CANCER LEADERSHIP COUNCIL

A PATIENT-CENTERED FORUM OF NATIONAL ADVOCACY ORGANIZATIONS ADDRESSING PUBLIC POLICY ISSUES IN CANCER

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Centers for Medicare & Medicaid Services
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Dear Deputy Administrator Seshamani:

The undersigned organizations representing cancer patients, health care professionals, researchers, and caregivers appreciate the opportunity to comment on the Initial Memorandum for Implementation of the Medicare Drug Price Negotiation Program. The negotiation of drug prices may have substantial effects on cancer patients, and we offer advice below regarding actions that the Centers for Medicare & Medicaid Services (CMS) can take to ensure that the advice of cancer patients, cancer care providers, and other cancer stakeholders is obtained and fully considered during the negotiation process.

For cancer patients and their cancer care teams and families, a cancer diagnosis begins a complex and difficult journey. Many cancer patients have benefited greatly from advances in screening, diagnosis, and treatment advances, and as a result the cancer journey is a long one. For some, the journey ends in cure and for others a good life even without a cure.[1] Cancer patients often find treatment a complicated process, with the need to manage not only their treatment but also the side effects of cancer and cancer treatment, including physical symptoms, psychosocial issues, employment issues, and financial toxicities. Cancer patients, even when faced with a life-changing diagnosis, are required to plan and manage their care and their lives. All too often, they become expert at addressing both expected and "unintended" consequences of cancer and cancer treatment.

[1] The cancer death rate has declined by 33 percent since 1991, due to treatment and screening advances and less smoking. Siegel, et al. Cancer Statistics, 2023. CA: A Cancer Journal for Clinicians. January 12, 2023.

Cancer survivors and cancer advocates, because of their cancer experiences, are well-qualified to offer advice about the drug price negotiation process and to recommend options for monitoring the possible unintended consequences of price negotiation.

Input Regarding Clinical Benefit

In the guidance document, CMS generally describes a process through which it will seek information about the clinical effectiveness of a selected drug and the drug's therapeutic alternatives. Cancer patients are, as we describe above, well-prepared to offer advice about clinical effectiveness of selected drugs. CMS notes that it is interested in real-world evidence about selected drugs, and cancer patients can supply that evidence, including about drugs' side effects and tolerability. They can offer detailed real-world perspectives on selected drugs and therapeutic alternatives. In these comments we focus on the input of cancer survivors but believe that health care professionals, including those involved in the development of evidence-based practice guidelines, should be part of the process for evaluating clinical benefit and comparing therapeutic alternatives.

In recent years, the Center for Medicare & Medicaid Innovation (CMMI) at CMS has sought and received the advice of cancer patient advocates related to alternative payment and delivery models, including the Oncology Cancer Model and the Enhancing Oncology Model. Patient advocates have found CMMI open and transparent in the consultation process, in some circumstances agreeing to attend meetings convened by advocacy organizations to receive those advocates' advice.

We urge that a process or procedures be established to solicit the advice of patients about selected drugs and that the advice be solicited and evaluated in timely fashion. Some have suggested that there be something akin to an ombudsman as the central point for engagement with patients, with the Patient Affairs Office at the Food and Drug Administration cited as a model. Others have suggested a standing panel of patient stakeholders to be consulted by CMS. We do not reject these suggestions but are concerned that these structures or processes may not result in timely advice from patients, which we define as advice about clinical benefit and therapeutic alternatives during the negotiation process.

We want to avoid a situation where patients provide valuable advice about clinical benefit, but that advice is received at the end of the negotiation process, essentially serving as commentary on a completed process. Even when federal agencies have good intentions regarding patient input, they sometimes solicit and receive that advice "after the fact" of a dynamic public policy process.

Public notice to patient advocates about an ongoing negotiation process, alerting them to a meeting to discuss a selected drug and an opportunity to submit written comments, might be an efficient way to obtain patient advice. Because the price negotiation process is being implemented through sub-regulatory guidance, the agency has some flexibility regarding notice

and invitation to advocates and convening of panel meetings and acceptance of advice. The insights of patients are critical to the drug price negotiation process, and we look forward to flexibility and transparency from CMS in how it seeks and evaluates that research. CMS states in the initial guidance that the statute, "requires that CMS not use evidence from comparative clinical effectiveness research in a manner that treats extending the life of an individual who is elderly, disabled, or terminally ill as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill." We appreciate that CMS has, throughout the initial guidance, underscored the statutory limits on the use of QALYs and its intention to honor those limits.

Unintended Consequences of Drug Price Negotiation

As we have noted above, many cancer survivors have benefited tremendously from cancer research advances. When we talk about the expertise of cancer survivors across the continuum of care, that encompasses expertise about research and development of new therapies. Advocates are quite sophisticated about the drug development pipeline and will be monitoring the possible impact of drug price negotiation on investment in research and development. We urge CMS to regularize and formalize its efforts to ascertain the potential unintended consequences of price negotiation.

Pharmaceutical company representatives are raising alarms to patient advocates that their investment in research on supplemental indications of approved drugs will be significantly adversely affected by the price negotiation process. We are concerned about this assertion from the pharmaceutical industry, and research on supplemental indications will be among those research endeavors that the advocacy community will closely monitor.

Additional Efforts to Address Affordability of Drugs

We end our comments with observations and advice about other drug affordability issues. We realize that the issue of advice regarding the implementation of the "smoothing" of beneficiary cost-sharing responsibilities is outside the scope of this guidance. However, this issue is critically important to patients, and we look forward to implementation decisions regarding smoothing soon.

Clearly outside the scope of this guidance are additional efforts to address the affordability of drugs, including insurance reforms and limits on utilization efforts. We will pursue such reforms, as they are a critical complement to any relief that patients may see from drug price negotiation. We simply want to acknowledge that, whatever benefits are realized from drug

price negotiation, they will not fully address the drug affordability issues that are crippling for some cancer patients.

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We appreciate the opportunity to offer our input regarding the drug price negotiation initial guidance.

Sincerely,

Cancer Leadership Council

Association for Clinical Oncology
Cancer*Care*
Cancer Support Community
Children's Cancer Cause
Fight Colorectal Cancer
LUNGevity Foundation
Lymphoma Research Foundation
National Coalition for Cancer Survivorship
Ovarian Cancer Research Alliance
Susan G. Komen