



1700 K Street, NW | Suite 740 | Washington, DC 20006

T 202.293.2856

www.agingresearch.org

[@Aging_Research](https://twitter.com/Aging_Research)

July 20, 2021

The Honorable Ron Wyden
Senate Committee on Finance
219 Dirksen Senate Office Building
Washington, DC 20510

RE: Principles for Drug Pricing Reform

Dear Chairman Wyden,

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 very much appreciate Chairman Wyden's leadership 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 necessary medications. There is a growing body of evidence¹ 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. We look forward to the opportunity to meet with you soon. In the meantime, we want to share thoughts on key provisions under consideration for prescription drug pricing legislation

¹ Chandra, Amitabh, et al. "The Health Costs of Cost-Sharing." National Bureau of Economic Research. 8 Feb 2021. www.nber.org/papers/w28439.

and delineate how these policies are likely to enhance 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."² In 2019 alone, 3.8 million Medicare beneficiaries experienced OOP costs of more than \$5,100.³

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). While the Prescription Drug Pricing Reduction Act's (PDPRA - S. 2543 in the 116th Congress) \$3,100 cap is a significant step forward from the status quo, patients report affordability concerns when monthly OOP costs exceed \$200,⁴ which extrapolates to \$2,400 annually. We encourage you to explore lowering the cap to match beneficiaries at this point of need. 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.

² 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.

³ Centers for Medicare and Medicaid Services. "Medicare Part D Utilization: Number of Part D Utilizers, Average Annual Prescription Drug Fills¹ 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>.

⁴ PAN Foundation. Snapshot https://www.panfoundation.org/app/uploads/2021/01/PAN-Foundation_MC_January-2021-Survey.pdf

Limiting Part D Beneficiary Out-of-Pocket Expenses and Improving Affordability

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 in the PDPRA (S. 2543) in the 116th 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.⁵ Unfortunately, there was minimal participation in the voluntary demonstration leading to its cancellation,⁶ further 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 instruct the Secretary of the U.S. Department of Health and Human Services to promulgate regulations that will include appropriate 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.

⁵ 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>.

⁶ Centers for Medicare & Medicaid Services, Center for Medicare and Medicaid Innovation. "Part D Payment Modernization Model." Updated 14 July 2021. Accessed 20 July 2021. <https://innovation.cms.gov/innovation-models/part-d-payment-modernization-model>

Moderating Annual Increases in 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.⁷ 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. At the same time, we encourage the Committee to evaluate whether such a policy would lead companies to increase launch prices to counteract an inflationary cap.

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.⁸

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.

⁷ 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/.

⁸ 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.

Expanding Coverage for Dental, Hearing, and Vision Services

We support the expansion of the standard Medicare benefit to include dental, hearing, and vision services. While some Medicare Advantage plans and Medicaid programs recognize the importance of these services and provide coverage, there are still far too many older adults who need these services and are unable to access them. People who do not have access to these essential services are at higher risks for depression, social isolation, and overall higher medical costs. If the final package results in significant savings to the Medicare program, these savings should be reinvested to cover dental, vision, and hearing services for beneficiaries. However, creating sufficient savings to cover the cost of these services should not come at the expense of adopting policies that would restrict access to care or discriminate against the populations served by the Medicare program, such as through international reference pricing or a health technology assessment (HTA) board that uses quality-adjusted life year (QALY)-based cost-effectiveness analysis.

Use of QALY Methodology in Price Negotiation

The Committee should reject consideration of use of the QALY or QALY-derivative methodology such as the equal value of life years gained (evLYG) in prescription drug price negotiation. 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.⁹ As such, treatments for conditions that disproportionately affect Black and Latinx individuals, such as Alzheimer's disease, may be assessed as lower value. 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.¹⁰ 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.

⁹ 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>.

¹⁰ 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.

Beyond front-line concerns about the discriminatory impacts of QALYs, both the QALY and the evLYG fail to accurately capture the value of therapeutics that may not extend life, but address symptoms of the primary condition and improve quality of life. The Institute for Clinical and Economic Review (ICER), the leading developer of QALY-based value assessments in the U.S., largely purports that QALYs are a neutral calculation or, in the words of Sgt. Joe Friday, a “just the facts” analysis. However, any cost assessment methodology is subject to the assumptions and factors one chooses to include, and ICER’s value calculations tend to be payer-centric and exclude important considerations such as impact on caregivers, productivity, societal impact, and equity concerns.¹¹

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.¹² 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’ programs and services.¹³ 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.¹⁴ More recently, a ban on the use of the QALY in Medicare was included in the Affordable Care Act.¹⁵

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.¹⁶ 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.”¹⁷ Given the negative impact on patients and clear civil rights implications, policies that rely on QALY-driven pricing metrics should be prohibited.

Of additional concern is that QALY and QALY-derivative policies would severely impact medical innovation and access to new medicines. For example, the CBO offered a conservative estimate that an

¹¹ Pyenson, Bruce, et al. “Assessing the Value of Therapies in Alzheimer’s Disease: Considerations to Create a Practical Approach to Value.” 12 May 2021. https://www.agingresearch.org/app/uploads/2021/05/Assessing-the-Value-of-Therapies-in-Alzheimer%E2%80%99s-Disease_FINAL.pdf

¹² 29 U.S. Code § 794, 2017.

¹³ 42 U.S. Code § 12131, 1990.

¹⁴ Sullivan, Louis. “Oregon Health Plan is Unfair to the Disabled.” *The New York Times*. 1 Sept 1992

¹⁵ 42 U.S. Code § 1320e

¹⁶ 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.

¹⁷ Democratic National Committee. “Achieving Universal, Affordable, Quality Health Care.” <https://democrats.org/where-we-stand/party-platform/achieving-universal-affordable-quality-health-care/>.

International Pricing Index, as proposed in H.R. 3, 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.¹⁸ 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.¹⁹ Another independent analysis of the International Pricing Index 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.²⁰

For policymakers and academics alike, it is important to understand that QALYs were a step along the path to value assessment, not the end point. Ongoing efforts to advance patient-centered value assessment should be invested in and supported. At the same time, we should not codify reliance on methodologies in the interim that reinforce health disparities and disincentivize research into conditions that disproportionately impact individuals with disabilities or chronic conditions and older adults.

Addressing Prescription Drug Costs Holistically

Addressing patients' OOP costs for prescription drugs is a vital concern, as is ensuring the long-term viability of the Medicare program. In this discussion, it is important to recognize that many stakeholders have a role in reducing costs. Manufacturers have control over list prices, but that is just one piece of the puzzle. Pharmacy benefit managers charge manufacturers fees for preferred formulary placement and negotiate preferred acquisition cost rates. The savings from these negotiations generate financial gains for large PBMs – a business model so profitable that CVS Health was able to purchase Aetna, a large insurance plan – and shared gains with insurers and employers. At the same time, costs associated with these arrangements may be incorporated into list prices. In Medicare Part B, care providers by law receive an add-on payment (average sales price [ASP] + 6%) for administration that – due to its structure as a percentage of ASP – may incentivize prescribing practices. Addressing the ASP issue will grow in importance as precision medicine and additional biologics, which are likely to have immense clinical benefit but increased manufacturing complexity and costs, come into the market. Other drug pricing programs, like the 340B program, are well intentioned but in need of reform to ensure the benefit is well-targeted and to prevent program abuse.

Fixing prescription drug pricing and costs cannot be done well without addressing these systemic issues. Stakeholders at each step of the path to a beneficiary receiving a medication have a role to play

¹⁸ 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.

¹⁹ 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.

²⁰ 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.

in addressing costs; we encourage the Committee to take this opportunity to make common-sense reforms to address these issues and redirect savings to priorities that will improve coverage and patient care.

Conclusion

The Alliance thanks Chairman Wyden and the Senate Finance Committee for your commitment to lowering OOP prescription drug costs for Part D beneficiaries. We look forward to working with the Committee to advance proposals 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, or the Alliance's Vice President of Public Policy, Michael Ward, at 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