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35 Years of Patient Advocacy

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August 31, 2021

President Joseph R. Biden
The White House
1600 Pennsylvania Avenue, NW
Washington, DC 20500

RE: Principles for Lowering Prescription Drug Prices

Dear President Biden,

On behalf of the Alliance for Aging Research (Alliance), we are writing today to offer support for many of the outlined White House Principles for Lowering Prescription Drug Prices, as well as share our concerns regarding the use of international reference pricing or a QALY-based domestic HTA body for Medicare direct negotiation. Separately, we request a meeting with members of your team in the coming weeks to discuss these issues in greater detail.

We enthusiastically agree with your declaration that "Health care is a right, not a privilege, and ensuring that every American has access to the quality and affordable health care they need is the most important task of our country," The Alliance supports the Affordable Care Act, and has opposed efforts since its passage to dismantle it. We also share your belief that quality healthcare must be paired with affordability. As an advocacy organization for older adults, we are concerned about how Medicare beneficiaries are increasingly exposed to high out-of-pocket (OOP) costs for their overall healthcare costs, including medically necessary medications. A growing body of evidence[1] shows increases in patient OOP costs lead to lower drug adherence, higher mortality, and increased overall healthcare costs. In 2020, the Alliance started Project LOOP (Lowering Out-of-Pocket) Costs. This ad hoc coalition effort coordinates dozens of national patient and provider organizations to advance affordability for Part D beneficiaries. Project LOOP is currently focused on creating an annual OOP cap in the Medicare Part D program and implementing no-cost payment installments, known as a smoothing mechanism, to spread beneficiaries' financial liability over a longer timeframe to promote affordability.

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

The primary policy goal of any prescription drug legislation should be to improve patient affordability while preserving access to care. In addition, **any savings to Medicare resulting from drug pricing legislation should be invested back into the program to strengthen needed services and expand benefits.** At the same time, we must ensure that Medicare's coverage and reimbursement decision-making processes adhere to U.S. civil rights laws and avoid incorporating methodologies that discriminate against older adults and disabled individuals.

We very much appreciate your leadership on this critical issue. Our thoughts on the White House Principles, and key provisions under consideration for prescription drug pricing legislation in Congress, are below.

Prescription Drug Pricing Proposals the Alliance for Aging Research Supports

Cap out-of-pocket costs in Medicare Part D

Medicare is the only major insurer in the U.S. that lacks an OOP maximum for prescription drug costs. This absence exposes older adults and individuals with disabilities to potentially devastating costs that jeopardize their finances and health. For example, the Medicare Payment Advisory Commission (MedPAC) 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]

Proposals to create an annual cap structure would minimize exposure to financially overwhelming drug costs for many beneficiaries, especially those who live on fixed 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. Patients report affordability concerns when monthly OOP costs exceed $200,[4] which extrapolates to $2,400 annually. We encourage you to work with Congress to coalesce around a proposed annual cap of $2,400 or lower to provide meaningful relief for beneficiaries living on fixed or limited incomes.

Permit no-cost installment payments (smoothing mechanism)

Even with an annual OOP cap, patients face initial costs often in the hundreds or thousands of dollars before 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

[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 Fills[1] 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

mechanism would allow Medicare beneficiaries to pay costs through zero-interest installments over the course of a year. This would enable beneficiaries to avoid large lump-sum expenses, a barrier that can serve as a deterrent to filling prescribed medications. In addition to an annual cap, this concept 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,[6] further validating the need 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, Medicare Part D beneficiaries must be able to access the benefit when it is most useful and will have the most significant benefit in enhancing patients' ability to afford medications.

To maximize patients' benefit from a smoothing mechanism, legislation should avoid mandating a minimum OOP expenditure requirement for beneficiaries to qualify for cost smoothing. Under the previously mentioned CMMI demonstration, there was no prescribed minimum OOP threshold for eligibility. If smoothing is included in the final drug pricing bill, the Secretary of the U.S. Department of Health and Human Services should be directed 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, incentives for prescription drug plans must support operationalization and patient-centered methods for smoothing payment collection while also lessening the potential for some losses that plans may experience.

Restructure Medicare Part D

As the Administration and Congress consider legislation to restructure Part D, we encourage elected leaders 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

[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

basic benefit costs for which plan sponsors were responsible declined from 53 percent to 29 percent.[7] Additional comparisons of plan's responsibility for spending showed that Part D plans are responsible for only 34 percent of total prescription drug spending, compared to 85 percent in the commercial market. The Alliance supports MedPAC's recommendations to realign incentives for drug manufacturer rebates, change insurer liability in the catastrophic phase, and reduce government reinsurance liability.

Institute an inflationary cap to moderate 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.[8] When the list price of a drug increases over a short duration, 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 favors 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, market forces are complex and can result in unintended outcomes. One concern raised regarding an inflationary cap is that manufacturers may opt to increase launch prices to lessen the need for price increases. In developing this policy further, we encourage the Administration and Congress to evaluate whether such a policy would lead companies to increase launch prices to counteract an inflationary cap.

Broaden eligibility for the low-income subsidy

The Alliance also supports broadening eligibility for the low-income subsidy (LIS), which would help many financially vulnerable older adults who do not currently qualify for the LIS program. Because the LIS eligibility criteria for assets and income are at less than 150 percent of the federal poverty line, only a small portion of economically vulnerable Medicare beneficiaries qualify for the program. Millions of financially vulnerable Medicare beneficiaries do not qualify for the program. The LIS standards are so stringent that the share of Part D enrollees receiving low-income subsidies has declined over time, from 42 percent of Part D enrollees in 2006 to 28 percent in 2019. Often beneficiaries lose their eligibility because they do not return the required paperwork to the Social Security Administration or their state Medicaid agency to maintain eligibility rather than because of changes in income or assets.

[7] 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.
[8] 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/.

Expand 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 cannot access them. People who do not have access to these essential services are at higher risks for depression, social isolation, and higher medical costs. **Any savings from prescription drug pricing reform should be reinvested to cover dental, vision, and hearing services for beneficiaries. However, these services should not come at the expense of adopting policies that restrict access to care or discriminate against populations served by the Medicare program**, such as through international reference pricing or a health technology assessment (HTA) board that utilizes quality-adjusted life year (QALY)-based cost-effectiveness analysis.

Prescription Drug Pricing Proposals the Alliance for Aging Research Opposes

Use of international reference pricing or a QALY-based domestic HTA body for direct negotiation

The Administration should reject international reference pricing or a QALY-based domestic HTA body for direct negotiation in Medicare. 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[9] are assigned lower values. When applied to healthcare 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. As Medicare is the primary source of health insurance for the aging and disabled populations, **utilizing QALYs or similar metrics would be particularly harmful to the very groups the program is intended to serve.**

Objections about reliance upon QALY-based methodologies also extend to race. For example, Black Americans have an average life expectancy lower than whites.[10] 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.[11] Persistent systemic healthcare inequalities exist in patient-facing care dynamics and methodologies that reinforce and perpetuate historical injustices.

It is essential to avoid codifying standards that fail to incorporate equity considerations and inadvertently promote structural discrimination. Using QALY or QALY-derivative methodology will

[9] National Council on Disability. Quality-Adjusted Life Years and the Devaluation of Life with Disability: Part of the Bioethics and Disability Series. 6 Nov 2019. https://ncd.gov/sites/default/files/NCD_Quality_Adjusted_Life_Report_508.pdf
[10] 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.
[11] 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.

exacerbate existing and long-standing health disparities and undermine efforts to advance health equity.

In addition to the discriminatory impacts of QALYs, the metric and similar methodologies - such as the equal value of life years gained (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., broadly asserts 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. ICER's value calculations tend to be payer-centric and exclude essential considerations such as impact on caregivers, productivity, societal impact, and equity concerns.[12]

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.[13] 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.[14] 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.[15] More recently, a ban on the use of the QALY in Medicare was included in the Affordable Care Act.[16]

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.[17] 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."[18] **Given the**

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[12] 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.
[13] 29 U.S. Code § 794, 2017.
[14] 42 U.S. Code § 12131, 1990.
[15] Sullivan, Louis. "Oregon Health Plan is Unfair to the Disabled." The New York Times. 1 Sept 1992
[16] 42 U.S. Code § 1320e
[17] 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.
[18] Democratic National Committee. "Achieving Universal, Affordable, Quality Health Care." https://democrats.org/where-we-stand/party-platform/achieving-universal-affordable-quality-health-care/.

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 policies that directly or indirectly incorporate QALY and QALY-derivative assessment would severely impact medical innovation and access to new medicines. For example, the CBO offered a conservative estimate that an International Pricing Index, as proposed in H.R. 3, would reduce industry spending on research and development between $500 billion to $1 trillion and conservatively estimated a decrease in the number of new drugs between 8 to 15 over ten years.[19] Further, reductions in research investment 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.[20] Another independent analysis of the International Pricing Index has determined that small and emerging biotech companies would be particularly hit hard. Sixty-one fewer medicines are expected to make it to market from these companies over ten years.[21]

It is important for policymakers and academics alike to understand that QALYs were a step along the path to value assessment, not the endpoint. 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.

Ensuring Americans do not pay a disproportionate amount toward R&D

One of the drivers behind H.R 3's International Reference Pricing proposal is that U.S. consumers pay a greater share of the costs associated with research and development (R&D) – both in terms of the market price for a drug and federal funding for foundational research conducted by the National Institutes of Health – in comparison to individuals in other countries that utilize cost setting or a health technology assessment. While this is a legitimate concern, international reference pricing provides a misguided approach to the problem. Title I of H.R. 3 would tie a maximum negotiated price for drugs in the U.S. to a price index of six other countries, many of which rely on the QALY to set prices. Part of the rationale for this design is an assumption the resulting downward pressure on prices in the U.S. would result in price increases in referenced countries to distribute R&D costs more equitably. However, this assumption ignores the very reason that costs are low in many of the referenced countries – a central governing board establishes prices for a drug for the entire country. There is no guarantee that those entities would set a higher price for prescription drugs as a result of costs in the U.S., nor is it likely.

[19] 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.
[20] 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.
[21] 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 comparison to Congress, the Administration has additional and more appropriate tools to help address these inequities. Trade agreements are often utilized to ensure that U.S. consumers do not pay unduly high costs due to anti-competitive market practices in other nations. **We call on the Administration to explore trade agreements to address these concerns in the prescription drug market.** These multinational discussions will require time and effort. However, it is important to ensure that enacted policies address market failures rather than create unintended consequences that could reduce investment in difficult therapeutic areas and result in the potential loss of nearly 1 million U.S. jobs.[22]

Conclusion

The Alliance thanks President Biden for your commitment to lowering OOP prescription drug costs for Part D beneficiaries. We look forward to working with the Administration to advance proposals to improve prescription drug access and affordability 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, 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 considering 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

[22] 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.