

August 17, 2007

Steve Phurrough, MD, MPA
Director, Coverage and Analysis Group
Centers for Medicare and Medicaid Services
7500 Security Blvd.
Mail Stop C10-9-06
Baltimore, Maryland 21244-1850

RE: Proposed Decision Memo for Clinical Trial Policy (CAG-00071R2)

Dear Dr. Phurrough:

The undersigned cancer organizations, representing cancer patients, researchers, and caregivers, are writing to express their strong objections to the proposed decision memo for clinical trial policy (CAG-00071R2) issued on July 19, 2007. The proposal represents a significant reversal of the standards for Medicare coverage of clinical trials that have been in effect since 2000, and it poses a threat to the ability of Medicare beneficiaries to receive care in clinical trials. We urge the Centers for Medicare & Medicaid Services (CMS) to rescind this proposal. If any changes in the 2000 policy are necessary, they relate only to narrow questions of minor refinements to a responsible policy that has enhanced health care quality for many Medicare beneficiaries.

The Benefits of the 2000 Clinical Trial Coverage Decision

The cancer community engaged in a decade-long effort to secure Medicare coverage of the routine patient care costs for those enrolled in clinical trials, culminating in President Clinton's issuance in 2000 of an Executive Memorandum requiring Medicare coverage of clinical trials. This coverage policy was essential for ensuring that cancer patients have access to quality care in a clinical trial (perhaps their best or only treatment option); furthering our knowledge about the best cancer therapies for senior citizens; and accelerating accrual to and the completion of clinical trials answering important treatment questions for cancer patients of all ages.

Before the 2000 Executive Memorandum, it was estimated that as few as 1 to 3 percent of Medicare beneficiaries participated in clinical trials. This low participation rate meant that Medicare patients were often not receiving the cutting-edge therapy they needed. In addition, because as many as 60 percent of cancer diagnoses occur in the elderly, the low rate of trial participation among this population affected overall trial accrual and the pace of clinical research.

