Brigham and Women's Hospital
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HARVARD MEDICAL SCHOOL

MULTI-REGIONAL CLINICAL TRIALS
THE MRCT CENTER of BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

The Honorable T. March Bell
Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
330 Independence Avenue, SW
Washington, DC 20201

August 23, 2026

Re: **Medicare and State Health Care Programs: Fraud and Abuse; Request for Information Regarding the Federal Anti-Kickback Statute and Beneficiary Inducements CMP (OIG-2602-N), 91 Fed. Reg 37902 (June 24, 2026).**

Submitted electronically via Regulations.gov

Dear Inspector General Bell:

The Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard ("MRCT Center") appreciates the opportunity to comment in response to the Office of Inspector General's Request for Information concerning the application of the Federal Anti-Kickback Statute (AKS) and Beneficiary Inducements Civil Monetary Penalty (CMP) provisions to remuneration associated with participation in clinical trials. We appreciate OIG's interest in examining whether existing regulatory frameworks appropriately balance program integrity concerns with the need to facilitate important and ethically conducted research.

The MRCT Center is a research and policy center that seeks to improve the ethics, conduct, oversight, and regulatory environment of international, multi-site clinical trials. It functions as an independent convener to engage stakeholders from industry, academia, patients and patient advocacy groups, non-profit organizations, and global regulatory agencies. The MRCT Center focuses on pre-competitive issues, to identify challenges, and to deliver ethical, actionable, and practical solutions for the global clinical trial enterprise. The responsibility for the content of this document rests with the leadership of the MRCT Center, not with its collaborators nor with the institutions with which its authors are affiliated.[1]

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We commend the Office of Inspector General (OIG) and the Department of Health and Human Services (HHS) for examining whether existing fraud-and-abuse regulations appropriately balance the government's longstanding commitment to program integrity with the equally important public interest in advancing biomedical research and ensuring access to clinical trials. The MRCT Center fully endorses the adoption of an AKS safe harbor that permits clinical trial sponsors and other funders to provide funds to provide compensation to, and support costs incurred by, clinical trial participants without incurring AKS or Beneficiary Inducement CMP concerns. In addition to the discussion below, this position supports the goals of Operation TrialBlazer drive (1) to restore US leadership in clinical research and scientific innovation, and (2) to address a national security concern.

Clinical trials remain the foundation of evidence generation for the development of new drugs, biologics, diagnostics, devices, and healthcare interventions. Their scientific validity, however, depends upon the ability to recruit and retain participants who reflect the populations that will ultimately use these products and interventions in clinical practice. Financial and logistical obstacles frequently impede participation, particularly among individuals with limited resources, those living in rural or other geographically underserved areas, older adults, and patients with substantial disease burdens or needs (e.g., accommodations for disability). We therefore support the development of a regulatory framework that permits reasonable assistance intended to reduce barriers to trial participation while maintaining effective safeguards against fraud and abuse. We first discuss the general issue, and then we provide succinct responses to the questions posed in the RFI.

Clinical Trial Participation and Financial Barriers

Appropriately structured financial support can play an important role in enabling participation in clinical research. Many individuals incur expenses solely because they have agreed to participate in a trial. These may include transportation, lodging, meals, parking, childcare, eldercare, caregiving expenses, technology needs, and other costs associated with study visits and protocol requirements. Participation may also require time away from work or other responsibilities, which can impose additional economic burdens.

For many patients, these obligations present practical challenges that may discourage enrollment or contribute to premature withdrawal from a study. Such barriers can disproportionately affect individuals with lower incomes, those who reside far from specialized research centers, and populations that have historically been underrepresented in clinical research. Reducing these burdens can improve access to clinical trials and support broader participation and proportionate representation in research. By increasing the number of individuals who can enroll in and complete a study,

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the time to study completion decreases, reducing overall system costs and accelerating meaningful discovery.

A more representative clinical trial population benefits not only research participants but also patients, clinicians, regulators, and payers by strengthening the generalizability and applicability of the resulting evidence. Enabling participation by individuals who might otherwise be excluded due to financial constraints is therefore an important research and public health objective. We therefore strongly support the development and approval of a regulatory framework that protects clinical-trial-related participant support while preserving appropriate safeguards against fraud, abuse, inappropriate inducement, patient steering, and overutilization.

Ethical Oversight and the Central Role of Institutional Review Boards

Before a clinical trial may enroll participants, an Institutional Review Board (IRB) must determine that risks to participants have been minimized to the extent possible and that any remaining risks are reasonable in relation to anticipated benefits and the importance of the knowledge expected to result from the research. The IRB must also review informed consent procedures, participant protections, recruitment methods, and other ethical considerations. Importantly, the IRB is instructed by regulation to render its determinations independently of any consideration of payment or reimbursement offered to participants. Payment cannot be considered a benefit in the risk-benefit assessment. Rather, a study must first satisfy applicable ethical and regulatory requirements before participant support is considered. Only after a trial has been determined to present an acceptable benefit-risk relationship does the IRB evaluate proposed reimbursement and compensation arrangements.

Because the benefit-risk assessment is conducted independently of payment, financial support approved by an IRB cannot reasonably be viewed as making an otherwise unacceptable study acceptable. Instead, participant support serves a different purpose: reducing the financial and logistical burdens associated with participation in research that has already been determined to be ethically appropriate.

Accordingly, IRB review provides an important safeguard against undue influence. Independent review of the type, amount, timing, frequency, and disclosure of participant support helps ensure that payment facilitates participation but does not command or unduly influence it. IRB approval should be a foundational element of any AKS safe harbor addressing clinical trial participant support.

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Impact of the AKS and Beneficiary Inducements CMP

Although the AKS and Beneficiary Inducements CMP serve vital functions in protecting federal health care programs and beneficiaries from abusive practices, uncertainty regarding their application to clinical trial support programs discourages sponsors, research institutions, investigators, and other stakeholders from providing assistance that would otherwise be appropriate and beneficial.

Organizations seeking to assist participants frequently encounter uncertainty regarding whether travel assistance, lodging support, childcare reimbursement, cost-sharing assistance, or modest stipends could be considered prohibited remuneration. Even when the purpose of such assistance is solely to facilitate participation in ethically approved research, concerns about potential fraud-and-abuse implications and the absence of clear, generally applicable protections may lead sponsors to avoid offering support altogether.

The resulting uncertainty can unintentionally reinforce barriers to participation that clinical research enterprises are otherwise attempting to address. A clearer regulatory pathway would enhance compliance while enabling responsible patient-support practices.

Clinical Trial Support is distinct from Healthcare Utilization Incentives

The fundamental purpose of participant support in clinical research differs from the purpose of remuneration ordinarily associated with AKS concerns. Clinical trial support is intended to facilitate participation in scientific research. It is not intended to induce utilization of medically reimbursable items or services, influence provider selection, reward referrals, or generate future healthcare expenditures. The protocol-based stipend or payments address costs and burdens and are materially different from remuneration designed to influence healthcare purchasing decisions. This distinction should be acknowledged in a future safe harbor proposal.

Framework for Evaluating Participant Support Arrangements

OIG's prior advisory opinions suggest several recurring considerations that may provide an appropriate foundation for future regulatory protections.

1. Alignment With Legitimate Scientific and Public Objectives

The clinical trial AKS safe harbor should be available for clinical trials conducted in accordance with applicable federal research requirements and independent ethical oversight. Support should advance legitimate scientific and public health objectives by

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facilitating participation in human participant research rather than promoting commercial utilization of healthcare products or services. At a minimum, applicable clinical trials, as defined by FDAAA 801, should be included, as should NIH- and other federally supported clinical trials.

2. Reasonable and Necessary Support

Protection should extend to remuneration for expenses and payment for burdens arising from participation in a clinical trial. Examples include transportation, lodging, meals, parking, childcare, eldercare, dependent care expenses, caregiver support, communication technology, and other costs incurred due to protocol requirements. Reasonable stipends that recognize the time, inconvenience, and burdens associated with participation, along with small incentives, may also be appropriate when established prospectively and approved through the IRB process.

3. Safeguards Against Steering and Overutilization

Any protected arrangement should include objective eligibility criteria, documentation requirements, transparency in the informed consent process, and ongoing oversight. Participant support should not be conditioned upon the selection, use, prescription, purchase, or continued use of any healthcare provider, practitioner, supplier, manufacturer, product, service, or health plan outside the clinical trial. Support should remain separate from referral patterns and healthcare utilization decisions.

4. Prevention of Downstream Commercial Exploitation

Participant support in a clinical trial cannot serve as a mechanism to create future demand for products or services reimbursable by Federal healthcare programs. The safe harbor should be designed to facilitate participation in research and not used to influence future treatment choices, create ongoing dependence on a sponsor's products, or generate post-study utilization.

Recommendations for a New Clinical Trial Participant Support Safe Harbor

We recommend the establishment of a dedicated AKS safe harbor specifically addressing clinical-trial-related participant support. Existing safe harbors were developed in different regulatory contexts and do not adequately address the unique operational and ethical characteristics of clinical research. Clinical trials operate under protocol-driven requirements, informed consent obligations, independent IRB oversight, enrollment criteria, and participant protections that distinguish them from ordinary healthcare

transactions. A dedicated safe harbor would provide greater clarity and consistency, and simplify administrative processes, than attempting to adapt existing protections designed for unrelated settings.

To qualify for protection, support should be provided in accordance with a written protocol approved in advance by the responsible IRB. The protocol should:

- Identify permissible categories of participant support;
- Specify applicable payment methodologies;
- Describe eligibility criteria;
- Establish any reasonable limitations or caps;
- Provide for contemporaneous documentation; and
- Permit oversight and audit as appropriate.

The safe harbor should permit reimbursement, direct and indirect payment, or other reasonable support for participation-related expenses, including transportation, lodging, meals, parking, childcare, caregiver support, communication technology, and additional costs that arise from protocol participation. The safe harbor should include payment for time, burden, and be distributed to the participant when the expense, time, or burden is incurred, not at the end of the trial.

The safe harbor should prohibit shifting these costs to Federal healthcare programs and prohibit conditioning support upon the receipt or future utilization of healthcare items or services outside the study.

Types of Support That Merit Protection

We believe OIG should recognize that support designed to offset the incremental burdens created by clinical trial participation differs fundamentally from remuneration intended to generate utilization, referrals, or patient steering.

Categories of support that warrant consideration for protection include:

- Transportation and travel expenses;
- Lodging expenses associated with study participation;
- Parking and meal expenses incurred during study visits;
- Childcare or dependent-care expenses;
- Necessary caregiver travel and support costs;
- Technology or communication resources needed to comply with study requirements;

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- Reimbursement of trial-related out-of-pocket medical expenses; and
- Modest stipends intended to recognize participant time, inconvenience, and recurring trial-related burdens.

Support should be reasonable, proportionate, and connected to the requirements of trial participation. Assistance should be designed to alleviate burdens rather than serve as an inducement unrelated to research activities.

For operational simplicity, the safe harbor should allow payment of overall stipends rather than itemized receipt reimbursement if that stipend is based on a documented methodology and the amount approved by an IRB.

Safeguards Against Fraud and Abuse

Any safe harbor or protected arrangement should incorporate safeguards designed to prevent inappropriate steering, overutilization, or marketing abuses.

Potential safeguards include:

- Advance approval through an IRB-reviewed study protocol;
- Written documentation describing permissible forms of support;
- Pre-established and consistently applied eligibility criteria;
- Transparent disclosure during the informed consent process;
- Documentation of payments and reimbursement activities;
- Prohibition on shifting support costs to federal health care programs;
- Prohibition on conditioning support upon use of items or services outside the clinical trial;
- Protection of participant freedom to change providers or withdraw from the study at any time; and
- Restrictions on using support programs as marketing or promotional mechanisms.

These protections would enable legitimate participant support while preserving the integrity and independence of federal health care programs.

Scope of Protection

Protection should not be limited on the phase of development or sponsorship category of a clinical trial. The financial burdens experienced by participants are generally driven by the practical requirements of the study and the circumstances of the participant rather than by whether a study is sponsored by government, academia, industry, or another

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entity. Similarly, participant expenses may arise during any stage of clinical development. The safe harbor framework should focus on the nature of the support provided, the safeguards governing its provision, and the purpose it serves, rather than the identity of the sponsor or the phase of research.

Recommended Safe Harbor

We encourage OIG to establish a new safe harbor under the Federal Anti-Kickback Statute specifically addressing reasonable clinical trial participant support. A well-designed safe harbor could permit reimbursement and provision of defined categories of trial-related assistance when certain conditions are met, including documentation requirements, IRB oversight, transparency obligations, and restrictions against patient steering.

Such a safe harbor would offer clarity and predictability to sponsors, research institutions, investigators, and participants while simultaneously promoting adherence to program integrity standards. Because protection under the Beneficiary Inducements CMP may follow from AKS safe-harbor protection, a carefully crafted AKS safe harbor could provide an efficient and comprehensive regulatory solution.

Broader Benefits

Reducing participation barriers has the potential to improve enrollment, retention, and diversity in clinical trials. More inclusive participation can strengthen scientific evidence, improve trial efficiency, and increase confidence that study findings are applicable to the populations ultimately receiving approved therapies. At the same time, structured support programs should be designed to mitigate any risks of unnecessary utilization or increased program expenditures. Assistance that merely offsets participation-related burdens is distinct from remuneration intended to encourage inappropriate use of medical services.

Guidance and Rulemaking

While OIG guidance could provide useful interim clarification, guidance alone is unlikely to provide the degree of certainty required by sponsors and research organizations operating in a highly regulated environment. Because the AKS carries significant legal consequences, stakeholders frequently require explicit regulatory protection before implementing participant-support programs. Accordingly, formal rulemaking establishing a new safe harbor would provide the most effective and durable solution. Supplemental guidance could then be used to address implementation questions and offer additional examples of low-risk arrangements.

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Direct Responses to RFI Questions

With this background, we now provide brief answers to the questions in the RFI, drawing on the discussion above to substantiate our responses.

1. Does remuneration facilitate clinical trial participation?

Yes. Reasonable financial support helps address practical barriers that prevent otherwise eligible individuals from participating in clinical trials. Such barriers include travel, lodging, meals, parking, childcare, caregiver expenses, lost work time, and other costs that arise solely because of participation in a research protocol. Importantly, remuneration should include not only direct but also indirect expenses, compensation for time and burden, and reasonable other payments, if prospectively approved by an IRB.

By reducing these constraints and burdens, remuneration can improve enrollment, retention, and representation of populations that have historically faced obstacles to participation, including rural, medically underserved, lower-income, and older populations. More representative participation improves the quality, generalizability, and applicability of clinical research findings.

2. Do the AKS and Beneficiary Inducements CMP create barriers to appropriate remuneration?

Yes. While the AKS and Beneficiary Inducements CMP serve critical program-integrity functions, uncertainty regarding their application to clinical trial support programs discourages sponsors, research institutions, and other stakeholders from providing assistance that would otherwise be appropriate and ethically justified.

3. What categories of remuneration are useful and appropriate?

The most useful forms of remuneration are those that address burdens directly attributable to participation in a clinical trial.

These include:

- Transportation and travel expenses
- Lodging costs
- Mileage allowance and parking expenses
- Meals associated with study visits
- Childcare, eldercare, and dependent-care expenses

- Caregiver support expenses
- Technology, hardware, software, and communication resources (e.g., data plans) needed for participation
- Reasonable protocol-based stipends recognizing participant time, burden, and inconvenience. We recommend, for fairness across populations and ease of administration, that the stipend for participant time be a multiple of the prevailing minimum wage, and not be based on an individual's actual salary.

Support should be reasonable, proportionate, prospectively defined, and directly related to study participation.

4. Should there be limits or caps on remuneration?

Any protected arrangement should clearly identify permissible categories of support, applicable payment methodologies, and documentation requirements. Support should be designed to offset participation-related expenses, time, and burdens rather than serve as a marketing incentive. Flexibility is important because participation-related Burdens vary substantially depending on disease, protocol requirements, geographic location, and participant circumstances, necessitating flexibility in both program administration and amount of remuneration. The process of determining payment amounts and payment caps should be transparent.

5. Should limitations exist regarding who may provide remuneration?

Support may appropriately be provided by sponsors, research institutions, nonprofit organizations, foundations, or other entities acting pursuant to a clinical-trial protocol, provided that safeguards are in place to prevent steering, marketing, or inappropriate commercial influence.

6. What is the role of the IRB?

IRBs provide an important safeguard in clinical research. Before compensation is considered, IRBs determine whether risks have been minimized and whether the risk-benefit relationship of a study is acceptable. By design and instruction, IRBs consider the ethical acceptability of a study independently of remuneration. Thus, participant support does not affect the benefit-risk assessment; rather, it is an independent determination made only after a study is deemed ethically acceptable. IRB-approved support should not considered "undue" influence.

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IRBs should review the amount, timing, frequency, disclosure, and methodology of participant support. Accordingly, IRB approval should be a foundational requirement of any future safe harbor.

7. What safeguards should prevent inappropriate steering?

Protected support should:

- Not be conditioned on receipt of healthcare services outside the trial
- Not require continued use of any provider, supplier, manufacturer, or product
- Not influence treatment decisions after trial completion
- Use objective eligibility criteria
- Be transparently disclosed through informed consent
- Be documented and subject to oversight

Support should facilitate participation in research, not influence healthcare utilization.

8. Should remuneration differ by trial phase?

Participant expenses, time, and burden are driven primarily by protocol requirements and participant circumstances rather than by the phase of development. Appropriate support should therefore depend on the demands of the study rather than on the phase of the trial. Different considerations may apply to remuneration in phase 1 studies that recruit healthy volunteers.

9. Should only certain types of trials receive protection?

Participant needs do not vary by sponsor type or trial type. Appropriate safeguards can be applied across clinical trials sponsored by industry, academic institutions, nonprofit organizations, healthcare systems, and government entities. The trial design should be selected to answer the study question as efficiently and reliably as possible, and not influence remuneration.

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10. Should advertising restrictions apply?

Information regarding participant support should be factual, transparent, and included in IRB-approved recruitment and consent materials. We have previously addressed both ethical and practical considerations of including payment in advertising materials.[2]

Support should not be marketed as a reward, incentive program, rebate, or promotional benefit. Appropriate disclosure is important, but remuneration should never serve as a marketing tool.

11. What new safe harbor should OIG adopt?

OIG should establish a dedicated AKS safe harbor for clinical-trial participant support. The safe harbor should protect support provided pursuant to an IRB-approved written protocol and should permit reasonable reimbursement or direct payment of participation-related expenses, time, and burden.

Key protections should include:

- IRB approval
- Written protocol requirements
- Objective eligibility criteria
- Documentation and audit requirements
- Prohibitions on patient steering
- Restrictions on marketing and commercial exploitation

A properly structured AKS safe harbor would also provide protection under the Beneficiary Inducements CMP.

12. Why are existing safe harbors inadequate?

Developed for different regulatory and operational contexts, current safe harbors do not adequately address the unique features of clinical research, including protocol-driven activities, informed consent requirements, independent ethical oversight, participant protections, and research-specific support needs. As a result, sponsors and research

[2] Gelinas L, Lynch HF, Largent EA, Shachar C, Cohen IG, Bierer BE. Truth in Advertising: Disclosure of Participant Payment in Research Recruitment Materials. Ther Innov Regul Sci. 2018 May;52(3):268-274. doi: 10.1177/2168479018770644.

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institutions lack regulatory certainty regarding common participation-support arrangements.

13. What broader impacts might result?

A clinical-trial safe harbor would be likely to:

- Improve access to clinical research
- Increase participation by underserved populations (rural areas, elderly, lower income, etc.)
- Improve enrollment and retention
- Enhance diversity and representativeness of study populations
- Strengthen the quality and generalizability of clinical evidence
- Support more efficient completion of clinical trials

Properly structured support should not be interpreted as posing significant risks of inappropriate utilization, as its purpose is to reduce barriers to participation rather than generate healthcare demand.

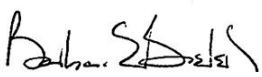
14. Is guidance sufficient?

Formal rulemaking establishing a dedicated safe harbor would provide the clearest and most durable solution. Guidance could play a valuable complementary role by providing examples, implementation recommendations, and clarification of low-risk arrangements.

Thank you for considering these comments. We appreciate OIG's efforts to ensure that federal fraud and abuse laws continue to protect program integrity while supporting ethically conducted clinical research that benefits patients and the public. We fully support establishing a dedicated safe harbor for clinical trial participant support.

We would be happy to discuss these comments with you at any time. Please direct inquiries to me at bbierer@bwh.harvard.edu.

Respectfully submitted,
On behalf of the MRCT Center



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