Tax and Legal Considerations for Compensation Programs for Clinical Trial Participants

Policy Solutions for Mitigating Risks

EQUITABLE ACCESS TO CLINICAL TRIALS

Executive Summary

Financial toxicity, the economic burden related to medical care that can negatively impact patients' quality of life, has been well documented among patients with cancer, but it affects patients across multiple diseases. More than just the cost of the therapy/treatment, financial toxicity arises from out-of-pocket *medical* costs (e.g., insurance copays and deductibles, uncovered lab tests, exams) as well as *non-medical* costs (e.g., transportation, lodging, time off work). These out-of-pocket costs exist whether a patient is participating in a clinical trial or is receiving standard care outside of a trial; however, the costs of trial participation may be higher than standard care depending on the trial's design and/or location.

There are three main approaches to providing financial support to clinical trial participants for non-medical costs: reimbursement, prepayment, and stipends. For reimbursement, the trial sponsor (or other entity administering the program) will reimburse trial-related expenses for which there is substantiation. For prepayment, sponsors use a variety of approaches to provide prepayment for non-medical expenses and automate the collection of receipts. With stipends, sponsors offer fixed monies to participants for completing study visits or other study activities.

Each of these approaches for offsetting out-of-pocket non-medical costs associated with trial participation raises a variety of ethical and legal considerations for sponsors and patients, including concerns about inducement, anti-kickback restrictions, tax implications, and impact on eligibility for safety net programs.

These concerns pertain to both perceived and real risks for the various stakeholders, most of which could largely be mitigated by implementation of policy solutions outlined in this brief, including:

- Updating federal statutes and regulations to ensure that receipt of support to offset the financial impact of out-of-pocket non-medical costs incurred as a result of participating in clinical trials does not engender tax obligations nor lead to loss of eligibility for income-based services
- Creating clear safe harbors for clinical trial sponsors and/or other entities providing financial support for trial participants' out-of-pocket non-medical costs to shield them from federal civil and criminal penalties

This document was prepared as part of the Equitable Access to Clinical Trials Project. For more information, visit www.eactproject.org .

Overview

Clinical trials are an important treatment option for today's patients, and robust and diverse participation is paramount for continued progress in developing new treatments. Despite clear benefits to the field and to individual patients, clinical research struggles with low overall enrollment in trials and inadequate racial, ethnic, and socioeconomic diversity among trial participants. Lower-income patients ($20,000-$49,999 annual household income) are consistently less likely to participate in clinical trials than their higher-income peers ($50,000+ annual household income).[1]

Financial toxicity, the economic burden related to medical care that can negatively impact patients' quality of life, has been well documented among patients with cancer[2,3] but affects patients across multiple diseases. More than just the cost of the therapy/treatment, financial toxicity arises from out-of-pocket *medical* costs (e.g., insurance copays and deductibles, uncovered lab tests, exams) as well as *non-medical* costs (e.g., transportation, lodging, time off work). These out-of-pocket costs exist whether a patient is participating in a clinical trial or is receiving standard care outside of a trial; however, the costs of trial participation may be higher than standard care depending on the trial's design and/or location.

One study examining costs incurred as part of cancer clinical trial participation found that 64% of survey respondents had unanticipated non-medical expenses.[4] These expenses amounted to at least $600 per month for 51% of respondents, while 21% of respondents spent $1,500 per month or more on non-medical expenses. Another study found that individuals from economically disadvantaged neighborhoods traveled more than three times as far as individuals from non-poor neighborhoods for clinical trial participation (58.3 vs 17.8 miles each way),[5] creating additional financial burden through transportation costs and time away from home or work for those who can least afford it.

Offering to reimburse patients for costs associated with trials increases patients' willingness to enroll and may also increase trial diversity. This was clearly demonstrated in a recent American Cancer Society Cancer Action Network (ACSCAN) Survivor Views survey, in which 79% of respondents indicated that sponsor support for lodging and transportation would make them more likely to enroll in a trial outside of their local area.[6]

As part of an initiative to understand real and perceived barriers to providing support to patients for out-of-pocket non-medical costs stemming from participation in clinical trials, a multistakeholder group evaluated the landscape of reimbursement practices and developed resources to advance solutions. Two areas of focus were tax implications on the part of trial participants for taking part in financial support programs and legal implications for trial sponsors seeking to provide such programs.

Compensation for Clinical Trial Participation

There are three main approaches to providing financial support to clinical trial participants for non-medical costs: reimbursement, prepayment, and stipends. Each of these methods of support has benefits and drawbacks, as outlined below.

Reimbursement

Many financial support programs use reimbursement for non-medical expenses associated with participating in a clinical trial. In this model, the trial sponsor (or other entity administering the program) will reimburse trial-related expenses for which there is substantiation, usually in the form of receipts. Although this approach ensures trial participants eventually recoup non-medical financial outlays, lower-income individuals may not have the wherewithal to pay some of these expenses out of pocket and/or to wait the 30 to 60 days it generally takes to process reimbursements. Additionally, the burden of submitting reimbursement paperwork while undergoing cancer treatment can reduce or eliminate the value to the patient of this type of financial support.

Prepayment

To decrease the financial and administrative burdens associated with reimbursement, some sponsors provide prepayment for non-medical expenses (e.g., through prepaid debit cards or direct deposit to a bank account). Alternatively, they may offer logistical support—often through third-party vendors—such that participants do not need to book and pay for travel on their own. Although these methods help ensure that participants do not have to bear certain expenses that might cause financial strain, they do constitute reimbursement, and receipts for allowable expenses must be kept and provided as substantiation.

Stipends

Stipends are fixed monies offered to participants for completing study visits or other study activities. For example, sponsors may provide stipends to participants for completing e-diary entries and/or for time spent at protocol-required visits. Stipends are intended to demonstrate appreciation for patients' time and sacrifice in contributing to the greater good by participating in clinical trials. Practically speaking, the monies can be used to cover or help offset expenses that may be more difficult to substantiate or are not included in the support program, such as lost wages or childcare/eldercare/pet care provided by a friend or family member.

Comparison of Compensation Methods

	ADVANTAGES	DISADVANTAGES
REIMBURSEMENT	• Reimbursement is specific to each participant and reflects the actual costs they shoulder based on differing, individual circumstances (e.g., one participant spends $25 on a taxi to the trial site but another spends $450 on airfare; both costs are deemed acceptable under the trial's reimbursement program) • Participants do not need to include payments received as reimbursement as income for tax purposes	• Participants must pay out of pocket for trial-related expenses • Not all participants will be financially able to pay out of pocket • Participants must provide receipts as justification for reimbursement • Receipts provided must be reviewed/approved, which may result in long wait times for receiving reimbursement • Not all non-medical expenses may be eligible for reimbursement, and/or expenses may be reimbursed only up to a certain amount
PREPAYMENT	• Participants do not have to wait for reimbursement • It ensures that participants already have funds to pay for costs associated with the trial • Participants do not have to keep track of whether they are getting reimbursed to recoup personal funds • It can be automated, which further reduces patient burden	• Each participant could incur different costs for the same category (e.g., travel), and the prepayment amount may not cover the given expense for every participant • Prepayments could be considered income and therefore taxable if the total amount exceeds $600/year. To avoid this, participants would still need to demonstrate that the monies were used for clinical trial expenses (e.g., with receipts)
STIPENDS	• Stipends recognize participants' contribution of time and effort • They can be automated and/or issued quickly, which reduces burden for both patients and administrators (e.g., sponsor, site staff, vendor)	• Set stipend amount might not meet some patients' expectations of fair compensation for their time and burden • Payments and/or stipends are considered taxable income if the total amount is at least $600/year

Perceived Barriers to Providing Compensation

Ethical Considerations

While compensating trial participants can improve trial enrollment, especially among populations often underrepresented in clinical research,[7,8] it is not without controversy because of the perception that it could unduly influence participation decisions.[9] This concern stems from the Belmont Report[10]—the output of the Commission charged with laying out the ethical principles that should govern all research involving human subjects in the US. The Belmont Report states that agreement to participate in research is valid only if it is given voluntarily, defined therein as "free of coercion or undue influence." Although coercion—using threat of harm to achieve a desired result—is not relevant to reimbursement and/or compensation for research participation, such payments could be perceived as undue influence: "an offer of an excessive, unwarranted, inappropriate or improper reward."[10] Unfortunately the Report does not elaborate on what would constitute undue influence in the context of compensation.

Similarly, federal regulations governing clinical investigations do not explicitly mention compensation of research participants, noting only that the informed consent process should "minimize the possibility of … undue influence."[11, 12] Conservative interpretations of the Belmont Report and federal regulations by either clinical trial sponsors or institutional review boards (IRBs; groups that review clinical research proposals to ensure they meet applicable legal, ethical, and professional standards) could result in lack of offer or approval of compensation for trial participants, respectively.

Recent guidance from the Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP)[13] and the US Food and Drug Administration (FDA)[14] provide useful context for industry, IRBs, and investigators on the extent and acceptability of payment for research participation. FDA states that it does not consider "reimbursement for travel expenses … and associated costs such as airfare, parking, and lodging to raise issues regarding undue influence." Both FDA and OHRP acknowledge that paying participants "is a common and, in general, acceptable practice," but they note that IRBs must determine how much money and for what reason(s) participants should be paid to avoid unduly influencing consent decisions. The DHHS Secretary's Advisory Committee on Human Research Protections (SACHRP) goes further, recommending that OHRP and FDA clarify that compensating participants for their time and effort and providing "appreciation payments" do not constitute undue influence.[15]

Although IRBs' interpretations of regulations and guidance vary across clinical trial sites, historically they have been more conservative than what is allowed within the specified legal framework.[16] Consistent with guidance, IRBs typically do not raise questions around reimbursement of out-of-pocket non-medical expenses resulting from trial participation. Allowance of stipends in recognition of participants' time and inconvenience is becoming more common but still is not widely accepted practice. Recent work to encourage trial sponsors and investigators to situate proposed financial support in a framework that clarifies why or for what purpose payment is being offered[17] can help IRBs more clearly assess the appropriateness of payment offers[16] and, together with a societal shift toward expectation of compensation, could lead to broader acceptance of payment of research participants.

Potential Legal Penalties for Sponsors

Two pieces of federal law are sometimes interpreted as prohibiting the provision of financial support for clinical trial participation. One is the Anti-Kickback Statute, which establishes criminal liability for offering remuneration (e.g., money, goods, or services) that could induce individuals to seek services billable to the federal government.[18] The second is the Civil Monetary Penalty Statute, which establishes monetary penalties for the same actions.[19]

The idea behind these laws is that a physician could not, for example, give seniors a gift card to come in for a checkup that would be billable to Medicare. Providing financial support for non-medical costs associated with clinical trial participation could conceivably fall under this restriction, as routine care costs incurred as part of trial participation could be paid for by Medicare for Medicare enrollees. In practice, many sponsors feel that such support does not run afoul of this prohibition and actively provide this support to patients in their trials. To date, no lawsuits have been brought against sponsors, and numerous DHHS advisory opinions have allowed such support. However, some sponsors have pointed to this risk as a reason to refrain from providing financial support programs.

Financial Liabilities for Trial Participants

While providing financial support has been shown to relieve patient burdens in the near term, thus increasing the likelihood of patients enrolling in clinical trials, recipients of support outside of simple reimbursement can be subject to tax and income reporting requirements, which can create administrative and financial burdens.

Form 1099 is a federal information return that reports various types of payments made to a taxpayer outside of an employee-employer relationship. The payer (which, in this case, would be the trial sponsor or other entity administering the financial support program) completes Form 1099 and sends copies to the trial participant and the Internal Revenue Service (IRS).

There are several types of 1099 forms. Payers making payments totaling $600 or more during the calendar year to a non-employee must file a Form 1099-MISC (Miscellaneous Income) for each recipient.[20] In 2009, the inclusion of "a payment or series of payments made to individuals participating in a medical research study" was added to the 1099-MISC form instructions.[21] All research-related payments must be included except for reimbursements for actual expenses, which can be excluded if the expenses are substantiated (i.e., verified by a receipt) based on the IRS accountable plan rule. Depending on a participant's individual income tax filing circumstances (e.g., filing status, other income, exemptions, deductions, etc.), the income reported on Form 1099-MISC may be subject to federal and state income tax.[22]

The reporting requirement for clinical trial participant payments creates significant challenges for both the trial site and participants. To ensure compliance with tax reporting rules,[23] a participant would be asked for their Taxpayer Identification Number (TIN; commonly a Social Security Number) during the informed consent process or when applying for a financial support program. This could be a barrier for potential trial participants, especially those from sensitive populations (e.g., people experiencing homelessness or undocumented immigrants). If a valid TIN is not provided, 24% of the *reportable payment* is withheld.[24] A reportable payment includes payment for services, such as participation in a clinical trial.

In addition to potentially triggering a tax liability, stipends for clinical trial participation could affect a recipient's eligibility for safety net programs such as Supplemental Nutrition Assistance Program (SNAP) benefits, Medicaid, Insurance Marketplace subsidies, or Veterans Affairs (VA) benefits, all of which often have both annual income limits and assets tests. There is currently a $2,000 exclusion from income calculations for Supplemental Security Income (SSI) eligibility when a patient receives support for a rare disease clinical trial.[25]

Policy Recommendations

Policy changes are needed to advance the goal of making clinical trial participation a financially neutral treatment option for patients. Patients should be shielded from out-of-pocket non-medical costs of trial participation such as travel, parking, childcare, and lodging, and protected from negative consequences related to receipt of support for those costs. Moreover, entities that offer or facilitate such support should not be subject to federal criminal or civil penalties for doing so.

Recommendation 1

Ensure that receipt of support to offset the financial impact of out-of-pocket non-medical costs incurred as a result of participating in clinical trials does not engender tax obligations nor lead to loss of eligibility for income-based services.

- Recommendation 1a: Remove the "rare disease or condition" qualifier from the exemption from income for compensation for clinical trial participation in the appropriate federal statute(s).
- Recommendation 1b: Amend appropriate federal statutes and regulations to reflect that compensation for clinical trial participation does not affect eligibility for Medicaid, Children's Health Insurance Program (CHIP), Affordable Care Act marketplace insurance subsidies, and SNAP benefits.

Recommendation 2

Create clear safe harbors for clinical trial sponsors and/or other entities providing financial support for trial participants' out-of-pocket non-medical costs to shield them from federal civil and criminal penalties (i.e., Anti-Kickback Statute and Civil Monetary Penalties Law, respectively).

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