



September 10, 2024

The Honorable Raul Ruiz
U.S. Representative
2342 Rayburn House Office
Building Washington, DC 20515

The Honorable Larry Bucshon
U.S. Representative
2313 Rayburn House Office
Building Washington, DC 20515

Dear Representatives Ruiz and Bucshon:

We write today on behalf of Livestrong, the nonprofit organization dedicated to improving cancer patients' and survivors' quality of life, to thank you for introducing H.R.8412, the Clinical Trial Modernization Act, and to express our support for this important legislation.

As you know, clinical trials are key to advancing new standards of care that can improve survival and quality of life for people with cancer and other life-threatening diseases. To be successful, it is important that trials enroll an adequate number of participants that reflect the diversity of patients with the disease. However, patient enrollment in clinical trials is an ongoing challenge, and some population groups are underrepresented, including certain racial and ethnic groups, older adults, rural residents, and those with limited incomes.

We also know that concerns about potential costs of participation in a clinical trial often prevent otherwise interested patients from enrolling. For patients, clinical trial costs involve both direct medical and non-medical costs. While most insurers are required to cover the direct medical or "routine costs" of treatment ordinarily administered absent a clinical trial (e.g., standard of care diagnostic testing), patients often still have cost-sharing requirements associated with their coverage (e.g., deductibles, copays, coinsurance).

Additionally, participation in a trial can come with associated non-medical costs including transportation, lodging, and meals associated with clinic visits necessary for participation in a trial. These nonmedical costs can be especially challenging when no local trials are available and patients must travel to distant trial sites, or when there is a need for more frequent clinic visits for additional trial-related treatment or monitoring. Patients receiving care at community cancer centers — where most cancer care is provided — have much less access to locally available clinical trials and tend to be the most affected by financial burdens of travel. These additional costs can lead to disparate participation rates between high- and low-income patients and between patients in different geographies. In fact, we know that cancer patients from households making less than \$50,000 per year are nearly 30% less likely to enroll in clinical trials.

Studies have shown that offering to reimburse patients for non-medical costs associated with trials can increase overall enrollment and may also increase participation from underrepresented groups. While some trial sponsors provide financial support for non-medical costs, those that do not often cite concerns about violating federal restrictions on providing patients with what could be viewed as a financial incentive. For patients, especially low-income patients, receipt of financial support can create challenges with potential tax burdens for any stipend-style payments, or potential disqualification from safety net programs if such trial support is considered income.

For these reasons, we are excited by the introduction of the Clinical Trial Modernization Act, which would make it easier for people to participate in clinical trials by addressing barriers they currently face. Specifically, the Clinical Trial Modernization Act:

- Removes economic barriers to increase clinical trial participation from all demographic, socioeconomic, and geographic populations by allowing sponsors to financially support trial participants for both medical (e.g., copay and co-insurance) and non-medical (e.g., travel, lodging, childcare) costs associated with trial participation.
- Facilitates remote participation in clinical trials by allowing trial sponsors to provide patients with digital health technology (e.g., smartwatch and/or tablet) necessary for participation at no cost to the patient.
- Encourages clinical trial enrollment by underrepresented groups by allowing the Department of Health and Human Services (HHS) to issue grants to support community education, outreach, and recruitment for trials, including grants to trusted messengers.
- Ensures that up to \$2,000 of non-reimbursable financial support from clinical trial sponsors provided to patients is not subject to taxation or counted against income limitations for safety net programs, which would protect 98% of cancer trial participants.

These important provisions are key to increasing clinical trial participation and, thereby, driving innovation and the development of new treatments. This benefits not only trial participants, but all of us.

Once again, we thank you for your leadership on this issue and please do not hesitate to call on us in any way that we can be supportive.

Sincerely,

Livestrong