

September 9, 2021

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

Ranking Member Mike Crapo
Senate Committee on Finance
219 Dirksen Senate Office Building
Washington, DC 20510

Chairman Frank Pallone
House Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

Ranking Member Cathy McMorris Rodgers
House Committee on Energy and Commerce
2157 Rayburn House Office Building
Washington, DC 20515

Chairman Richard Neal
House Committee on Ways and Means
1102 Longworth House Office Building
Washington, DC 20515

Ranking Member Kevin Brady
House Committee on Ways and Means
1139 Longworth House Office Building
Washington, DC 20515

Chairman Bobby Scott
House Committee on Education and Labor
2176 Rayburn House Office Building
Washington, DC 20515

Ranking Member Virginia Foxx
House Committee on Education and Labor
2101 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Wyden, Chairman Pallone, Chairman Neal, Chairman Scott, Ranking Member Crapo, Ranking Member McMorris Rodgers, Ranking Member Brady, and Ranking Member Foxx,

The 132 undersigned organizations representing older Americans, patients, family caregivers, people with disabilities, diverse communities, and healthcare providers are writing to urge you to address the unaffordable out-of-pocket (OOP) costs in the Medicare Part D program as you draft the budget reconciliation package.

The current OOP burden faced by beneficiaries impedes patient access to prescribed medications. These costs are especially acute when deductibles and benefits reset at the beginning of each year. A growing body of evidence shows increases in patient OOP costs lead to lower drug adherence, higher mortality, and increased overall healthcare costs. Earlier this year, the National Board of Economic Research (NBER) found that "patient cost-sharing introduces large and deadly distortions into the cost-benefit calculus." This finding remained true regardless of the beneficiaries' socioeconomic status.¹ Analysis of Medicare data found that OOP cost growth of just \$10.40 per prescription leads to a 23 percent drop in total drug consumption and a 33 percent increase in monthly mortality. As cost-sharing increases, this stark rise in mortality is due to patients cutting back on life-saving medications such as antihypertensives, anticoagulants, and statins.

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 number of Medicare beneficiaries facing high OOP costs for prescription drugs is growing. A new analysis by the Kaiser Family Foundation has found that the number of non-Low-Income Subsidy (LIS) beneficiaries reaching the catastrophic phase of the Part D benefit has increased since 2010. In 2019, almost 1.5 million beneficiaries had out-of-pocket expenses exceeding the catastrophic threshold of \$5,100.² This growth in the number of beneficiaries facing catastrophic costs comes even though the OOP spend required to reach the catastrophic phase grew substantially over the last decade (\$4,700 in 2012 versus \$7,050 in 2022).^{3,4}

Millions of beneficiaries cannot afford their medication due to high cost-sharing requirements, and millions more will not be able to afford their medicines in the future unless Congress directly addresses this crisis. The below set of recommendations will help the sickest and most vulnerable Part D patients better afford their physicians prescribed medications.

Recommendations to Advance Affordability in Medicare Part D

1. Congress should create an out-of-pocket maximum (i.e., an annual cap) on Medicare beneficiary Part D out-of-pocket expenses. Medicare is the only major insurer in the U.S. that lacks an OOP maximum. While all proposals under current consideration include an annual OOP cap, patients would derive greater benefit from a consistent, monthly cap on Part D OOP expenses. Patients report affordability concerns when monthly OOP costs exceed \$200,⁵ which extrapolates to \$2,400 annually. **We encourage Congress to meet patients at this point of need by creating a monthly OOP cap or coalescing around a proposed annual cap of \$2,400 or lower to provide meaningful relief for beneficiaries.**
2. **Any proposal that adopts an annual – rather than a monthly – OOP cap in Medicare Part D should be paired with a "smoothing mechanism."** Smoothing would allow beneficiaries the option to evenly spread costs over a plan year, thereby avoiding large lump sum OOP expenses. Many beneficiaries cannot afford to make lump sum out-of-pocket payments at the pharmacy counter, leading to abandoned prescriptions and lower treatment adherence.
 - a. This flexibility should be available to all beneficiaries, at any time during the benefit year, regardless of a beneficiary's level of OOP spending. Ideally, beneficiaries should be able to utilize payment installments no later than their first prescription fill following the payment of their annual deductible.
 - b. Congress should ensure the program includes strong patient protections, such as hardship exceptions or other mechanisms to allow beneficiaries a payment grace period. There are legitimate reasons a beneficiary might miss a payment (e.g., illness

² Kaiser Family Foundation. *Millions of Medicare Part D Enrollees Have Had Out-of-Pocket Drug Spending Above the Catastrophic Threshold Over Time*. 23 Jul 2021. <https://www.kff.org/medicare/issue-brief/millions-of-medicare-part-d-enrollees-have-had-out-of-pocket-drug-spending-above-the-catastrophic-threshold-over-time/>

³ Kaiser Family Foundation. *The Medicare Part D Prescription Drug Benefit*. Oct 2017. <https://files.kff.org/attachment/Fact-Sheet-The-Medicare-Part-D-Prescription-Drug-Benefit>

⁴ Centers for Medicare and Medicaid Services. *Announcement of Calendar Year (CY) 2022 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies. Table V-2*. 15 Jan 2021. <https://www.cms.gov/files/document/2022-announcement.pdf>

⁵ PAN Foundation. *Snapshot of 2020 Healthcare Costs*. Accessed 20 Aug 2021. Jan 2021. https://www.panfoundation.org/app/uploads/2021/01/PAN-Foundation_MC_January-2021-Survey.pdf

or hospitalization, relocation) that should not disqualify them from utilizing the flexibility. Further, plans should be required to notify patients when they are behind on their payments and inform them of the ability to apply for a hardship exception.

- c. Congress should ensure that smoothing is the default position rather than requiring Medicare beneficiaries to opt-in or otherwise enroll. This approach will ease implementation and lower administrative barriers to participation.
3. Congress should look to CMS's Part D Senior Savings Model,⁶ a program that allows patients with diabetes enrolled in participating Medicare Part D plans to access insulin for \$35 per monthly prescription, to determine if expanding a low-cost maximum copay model would broadly benefit beneficiaries or improve outcomes for patients with other conditions.

Do Not Use Utilize Methodologies Harmful to Medicare Beneficiaries

Addressing patient OOP costs is essential. Similarly, proposals to address systemic issues that lead to growing prescription drug costs should be evaluated. However, **Congress should reject consideration of using the QALY or similar average metrics.**⁷ 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,⁸ older, or have a disability⁹ are assigned lower values. QALYs also fail to account for health disparities, thereby incorporating a bias that can adversely impact communities of color. When applied to healthcare decision-making by payers, this can mean that treatments for these more vulnerable beneficiaries are deemed "too expensive" and therefore "not cost-effective" to cover. Due to these impacts, the U.S. has repeatedly rejected QALY-based assessments through legislation - including the Rehabilitation Act,¹⁰ Title II of the Americans with Disabilities Act,¹¹ and the Affordable Care Act¹² - and regulation.¹³ As Medicare is the primary source of health insurance for older adults and people with disabilities, utilizing QALYs or similar metrics in pricing would be particularly harmful to the very groups the program is intended to serve.

Conclusion

Congress must take action to address the unsustainable OOP burden faced by Medicare Part D beneficiaries. We call on your committees to include Part D reforms that ensure patients can access the medications needed to improve and maintain their health in the budget reconciliation package.

⁶ Centers for Medicare and Medicaid Services. *Part D Senior Savings Model*. Accessed 20 Aug 2021. Updated 11 Aug 2021. <https://innovation.cms.gov/innovation-models/part-d-savings-model>

⁷ American Association of People with Disabilities. *Reject Health Policies that Discriminate*. Apr 2021. <https://www.aapd.com/wp-content/uploads/2021/04/Updated-Open-Letter-Reject-Health-Policies-That-Discriminate.pdf>

⁸ 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

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 29 U.S. Code § 794, 2017.

¹¹ 42 U.S. Code § 12131, 1990.

¹² 42 U.S.C. 1320e-1

¹³ Sullivan, Louis. "Oregon Health Plan is Unfair to the Disabled." *The New York Times*. 1 Sept 1992

The undersigned patient advocacy organizations appreciate your consideration of our recommendations. If you would like to discuss these priorities further, please contact the Alliance for Aging Research's Vice President of Public Policy, Michael Ward, at mward@agingresearch.org.

Sincerely,

ACCSES--The Voice of Disability Service Providers
Aging Life Care Association
Aimed Alliance
Allergy & Asthma Network
Alliance for African Assistance
Alliance for Aging Research
Alliance for Patient Access
Alliance Health Clinic
Alpha-1 Foundation
Alstrom Syndrome International
American Academy of Allergy, Asthma & Immunology
American Association for Respiratory Care
American Association of Kidney Patients
American Association on Health and Disability
American Autoimmune Related Diseases Association
American Behcet's Disease Association (ABDA)
American Cancer Society Cancer Action Network
American Society of Consultant Pharmacists
American Society on Aging
Amyloidosis Support Groups, Inc.
Arthritis Foundation
Association of American Indian Physicians
Association of Black Cardiologists
Association on University Centers on Disabilities
Asthma and Allergy Foundation of America
Autistic Women and Nonbinary Network
Barth Syndrome Foundation
Beyond Type 1
CancerCare
Caregiver Action Network

CaringKind, The Heart of Alzheimer's Caregiving
Center for Independence of the Disabled, NY
Children with Diabetes
Chronic Care Policy Alliance
Clinical Neurological Society of America
ClinWiki
CLL Society
Coalition of Texans with Disabilities
Coalition of Wisconsin Aging and Health Groups
Color of Crohn's & Chronic Illness
Cure HHT
Cutaneous Lymphoma Foundation
Davis Phinney Foundation for Parkinson's
Debbie's Dream Foundation: Curing Stomach Cancer
Dementia Alliance International
Diabetes Leadership Council
Diabetes Patient Advocacy Coalition
Fabry Support & Information Group
FORCE: Facing Our Risk of Cancer Empowered
Foundation for Sarcoidosis Research
Friends of Cancer Research
Fund for Community Reparations for Autistic People of Color's Interdependence, Survival, & Empowerment
Genetic Alliance
GI Cancers Alliance
Global Healthy Living Foundation
Global Liver Institute
GO2 Foundation for Lung Cancer
Hawai'i Parkinson Association
Haystack Project
HD Reach
Health Hats

HealthyWomen
Hepatitis C Mentor and Support Group-
HCMMSG
Hermansky-Pudlak Syndrome Network
HFC
HIV + Hepatitis Policy Institute
ICAN, International Cancer Advocacy
Network
International Essential Tremor Foundation
International Foundation for Autoimmune &
Autoinflammatory Arthritis (AiArthritis)
International Pemphigus Pemphigoid
Foundation
JDRF
kids with heart natl assn for children's heart
disorders, inc
Lakeshore Foundation
Livpact
Lupus and Allied Diseases Association, Inc.
Lupus Foundation New England
Lupus Foundation of America
Melanoma Research Foundation
Mental Health America
MLD Foundation
Movement Disorders Policy Coalition
National Alliance for Caregiving
National Association for Continence
National Association of Nutrition and Aging
Services Programs
National Consumers League
National Fabry Disease Foundation
National Grange
National Health Council
National Kidney Foundation
National Menopause Foundation
National Organization for Tardive
Dyskinesia
National Psoriasis Foundation
National Rural Health Association
NeedyMeds, Inc
Neuropathy Action Foundation

Nevada Chronic Care Collaborative
Noah Homes, Inc
Not Dead Yet
Organic Acidemia Association
Parkinson & Movement Disorder Alliance
Partnership to Fight Chronic Disease
Patient Empowerment Network
Patients Rising Now
Prostate Cancer International
PSC Partners Seeking a Cure
PXE International
Rare New England, Inc
RASopathies Network
Raymond Foundation
RetireSafe
Second Wind Dreams
Sick Cells
StopAfib.org
Support Services of Virginia, Inc.
Susan G. Komen
Syngap1 Foundation
The AIDS Institute
The Bonnell Foundation: Living with Cystic
Fibrosis
The Coelho Center for Disability Law, Policy
and Innovation
The Gerontological Society of America
The Headache and Migraine Policy Forum
The Mended Hearts, Inc.
The Michael J. Fox Foundation for
Parkinson's Research
Triage Cancer
TSC Alliance
U.S. Pain Foundation
United Leukodystrophy Foundation
UsAgainstAlzheimer's
Vasculitis Foundation
VHL Alliance
WomenHeart
ZERO - The End of Prostate Cancer