



Dear Congress:

As patient representatives, we advocate on behalf of patient interests and interpret how certain policies will positively or negatively affect them. Patients know firsthand the benefits of a strong health care system that provides access to new and groundbreaking treatments. In recent years, we have seen great strides in the treatment of ALS, cancer and Alzheimer's disease that have increased lifespan, slowed the ravage of disease and improved the quality of lives.

Last year, Congress passed significant policies within the Inflation Reduction Act (IRA) focused specifically on patient costs. We were especially pleased by the improvements to Medicare Part D that included adding an out-of-pocket cap, establishing a \$35 limit on monthly insulin costs, and eliminating cost sharing for vaccines. These policies will provide immediate relief to patients. Thank you.

However, other policies around prescription drug prices faced significant debate during the legislative process. Policymakers must keep in mind the unknown long-term impacts on the development of new treatments – especially those for complex and rare diseases – and patients' ability to access those new therapies.

Now it is time for the real work as the Administration begins the lengthy process of implementing IRA's policies. We urge Congress to continue oversight throughout the implementation process and insist that patient voices are heard.

The Medicare Drug Price Negotiation Program contained in the law seeks to establish negotiated rates, or the Maximum Fair Price (MFP), for medications. While focused on reducing drug costs, the unintended negative consequences for drug coverage, formulary priority, access and further research and development could harm patients. For example, as new prices are determined, payors may favor products on their formularies that have a negotiated price. This could ultimately make other medications more difficult to access as payors encourage use of these negotiated price medications and discourage others. Payors already utilize cost saving measures that negatively impact patients such as restrictive formularies, step therapy and strict prior authorizations. Patients need access to the correct treatments, or they will suffer. The addition of products with artificially lowered prices is likely to create yet another restrictive process for patients.

We urge Congress to ensure that regulators at CMS create specific opportunities for patient advocates to participate in the regulatory process.

Our specific recommendations include:

- **Host regional roundtables to solicit feedback from patients.** We strongly recommend that CMS create a structure similar to that used to implement the Affordable Care Act (ACA) and utilize the CMS regional staff to hold patient-centered roundtable discussions throughout the country to ensure that patients have the opportunity to share their experiences and insights directly with CMS, regardless of their physical location. Providing regional opportunities is particularly important in the patient community where resources may make participation at the federal level more of a challenge than in their state and local communities.
- **Release draft guidance, solicit written comments.** We are pleased that CMS has announced that it will issue draft guidance that seeks public input on key provisions of the MFP program. We hope that the draft guidance includes and seeks feedback on the process, including the methodology CMS uses to determine the MFP. Soliciting written comments from the public is critical.
- **Develop patient-centered criteria.** CMS should also develop, with significant input from patients, patient-centered criteria that must be adhered to as CMS implements the drug pricing provisions. This will ensure patient perspectives are heard and patient needs are prioritized. The ACA required that the Center for Medicare and Medicaid Innovation develop similar criteria.
- **Meaningfully engage patients in determining the MFP for each drug.** Patient advocates can offer both substantial and critical perspectives as CMS considers what a price should be for a specific drug. CMS should create a process through which it will consistently and meaningfully engage with patients determining each drug's price, and ensure they have a say in the outcome.
- **Study the impact of the drug pricing provisions on patients.** CMS should study the impact that negotiation has on patients prior to negotiation, focusing on issues related to access to current and future therapies. For example, CMS should study the impact of the drug pricing provisions on Medicare Part D coverage, including formulary placement and utilization management.

Should you have any questions or comments, please contact Liz Helms, Founding Director, CCPA at lizh@chroniccarealliance.org. Thank you for your time and attention to these critical issues.

Sincerely,

Chronic Care Policy Alliance (CCPA)

Alliance for Aging Research

ALLvanza

American Behcet's Disease Association (ABDA)

American Cancer Society Cancer Action Network – Nevada

Applied Pharmacy Solutions

Autoimmune Association

Axis Advocacy

Black, Gifted & Whole Foundation

Cancer Support Community

Chronic Disease Coalition

Coalition of Wisconsin Aging and Health Groups

Colorado Gerontological Society

GO2 for Lung Cancer

Healthy Men Inc.

Hereditary Neuropathy Foundation

HIV + Hepatitis Policy Institute

ICAN, International Cancer Advocacy Network

International Foundation for AiArthritis

Lazarex Cancer Foundation

Let's Talk About Change

Looms For Lupus

Men's Health Network

MLD Foundation

National Association of Nutrition and Aging Services Programs (NANASP)

National Hispanic Medical Association

National Patient Advocate Foundation

National Puerto Rican Chamber of Commerce

Neuropathy Action Foundation (NAF)

Nevada Chronic Care Collaborative

Partnership for Innovation and Empowerment

Partnership to Fight Chronic Disease

Patients Rising Now

RetireSafe

Southern Christian Leadership Global Policy Initiative (SCL-GPI)

Support For People With Oral And Head And Neck Cancer, Inc. (SPOHNC)

The National Puerto Rican Chamber of Commerce