



October 23, 2007

The Honorable Benjamin L. Cardin
U.S. Senate
509 Hart Senate Office Building
Washington, DC 20510

The Honorable Sam Brownback
U.S. Senate
303 Hart Senate Office Building
Washington, DC 20510

Dear Senators Cardin and Brownback:

As organizations representing over 24,000 cancer researchers and clinicians, 90 of the nation's top cancer centers, 126 U.S. and 17 Canadian accredited medical schools, and nearly 400 teaching hospitals and health systems, we write in strong support of your amendment expressing the sense of the Senate that the Centers for Medicare and Medicaid Services (CMS) should make permanent its decision rendered October 17, 2007 to maintain automatic coverage for federally sponsored and/or reviewed clinical trials. While we applaud the agency's decision not to proceed with its draft policy, a message from the Senate in opposition will help ensure that they do not move forward with any change in status for federally funded or reviewed trials.

We are deeply concerned about any proposal to change the automatic or deemed coverage for federally funded or reviewed trials. In establishing the existing policy in 2000, CMS determined that these trials already undergo extensive scientific and ethical review to ensure scientific merit and quality design. As a result, CMS decided not to require additional certification for these trials. Providing deemed status assures beneficiaries, investigators, and institutions that Medicare coverage is provided and that they will have prompt access to clinical trials.

Enrollment of seniors in clinical trials is critical to ensuring that we collect data on the outcomes of treatments on the Medicare population and provides them an opportunity to benefit from early advances in biomedical research. The rate at which we are able to enroll patients in clinical trials impacts the speed with which we are able to generate better evidence. Ultimately, all parties to the health care system, including payers such as CMS, benefit from quality evidence to identify the most effective treatments. This beneficial relationship is the reason that the Institute of Medicine concluded in its 2000 report that the Medicare program should provide coverage for clinical trials, stating that "The new emphasis on evidence-based medicine reflects the realization that intelligent decisions require substantial information that properly conducted clinical trials can provide."

The 2000 coverage policy has worked well and maintaining deemed coverage for trials that have already undergone federal agency review represents sound public policy. Imposing additional documentation requirements could create redundancies that significantly delay access to clinical trials, contribute to uncertainty for Medicare beneficiaries and researchers about whether coverage will be provided, and likely decrease or eliminate seniors' enrollment in clinical trials.

Thank you for your longstanding support of clinical research and Medicare coverage of clinical trials. Your efforts are critical to ensuring that we are able to develop improved health care treatments.

Sincerely,

American Society of Clinical Oncology
Association of American Cancer Institutes
Association of American Medical Colleges