

Non-Medical Costs Associated with Clinical Trials Continue to be Barrier to Diverse Participation

21 public health groups ask Health and Human Services Office of Inspector General for regulatory reform to address the issue.

February 12, 2024 By American Cancer Society Cancer Action Network

On February 2, the American Cancer Society Cancer Action Network (ACS CAN) was joined by 20 other organizations in proposing the Health and Human Services Office of Inspector General adopt a new regulatory safe harbor from the Anti-kickback Statute that would allow clinical trial sponsors to financially support patients to offset indirect or non-medical costs associated with clinical trial participation, such as travel, parking and lodging. The letter reads in part:

“Although there are myriad reasons for the lack of diversity in clinical trials, one is straightforward: many diverse individuals simply cannot afford to participate in clinical trials. A clinical trial participant incurs two types of costs: direct medical costs (“direct costs”) and indirect ancillary costs (“indirect costs”).

“Indirect costs, which are the subject of this proposal, are non-medical costs that, but for participation in the clinical trial at issue, the participant would not incur. By way of example only, depending on the particular clinical trial and participant, indirect costs might include costs associated with travel, parking, lodging, childcare, and lost wages that, but for enrolling in the clinical trial at issue, the participant would not have incurred.”

The letter cites a recent study, which found that participants in cancer clinical trials incurred an average of \$600 per month—or \$7,200 per year—in indirect costs. Not surprisingly, then, indirect costs pose a far greater barrier to clinical trial participation by those with lower socioeconomic status.

Read the full letter [here](#).

The following is a list of groups that signed the letter: American Cancer Society Cancer Action Network, Association of American Cancer Institutes, American Association for Cancer Research, American Society of Clinical Oncology, American Society for Radiation Oncology, Fight Colorectal

Cancer, Friends of Cancer Research, International Myeloma Foundation, Triage Cancer, LUNgevity Foundation, Melanoma Research Foundation, Men's Health Network, National Cancer Registrars Association, National Comprehensive Cancer Network, Oncology Nursing Society, Ovarian Cancer Research Alliance, Pennsylvania Prostate Cancer Coalition, Society for Gynecologic Oncology, Susan G. Komen, Tigerlily Foundation, and Zero Prostate Cancer.

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