July 8, 2025

Dr. Mehmet Oz
Administrator
Centers for Medicare & Medicaid Services (CMS)
7500 Security Boulevard
Baltimore, MD 21244

RE: Prioritize Patient Access & Engagement in Implementation of the Medicare Drug Price Negotiation Program (MDPNP)

Dear Administrator Oz:

We, the undersigned organizations, collectively represent a diverse community of individuals including patients, survivors, and caregivers who are impacted by cancer and other complex conditions including cardiovascular, mental health, autoimmune, respiratory, allergic, gastrointestinal, and rheumatological illnesses. We are focused on bringing together patients and their loved ones, advocates, and policy experts to ensure that the patient voice plays an integral role in policymaking that impacts healthcare access, patient and caregiver experiences, and health outcomes.

We would like to sincerely congratulate you on your appointment to the role of Administrator of the Centers for Medicare & Medicaid Services (CMS). We stand ready and eager to work with you in your new role to address key healthcare access challenges facing American patients, caregivers, and their families. We look forward to working alongside you and your office to ensure that the needs and concerns of patients are at the forefront of key policies impacting healthcare access across the country. In particular, as you work with those responsible for the oversight of the Medicare Drug Price Negotiation Program (MDPNP) that was established through the Inflation Reduction Act (IRA), we ask you to ensure that patient and caregiver perspectives are considered and incorporated into the ongoing implementation of the program.

Over the last two years, Cancer Support Community (CSC) – in close collaboration with patient advocacy, caregiver, and healthcare innovator communities – has facilitated important conversations about the impacts that healthcare policy changes such as the MDPNP will have on patients, survivors, and caregivers impacted by cancer and other complex and chronic conditions. Critical collaboration with patients, caregivers, and patient and caregiver advocates is necessary to ensure that what patients value, including preferences, input, and feedback, is meaningfully integrated into MDPNP implementation, to preserve access to medically necessary treatments for millions of Americans.

As such, **we urge CMS to proactively address how ongoing implementation of the MDPNP will impact patient access to life-changing and life-saving medications and treatments, ensure provision of timely and transparent responses to patients, and allow for physician and patient choice based on individual patient medical needs and desired outcomes. In addition, we urge CMS to establish a feedback mechanism to monitor the use of utilization management tools intended to control costs, as they apply to Medicare Part D drugs subject to price negotiation.**

Emerging research suggests that the MDPNP could have a negative impact on the ability of patients to access and afford prescription medications that are subject to Medicare drug price negotiation. The IRA Medicare Drug Access Tracker, recently developed to monitor the impact of the drug pricing provisions in the IRA, indicates that seven of nine commonly prescribed medications subject to price setting under the IRA saw an increase in out-of-pocket costs for patients.[1] The tracker also indicates that average out-of-pocket costs for the nine commonly prescribed medications rose 32 percent since becoming subject to price negotiation.[2] A recent DLA Piper study found that access to treatments in Medicare is reduced as the IRA is implemented, with analyzed drugs facing a nearly 4-percent decline in on-formulary placement in the last year.[3]

Recognizing the need for meaningful patient and caregiver engagement in policy decision-making, in 2024, CSC worked in collaboration with other healthcare stakeholder communities to establish a set of recommended principles for patient-centered engagement to guide and support the policymaking process.[4] While the original set of principles was designed with a focus on the process that CMS uses to implement the MDPNP within the IRA, the principles were created to be applicable to all types of policy making that stands to impact patients.

Being a patient is a full-time job – many who are living with cancer, chronic conditions, and other complicated diagnoses are often required to plan and manage their care while continuing with daily responsibilities. Patients are left to become experts at addressing both expected and unintended consequences, such as side effects or the unavailability of a prescribed drug, that arise as a result of their diagnosis and treatment. Although patients may be warned of these unintended consequences by their provider, that does not lessen the impact of such events on their physical, mental, and emotional health.

It is critical to prioritize patient and caregiver perspectives and input when considering policy and legislation to address access and affordability issues of potentially life-saving treatments. Engaging with patients, survivors, caregivers, and advocacy organizations that represent them is the only way for policymakers and regulators to understand the true impacts of the MDPNP – or any other policy – on the patient experience and inform policy solutions to mitigate adverse, downstream effects.

Policies such as the MDPNP must be adaptable, not standardized, because each patient has unique needs. A one-size-fits-all approach to implementing policies will not benefit patients and may take away the choice and empowerment that patients often seek in choosing their care.

We recognize and support that the original intent of the IRA was to increase access to medicines for Medicare beneficiaries, and there are indeed some policies within the law that will undoubtedly achieve this goal. However, like any policy, we must continue to evaluate how patients will be impacted by these policies and provide accessible and intentional opportunities for feedback, especially as CMS begins the negotiation process with drug manufacturers for the second round of drugs selected for negotiation, and the subsequent selection of treatments for the third round of negotiation.

This year, both the Trump Administration and Congress have taken steps to address some of the unintended consequences within the IRA. Under the IRA, small molecule drugs, most frequently taken as

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[1] Pioneer Institute. Pioneer Institute Launches Tracker Showing Drug Price Controls Are Raising Out-of-Pocket Costs for Medicare Patients. (2025)
[2] Pioneer Institute. Pioneer Institute Launches Tracker Showing Drug Price Controls Are Raising Out-of-Pocket Costs for Medicare Patients. (2025)
[3] DLA Piper. Keeping watch on the Inflation Reduction Act: Medicare poses Part D formulary access challenges. (2025)
[4] Cancer Support Community. Principles for Patient-centered Engagement. (2024)

a pill, syrup, or in inhaled form, can become subject to negotiated prices nine years after approval from the Food & Drug Administration (FDA). However, large molecule biologic drugs, which are most often injected or infused in a doctor's office or hospital setting, can be subject to negotiated prices 13 years after FDA approval – an additional four years compared to small molecule drugs. This policy – the "pill penalty" – threatens to chill the pipeline of innovation for small molecule drugs, which have proven to hold invaluable benefit to patients and their loved ones.

Small molecule medicines can be taken at home, alleviating the administrative, financial, and logistical burdens on patients and their loved ones that accompany needing to travel to receive an infusion. A survey found that 91 percent of respondents indicated that being "able to take the medicine at home" was important or extremely important to them.[5] The option to take treatments at home is especially important for rural communities who may have less access to pharmacies and health centers and be burdened by longer travel times to receive necessary care.[6] Moreover, small molecule drugs hold unique clinical benefit because of their ability to cross the blood-brain barrier and reach medicine targets inside of cells, providing significant benefits for patients with cancer, neurodegenerative conditions, and other complex conditions – all of which impact older Americans and rural communities. In 2022, 24% of men and 15% of women aged 65 and older were in the labor force, a number that is projected to rise over the next several years to 25% for men and 17% for women in 2032.[7] Small molecule drugs will enable older Americans to remain in and contribute to the workforce for longer.

In February 2025, lawmakers introduced the Ensuring Pathways to Innovative Cures (EPIC) Act (S. 832/H.R. 1492) which would align the timeline for when small and large molecule drugs are eligible for negotiation within the MDPNP. [8,9] In a May 2025 Executive Order, President Trump signaled his support for the EPIC Act as a solution to the addressing the "pill penalty."[10] CMS must take patient preferences and the potential consequences of disincentivizing the development of small molecule drugs into account when selecting drugs for negotiation within the MDPNP.

Patient input from a broad group of populations and communities is critical to achieving policies that incorporate and reflect their needs, perspectives, and goals as it relates to treatment outcomes. And it all starts with meaningful and ongoing patient engagement.

As you shape healthcare policy within Medicare and Medicaid, including but not limited to the MDPNP, we urge you to prioritize patient-centered engagement, ensure that no patient will face unintended consequences as a result of healthcare policy changes and ascertain that patient, survivor, and caregiver perspectives are considered and integrated into policies that stand to impact them most.

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[5] Partnership to Fight Chronic Disease. Sign up for: Preserving Accessibility and Incentives for Development of Small Molecule Medicines for Chronic Diseases.

[6] Global Coalition on Aging. The Inflation Reduction Act & Small Molecule Development: Policy Brief. (2025)

[7] Population Reference Bureau. Fact Sheet: Aging in the United States. (2024)

[8] Office of U.S. Congressman Greg Murphy, M.D. Murphy Introduces Legislation to Eliminate IRA "Pill Penalty" and Improve Small Molecule Drug Innovation. (2025)

[9] Office of U.S. Senator Thom Tillis. Tillis Leads Legislation to Eliminate Biden's "Pill Penalty," Restore Incentives for Life-Saving Drug Innovation. (2025)

[10] The White House. LOWERING DRUG PRICES BY ONCE AGAIN PUTTING AMERICANS FIRST. (2025)

Thank you for your commitment to addressing patient access and affordability issues. If you have any questions or if our organization can be a resource to you, please contact Daneen Sekoni at dsekoni@cancersupportcommunity.org.

Sincerely,

Cancer Support Community
Cancer Support Community Arizona
Cancer Support Community of Greater Ann Arbor
Cancer Support Community Greater Cincinnati-Northern Kentucky
Cancer Support Community Greater Philadelphia
Cancer Support Community of Greater St. Louis
Cancer Support Community Indiana
Cancer Support Community Los Angeles
Cancer Support Community Montana
Cancer Support Community San Francisco Bay Area
Cancer Support Community Southwest Colorado
Gilda's Club Chicago
Gilda’s Club Kentuckiana
Gilda's Club Madison Wisconsin, Inc.
Gilda's Club Minnesota
Indian Family Health Clinic

ADAP Advocacy Association
AiArthritis
Allergy & Asthma Network
Alliance for Aging Research
Alliance for Women's Health and Prevention
ALS Association
American Foundation for Women's Health
APNH: A Place to Nourish your Health
Autoimmune Association
Biomarker Collaborative
Brem Foundation to Defeat Breast Cancer
CancerCare
Caregiver Action Network
Caring Ambassadors Program
Cervivor, Inc.
CLL Society
Coalition of State Rheumatology Organizations (CSRO)
Depression and Bipolar Support Alliance (DBSA)
Derma Care Access Network
Exon 20 Group
Fight Colorectal Cancer
FORCE: Facing Our Risk of Cancer Empowered
Global Coalition on Aging Alliance for Health Innovation
Health, Hope & Hip-Hop Foundation
HealthTree Foundation

HealthyWomen
HIV+Hepatitis Policy Institute
ICAN, International Cancer Advocacy Network
LUNGevity Foundation
Lupus and Allied Diseases Association, Inc.
Lupus Foundation of America
Lymphoma Research Foundation
MET Crusaders
National Alliance for Caregiving
National Patient Advocate Foundation (NPAF)
Ovarian Cancer Research Alliance (OCRA)
Patient Empowerment Network
Patients Rising
PDL1 Amplifieds
PlusInc
RetireSafe
Sick Cells
StopAfib.org
Susan G. Komen
The Guardian Health Association, Inc.
The Headache and Migraine Policy Forum
The Mended Hearts, Inc.
Tigerlily Foundation
Triple Negative Breast Cancer Foundation
Voices of Alzheimer's
Young Survival Coalition
ZERO Prostate Cancer

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Principles for Patient-Centered Engagement When Implementing the Medicare Drug Price Negotiation Program (MDPNP)

- **Engage patient advocacy organizations, patients, and caregivers** in structured, meaningful ways throughout the MDPNP process.

- **Define clinical benefit** to prioritize evaluations around endpoints, patient reported outcomes, patient experience data including impact on quality of life, and preferences that matter most to patients living with cancer and other complex conditions. This includes both qualitative and quantitative measures such as clinical endpoints, patient preference data/models, patient reported outcomes, and social impacts.

- **Develop critical infrastructure** necessary to educate the patient community and facilitate meaningful feedback that prioritizes patient definitions of value, including feedback on the evidence being considered by CMS and whether it reflects patient experiences and preferred outcomes.

- **Refer to patient navigators** to provide information to patients about the impact of these policies and to receive feedback from patients, with an explicit goal to identify any changes in utilization management practices as a result of IRA implementation.

- **Develop a monitoring and evaluation platform** and reporting framework surrounding the MDPNP and its impacts on patients to support continuous improvement in ongoing implementation.

- **Collect and report specifically on access challenges facing patients** as a result of the IRA to allow for continuous improvement of the MDPNP process and lessen the unintended consequences of this process on patients.

- **Collect and incorporate meaningful data and real-world evidence** that amplifies patient values and input within the MDPNP implementation process, including patient reported outcomes, patient experience data, impact to quality of life, and models that capture the dynamic and varied preferences of patients.

- **Prioritize outreach to patients, people with disabilities, and people living in rural communities** to ensure that the MDPNP supports all patient populations and does not threaten healthcare access.

- **Consider the groups and populations that have not already engaged** in defining patient-focused clinical benefit and impact of the MDPNP process and determine how best to activate those individuals.

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