

May 4, 2007

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**RE: Administrative File: CAG-00071R  
Clinical Trial Policy; Proposed Decision Memorandum for Medicare  
National Clinical Trial Policy**

Dear Dr. Phurrough:

The Association of Community Cancer Centers (ACCC) appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed decision regarding Medicare National Clinical Trial Policy.<sup>1</sup> ACCC is a membership organization whose members include hospitals, physicians, nurses, social workers, and oncology team members who care for millions of patients and families fighting cancer. ACCC's more than 700 member institutions and organizations treat 45% of all U.S. cancer patients.

ACCC is committed to ensuring that cancer patients have access to the entire continuum of quality cancer care, including access to the most appropriate cancer therapies, both through participation in clinical trials and outside clinical trials. We share CMS' interest in developing better evidence for use by patients, physicians, and policymakers. We strongly support efforts to increase the coverage of trials that may help in the treatment of cancer and other diseases. We believe that continued clinical research is essential to improving patient care and must be a priority for all stakeholders involved in cancer care, including CMS.

<sup>1</sup> <http://www.cms.hhs.gov/mcd/viewdraftdecisionmemo.asp?id=186>

ACCC appreciates CMS' efforts to develop revised policies on Medicare coverage of clinical research studies. We offer the following comments on CMS' proposed Clinical Research Policy (CRP).

- ACCC supports the decision to have all research studies subject to the CRP posted on a central website, so patients and providers alike will be able to better keep track of available trials.
- We also support the proposal that sponsors consider the potential benefits to Medicare populations and other subpopulations in designing a research study. However, we want to stress that this requirement should be applied in a manner that reflects the broad range of research studies that may be covered by the CRP and should not limit any Medicare beneficiary from participation in a research study.
- ACCC disagrees with the decision to no longer automatically cover IND-exempt trials as "deemed" to meet the standards of the CRP. This type of research study has been critical to the development of innovative treatments, particularly in the area of oncology. Furthermore, the Food and Drug Administration (FDA) has expressly encouraged researchers to use the IND-exempt process for oncology research. We urge CMS to continue to work closely with the FDA to resolve the many remaining questions regarding IND-exempt trials that takes into account the many stakeholder comments received on the CRP.

ACCC greatly appreciates this opportunity to comment on the proposed CRP. ACCC strongly supports clinical research and appreciates the need to expand research to enhance clinical decision-making. ACCC urges CMS to work closely with physicians, clinical trial sponsors, and other stakeholders to ensure that the implementation of this decision is consistent with these principles.

We would be pleased to answer any questions regarding these comments. Please contact Matthew Farber at 301-984-9496 ext. 221 if ACCC can be of any assistance as CMS continues to evaluate and develop its approach to Medicare coverage of clinical research studies.

Sincerely,



Edward L. Braud, MD  
Chair, Governmental Affairs Committee  
Association of Community Cancer Centers (ACCC)