

CANCER LEADERSHIP COUNCIL

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

December 8, 2009

Charlene Frizzera
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: CMS-4085-P

Dear Ms. Frizzera:

The undersigned organizations, representing cancer patients, providers, and researchers, submit the following comments on the proposed rule related to changes in Medicare Advantage (MA) and the prescription drug program (Part D). We commend the efforts of the Centers for Medicare & Medicaid Services (CMS) to clarify MA and Part D plan offerings, strengthen beneficiary protections, and address formulary issues. We recommend several changes in the proposal to provide cancer patients additional protections.

Out-of-Pocket Limits and Cost-Sharing Tier Limits to Ensure Nondiscrimination

We are pleased that CMS proposes an annual review of MA out-of-pocket maximum amounts and Part D tiered cost-sharing amounts in order to set limits that are considered non-discriminatory. Tiered cost-sharing, by putting certain therapeutic classes in tiers with high co-insurance requirements, discriminates against patients with the relevant diagnoses and conditions. The practice of tiered cost-sharing has resulted in the creation of specialty tiers with burdensome cost-sharing requirements that are straining the ability of cancer patients to pay for their treatment.

In undertaking its review of non-discriminatory cost-sharing tiers, CMS should evaluate carefully the impact of specialty tier cost-sharing on treatment decision-making by patients. Patients and their physicians report that decisions about treatment may be altered by the cost-sharing responsibility that the patient bears. It is our concern that this practice may force the patient to choose a treatment that is not necessarily considered his or her best treatment option.

Annual review of cost-sharing tiers and out-of-pocket maximums is an important first step, but we urge that CMS, after undertaking its first annual review, also consider limiting tiered cost-sharing through notice-and-comment rulemaking that will ensure public comment.

Protected Classes of Drugs

In general, we believe that the agency has improved the process for identifying classes or categories of drugs for which access should be provided to all or substantially all drugs in the class. The proposed definitions of “major or life threatening clinical consequences,” “restricted access,” and “significant need for access to multiple drugs” seem to provide an appropriate level of protection to beneficiaries with special need for access to all drugs in certain classes or categories. We note specifically the definition of need for access to multiple drugs, which encompasses both those situations where drugs are needed in combination and situations where different drugs may be needed in sequence. This definition is important to cancer patients who may find themselves in both medical situations.

CMS has rejected the position that it was the intent of Congress, when it enacted the Medicare Improvements for Patients and Providers Act (MIPPA), to codify the six protected classes of drugs. The agency notes that the six classes are not expressly identified by the MIPPA. In fact, cancer is included in the MIPPA provision related to protected classes. We believe this specific reference does indicate the intent of Congress that cancer be considered a protected class for ensuring inclusion of all drugs on Medicare prescription drug plan formularies. We urge CMS to identify cancer as a protected class, even as it proceeds to designate additional classes for this protection.

The proposal would require that all chemically distinct drugs in the protected classes be included on formularies. However, if two drug products are determined to be therapeutic equivalents, there would be no requirement that both be on all formularies. We urge CMS to reconsider this standard and require that all drugs in a protected class be included on formularies. This standard of inclusion is necessary to ensure that cancer patients have access to all necessary therapies. A physician may prescribe a specific drug and reject an asserted therapeutic equivalent because, in the physician’s judgment, it does not provide the same benefits or poses special risks to a patient. Cancer patients can be assured timely access to therapy only if all drugs in the class of anti-cancer therapies are included on formularies.

We appreciate the opportunity to comment on the proposed rules to improve the prescription drug plan offerings and the protection of patients who rely on MA and prescription drug plans.

Sincerely,

Cancer Leadership Council

American Cancer Society Cancer Action Network
American Psychosocial Oncology Society
American Society of Clinical Oncology
Breast Cancer Network of Strength
The Children's Cause for Cancer Advocacy

Coalition of Cancer Cooperative Groups
International Myeloma Foundation
Kidney Cancer Association
Lance Armstrong Foundation
Leukemia & Lymphoma Society
Lymphoma Research Foundation
Multiple Myeloma Research Foundation
National Coalition for Cancer Survivorship
National Lung Cancer Partnership
Ovarian Cancer National Alliance
Pancreatic Cancer Action Network
Prevent Cancer Foundation
Sarcoma Foundation of America
Us TOO International Prostate Cancer Education and Support Network
The Wellness Community