

February 9, 2024

Meena Seshamani, MD, PhD  
Deputy Administrator and Director of the Center for Medicare  
Centers for Medicare & Medicaid Services (CMS)  
U.S. Department of Health and Human Services (HHS)  
200 Independence Avenue SW  
Washington, DC 20201

**RE: Incorporate Patient Perspectives Throughout Medicare Drug Price Negotiation Implementation Process**

Dear Deputy Administrator Seshamani,

We, the undersigned organizations, represent diverse patient populations living with cancer and other chronic and rare conditions. On behalf of the patient, provider, and caregiver communities we serve, we thank you for your commitment to improving access to critical health care treatments and services and finding solutions that empower patients to manage their health and well-being. We applaud the Biden administration and Centers for Medicare & Medicaid Services (CMS) for implementing policies that support individuals who struggle to afford, access, and adhere to lifesaving and life-enhancing care and engage impacted stakeholders in those processes. However, like many other advocates, we have strong concerns that some of these policies – namely the Medicare Drug Price Negotiation Program (MDPNP) within the Inflation Reduction Act (IRA) – may have unintended negative consequences on patients and fail to incorporate the perspectives of those who are most impacted. Our organizations urge you to ensure that patients and their caregivers have a prominent voice and seat at the table in defining patient-centered clinical benefit for the purpose of Medicare Part D drug price negotiations and future health care policies that impact treatment access and affordability.

For many patients living with a chronic condition or disability, a diagnosis is just the beginning of their journey. People living with a disability or chronic health conditions such as cancer, HIV, multiple sclerosis, cardiovascular disease, diabetes, depression, Alzheimer's, dementia, lupus, headaches and migraines, or rheumatoid arthritis often require consistent screenings, treatments, doctor's visits, and more. Patients have benefited greatly from advances in screening, diagnosis, and treatment capabilities, but many patients can find treatment of their condition to be a complicated and overwhelming process, with the need to manage not only their treatment plan, but also the physical symptoms, psychosocial issues, employment issues, and financial barriers that come with managing a complex disease. Patients living with chronic conditions are often required to plan and manage their care and continue daily responsibilities, becoming an expert at addressing both expected and "unintended" consequences of chronic illness management.

As CMS continues to implement health care provisions within the IRA, particularly the MDPNP, the agency must meaningfully incorporate patient experience data throughout the process and in definitions of “clinical benefit.” **Definitions of a drug’s clinical benefit must be determined through an infrastructure that adequately captures and accounts for a broad representation of unique patient and caregiver experiences.**

As patient and provider advocates who are on the frontlines of patient education, empowerment, and support, we know all too well that defining clinical benefit is not a one-size-fits-all approach. Patients, caregivers, families, and others impacted by cancer and other conditions may experience the same events in entirely different ways and what they value most as a treatment outcome may vary. We hear every day from patients who are fighting the same disease but doing so on a unique path and journey, and policies such as the MDPNP must recognize that to ensure patients are empowered in their care. Programs and policies that are intended to alleviate cost or access barriers to care must be dynamic and adaptable, not static and standardized. Such rigidity poses a risk of discrimination and could result in patients experiencing severe adverse consequences due to such policies.

Although well-intentioned, CMS’ recent patient-focused listening sessions surrounding the MDPNP did not adequately represent a broad and diverse range of patient and caregiver perspectives, highlighting the need for continued opportunities for patients to share their care preferences, impacts on quality of life, and what they value about specific treatment plans as implementation of the MDPNP continues.

As such, we have come together as a community to align on patient-centered principles to inform a definition of clinical benefit for patients and caregivers that can be used throughout engagement with CMS as the agency continues to implement the MDPNP and other similar policies. These principles have been developed to guide future engagement with you, others at CMS, and other policymakers on these challenging and important issues, to ensure we are working together to prioritize the endpoints that matter most to patients. Those principles are outlined below and were developed out of group discussions led by Cancer Support Community’s IRA Summit on Patient-Centered Policymaking in IRA Drug Price Negotiations and other policies. They also incorporate best practices from ongoing engagement with the agency and other health care stakeholders.

While the passage and implementation of IRA remains a positive step forward for patients and caregivers, the potential for adverse consequences for patients demands that CMS establish an infrastructure that adequately captures patient and caregiver experiences, and that feedback is incorporated throughout implementation of the MDPNP. We stand ready to work with you to implement these principles as you continue to implement this program and others.

If you have any questions or need additional information, please contact Daneen Sekoni, Vice President, Policy and Advocacy, Cancer Support Community, at [dsekoni@cancersupportcommunity.org](mailto:dsekoni@cancersupportcommunity.org) or (202) 659-9707.

Sincerely,

Cancer Support Community  
Aimed Alliance  
Alliance for Aging Research  
AnCan Foundation  
CancerCare  
CLL Society  
Global Coalition on Aging  
Global Coalition on Aging Alliance for Health Innovation  
GO2 for Lung Cancer  
Healthcare Leadership Council  
LUNgevity  
Lupus and Allied Diseases Association, Inc.  
Lupus Foundation of America  
Partnership to Advance Cardiovascular Health  
Partnership to Improve Patient Care  
The AIDS Institute  
The Headache and Migraine Policy Forum  
Tigerlily Foundation  
Triage Cancer

Cancer Support Community Network Partners\*

Cancer Support Community of Greater St. Louis  
Cancer Support Community Montana  
Cancer Support Community Ann Arbor  
Cancer Support Community Washington D.C.  
Cancer Support Community Delaware  
Cancer Support Community Valley/Ventura/Santa Barbara  
Cancer Support Community Arizona  
Gilda's Club Kansas City  
Gilda's Club Chicago  
Gilda's Club Kentuckiana  
Gilda's Club of South Florida, Inc.  
Indian Family Health Clinic

*\* CSC is a global nonprofit network with 190 locations, including CSC and Gilda's Club centers as well as healthcare partnerships. These locations, along with a toll-free helpline, digital services,*

*and award-winning education materials, provide \$50 million in free support services to patients and families each year.*

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## **Principles for Patient-Centered Engagement for CMS**

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- 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.
- Work to include broad diversity in outreach to patients and people with disabilities to ensure that the MDPNP supports all patient populations and does not threaten treatment access.
- Hire 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 and expansion.
- 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 these 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.
- 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 to avoid exacerbating existing health equity challenges.

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