Date

The Honorable (insert Congressman/women name)

Address

Cite, State Zip

Dear Congressman/women (insert with actual name):

My name is (add your name) and I live in district (your district). (Insert a personal message)

Per the WHO, acknowledging health as a human right recognizes a legal obligation (on states) to ensure access to timely, acceptable, and affordable health care – yet we continue to perpetuate health disparities through existing legislation that works for some but not all – especially as it relates to clinical trial access and diversity. The purpose of this letter is to highlight several actionable items that can change the current status quo, reduce patient burden, and achieve clinical trial diversity and equitable access.

The purpose of this letter is to focus your attention on the issues listed below and the negative impact they have on patients. This causes unnecessary friction for any patient entering a clinical trial. If these issues are not addressed, we will NOT be able to adequately focus on issues we face with diversity in clinical trials. I ask for your support in addressing these points.

1. Establish patient reimbursements as nontaxable income. Congress has raised the cap of reportable amounts for rare diseases. However, it should be eliminated as taxable income as patients are not in the business of being clinical trial participants.
2. Eliminate the newly required CMS Medicaid form created by Section 210 of the Consolidated Appropriations Act of 2021. This form causes additional and unnecessary burden on the enrollment of the Medicaid population into clinical trials. No other payor (including Medicare) discriminates against their population in this manner and the added burdens and cost of the form is contrary to the intent of the law in increasing diversity in the clinical trial population.
3. Establish travel reimbursement for clinical trial participants exempt from the OIG restrictions on travel offerings. The OIG guidance limits amounts and distance (i.e., only 25 or 50 miles) for reimbursement. These guidelines may work when there is a physician or hospital in every town. In reality, there is arguably less than one trial site per state to service a patient which requires a larger mileage range to cover these patients. Studies have shown that patients must travel on average much higher distances to get to a clinical trial site. As a corollary to this, they should change the IRB and OIG rules from equality to equity for transportation reimbursement. If one patient requires $40 of transportation to get back and forth to the trial site and another requires $140, the general norm set up today is equality based (e.g., everyone gets $40). Arevised law can state that transportation reimbursement is equity based (you can reimburse one $40 and the other $140 as this is what it takes to get both to the trial site).
4. Allow for clinical trial sponsors to pay for Medicare beneficiaries’ copays and deductibles for routine care items and services required by qualifying clinical trials.
5. Establish a stakeholder meeting to review additional barriers to participation, including but not limited to simplifying the complex and inconsistent rules CMS imposes for trial-related coverage of routine care items.

I am asking for your support in advocating for these issues to be fully addressed and included in the Cures 2.0 Act. I am grateful for your leadership in making a difference for patients and ensuring equity and access for diverse populations is possible and required. I look forward to working with you on this and other proposals that will improve the lives of people across America.

Respectfully,

Your Name:

Credentials

Email address

Phone number