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May 3, 2021

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

The Honorable Anna Eshoo  
House Subcommittee on Health  
2125 Rayburn House Office Building  
Washington, DC 20515

The Honorable Cathy McMorris Rodgers  
House Committee on Energy and Commerce  
2322-A Rayburn House Office Building  
Washington, DC 20515

The Honorable Brett Guthrie  
House Subcommittee on Health  
2322-A Rayburn House Office Building  
Washington, DC 20515

**RE: House Committee on Energy and Commerce Subcommittee on Health Hearing on Negotiating A Better Deal: Legislation to Lower the Cost of Prescription Drugs**

Dear Chairman Pallone, Chairwoman Eshoo, Ranking Member McMorris Rodgers, and Ranking Member Guthrie,

The [Alliance for Aging Research](http://www.agingresearch.org) (Alliance) is the leading nonprofit organization dedicated to accelerating the pace of scientific discoveries and their application to vastly improve the universal experience of aging and health. Additionally, in 2020 the Alliance started [Project LOOP \(Lowering Out-of-Pocket\) Costs](#), an ad hoc coalition effort that coordinates dozens of national patient and provider organizations that support creating an annual out-of-pocket (OOP) cap in the Medicare Part D program and implementing a smoothing mechanism to spread beneficiaries' financial liability over a longer timeframe to promote affordability. We thank you for this opportunity to submit comments for the record for the May 4, 2021, hearing, "*Negotiating A Better Deal: Legislation to Lower the Cost of Prescription Drugs*." We very much appreciate your leadership in holding a hearing on this critical issue and urge you to work to craft and advance bipartisan legislation to address the rising cost of healthcare for America's older adults, starting with reducing OOP costs for prescription drugs.

All people should have access to high-quality healthcare. However, quality must be paired with affordability, as Medicare beneficiaries are increasingly exposed to high OOP costs for medically

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necessary medications. There is a growing body of evidence<sup>1</sup> that shows increases in patient OOP costs lead to lower drug adherence, higher mortality, and increased overall healthcare costs. Accordingly, the primary policy goal of any prescription drug legislation must be to improve patient affordability and ensure access to care. Furthermore, any savings resulting from drug pricing legislation should be invested back into the Medicare program to strengthen the program and provide needed services and expanded benefits. Through this statement for the record, we seek to delineate key provisions included in the bills under consideration and discuss how these policies will improve patient affordability or, in some cases, hinder patient access.

### **Ensuring Affordability in the Part D Program**

Currently, there is no limit on Medicare beneficiaries' potential OOP costs for prescription drugs. This absence exposes older adults and individuals with disabilities to potentially devastating costs that can jeopardize their finances and health. For example, the Medicare Payment Advisory Commission notes, "an increasing number of beneficiaries are meeting the OOP threshold with a single claim. In 2010, just 33,000 beneficiaries filled a prescription in which a single claim would have been sufficient to meet the OOP threshold. By 2016, that number rose more than 10-fold to over 360,000."<sup>2</sup> In 2019 alone, 3.8 million Medicare beneficiaries experienced OOP costs of more than \$5,100.<sup>3</sup>

The inability to pay for OOP costs can often make the difference between health and sickness and, in some cases, lead to lost independence and even death. Since it first was implemented 15 years ago, the Part D program has helped make prescription drugs more accessible and affordable for most Medicare beneficiaries. *However, Medicare Part D is the only type of health insurance in America that does not have a limit on OOP expenses for prescription drugs, keeping access out of reach for many of those most in need of treatment.*

Proposals to create an annual cap structure would minimize exposure to financially overwhelming drug costs for many beneficiaries, especially those who live on fixed and/or limited incomes. The Alliance favors cap proposals that provide the most relief for Medicare Part D beneficiaries through instituting an annual OOP cap threshold, lower than those currently proposed (or, as low as possible). The Alliance also supports broadening eligibility for the low-income subsidy (LIS) program, which would help many financially vulnerable older adults who do not currently qualify for the LIS program.

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<sup>1</sup> Chandra, Amitabh, et al. "The Health Costs of Cost-Sharing." National Bureau of Economic Research. 8 Feb 2021. [www.nber.org/papers/w28439](http://www.nber.org/papers/w28439).

<sup>2</sup> Medicare Payment Advisory Commission. "The Medicare Prescription Drug Program (Part D): Status Report." March 2019. [http://medpac.gov/docs/default-source/reports/mar19\\_medpac\\_ch14\\_sec.pdf](http://medpac.gov/docs/default-source/reports/mar19_medpac_ch14_sec.pdf).

<sup>3</sup> Centers for Medicare and Medicaid Services. "Medicare Part D Utilization: Number of Part D Utilizers, Average Annual Prescription Drug Fills<sup>1</sup> and Average Annual Gross Drug Cost Per Part D Utilizer, by Part D Coverage Phase and Area of Residence (Calendar Year 2019)." Accessed 30 Apr 2021. <https://www.cms.gov/files/document/2019cpsmdcrutlznd11.pdf>.

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**Smoothing Out OOP Expenses**

Even with an annual OOP cap, patients face initial costs often in the hundreds or thousands of dollars prior to hitting a proposed OOP maximum. To increase the affordability of prescription drugs in the Part D program, Medicare Part D plans should be required to offer Part D beneficiaries the option of "smoothing" cost-sharing payments throughout the remaining months of a plan year. A smoothing mechanism would allow Medicare beneficiaries to pay costs through zero-interest installments over the course of a year. This flexibility would allow beneficiaries the ability to avoid large lump-sum expenses for necessary medicines that can serve as a deterrent to filling prescribed medications. This concept—in addition to an annual cap—has broad bipartisan support as illustrated by its inclusion in H.R. 3, H.R. 19, and the Senate Finance proposal S. 2543 in the 116<sup>th</sup> Congress. The Center for Medicare and Medicaid Innovation (CMMI) also began a demonstration project in 2020 that provided Part D plans the option in the second year of the demo to offer beneficiaries the ability to smooth out their OOP costs over the plan year.<sup>4</sup> Unfortunately, there was minimal participation in the voluntary demonstration, validating the need for Congress to legislate this important change.

We appreciate that these comprehensive drug pricing bills have included smoothing provisions. However, these proposals often have strict eligibility criteria, requiring beneficiaries to have OOP costs accrue in the thousands of dollars before patients can access the flexibility. This is not sufficient. For a smoothing mechanism to be meaningful, Congress must ensure Medicare Part D beneficiaries can access the benefit when it is most useful and will have the greatest benefit in enhancing patients' ability to afford medications.

To maximize the patient population who would benefit from a smoothing mechanism, Congress should not incorporate a minimum OOP expenditure requirement for beneficiaries to qualify for cost smoothing. Under the previously mentioned CMMI demonstration, there is no prescribed minimum OOP threshold for eligibility. Additionally, Congress should incorporate sufficient patient protections, including a payment grace period and the ability to apply for a hardship appeal for extenuating circumstances, to enable continued access to the smoothing benefit. Further, provisions should be incorporated to ensure prescription drug plans are incentivized to operationalize and support patient-centered methods for smoothing payment collection while also lessening the potential for some losses that plans may experience.

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<sup>4</sup> Centers for Medicare & Medicaid Services, Center for Medicare and Medicaid Innovation. "Part D Payment Modernization Model Request for Applications for CY 2022." 16 Mar. 2021. <https://innovation.cms.gov/media/document/partd-payment-modernization-cy22rfa>.

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### **Moderating Drug Prices**

Older adults are all too familiar with having the price of their prescription medications increase from year-to-year. The reasons behind these price increases are complex, but the result is higher OOP costs for patients. According to an analysis by the Kaiser Family Foundation, of the 2,879 reported brand-name and generic drugs covered by Medicare Part D plans, 60 percent had list price increases that exceeded the inflation rate between July 2016 and July 2017, which was 1.7 percent.<sup>5</sup> When the list price of a drug increases over a short duration of time, Medicare beneficiaries will have to pay more for their medications through cost-sharing. Previous policies in the Medicaid program required manufacturers to issue an additional rebate when average manufacturer prices for a drug increase faster than inflation, as measured by the Consumer Price Index for All Urban Consumers (CPI-U).

The Alliance is in favor of inflationary cap proposals that would require manufacturers to pay a rebate if the prices of Medicare Part D drugs increase above the rate of inflation without justification. The savings that result from placing an inflationary cap in the Part D program must be invested back into the program to create additional benefits and improvement, such as expanding Medicare coverage to include dental, vision, and hearing services. Older adults who do not have access to these services are at higher risks for depression, social isolation, and overall higher medical costs.

### **Part D Restructuring**

As the Committee considers legislation to restructure Part D, we encourage Congress to focus on policies that modernize the program. The program and participants have experienced shifts that merit rebalancing to ensure Part D continues to operate and distribute risk in its intended manner. For example, MedPAC's 2020 report to Congress noted that private plan sponsors are now at risk for a much lower percentage of enrollees' benefit spending than during the early years of the Part D program. Between 2007 and 2017, among enrollees without Part D's LIS, the share of basic benefit costs for which plan sponsors were responsible declined 53 percent to 29 percent.<sup>6</sup>

The Committee should prioritize true regulatory reforms that can achieve savings, be reinvested into the Medicare program, and not adversely impact beneficiary access to care. We support MedPAC's recommendations to realign incentives for drug manufacturer rebates, change insurer liability in the catastrophic phase, and reduce government reinsurance liability.

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<sup>5</sup> Cubanski, Juliette, and Tricia Neuman. "Assessing Drug Price Increases in Medicare Part D and the Implications of Inflation Limits." Kaiser Family Foundation. 18 Oct 2019. [www.kff.org/medicare/issue-brief/assessing-drug-price-increases-in-medicare-part-d-and-the-implications-of-inflation-limits/](http://www.kff.org/medicare/issue-brief/assessing-drug-price-increases-in-medicare-part-d-and-the-implications-of-inflation-limits/).

<sup>6</sup> Medicare Payment Advisory Commission. "Report to The Congress Medicare and the Health Care Delivery System: June 2020." June 2020. [www.medpac.gov/docs/default-source/reports/jun20\\_reporttocongress\\_sec.pdf?sfvrsn=0](http://www.medpac.gov/docs/default-source/reports/jun20_reporttocongress_sec.pdf?sfvrsn=0).

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### **International Reference Pricing**

The Alliance firmly opposes using an International Pricing Index (IPI) to be used as the basis for pricing drugs in Medicare. Implementation of international reference pricing in the United States would effectively endorse the use of discriminatory cost-effectiveness standards utilized by foreign governments. Most countries included in IPI proposals, such as the United Kingdom, Canada, and France, make drug reimbursement and coverage decisions based on inherently flawed cost-effectiveness assessment methodologies tied to the quality-adjusted life-year (QALY). These QALY assessments assign a value between 0 (death) and 1 (perfect health) to the people for whom a given treatment is intended. People who are sicker, older, or have a disability are assigned lower values. When applied to health care decision-making by insurance companies, this can mean that treatments for these more vulnerable people are deemed "too expensive" and therefore "not cost-effective" to cover.

Objections about reliance upon QALY-based methodologies also extend to race. For example, Black Americans have an average life expectancy lower than whites.<sup>7</sup> As such, treatments for conditions that disproportionately affect Black individuals may be assessed as lower value. Furthermore, Black and Latinx communities experience Alzheimer's disease at higher rates than the general population. Data from the CHAP study shows that 18.6 percent of Black Americans and 14 percent of Hispanic Americans aged 65 and older have Alzheimer's disease compared to 10 percent of White Americans.<sup>8</sup> Persistent systemic healthcare inequalities exist not only in patient-facing care dynamics but also in methodologies that reinforce and perpetuate historical injustices. It is essential that Congress does not codify the use of standards that fail to incorporate equity considerations and inadvertently promote structural discrimination. Using this methodology will exacerbate existing and long-standing health disparities and thwart efforts to advance health equity.

There has been long-standing, bipartisan opposition to the use of the QALY; four Administrations – three Republican and one Democratic, over 37 years, have made clear the QALY is not appropriate for use in American healthcare programs. The Rehabilitation Act of 1973, signed into law by President Nixon, ensured individuals with disabilities would not "be excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination" under any program offered by any executive agency, including Medicare.<sup>9</sup> Further, Title II of the Americans with Disabilities Act (ADA), enacted in 1990 by President George H.W. Bush, extended this protection to state and local governments'

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<sup>7</sup> Arias, Elizabeth, et al. "Provisional Life Expectancy Estimates for January through June 2020." Centers for Disease Control and Prevention. February 2021. Accessed April 30, 2021. <https://www.cdc.gov/nchs/data/vsrr/VSRR10-508.pdf>.

<sup>8</sup> Rajan KB, Weuve J, Barnes LL, McAninch EA, Wilson RS, Evans DA. "Population Estimate of People with Clinical AD and Mild Cognitive Impairment in the United States (2020-2060)." *Alzheimers Dement* 2021;17. In press.

<sup>9</sup> 29 U.S. Code § 794, 2017.

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programs and services.<sup>10</sup> Further, in 1992, President George H.W. Bush's Administration established it was an ADA violation for states to employ cost-effectiveness standards in Medicaid out of concern it would discriminate against people with disabilities.<sup>11</sup> More recently, a ban on the use of the QALY in Medicare was included in the Affordable Care Act.<sup>12</sup>

Moreover, in 2019, the National Council on Disability (NCD), an independent federal agency, cautioned against relying on the QALY in any federal program, finding that relying on the QALY to make coverage decisions would violate United States disability and civil rights laws.<sup>13</sup> Additionally, the 2020 Democratic National Committee platform stated, "Democrats will ensure that people with disabilities are never denied coverage based on the use of quality-adjusted life-year (QALY) indexes."<sup>14</sup> Given the negative impact on patients and clear civil rights implications, policies that rely on QALY-driven international pricing metrics should be prohibited.

Of additional concern is that international reference pricing policies would severely impact medical innovation and access to new medicines. The CBO offered a conservative estimate that the IPI would reduce industry spending on research and development between \$500 billion to \$1 trillion and decrease the number of new drugs between 8 to 15 over ten years.<sup>15</sup> Further, reductions in research investments would disproportionately impact hard-to-treat conditions such as Alzheimer's disease, which presents an enormous burden not only on medical resources and costs but on family caregivers and communities.<sup>16</sup> Another independent analysis of the IPI has determined that small and emerging biotech companies would be particularly hit hard. It is expected there will be 61 fewer medicines making it to market from these companies over ten years.<sup>17</sup> It is essential that the Committee removes provisions from legislation that seek to lower prescription drug prices through an IPI.

## **Conclusion**

The Alliance thanks the Committee leadership for its commitment to lowering OOP prescription drug costs for Part D beneficiaries. We look forward to working with the Committee to advance proposals

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<sup>10</sup> 42 U.S. Code § 12131, 1990.

<sup>11</sup> Sullivan, Louis. "Oregon Health Plan is Unfair to the Disabled." The New York Times. 1 Sept 1992

<sup>12</sup> 42 U.S. Code § 1320e

<sup>13</sup> National Council on Disability. "Quality-Adjusted Life Years and the Devaluation of Life with Disability." 6 Nov 2019.

[www.ncd.gov/sites/default/files/NCD\\_Quality\\_Adjusted\\_Life\\_Report\\_508.pdf](http://www.ncd.gov/sites/default/files/NCD_Quality_Adjusted_Life_Report_508.pdf).

<sup>14</sup> Democratic National Committee. "Achieving Universal, Affordable, Quality Health Care." <https://democrats.org/where-we-stand/party-platform/achieving-universal-affordable-quality-health-care/>.

<sup>15</sup> Congressional Budget Office. "Effects of Drug Price Negotiation Stemming from Title 1 of H.R. 3, the Lower Drug Costs Now Act of 2019, on Spending and Revenues Related to Part D of Medicare." 11 Oct 2019. [www.cbo.gov/publication/55722](http://www.cbo.gov/publication/55722).

<sup>16</sup> Vital Transformation. "Alzheimer's Drug Discovery: Potential Impacts of H.R. 3." 22 Apr 2021.

[www.agingresearch.org/app/uploads/2021/04/Alzheimers-H.R.-3-Impact\\_FINAL.pdf](http://www.agingresearch.org/app/uploads/2021/04/Alzheimers-H.R.-3-Impact_FINAL.pdf).

<sup>17</sup> Vital Transformation. "H.R. 3 and Reference Pricing: Total Market Impact." 22 Mar 2021. [vitaltransformation.com/wp-content/uploads/2021/04/HR3\\_4.5.21\\_v10.1.pdf](http://vitaltransformation.com/wp-content/uploads/2021/04/HR3_4.5.21_v10.1.pdf).

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that will improve prescription drug access for older adults. If you have questions for our organization or if we can be of any assistance to you on these or other matters impacting older Americans and people with disabilities, please contact the Alliance's President and CEO, Sue Peschin, at [speschin@agingresearch.org](mailto:speschin@agingresearch.org), or the Alliance's Vice President of Public Policy, Michael Ward, at [mward@agingresearch.org](mailto:mward@agingresearch.org). Thank you for your consideration of our concerns and recommendations. We stand ready to serve as a resource to you and your staff as these important discussions continue.

Sincerely,



Susan Peschin, MHS  
President and CEO



Michael Ward, MS  
Vice President of Public Policy