

July 20, 2020

Speaker of the House Nancy Pelosi United States House of Representatives H-222, The Capitol Washington, D.C. 20515

Minority Leader Rep. Kevin McCarthy United States House of Representatives H-204, The Capitol Washington, D.C. 20515 Majority Leader Mitch McConnell United States Senate 317 Russell Senate Office Building Washington, D.C. 20510

Minority Leader Chuck Schumer United States Senate 322 Hart Senate Office Building Washington, D.C. 20510

Dear Speaker Pelosi, Senate Majority Leader McConnell, House Minority Leader McCarthy, and Senate Minority Leader Schumer,

The undersigned patient advocacy and provider organizations are writing to express our concern over continued unaffordable out-of-pocket (OOP) costs in the Medicare Part D program, and to implore Congress to work together in a bipartisan manner to take action. The challenges presented by high OOP expenses have been exacerbated by the COVID-19 pandemic. The brunt of the pandemic has disproportionately impacted older Americans and those living with chronic diseases, while the accompanying economic downturn has further exposed weaknesses in the Part D program. To address affordability-related challenges faced by patients, we recommend the next COVID-19 financial relief package include:

- An annual OOP cap in the Medicare Part D program;
- A mechanism to "smooth" patient OOP costs over a plan year; and
- A commitment that Part D reforms will <u>not</u> include international reference pricing or any other
 proposals that discount the value of a person's life because of an individual's disability, age, or
 chronic illness in coverage or reimbursement decision-making.

Before the pandemic, one in five adults aged 60 years and older reported that they struggle to pay for their prescription medication, and nearly one in four older adults with a chronic condition reported they stopped taking a prescription medication due to cost.¹ The elevated risk of illness and death associated with COVID-19 among older individuals and those with chronic conditions has exacerbated affordability issues. While Medicare and Medicare Advantage provides coverage for COVID-19 related services, patients are typically still responsible for copayments and deductibles.² Treatments in development for COVID-19 such as anti-viral medications, treatments for respiratory issues, and pneumonia are likely to

¹ "New Survey Shows Older Adults Are Willing to Pay More in Monthly Medicare Premiums to Ensure a Cap on Out-Of-Pocket Prescription Drug Costs." Alliance for Aging Research. 16 July 2019. https://www.agingresearch.org/press-release/new-survey-shows-older-adults-are-willing-to-pay-more-in-monthly-medicare-premiums/.

² "COVID-19: The Impact on Medicare Beneficiaries." Patient Access Network Foundation. May 2020. www.panfoundation.org/app/uploads/2020/05/COVID-19-Brief.pdf.

contribute to additional OOP costs. Simultaneously, the pandemic has adversely impacted many Americans' personal finances.

Addressing OOP costs must be a priority due to the magnitude of the problem. Even before the COVID-19 pandemic, nearly 23 percent – equivalent to 58 million Americans – reported an inability to pay for a prescription within the past year.³ Not filling, delaying, or curtailing the use of prescription medications can have life-threatening consequences. As a result, excessive OOP costs can lead to patients making difficult choices between financial solvency and their health.

We must do more to make sure older adults and individuals living with chronic disease – those hardest hit by COVID-19 – have affordable access to their prescribed medications. The Medicare Part D standard benefit does not provide sufficient coverage for beneficiaries who face catastrophic drug costs but cannot access low-income subsidies through the Part D Extra Help subsidy program.⁴ Patients should not be required to navigate the stress of managing a complex illness while confronting an undue financial burden of treatment for their medical condition.

First, we advocate for an annual OOP cap in the Medicare Part D program. The current absence of an OOP limit exposes Medicare beneficiaries to potentially devastating costs that can jeopardize their finances and health. An annual cap on Part D OOP expenses will help ensure that beneficiaries can access prescribed medically necessary drugs that allow them to live healthier, more productive lives. There is a broad agreement among Members of Congress and patient groups that a "hard cap" on OOP costs is necessary for Medicare Part D beneficiaries who reach the catastrophic threshold of their insurance benefit. Including an OOP cap in Part D is a sensible evolution of the program that will limit patients' financial exposure for costs associated with needed care.

Current legislation from both the House of Representatives and the Senate has proposed putting a cap on OOP costs when Medicare Part D beneficiaries hit certain thresholds. The Elijah E. Cummings Lower Drug Costs Now Act (H.R. 3) would limit OOP spending to \$2,000 beginning in 2022 and the Prescription Drug Pricing Reduction Act of 2019 (S. 2543) would limit OOP spending to \$3,100 beginning in 2022, indexed to growth in Part D spending. The proposed cap in both bills would constitute significant progress in constraining the growth of OOP costs for Part D beneficiaries. We support a cap structure that minimizes financial exposure, as many Medicare beneficiaries live on fixed and limited incomes.

Second, we advocate for the implementation of a "smoothing" mechanism in the Medicare Part D program. Even if an OOP cap becomes part of the Part D benefit design, beneficiaries taking high-cost medications bear a significant financial burden. For example, at the beginning of a plan year or the initiation of a course of treatment, the cost of some medications can "burn through" the enrollee's deductible and initial coverage phase very quickly. Beneficiaries would benefit from additional policies that spread OOP expenses over a plan year. A smoothing mechanism distributes OOP costs evenly over time and protects patients from receiving a single lump-sum bill for necessary medicines.

Both the Senate Finance and H.R. 3 bills include provisions that would enable drug plans and MA-PD plans to spread OOP costs throughout the benefit year. The bipartisan Seniors Prescription Drug Relief Act (S. 2911), introduced by Senators Bill Cassidy and Bob Menendez, would allow Part D beneficiaries

³ Witters, Dan. "Millions in U.S. Lost Someone Who Couldn't Afford Treatment." Gallup.com. 20 May 2020.

⁴ Gretchen Jacobson, Shannon Griffin. "Income and Assets of Medicare Beneficiaries, 2016-2035." Kaiser Family Foundation. 21 Apr 2017. www.kff.org/medicare/issue-brief/income-and-assets-of-medicare-beneficiaries-2016-2035/.

who incur costs equal to or greater than a "significant percentage" of their annual out-of-pocket threshold within a given month to pay the costs in equal installments throughout the remaining months of the plan year. We are supportive of policies that help patients to afford their prescriptions and maintain medication adherence. We further support a smoothing design that would require Part D plans to offer beneficiaries the option to pay costs – without regard to whether expenses were incurred cumulatively or during a brief period – through regular installments over a benefit year.

Third, reforms to lower OOP costs in Medicare Part D should not include reference to pricing models from foreign countries. An International Pricing Index (IPI) would require U.S. drug prices to be based on an international average of prices comprised of mostly European countries. This policy would harm newer and more innovative medical products on the market and would require the U.S. to effectively adopt the discriminatory cost-effectiveness standard used by foreign governments, known at the Quality-Adjusted Life Year (QALY). The use of QALY in healthcare decision-making has the potential to limit access to medications and treatments for older adults, people with disabilities, and patients with chronic conditions. QALY relies upon the discriminatory assumption that the value of a year of life of a person not in perfect health is lower in comparison to an individual in perfect health. QALY also fails to account for health disparities, thereby incorporating a bias that can adversely impact minority and lowincome communities.

The U.S. has repeatedly rejected QALYs and similar assessments as the basis for making drug coverage and reimbursement decisions. The Rehabilitation Act 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. Title II of the Americans with Disabilities Act (ADA) extended this protection to programs and services offered by state and local governments. In 1992, President George H.W. Bush's Administration established it was an ADA violation for states to use cost-effectiveness standards in Medicaid out of concern it would discriminate against people with disabilities. Please do not turn back the clock on these important civil rights determinations. Effectiveness should be measured by improvements to a patient's condition and quality of life, rather than personal characteristics or health status.

In conclusion, Congress must once and for all fix the problem in the next relief package by enacting an annual OOP cap that would apply to all Part D drugs and a mechanism to "smooth" out costs throughout the benefit year. We call on Congress to include Part D reforms which will provide financial security to the most vulnerable older adults and patients. We must also work together to make sure that the tools by which we determine the value of medical treatments or medications do not discriminate against older adults, patients with chronic conditions, or people with disabilities.

The undersigned patient advocacy organizations appreciate your consideration of our concerns. If you have questions about this letter or our policy requests, please do not hesitate to contact the Alliance for Aging Research's Manager of Public Policy, Ryne Carney, at rcarney@agingresearch.org.

Sincerely,

AliveAndKickn Allergy & Asthma Network

⁵ Romano, Neil. "Quality-Adjusted Life Years and the Devaluation of Life with Disability." National Council on Disability. 6 Nov 2019. https://ncd.gov/sites/default/files/NCD_Quality_Adjusted_Life_Report_508.pdf.

Alliance for Aging Research

Alliance for Patient Access

American Association on Health and Disability

American Society of Hematology

Amyloidosis Support Groups, Inc.

CancerCare

Caregiver Action Network

COPD Foundation

Cure HHT

Cutaneous Lymphoma Foundation

Depression and Bipolar Support Alliance

FND Hope

Genetic Alliance

Global Healthy Living Foundation

Global Liver Institute

GO2 Foundation for Lung Cancer

Haystack Project

HealthyWomen

Hermansky-Pudlak Syndrome Network

HIV + Hepatitis Policy Institute

International Pemphigus Pemphigoid Foundation

Kids With Heart National Association for Children's Heart Disorders, Inc.

Lakeshore Foundation

Lupus and Allied Diseases Association, Inc.

Lupus Foundation of America

Men's Health Network

MLD Foundation

Movement Disorders Policy Coalition

National Alliance for Caregiving

National Association of Area Agencies on Aging

National Kidney Foundation

National Organization for Tardive Dyskinesia

National Psoriasis Foundation

National Urea Cycle Disorders Foundation

NBIA Disorders Association

Parkinson & Movement Disorder Alliance

Partnership to Fight Chronic Disease

PTEN World

RASopathies Network

Respiratory Health Association

RetireSafe

Sophie's Neighborhood

The Mended Hearts

The Michael J. Fox Foundation for Parkinson's Research

The Myositis Association

Tuberous Sclerosis Alliance