April 14, 2023

Dr. Meena Seshamani, M.D., Ph.D.
CMS Deputy Administrator, Director of the Center for Medicare
Centers for Medicare & Medicaid Services
200 Independence Avenue SW
Washington, DC 20201

Dear Dr. Seshamani,

The undersigned organizations representing a variety of individuals including survivors, and caregivers impacted by cancer diagnoses would like to thank you for the opportunity to provide comments on proposed guidance implementing provisions in the Inflation Reduction Act (IRA). We applaud Congress and the administration for passing and implementing policy to assist individuals who struggle to afford lifesaving and life-enhancing care. However, like many other stakeholders, we also have concerns that some of these policy changes may have unintended negative consequences.

Centers for Medicare & Medicaid Services (CMS) has the opportunity, now, to implement the IRA in such a way that many of these externalities can be prevented. Equally important, however, CMS also has the opportunity to articulate how it will benchmark and assess implementation and monitor its impact on insurance premiums, industry investments, and development of new therapies. In failing to set up an infrastructure to evaluate down-stream impacts, CMS is inviting the worst. The patient community cannot afford to wait for regulators to notice that the patient community is struggling. We have to equip ourselves with the right tools, now, to ensure everyone is kept safe.

Because the IRA is being implemented through sub-regulatory guidance, CMS will have the opportunity to offer timely corrections before unintended downstream consequences and accidental loopholes become permanent features of these new policies. This will only work if CMS sets up the infrastructure to collect that feedback and act on it in a timely manner. As we have seen with policies like prior authorization in the Medicare Advantage program, adjusting or clarifying existing policy after it is already firmly in place, can be difficult, if not impossible to accomplish.

Drug Price Negotiations

In this guidance, CMS outlines a plan for how drug prices will be negotiated. In separate guidance, CMS explains how it will evaluate a drug's "clinical benefit." However, neither of these documents demonstrate how patient needs will be incorporated in this process. It makes sense that the needs of patients and caregivers will change over time, and it makes sense that two individuals might experience the same events in entirely different ways, yet policy consistently dictates that patient feedback is static and standardized.

CMS must use this opportunity to build a new system that acknowledges and responds to these truths. ***To be clear: asking for comment letters at this stage and allowing for submission of evidence once drugs have been selected for negotiation is not enough***. Patients must have the opportunity to share their care preferences, impacts on quality of life, and what they value about our treatment.

1) **We call on CMS to host a town hall meeting with patient stakeholders prior to finalizing guidance to inform how CMS will establish the definition of clinical benefit used in drug price negotiations and discuss the infrastructure for continuing patient engagement.**

2) **We respectfully ask that CMS consider the following:**
   a. **For each drug assessed, a panel of patients and caregivers should be convened to provide input and feedback at multiple steps in the evaluation of a drug's benefits. There should be an open and transparent process for patients and caregivers to apply to be part of these panels.**
   b. **Patient input should not just be considered qualitative and described in written form. Rather, it should be quantified and incorporated into any methodology used to assess product value.**
   c. **CMS should be transparent and clearly outline how patient input was considered and impacted the negotiation process.**
3) **We endorse recommendations explained in more detail in the patient- and disability-community letter penned by the Partnership to Improve Patient Care (PIPC).**

Patient Access

According to the recent guidance, Medicare Part D plans shall include each covered Part D drug that is a selected drug on Part D formularies during Contract Year (CY) 2026 and all subsequent years for which the MFP of the selected drug is in effect during the price applicability period. While patient groups are optimistic that these changes will allow patients to afford needed treatments, we remain cautious. Historically, health plans have used creative formulary design, onerous prior authorization schemes, and step therapy delays to limit plan liabilities, all of which adversely affect patient access to medicines. We are disappointed that CMS did not proactively address these patient access concerns in the guidance. We are also concerned that without appropriate guardrails and patient protections on utilization management, health plans will expand their inappropriate overutilization of these tools to recoup their perceived losses.

We urge CMS to ensure that health plan utilization management techniques follow clinical guidelines, provide timely and transparent responses to patients, and allow for physician/patient choice based on individual patient medical needs and desired outcomes. In addition, we urge CMS to establish a feedback mechanism to monitor overutilization of these cost control tools, particularly as they apply to Part D drugs subject to this policy. CMS must also proactively address how Part D redesign changes will impact patient access to both negotiated and non-negotiated cures.

Out of Pocket Caps

The IRA caps the out-of-pocket costs paid annually by Medicare beneficiaries for prescription drugs at $2,000 and allows patients to spread those costs across 12 months through a "smoothing" mechanism. The redesign also eliminates the coverage gap discount program. If implemented correctly, and in collaboration with patient advocacy organizations like those included on this letter, these policies could help to deliver essential treatments to Medicare beneficiaries and help them avoid the financial toxicity that frequently accompanies a cancer diagnosis. **CMS must invest in education and assistance programs to ensure that they are well understood.** We stand ready to help CMS to build education tools, assist in education, and outreach efforts to ensure that the smoothing process does not end up adding to more confusion and unexpected and compounded healthcare debt.

The Impact to Oncology Research and Development

The IRA allows Medicare to set prices on small molecule drugs after they have been on the market for nine years. That is much shorter than the 13-year window granted to large molecule "biologic" drugs,

which are typically injected or infused in doctors' offices, clinics, and hospitals and are subject to Medicare Part B.

Clinical trials are resource-intensive endeavors that take years to complete. The trials that drug developers run to assess whether an FDA-approved drug can be used to treat an earlier stage of a disease, in combination with another therapy, or in a different cancer type or population, can take more than three years to finish on average. Over 60 percent of oncology drugs approved between 2010-2012 received an additional FDA indication, and more than 70 percent of these additional approvals occurred seven or more years after initial approval.[1] We are concerned that pharmaceutical companies will determine that it is not viable to invest in clinical research supporting approval for additional indications if they cannot count on the same return – which can only limit treatment options for patients who might have otherwise benefitted from existing, sound, and life-saving or life-improving science.

CMS must articulate how it will monitor industry investment and drug development and this plan has to provide an opportunity for patient engagement. None of us can afford to watch lifesaving or life-enhancing treatments languish.

This year, nearly two million Americans will be diagnosed with cancer.[2] Life-saving treatments for some of those patients may already be on the market. But the IRA's timelines could prevent scientists and doctors from discovering new uses for those already-approved drugs. Since 1991, the cancer death rate has declined by 33 percent.[3] This is in large part due to advances in treatment.

While the passage and implementation of IRA represents a positive step for patients and caregivers, the opportunity for negative consequences demands that CMS establish an infrastructure that monitors predicted trends and ensures the opportunity for feedback. We are ready and eager to assist in this process and look forward to collaboration. Please contact Courtney Yohe Savage, MPP at cysavage@cancersupportcommunity.org or 202-680-8985 with any questions or follow-up.

Sincerely,

Cancer Support Community
Association of Community Cancer Centers
Bladder Cancer Advocacy Network (BCAN)
COA Patient Advocacy Network (CPAN)
Community Oncology Alliance (COA)
Global Coalition on Aging Alliance for Health Innovation
Global Liver Institute
HealthHIV
National Oncology State Network

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[1] https://www.pharllc.com/wp-content/uploads/2022/11/Clinical-Benefits-of-Post-Authorization-Research-Brief.pdf

[2]https://pubmed.ncbi.nlm.nih.gov/36633525/#:~:text=In%202023%2C%201%2C958%2C310%20new%20cancer,occur%20in%20the%20United%20States.

[3] https://www.fiercehealthcare.com/providers/study-finds-cancer-death-rate-declined-33-1991-treatment-advances

Ovarian Cancer Research Alliance
Partnership to Improve Patient Care
Patients Rising Now
Preparedness and Treatment Equity Coalition
Support For People With Oral And Head And Neck Cancer, Inc. (SPOHNC)
Triage Cancer

Cancer Support Community Network Partners*
- Cancer Support Community at Gilda's Club, Rochester NY
- Cancer Support Community Central Ohio
- Cancer Support Community Montana
- Cancer Support Community Valley/Ventura/Santa Barbara
- Gilda's Club Kansas City
- Gilda's Club Kentuckiana
- Gilda's Club South Florida
- Gilda's Club South Florida, Inc.

** Cancer Support Community is a global non-profit network of 190 locations, including CSC and Gilda's Club centers, hospital and clinic partnerships, and satellite locations that deliver more than $50 million in free support and navigation services to patients and families.*