



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

May 9, 2007

Leslie Norwalk, Esq.
Acting Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, S.W.
Room 314-H – HHH Bldg.
Washington, DC 20201

RE: CLC Comments Re CMS Proposed Decision Memorandum
On Medicare National Clinical Trial Policy -- CAG-00071R

Dear Ms. Norwalk:

The undersigned members of the Cancer Leadership Council (CLC) represent cancer patients, providers and researchers throughout the nation. We are writing to express our deep concern over the proposal to change the “deemed status” of IND exempt trials, eliminating their automatic coverage by Medicare under the 2000 National Coverage Determination (NCD) on clinical trials.

Many CLC members have worked for years not just to achieve the Medicare policy on clinical trials but also to obtain passage of state legislation modeled after that policy. We are very disappointed to see that the Centers for Medicare & Medicaid Services (CMS) has deleted an important element of the policy, coverage for IND exempt trials, without offering a satisfactory justification. The Food and Drug Administration (FDA) has made a science-based decision that IND exempt trials do not require the same level of oversight as other trials, and CMS should respect that decision. These trials offer important treatment options for many patients, and they also provide incremental advances in our knowledge of how chemotherapy drugs may be best utilized. It is not insignificant that, as CMS acknowledges, every comment submitted on this topic advocated retaining the automatic coverage of IND exempt trials.

CMS committed to the development of a self-certification process for these trials, but no such process has emerged. We feel that it is not an acceptable response for CMS simply to abandon coverage for IND exempt trials without further consideration of methods for assuring that these trials are appropriately covered – though we firmly believe that FDA’s judgment on this issue should be controlling.

