



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

March 6, 2006

Via Telecopy

Mark A. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
200 Independence Ave., S.W.
Room 314-G – HHH Bldg.
Washington, DC 20201

Dear Dr. McClellan:

The undersigned organizations of the Cancer Leadership Council (CLC), representing cancer patients, providers, and researchers, offer the following comments regarding the implementation of the Medicare Part D prescription drug benefit. Our comments address the draft transition process requirements for Part D sponsors and the 2007 draft guidelines for review of Part D formularies and are aimed at ensuring that Part D is responsive to the needs of cancer patients.

Continuation of the “All or Substantially All” Requirement

We commend the decision to continue the requirement that Part D plan formularies include all or substantially all drugs in six classes, including the antineoplastic class, in calendar year 2007. The continuation of this policy reflects the desire of the Centers for Medicare & Medicaid Services (CMS) to prevent disruptions in treatment and ensure access to appropriate care for individuals who rely on drugs in these classes. However, we note that plan sponsors are allowed to use techniques to manage the antineoplastic drug class, including prior authorization or step therapy requirements, and these techniques may have the effect of creating barriers to those therapies that are most appropriate and effective for cancer patients. As implementation of Part D continues, we will monitor the impact of these management tools on cancer patients' access to appropriate drug therapy and may recommend revisions of this policy for management of antineoplastic therapies.

Inclusion of New Anticancer Therapies in Part D Formularies

According to the 2007 draft guidelines, formularies will be required to include substantially all drugs in the six special classes that are available on April 17, 2006. Drugs that come onto the market after the April 17, 2006, deadline would be required to undergo review by the plan's Pharmacy and Therapeutic (P&T) committee. Because P&T committees are permitted 180 days from market availability of a drug to make decisions about inclusion of that drug on plan formularies, this standard may seriously hinder cancer patients' access to new cancer therapies. Allowing P&T review on a six-month schedule has the effect of undermining the protections that cancer patients expect from the "all or substantially all" standard for formularies.

Because new anticancer therapies may represent the best treatment option for cancer patients, allowing P&T review of these treatments may create a significant quality of care issue. We understand that Part D enrollees may be able to obtain these new anticancer drugs via the exceptions process, but that process may represent a serious burden and unacceptable delay in availability of the best cancer care.

We urge CMS to modify the 2007 formulary guidelines to require Part D sponsors to include antineoplastic drugs in their formularies upon their introduction to the market. The P&T committee could affirm the inclusion of the new drug at its next regularly scheduled meeting, and in the interim the new antineoplastic drug would be placed in the specialty tier for high cost and unique items. We believe this policy offers the greatest protection to cancer patients and should also minimize administrative burdens for plan sponsors, which will certainly receive requests for exceptions for access to new cancer drugs.

Implementation of Part D and Beneficiary Education

Many of the organizations in the Cancer Leadership Council provide a wide range of educational and support services to cancer patients and their families and friends. Those organizations have undertaken to serve as a resource for Medicare beneficiaries evaluating Part D enrollment options. This has proven to be a challenge for our organizations and those we serve, but we remain committed to providing solid educational materials about Part D. We look forward to continued communication with CMS regarding the implementation of Part D.

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We appreciate the opportunity to comment on Part D and look forward to your response regarding these issues of importance to cancer patients and providers.

Sincerely,

Cancer Leadership Council

American Psychosocial Oncology Society
American Society of Clinical Oncology
American Society for Therapeutic Radiology & Oncology
C3: Colorectal Cancer Coalition
Cancer Care
Cancer Research and Prevention Foundation
Coalition of Cancer Cooperative Groups
International Myeloma Foundation
Kidney Cancer Association
Lance Armstrong Foundation
The Leukemia & Lymphoma Society

The Lung Cancer Alliance
Lymphoma Research Foundation
National Coalition for Cancer Survivorship
National Patient Advocate Foundation
North American Brain Tumor Coalition
Ovarian Cancer National Alliance
Pancreatic Cancer Action Network
Sarcoma Foundation of America
Us TOO International Prostate Cancer Education and Support Network
Y-ME National Breast Cancer Organization