 84 Fed. Reg. 23840, May 23, 2019.
[25] Medicare Prescription Drug Benefit Manual, Chap. 6, Section 30.2.
[26] Medicare Prescription Drug Benefit Manual, Chap. 6, Section 30.2.
[27] Douglas B. Jacobs & Benjamin D. Sommers. Using Drugs to Discriminate: Adverse Selection in the Insurance Marketplace. *New England Journal of Medicine*. 2015;372: 399-402.

an increase from the 50 percent paid previously. If these contributions are shifted within the benefit, any manufacturer liability should be optimized to address patients' affordability challenges and should not be used to replace Part D plans' role as the entity bearing risk and providing the insurance benefit. We also note that any shift in liability to the catastrophic phase of the benefit would change that liability from a capped burden that ends once drug spending reaches a set threshold, to a burden limited only by the calendar year.

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

PhRMA thanks the Committees for their interest in improving affordability for low- and moderate-income beneficiaries and ensuring affordability for cost sharing below the catastrophic level. As discussed earlier in our comments, many non-LIS patients face significant affordability challenges before they reach the catastrophic phase of the benefit. Below we discuss several potential policies to improve affordability for patients and would complement a change to add an out-of-pocket maximum to Part D.

Changing Part D so that cost sharing is based on a medicine's net price:

The Part D program's success is due to strong competition among private health plans that work to keep costs low by negotiating rebates with biopharmaceutical companies. These privately negotiated rebates can result in substantial savings—reducing list prices for some medicines by as much as 30 percent to 70 percent.[28] However, Part D beneficiaries often face charges at the pharmacy counter based on undiscounted "list prices" for medicines. A recently-proposed rule from the U.S. Department of health and Human Services' (HHS) Office of the Inspector General (OIG) [29] takes aim at the complex, rebate-based system that shapes both government and patient costs for Medicare prescription drugs. The proposed rule is a bold step by HHS and OIG that would help address the affordability challenges many beneficiaries face today.

PhRMA supports the policies underlying the OIG proposed rule to achieve solutions that will help patients and yield better, more efficient health care. Patients with Medicare Part D coverage are likely to benefit from the proposed changes if they are in the deductible or paying coinsurance based on a list price that does not reflect discounts received by their insurers and

[28] QuintilesIMS Institute. Estimate of Medicare Part D Costs After Accounting for Manufacturer Rebates. October 2016; Gronholt-Pedersen J, Skydsgaard N, Neely J. Novo Nordisk Defends U.S. Diabetes Drug Pricing. *Reuters*. November 4, 2016.; Silverman E. What the 'Shocking' Gilead Discounts on its Hepatitis C Drugs Will Mean. *Wall Street Journal*. February 4, 2015; Barrett P, Langreth R. The Crazy Math Behind Drug Prices: Intermediaries that Negotiate to Lower Prices May Cause Them To Increase Too. *Bloomberg Businessweek*, June 29, 2017.
[29] Department of Health and Human Services (HHS) Office of the Inspector General (OIG), "Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees." January 2019, RIN 0936-AA08.

their agents (pharmacy benefit managers / "PBMs"). According to an Avalere Health analysis, 58 percent of covered drugs in Part D were subject to coinsurance in 2016—meaning patient cost sharing for those drugs is likely tied to list price. [30] Additionally, Avalere found that beneficiaries enrolled in prescription drug plans (PDPs) with more than one tier requiring coinsurance spiked to 96 percent in 2016, up from 39 percent in 2014—a growing trend leading to high out-of-pocket costs for beneficiaries. OIG reports that, on average, Medicare Part D beneficiaries who do not receive low-income subsidies (non-LIS) would pay 10 to 19 percent less in cost sharing over the next 10 years under the administration's proposed system of upfront discounts.[31] Patients who take brand medicines with relatively large rebates, such as medicines for diabetes, asthma, and autoimmune disorders, would be likely to see larger than average reductions in out-of-pocket costs because the rebates would be passed on to them directly.[32]

Policies to more evenly distribute cost sharing throughout the year:

In the beginning of each calendar year, patients with a serious illness or multiple chronic conditions can rapidly progress through the deductible, initial coverage phase, and the coverage gap within a month or two, resulting in a large upfront cost burden. As discussed earlier, one study found that Part D beneficiaries with rheumatoid arthritis (RA), multiple sclerosis, or chronic myeloid leukemia (CML)—whose average annual out-of-pocket spending ranged from $3,900 to $6,300—incurred 25 to 40 percent of these costs in January alone and between 54 and 66 percent of these costs in the first three months of the year.[33] To make spending more manageable, policies that increase the use of fixed copayments will lead to more predictable cost sharing and will likely decrease the share of beneficiaries facing thousands of dollars of cost sharing in January. Other policies could potentially spread cost-sharing obligations more evenly throughout the year. One of the many advantages of adding an out-of-pocket maximum to Part D is that it would make it easier to calculate the maximum total cost sharing and develop policies to spread those costs throughout the year, helping patients to better manage their expenses.

Fixing the out-of-pocket cliff:

Another important step Congress could take to improve Part D affordability would be to address the looming out-of-pocket cliff. Changes made under the Affordable Care Act (ACA) temporarily slowed the annual rate of increase in the catastrophic threshold from 2014 to 2019,

[30] Avalere Health. Majority of Drugs Now Subject to Coinsurance in Medicare Part D Plans. March 2016. Available at: https://avalere.com/press-releases/majority-of-drugs-now-subject-to-coinsurance-in-medicare-part-d-plans
[31] HHS OIG, RIN 0936-AA08. See regulatory impact analysis, Table 2.B.
[32] HHS OIG, "Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees." January 2019, RIN 0936-AA08.
[33] Doshi JA, Pengxiang L, Pettit AR, et al. Reducing Out-of-Pocket Cost Barriers to Specialty Drug Use Under Medicare Part D: Addressing the Problem of "Too Much Too Soon." *American Journal of Managed Care*. 2017;23(3 Suppl):S39-S45.

reducing the amount of beneficiary out-of-pocket spending required to enter catastrophic coverage. Normally, the catastrophic threshold would grow at the rate of beneficiary per capita spending, just like the other phases of the Part D benefit. At the end of 2019, the temporary suppression of the growth rate is set to expire, which will cause the catastrophic threshold to jump up suddenly in 2020, as if the growth rate had never been slowed in the first place. This steep increase of $1,250 (from $5,100 in 2019 to $6,350 in 2020)[34] in the catastrophic threshold is known as the out-of-pocket cliff. It appears Congress has missed the window to protect beneficiaries from this change in 2020 but should act swiftly to reverse the effects of the out-of-pocket cliff for patients in 2021 and beyond.

LIS cost-sharing:

It is crucial that any changes to Part D not increase brand cost sharing for those who receive low-income subsidies, as has been suggested by MedPAC. The MedPAC proposal would lower LIS copayments for generic drugs while increasing copayments for brands as much as twofold to drive generic utilization.[35] The evidence does not support a need for this policy, and in fact, MedPAC notes that use of generic drugs is already high among all Part D enrollees, including the LIS population, and that generics may not always be medically appropriate substitutes for brand medicines in a therapeutic class. Moreover, such increases in out-of-pocket expenses would fall on those least able to pay them.

On average, LIS beneficiaries are in poorer health than non-LIS patients.[36] Due to the complexity of their conditions, LIS beneficiaries fill more prescriptions than other Part D beneficiaries, on average.[37] Taking multiple medications for several conditions increases the likelihood that one or more medicines will be a brand for which there is no generic equivalent or medically appropriate substitute. This makes LIS beneficiaries particularly vulnerable to any copay increase for brand medicines.

4) Comments on discussion draft:

The discussion draft legislative text would add an out-of-pocket cap to Medicare Part D to be set at the current catastrophic threshold. It would also shift the share of drug costs paid by plans in the reinsurance period from 20 percent to 80 percent between 2020 and 2023.

As discussed earlier in this letter, PhRMA is very concerned about how the lack of an out-of-pocket cap is contributing to high cost sharing for some beneficiaries. We are heartened that the

[34] 2018 Annual Report of the Board of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Fund. June 5, 2018.
[35]MedPAC. Report to the Congress: Medicare and the Health Care Delivery System. Chapter 6: Improving Medicare Part D. June 2016.
[36] MedPAC. Report to Congress: Medicare Payment Policy. March 2012.
[37] MedPAC. A Data Book: Health care spending and the Medicare program. June 2018. Section10, p. 173.

Committees included an out-of-pocket cap in their discussion draft, which would give seniors the same protection that those with commercial coverage now have.

When paired with an out-of-pocket cap, PhRMA is not opposed to increasing the share of plan liability in the catastrophic phase of the benefit. As also discussed earlier in this letter, having Part D plan sponsors assume financial risk has been an important part of the program's success. However, the increase in plan liability in the catastrophic phase also could result in an increase in both appropriate use of plan formulary management tools and incentives to inappropriately engage in practices that may be discriminatory. Thus, it is important for the Committees to recognize that any increase in plan liability should be accompanied by sufficient protections to ensure that patients can access the medicines they need. For example, Congress should work to protect against non-medical switching and bolster a beneficiary's right to appeal coverage and tiering decisions for all medicines. Additionally, any increase in plan liability should be accompanied by robust enforcement of the current CMS Part D non-discrimination requirements.[38]

We also caution the Committees against augmenting their discussion draft with a policy to exclude coverage gap discounts from the calculation of True Out-of-Pocket Costs (TrOOP), as was recommended by MedPAC and was included in the President's budget.[39] Excluding manufacturer coverage gap discounts from the calculation of TrOOP spending would exacerbate, rather than address, beneficiary affordability challenges. By prolonging the amount of time spent in the coverage gap, this change would directly harm millions of chronically ill patients and undermine the value of an annual out-of-pocket cap. Higher out-of-pocket costs for this population would likely have the unintended consequence of increasing prescription abandonment, medication nonadherence, and premature discontinuation of therapy, leading to poor health outcomes and higher costs elsewhere in the Medicare program.

About 1.1 million non-LIS beneficiaries reached catastrophic coverage in 2016, and that number is estimated to reach 1.2 million in 2019.[40] If the calculation of TrOOP were changed to exclude manufacturer coverage gap discounts, about 65 percent (780,000) of these beneficiaries would remain in the coverage gap and no longer reach catastrophic[41] as the average annual out-of-pocket spending by non-LIS beneficiaries needed to reach the catastrophic threshold increased

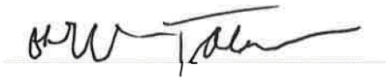
[38] Social Security Act § 1860D-11(e)(2)(D)(i), Medicare Prescription Drug Benefit Manual, Chap. 6.
[39] MedPAC. Report to the Congress: Medicare and the Health Care Delivery System. Chapter 6: Improving Medicare Part D. June 2016.; Office of Management and Budget. A Budget for a Better America: FY 2020 Budget of the U.S. Government. March 11, 2019.
[40] MedPAC. Report to the Congress: Medicare Payment Policy. Chapter 14: The Medicare prescription drug program (Part D): Status report. March 2019.; Xcenda. Analysis for PhRMA of the 2015 Medicare Part D Event Research Identifiable Files, 10% Sample. Modeling of patient completed by Xcenda based on standard benefit parameters for 2019. Part D and Medicare Advantage Part D Non-LIS enrollment estimates from the Congressional Budget Office April 2018 Medicare baseline.
[41] PhRMA analysis of Xcenda data.

by over 110% from $2,400 under current law to $5,100.[42] Patients with chronic illnesses—particularly those with congestive heart failure, diabetes, hypertension, high cholesterol, and kidney and liver failure—would be the most affected by the TrOOP change, while the relatively healthy would be unaffected. This proposed change to TrOOP would exacerbate the trend towards less meaningful coverage for sicker beneficiaries, which may threaten the future of Medicare Part D as a successful, market-based coverage model.

* * *

PhRMA appreciates the Committees' consideration of our concerns. We stand ready to engage with you on any of the issues raised in our letter.

Sincerely,



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CC: The Honorable Nancy Pelosi, Speaker of the House

The Honorable Steny Hoyer, House Majority Leader

The Honorable Kevin McCarthy, House Minority Leader

The Honorable Steve Scalise, House Minority Whip

[42] PhRMA analysis of Part D benefit parameters (from CMS Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter, April 2, 2018).