

CANCER LEADERSHIP COUNCIL

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

March 4, 2010

Charlene M. Frizzera
Acting Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

Dear Ms. Frizzera:

The undersigned cancer patient, provider, and research organizations commend the Centers for Medicare & Medicaid (CMS) for including in the 2011 Advance Notice and Call Letter for Medicare Advantage (MA) and Medicare prescription drug plans a clarification of cost-sharing requirements for MA beneficiaries enrolled in clinical trials. By requiring MA plans to reimburse beneficiaries for the cost-sharing associated with clinical trials, the agency will finally make the benefits and protections of the Medicare clinical trial policy available to those enrolled in MA plans.

The undersigned organizations aggressively advocated Medicare coverage of routine patient care costs for those enrolled in clinical trials, first pursuing this coverage standard through legislation and then supporting the Executive Memorandum that resulted in the coverage determination. CMS has demonstrated leadership by implementing a clinical trials policy that ensures Medicare beneficiaries payment for the routine patient care costs they incur when enrolled in clinical trials. This policy is critical for guaranteeing that beneficiaries can consider all treatment options, including those in a clinical study, and at the same time the policy advances clinical research that answers fundamental questions about the safety and efficacy of new treatments. The coverage policy has had a positive effect on senior citizen participation in clinical research studies during the decade it has been in effect.

Regrettably, the policy has not provided comparable protections to those in MA plans, as they have been required to pay fee-for-service levels of cost-sharing for services related to clinical trials. This cost-sharing requirement deterred MA beneficiaries from enrolling in trials.

We applaud the agency's decision to: 1) continue paying on a fee-for-service basis for clinical trials services and items provided to MA plan members that are covered under the clinical trials policy, and 2) require MA plans, beginning in 2011, to reimburse beneficiaries for cost sharing incurred for clinical trials services that exceeds MA plan in-network cost sharing for the same category of service.

With this action, the agency has addressed a long-standing shortcoming in the implementation of the clinical trials coverage decision.

Sincerely,

Cancer Leadership Council

American Cancer Society Cancer Action Network
American Psychosocial Oncology Society
American Society for Radiation Oncology
American Society of Clinical Oncology
Breast Cancer Network of Strength
C3: Colorectal Cancer Coalition
Cancer Support Community
The Children's Cause for Cancer Advocacy
Coalition of Cancer Cooperative Groups
International Myeloma Foundation
Kidney Cancer Association
Lance Armstrong Foundation
The Leukemia & Lymphoma Society
Lymphoma Research Foundation
Multiple Myeloma Research Foundation
National Coalition for Cancer Survivorship
National Comprehensive Cancer Network
National Patient Advocate Foundation
North American Brain Tumor Coalition
Pancreatic Cancer Action Network
Prevent Cancer Foundation
Sarcoma Foundation of America
Susan G. Komen for the Cure Advocacy Alliance

cc: Jonathan Blum
Acting Director
Center for Drug and Health Plan Choice

Paul Spitalnic, ASA, MAAA
Director
Parts C & D Actuarial Group
Office of the Actuary