

**Congress of the United States**  
**Washington, DC 20515**

October 16, 2007

Kerry Weems  
Acting Administrator  
Centers for Medicare and Medicaid Services  
200 Independence Avenue, S.W.  
Washington, DC 20201

Dear Mr. Weems:

We are writing to bring to your personal attention a troubling proposal that will undermine the Medicare clinical trial policy that has been in effect since September 2000. This coverage policy, implementing an Executive Memorandum issued in June of 2000, has improved the historically low rates of research trial participation by Medicare beneficiaries. As a result, more seniors have been afforded high quality care in clinical trials, and important research questions about medical therapies for seniors have been answered.

Recently, the Centers for Medicare & Medicaid Services (CMS) has undertaken an internally generated coverage reconsideration that would cease the current practice of relying on review and oversight by other federal agencies with expertise in clinical research, including the National Institutes of Health (NIH) and the Food & Drug Administration (FDA), to determine which clinical trials should be covered by Medicare. Under the current policy, trials reviewed by NIH and other federal funding agencies or privately sponsored trials under the jurisdiction of FDA are “deemed” qualified, and Medicare reimburses for routine patient care costs incurred in those trials. This “deemed,” or automatic, coverage has been instrumental to the success of the policy by avoiding the burdens of duplicative review by CMS.

Now CMS proposes to replace that efficient policy with a cumbersome certification process devised by CMS officials, ignoring the superior expertise of NIH and FDA. Leading medical societies representing clinical researchers in cancer and other diseases and major medical centers across the country have protested that the proposed changes in the coverage policy will add significant cost and delay and will deter participation by Medicare beneficiaries in clinical trials.

The 2000 coverage policy is critical to encouraging research on many serious and life-threatening diseases, but none more of a burden on the nation than cancer. More than 60 percent of cancer diagnoses occur among the elderly, and this burden will only intensify as the population ages. Researchers have long been concerned that a low rate of participation in clinical research by senior citizens has hindered their ability to identify the best treatments for seniors with cancer. The 2000 coverage policy has boosted senior


citizens' participation in cancer clinical research, a positive achievement for individuals fortunate enough to enroll in trials and for others with cancer whose treatment is enhanced through research.

The clinical trial coverage proposal offered by your agency has the potential to reverse the progress in clinical research participation that has been realized since 2000. The proposed policy does not serve the best interests of senior citizens who participate in trials or who benefit from the results of trials. Neither is it in the best interest of the Medicare program, which must rely on clinical research to answer questions about therapies the program should pay for and those it should not.

We strongly urge you to discontinue the reconsideration of the clinical trial policy and to leave in effect the coverage standard that has worked well since 2000.

Sincerely,

  
DEBORAH PRYCE  
Member of Congress

  
LOIS CAPPS  
Member of Congress

  
SUE MYRICK  
Member of Congress

  
STEVE ISRAEL  
Member of Congress