THE WHITE HOUSE

WASHINGTON

June 6, 2000

STATEMENT ON CLINICAL TRIALS PARTICIPATION FOR MEDICARE BENEFICIARIES

DATE:	June 7, 2000
LOCATION:	South Portico
BRIEFING TIME:	7:30am – 7:45am
EVENT TIME:	7:45am – 7:55am
FROM:	Bruce Reed, Chris Jennings

I. PURPOSE

To direct the Department of Health and Human Services to revise the Medicare policy to authorize payment for the cost of routine patient care associated with participation in clinical trials, and to promote Medicare beneficiary participation in clinical trials for all diseases.

II. BACKGROUND

The actions you are taking today follow the completion of a legal review conducted by the Department of Health and Human Services (HHS) after a recent Institute of Medicine report recommending policy changes to encourage greater use of clinical trials by older Americans. In your remarks, you will single out the longstanding commitment of the Vice President on this issue and commend Senators Rockefeller and Mack and Representatives Johnson and Cardin for their leadership in sponsoring legislation on this issue. You will also call on the Congress to extend similar enforcement provisions to all private plans for all types of clinical trials, underscoring that the Norwood-Dingell Patients' Bill of Rights legislation that is now stalled in the Congress has such provisions.

ACTION IS NECESSARY TO INCREASE THE PARTICIPATION OF SENIORS IN CLINICAL TRIALS. Today, you will highlight that:

Too few seniors participate in clinical trials. About one percent of seniors participate in clinical trials, despite the fact that the elderly bear the majority of the disease burden experienced nationally. For example, 63 percent of cancer patients are older than 65, but they constitute only 33 percent of those enrolled in clinical trials. The disparity is greater for breast cancer patients – elderly women make up 44 percent of breast cancer patients, but only 1.6 percent of women over the age of 65 are in clinical trials for the disease.

Scientists believe that higher participation in clinical trials could lead to faster development of therapies, as it often takes between three and five years to enroll enough participants in a clinical trial to make the results scientifically valid and statistically meaningful.

Current Medicare reimbursement policies often discourage seniors from participating in clinical trials. Because clinical trial investigators cannot guarantee that Medicare will pay for the care associated with participation in their clinical trial, seniors considering whether to enter these trials must assume that they may be responsible for costs simply because they are participating in a clinical trial. In addition, investigators and research centers are often reluctant to recruit them because of the uncertainty of Medicare reimbursement.

Increased participation is likely to have significant rewards. Striking progress made in treating and curing pediatric cancers was largely possible because of widespread participation in clinical trials. For decades now, well over 50 percent of pediatric cancer patients were enrolled in clinical trials, and today, 75 percent of cancers in children are curable. Experts believe that coverage of all clinical trials – not just those for cancer – is critically important to ensuring new breakthroughs in diagnostics, treatments, and cures for many of the most devastating diseases afflicting millions of Americans of all ages.

NEW EXECUTIVE ACTION TO ENCOURAGE PARTICIPATION IN CLINICAL TRIALS. Your Executive Memorandum directs HHS to:

Revise Medicare program guidance to explicitly authorize payment for routine patient care costs associated with clinical trials. This week, the Health Care Financing Administration (HCFA) will inform all claims processing contractors that Medicare will immediately begin to reimburse for the routine patient care costs and costs due to medical complications associated with participation in a clinical trial and remove this barrier to participation.

Launch activities to increase beneficiary awareness of the new coverage option. HHS will launch an effort to educate beneficiaries and providers about this policy change, including adding information on clinical trial coverage to the Medicare handbook and posting information on their website.

Establish a tracking system for Medicare payments. Before the end of the fiscal year, HCFA will implement a system to track spending in trials for which Medicare contributes financial support.

Ensure that the information gained from important clinical trials is used to inform coverage decisions. Beginning this summer, HCFA and the National Institutes of Health (NIH) will work with researchers prior to the beginning of a clinical trial in order to structure the trial to produce information necessary to inform subsequent Medicare

coverage decisions when the therapies or devices under review have significant implications for the Medicare program.

Review the feasibility and advisability of taking additional action to promote research on issues of importance to the Medicare population within 90 days. HHS should review the feasibility and advisability of:

The Institute of Medicine's recommendation that HCFA support certain clinical trials that are of particular importance to the Medicare population. Certain health care interventions are unique to the Medicare population and clinical trials on these issues could lead to more effective or less costly treatments. HHS should review the feasibility and advisability of providing additional financial support for monitoring and evaluation, device implantation, and other non-covered costs for trials of importance to Medicare beneficiaries.

Taking action to increase the participation of seniors in clinical trials. NIH should evaluate the feasibility and advisability of taking additional action to increase the participation of seniors in clinical trials to ensure that researchers can determine the best therapies for older as well as younger patients.

Developing a registry of ongoing clinical trials receiving Medicare reimbursement. In addition, HHS will review the feasibility and advisability of using the information contained in current NIH and FDA clinical trial registries to develop a national registry of all clinical trials receiving Medicare reimbursement. This new registry would provide a comprehensive picture of the types of trials ongoing, the participation rates, and how patients can access the trials, in addition to facilitating HCFA's ongoing review and oversight activities to ensure that only covered services are billed and reimbursed.

III. PARTICIPANTS

Briefing Participants:
Bruce Reed
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Statement Participant:
YOU

IV. PRESS PLAN

Open Press.

V. SEQUENCE OF EVENTS

- **YOU** will proceed to the podium in the Rose Garden.
- **YOU** will make remarks and depart.

VI. REMARKS

To be provided by speechwriting.