

August 17, 2007

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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.

In less than a decade, the Medicare clinical trial coverage policy has had a significant impact on seniors' participation in clinical research. Researchers at the Southwest Oncology Group (SWOG), one of the several cancer clinical trials cooperative groups funded by the National Cancer Institute (NCI), reported in 2006 that the 2000 coverage policy had resulted in an increase in Medicare beneficiaries' participation in cancer clinical trials. Prior to the 2000 coverage standard, the proportion of senior citizens in SWOG trials was only 25 percent, even though they accounted for 63 percent of the U.S. cancer population. In the period from 2001 to 2003, after the trials policy was implemented, seniors accounted for 38 percent of SWOG trial participants. The SWOG researchers considered other factors that might have influenced trial participation by seniors and concluded that the Medicare reimbursement policy was the major change in policy that positively influenced trial participation.<sup>1</sup>

### **The Potential Impact of the Self-Certification Policy**

In our years of advocacy for a responsible Medicare clinical trials policy, the cancer community argued that the standards for trial coverage needed to be simple and straightforward. We believed that trials that had been approved by federal agencies possessed the indicia of quality for Medicare coverage. These included trials reviewed and approved by the National Institutes of Health (NIH) (NCI, its cancer centers, and its cooperative groups) through peer review or other review processes, by the Veterans Administration (VA) or other federal agencies, or by the Food and Drug Administration (FDA) in granting an investigational new drug (IND) application (or determining that a trial is IND-exempt). We were gratified that CMS, in implementing the 2000 Executive Memorandum, determined that trials approved by federal agencies would be deemed covered by the Medicare program.

We recommended that, for those trials that did not fall squarely in the category of "deemed" trials, the process for certifying that they were quality trials needed to be simple, well-defined, and reasonable. CMS never defined that certification process in connection with the 2000 policy.

The cancer community objects to the introduction of a complex, resource-intensive, and potentially lengthy process for self-certification that will be imposed on clinical trials investigators. The self-certification process, which in the CMS proposal will replace entirely the deemed category of trials, requires that investigators answer 13 questions about their clinical trials in order to be eligible for Medicare reimbursement. Although the process is described as "self-certification," CMS would evaluate the documents submitted by investigators before declaring them eligible for Medicare payment. As delineated in the coverage proposal, the self-certification would be a time-consuming exercise for investigators and one of dubious value to the integrity of the research.

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<sup>1</sup> Unger JM, Coltman CA, Crowley JJ, et al., Impact of the year 2000 Medicare policy change on older patient enrollment to cancer clinical trials. *J Clin Oncol* 24:141-144, 2006.

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Clinical researchers reported prior to the issuance of this proposal that the regulatory and paperwork requirements for initiating a trial were mounting at the same time that reimbursement for the research aspects of a trial was shrinking. In this research and fiscal environment, we fear that investigators may choose not to seek certification for Medicare reimbursement, thereby effectively denying senior citizens the opportunity to enroll in clinical trials.

The possible negative impact of the proposed clinical trial policy on senior citizens is clear. However, the policy may also affect the overall quality of cancer care if it impedes investigation of the most effective cancer therapies.

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Cancer patients have demonstrated a keen interest in enrolling in clinical trials, not only to guarantee their access to quality care but also to advance the development of new and improved cancer treatments. The proposed clinical trial policy would thwart the altruism of Medicare beneficiaries as well as deny them access to the full range of treatment options. At a time when the population is aging and the proportion of cancer patients enrolled in Medicare is projected to increase, a policy that discourages research among the elderly with cancer is ill-advised.

We strongly urge CMS to withdraw this proposal, its second re-evaluation in slightly more than a year of the 2000 policy that has worked well for cancer patients and others and that we believe requires no revision.

Sincerely,

### **Cancer Leadership Council**

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  
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  
Multiple Myeloma Research Foundation  
National Coalition for Cancer Survivorship  
National Lung Cancer Partnership  
North American Brain Tumor Coalition  
Ovarian Cancer National Alliance  
Pancreatic Cancer Action Network  
Susan G. Komen for the Cure  
Us TOO International Prostate Cancer Education  
and Support Network  
The Wellness Community  
Y-ME National Breast Cancer Organization