

**EDICT Team “Assuring Healthcare Coverage in Clinical Trials” -
Comments to CMS Regarding Proposed Revisions to
Medicare Coverage of Clinical Trials – May 10, 2007**

We are writing to 1) express our concern regarding the proposed standard related to health disparities and 2) request that any new guidelines include education of beneficiaries regarding clinical trials coverage.

HEALTH DISPARITIES

The CMS standard as stated does not improve upon the existing NIH Revitalization Act of 1993 and the FDA Modernization Act of 1997, which have proven ineffective in bolstering the representation of underrepresented populations to date. Current research demonstrates that underrepresented groups are still not adequately represented in clinical trials:

- According to the Coalition of Cancer Cooperative Groups, 89 percent of participants enrolled in NCI clinical trials between January 2003 and June 2005 were white and;
- Nearly two-thirds of cancer patients are 65 and older, but this age group accounts for less than one-third of those in clinical trials, as referenced in a 2003 study.

Without adequate representation of these populations in clinical trials, researchers cannot learn about differences in safety and efficacy between groups and cannot ensure the generalization of scientific results. This also contributes to health disparities by keeping the newest techniques and drugs out of the reach of disadvantaged groups.

As it stands, we would recommend going back to the initially proposed policy language or modifying the revised standard to have more substantive impact on the problem of disparities in clinical trials and to ensure some mechanism of enforcement.

We recommend the addition (in brackets) to the proposed standard stated below:

“The research study protocol must have explicitly discussed inclusion criteria, considered relevant subpopulations (as defined by age, gender, race/ethnicity, socioeconomic or other factors), [and contain a plan for the retention and reporting of said populations on the trial.]”

Comments: Ideally, the protocol should also contain a plan for assuring that these communities will directly benefit from any outcomes of the trial. If the inclusion criteria can reasonably be expected to have a negative effect on the recruitment or retention of currently underrepresented groups so as to render the clinical trial unable to achieve a representative sample of the target population, the researcher should provide explanation as to why the discriminatory criteria were necessary. If it is discovered during or after a clinical trial that the researcher’s inclusive enrollment criteria failed at achieving a

representative sample of the target population, then a written explanation from the researcher will be necessary before further reimbursement will be allowed.

EDUCATION OF MEDICARE RECIPIENTS REGARDING CLINICAL TRIALS BENEFITS

In one study, 60% of respondents who have insurance, cited a fear of having their insurance denied as the reason they decided not to participate in a clinical trial.

We request that Medicare beneficiaries be educated about clinical trial participation and coverage in order to ensure that equitable access to clinical trials is not hindered by misconceptions or lack of information.

We, at the Eliminating Disparities in Clinical Trials (EDICT) Project, appreciate the opportunity to respond to the revised NCD and applaud CMS efforts to revisit the benefit issues related to clinical trials. The EDICT Project, launched in 2005, is a research study designed to address the problems and find workable solutions to recruiting and retaining populations that are underrepresented in clinical trials such as low income, elderly, racial-ethnic minorities or those who live in rural areas.

Sincerely,

Armin D. Weinberg, PhD

Principal Investigator

On behalf of the Leadership of the Opportunity Team, "Ensuring Healthcare Coverage in Clinical Trials"

EDICT (Eliminating Disparities in Clinical Trials) Project

Chronic Disease Prevention and Control Research Center

Baylor College of Medicine

Houston, Texas