



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

July 18, 2006

Via Telecopy

Mark B. 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 have a significant investment in the Medicare policy regarding coverage of patient care costs in clinical trials. Indeed, many of us were intimately involved in the advocacy that resulted in the adoption of that policy and that shaped its contours. Thus, we have a strong interest in the ongoing status of coverage of clinical trials treatment and the proposal by the Centers for Medicare & Medicaid Services (CMS) to revise the policy.

We do not oppose a revisiting of this policy after several years of operation. In fact, we believe that such review might very well result in enhancements in the policy. Nevertheless, we are concerned that the short time frame for comment will not permit all interested parties to share their views regarding possible changes in the policy. A 30-day comment period is inadequate, particularly if it occurs during the summer vacation interval, when many of our organizations would not be readily able to provide meaningful comment.

The issue of coverage of patient care costs in clinical trials is crucial to the willingness of patients to participate in research, and few policy issues are more important to the oncology community. Any CMS initiative to review, revise or reform the existing policy is of the utmost concern to our constituents. We urgently request that you extend the deadline for comments until September 8, providing a 60-day comment period. We understand that the Medicare statute establishes certain standards for the coverage determination process in the case of external requests for coverage determinations, including a 30-day period of public comment after CMS has accepted the external request. In this circumstance, in contrast, the reconsideration is internally generated and a longer period for public input is appropriate and permissible.

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This policy is of sufficient importance that it deserves a reasonable period for comment. Please extend that comment period until at least September 8, 60 days following the initial proposal.

Thank you for your consideration of our request.

Sincerely,

Cancer Leadership Council

American Cancer Society
American Society of Clinical Oncology
American Society for Therapeutic Radiology &
Oncology
Association of American Cancer Institutes
Bladder Cancer Advocacy Network
C3: Colorectal Cancer Coalition
Cancer Care
Cancer Research and Prevention Foundation
The Children's Cause for Cancer Advocacy
Fertile Hope
Gilda's Club Worldwide
International Myeloma Foundation

Kidney Cancer Association
Lance Armstrong Foundation
The Leukemia & Lymphoma Society
The Lung Cancer Alliance
Lymphoma Research Foundation
Multiple Myeloma Research Foundation
National Coalition for Cancer Survivorship
North American Brain Tumor Coalition
Ovarian Cancer National Alliance
Pancreatic Cancer Action Network
The Susan G. Komen Breast Cancer Foundation
The Wellness Community
Y-ME National Breast Cancer Organization

cc: Leslye K. Fitterman, Ph.D.