June 6, 2019

VIA EMAIL TO PartDImprovements@mail.house.gov

The Honorable Richard Neal
Chairman
Committee on Ways and Means
U.S. House of Representatives
Washington, DC 20515

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

Dear Chairman Neal and Ranking Member Brady:

On behalf of millions of seniors who need prescription drugs—and especially on behalf of seniors who need heavily rebated brand drugs to treat or cure medical conditions, some of them life-threatening—we appreciate the opportunity to comment on the Committee's bipartisan draft legislation on Medicare Part D.

This feedback is submitted solely on behalf of Patients Rising NOW (Patients Rising). Patients Rising does not act on behalf of any client or other organization. Patients Rising was organized to amplify the voice of individual patients in our nation's health policy and reimbursement discussions. Our mission is one of education and advocacy, and is grounded in the belief that empowered patients, armed with the right information, at the right time, can break down access barriers to vital therapies and services. We believe that a functioning, competitive environment is one that focuses on alignment between a program's incentives and patient needs, relies on auditable price offset rules and cost accounting principles, and facilitates long-term access to treatments while encouraging innovation toward new therapies.

As is well known to members of this Committee, the current approach to reimbursement in Medicare Part D requires unsubsidized beneficiaries (coinsurance), drug manufacturers (Discount Gap Coverage Program) and taxpayers (Catastrophic Coverage) to provide

reinsurance coverage, thus de facto subsidizing plan sponsors (who retain 100% of premiums and pay no reinsurance fees) in an extremely opaque and inefficient structure. Plan sponsors and CMS have access to tools and commercial reinsurance products to manage risk; beneficiaries, and to some extent drug manufacturers, do not. Exposure to inflated costs they can neither negotiate nor reinsure causes many individual beneficiaries to abandon their drug regimen or to exhaust their financial resources. In both cases, healthcare costs are ultimately shifted to taxpayers in the form of higher Medicaid or Medicare costs (including Low-Income Subsidy costs).

At present unsubsidized Part D beneficiaries are required to pay, in addition to the premiums they pay to plan sponsors, 5% coinsurance, without a hard cap, after entering the catastrophic phase of each benefit year. Part D plan sponsors currently base this 5% coinsurance on rebated brand drugs' full list price or gross pharmacy claims expense, a practice that impacts plan design parameters and inflates patient payment beyond 5% of the actual net cost for drugs to plan sponsors and Medicare Part D. In 2015, over a million Part D beneficiaries without subsidies entered the catastrophic phase of coverage each year, and that number is expected to rise.[1] The absence of a hard cap causes certain Part D beneficiaries to pay tens of thousands of dollars out-of-pocket during a single year, and many more to pay between $5,000 and $10,000 per year. (Patients Rising has separately commented on the HHS Office of the Inspector General's proposed rule to amend safe harbor protection for rebates: we agree with HHS policies aimed at passing savings along to patients by increasing transparency around prescription drug pricing.)

Patients Rising's feedback on the Committee's draft legislation, and our broader recommendations, can be summarized as follows:

- Beneficiaries' benefit design parameters and plan sponsors' reinsurance parameters should be dissociated, and a formal reinsurance program should be launched. This program could leverage CMS's extensive experience with structuring and managing the

[1] Juliette Cubanski 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 7, 2017. Available at: https://www.kff.org/medicare/issue-brief/no-limit-medicare-part-d-enrollees-exposed-to-high-out-of-pocket-drug-costs-without-a-hard-cap-on-spending/.

PPACA[2] cost-neutral reinsurance program,[3] but could also possibly require plan sponsors to reduce premiums by leveraging available commercial reinsurance products. The parameters of this reinsurance program (higher attachment point above $250,000 and reinsurance rate of 20% to 60%) should be designed to incentivize plan sponsors' cost containment, improve patients' therapeutic adherence, and ultimately lower healthcare costs.

- Trading partners such as drug manufacturers should not be required to provide free reinsurance coverage to plan sponsors. The Coverage Gap Discount Program is only free to plan sponsors. Ultimately, both patients and taxpayers pay. The Discount Gap Coverage Program, coupled with the current 85% stop loss reinsurance over a very low attachment point, creates a moral hazard for plan sponsors. The very high level of free reinsurance in the catastrophic phase disincentives Plan sponsors from vigorously managing high costs. Drug manufacturers thus have an opportunity to recover the reinsurance costs forced on them in the coverage gap phase in the form of inflated drug costs in the catastrophic coverage phase—costs that are disproportionately borne by taxpayers, not plan sponsors.

- All plan design parameters should be reset, based on drugs' net costs and aggregated net spending. In an ideal structure, Part D would remove individual patient cost-sharing once the initial deductible has been met. In the alternative, cost-sharing should be set to $0 after the initial coverage limit. In a prescription drug–only program, cost-sharing does not positively influence beneficiaries' behaviors. Beneficiaries have limited influence, if any, on their therapeutic regimen. They do not control prescribing nor dispensing. While cost-sharing does not deliver any incremental cost containment benefit to the program, it does increase abandonment—a leading cause of high healthcare costs.

- Any legislation that impacts reinsurance parameters in Medicare Part D should require, at least for the 3 years following its effective date, that CMS and plan sponsors report on premium increases (or decreases) caused by the legislation and caused by any subsequent failure, by plan sponsors, to avail themselves of existing commercial

[2] The Patient Protection and Affordable Care Act (Pub. L. 111–148), was enacted on March 23, 2010; the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) was enacted on March 30, 2010. These statutes are collectively referred to as "PPACA."

[3] Risk Adjustment, Reinsurance, and Risk Corridors Program Payments (45 CFR Part 153).

reinsurance coverage. The legislation should also include references to net cost and price offset accounting standards, as well as provide for periodic audit of the accuracy of the reported net costs and manufacturer rebates earned by plan sponsors in relation to point-of-sale transactions.

Responding now specifically to the Ways and Means Committee's draft legislation:

1. Patients Rising strongly supports eliminating all beneficiary out-of-pocket costs above the Medicare Part D deductible threshold.

The purpose of insurance is to protect individuals from catastrophic risk while incentivizing adherence to the prescribed drug regimen—the most effective cost containment strategy. The primary function of Medicare Part D is not to facilitate access to low-cost generics, but to protect patients whose treatment requires access to high-cost drugs. Uncapped cost-sharing based on prices that patients cannot individually negotiate or control leaves unsubsidized Part D beneficiaries exposed to unreasonable financial risk, often with life-threatening implications. In brand drug tiers, many Part D plans (PDPs) and MA-PD plans charge percentage coinsurance rather than flat copays, and nearly all plans currently base that coinsurance on list price or gross pharmacy claims expense, not the net cost to plan including rebates and other price offsets. List prices for many medicines—including some breakthrough treatments with life-changing benefit for patients—are increasing, even where net cost to payers is decreasing. At the same time, the wealth gap in the United States is growing. At a time when 40% of Americans would need to borrow or sell possessions to meet a $400 emergency,[4] a Part D program that sends a third of seniors[5] not qualifying for Low-Income Subsidy (LIS/Medicare Extra Help) into the catastrophic phase of coverage each year is arguably failing to fulfill its primary intended purpose. Unlimited personal liability is not a feature of a well-designed health insurance program. The effect of uncapped cost-sharing, which for many enrollees occurs year after year, is to deplete seniors' assets; the absence of a

[4] Alicia Adamzyck, "A third of middle-class adults can't afford to pay for a $400 emergency," May 17, 2019, cnbc.com. Available at: https://www.cnbc.com/2019/05/17/a-third-of-middle-class-adults-cant-cover-a-400-dollar-emergency.html.

[5] Erin Trish et al, "Growing Number Of Unsubsidized Part D Beneficiaries With Catastrophic Spending Suggests Need For An Out-Of-Pocket Cap," *Health Affairs* 37:7 (July 2018). Available at: https://www.healthaffairs.org/doi/10.1377/hlthaff.2018.0006.

hard cap in Part D thus ultimately shifts risks back to the Medicare program (and hence taxpayers) by moving previously unsubsidized seniors into the pool of enrollees eligible for Low-Income Subsidies.

2. Patients Rising supports, with some reservations, reducing Medicare Part D reinsurance subsidies over four years, as a change that would reduce plan sponsor moral hazard

Prescription-only insurance plans (PDPs) necessarily introduce moral hazard, and consequently must be tightly regulated, because plan sponsors do not share responsibility for health costs that occur outside the prescription drug benefit—e.g., a hospitalization for diabetic ketoacidosis that could have been prevented by timely, affordable access to standard-of-care analog insulin. MA-PDs may also be financially incentivized by risk scoring that increases payment if co-morbidities result from limited treatment access (e.g. cardiovascular disease diagnosed as a result of underusing insulin needed to treat diabetes)

Part D's current structure, with 80% government reinsurance in the catastrophic phase, further disincentivizes plan sponsors from optimizing patient access to the most effective treatments by reducing barriers to treatment up front. Both step therapy (by delaying access to the treatment the patient's doctor has deemed most likely to be effective) and excessive cost-sharing (including by basing coinsurance on inflated list price) can increase the likelihood that a patient will enter the catastrophic phase of coverage. A system where insurers' financial liability is very low in the catastrophic phase creates moral hazard first, under present plan designs, by incentivizing plans to prefer drugs with high list prices and large rebates (driving enrollees more rapidly through the coverage gap and into the catastrophic phase, where payer responsibility is low) and second, by incentivizing payers to act with reduced regard for potential long-term increases in therapeutic cost, as a plan may realize savings up front by pushing a patient into lower-cost treatment, but if delaying optimal treatment ultimately results in higher treatment costs, those will be largely externalized to the government reinsurer and thus to taxpayers. A system where the plan sponsor bears more financial risk in the catastrophic phase reduces perverse incentives in earlier phases of the plan year and thus contributes to improved patient health.

See, however, our comments in 3(3)(c), below, regarding private reinsurance and reporting by plan sponsors.

3. In response to the request for further comment on cost issues: Patients Rising encourages the Committee to (1) recognize that the current failure to distinguish publicly between list

price and net cost to plans, Medicare, and taxpayers must be addressed as part of any approach to "high cost drugs"; (2) recognize that however costs are shared within the system, basing patient payment on net cost (as proposed by HHS/OIG) is crucial to reduce moral hazard for plan sponsors and their PBM negotiators to prefer drugs with high list prices and large rebates; and (3) ensure that the premium impacts of reducing Medicare's reinsurance role are both minimized and clearly identified in public reporting.

(1) High Cost Drugs. Policy solutions to reduce cost must logically begin from a transparent and accurate definition of cost. Even when soliciting comment on "high cost drugs," and more particularly when developing legislation in responding to those comments, it is crucial that Ways and Means Committee members begin by distinguishing list price from net cost to plans, Medicare, and taxpayers. The Committee should also recognize that growing taxpayer burden and growing patient out-of-pocket spending burden are not correlated in all drug classes. Indeed, for medications like insulins, the Medicare/taxpayer burden—linked to net cost—is decreasing (on a per-unit basis), while patient out-of-pocket spending—which most plan sponsors currently choose to base on gross claims expense—is growing with rising list prices (i.e., there may be an inverse relationship between costs to plans or taxpayers and cost to individuals). The correct legislative response(s) to cost issues where patient burden is driven primarily by insurer practice may be different from legislative responses to high drug cost where net per-unit cost to plans and payers is also high or increasing. Ways and Means Committee members should further recognize that generating an artificially onerous individual patient cost burden is not an appropriate mechanism for managing rising U.S. drug prices. Patients have limited choices in treatment options, and where treatments are in fact medically interchangeable patients will respond to relatively small financial incentives to choose lower-priced alternatives; plan sponsor practices such as adverse formulary tiering and step therapy requirements, for Part D enrollees who do require treatment with brand drugs, are not the only mechanisms for negotiating discounts with manufacturers: the first of these practices, as HHS/OIG has proposed, should be eliminated, and the second reevaluated. (The proposed shift to transparent net pricing to Part D enrollees at the pharmacy point of sale would deliver the further benefit of generating more accurate data to healthcare economists and policy experts seeking to analyze which drugs in Part D are in fact "high cost" to plans and CMS, and in which cases net per-patient costs are declining—a project that has been significantly hindered because publicly available CMS data on drug cost is (gross) claims data.)

(2) Cost-sharing among beneficiary, plans, and manufacturers. In response to the Committee's question on cost-sharing, Patients Rising wishes to underscore our concern that net cost accounting be used for all purposes, including sharing of costs among trading partners and, within plans, for purposes of calculating any fixed copays and any percentage coinsurance for enrollees. For moderate-income beneficiaries, coverage gap coinsurance based on net cost (not list price) for heavily rebated medications like insulin can mean the difference between taking medications as prescribed versus rationing (an IQVIA study released in May 2018 indicated that at $250/month out of pocket, 69% of patients will abandon a prescription).[6] Basing beneficiary coinsurance on net cost, rather than list price, will further save many enrollees from ever reaching the catastrophic phase of coverage. The legislation that originally created Medicare Part D specified enrollee access to net/negotiated price. That provision was significantly modified in the regulatory process to facilitate plan sponsors' elective choice to base patient payment on list price—a choice that has likely been a key driver of the gross-to-net bubble in U.S. pricing for brand medications frequently prescribed in Part D, such as analog insulins. Patients Rising agrees with HHS's view that the current rebate system disadvantages patients and is a potential barrier to lowering drug costs. We believe that the healthcare system should be designed to pass through savings to beneficiaries, which would improve access and affordability as a result.

(3) Other improvements with respect to low-to-moderate income Part D beneficiaries: Reporting on any impact on premiums of changes to reinsurance. Finally, any legislation that shifts reinsurance risk from Medicare to plans, in a manner that isn't cost-neutral, should include provisions to minimize premium impact on individual beneficiaries and to report transparently on any premium changes attributable to the modification of reinsurance parameters.

Since 2006, Part D's plan sponsors have treated a good (rebates) generated directly by the pharmacy transactions of a subset of beneficiaries as a tool to gain competitive advantage by offering lower premiums. Actuarial firm Milliman has estimated that the impact on premiums from a shift to net cost accounting (and net-cost-based patient payment) in MA-PD plans would be minimal, and that impact in PDPs (which typically

[6] IQVIA, "Patient Affordability Part Two: Implications for Patient Behavior and Therapy Consumption," May 18, 2018. Available at: https://www.iqvia.com/locations/united-states/patient-affordability-part-two.

negotiate higher rebates) would be somewhat greater.[7] Economists have separately argued that the premium impact of a hard cap on out-of-pocket costs, in isolation, would be minimal ($0.40-1.31 per enrollee impact estimated based on 2015 data).[8] The legislation as drafted by the Committee on Ways and Means, however, proposes that the Part D hard cap be effected contemporaneously not only with anticipated rebate reforms contemplated by HHS OIG (which would shift the cost basis for Part D enrollees' coinsurance to a net cost basis) anticipated to take effect in January 2020—but also contemporaneously with insurers taking on a significantly higher share of responsibility for costs in the catastrophic phase, as the government reduces its contributions in 20% increments beginning in 2020. Without adequately communicating the impact of reducing government responsibility in the catastrophic phase, the public may be enticed unfairly to blame any premium increase caused primarily by this third change on the specific patients who have seen their cost-sharing burden reduced by the first two changes. Shifting risks from the national pool of all Medicare beneficiaries to any smaller subset of the population introduces inefficiencies, requiring plans to reinsure and/or increase premiums because multiple national carriers—or plans at a smaller state or even county level—would need to account for risk their smaller populations might include a rare 1 in a million or 1 in 10 million high-cost individual. The Committee on Ways and Means should therefore consider amending its draft legislation to specify: (a) reinsurance requirements for carriers; (b) whether reinsurance should be handled at the national holding company level or at some other level (because a handful of insurers control nationwide PDP plans, there is a strong argument for requiring management of risk at the national level to the greatest extent possible); and (c) reporting requirements over the four-year phase-in period, where carriers must report on (a) and (b) as well as specify the actual premium impact resulting from a legislated gradual reduction of Reinsurance Payment amounts. Insurers have demonstrated considerable willingness to publicly stigmatize people with certain medical conditions for "driving up premiums"; recognizing the extent to which a change in premiums reflects privatizing and making transparent a cost formerly borne by Medicare should thus be a priority for legislators and administrators.

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[7] Deanna Bell et al, "An end to manufacturer rebates as we know them today?" Milliman White Paper, May 2019. Available at: http://www.milliman.com/uploadedFiles/insight/2019/end-manufacturer-rebates.pdf.

[8] Trish et al, "Growing Number of Unsubsidized Part D Beneficiaries With Catastrophic Spending."

Conclusion: Combining market-driven revenue for corporate actors with socialized risk rarely turns out well for U.S. taxpayers. The purpose of a government program that contracts risk to private insurers is not, in the end, for those insurers to burden taxpayers by extracting the savings of more costly Part D members (with little regard for long-term population health) and then shifting a high-cost pool back to the government, either doing so annually during the catastrophic phase of coverage or doing so permanently via the LIS program after depleting enrollees' savings in the absence of a hard copay cap. A proper public-private partnership, by capping seniors' annual out-of-pocket costs and increasing private plan sponsors' risk in the catastrophic phase, could work to preserve the independence of a higher percentage of seniors over a longer period of time, incentivize insurers to optimize treatment access in the initial and coverage gap phases of the plan year—and encourage CMS and plan sponsors to evaluate more carefully the long-term financial impact both of rationing driven by artificially inflated coinsurance and of increasing overall treatment cost by delaying the most medically effective treatment via step therapy.

Patients Rising appreciates the opportunity to provide feedback on the Committee's proposed legislation for Part D reform. We remain enthusiastic about participating in a continuing dialogue as we move toward our shared goal of ensuring that Americans have access to high quality, cost-effective care.

Sincerely,

Terry Wilcox

Terry M. Wilcox
Co-Founder and Executive Director, Patients Rising Now