August 24, 2026

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

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)

Dear Inspector General Bell:

The Association for the Accreditation of Human Research Protection Programs (AAHRPP), National Advisory Committee on Human Research Protections (NACHRP), and Public Responsibility in Medicine and Research (PRIM&R) respectfully submit this joint comment on the request for information (RFI), 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).

We represent Human Research Protection Programs (HRPPs), professionals dedicated to protecting participants in research, and Institutional Review Boards (IRBs).

The comments below reflect support for an adoption of a new anti-kickback statute, 42 U.S.C. § 1320a-7b(b) (AKS), safe harbor for certain forms of financial support for research participants. As requested, we have identified the questions to which we are responding.

*1. Please explain whether offering Federal health care program enrollees remuneration facilitates clinical trial participation and the specific factors that make such remuneration either effective or ineffective at facilitating participation.*

Several studies identify financial challenges as significant barriers to participation in clinical trials and remuneration can play a role in offsetting them[1]. Financial burdens, including travel, lodging, childcare, and lost wages, are documented barriers to clinical trial participation, disproportionately affecting lower income, rural, and minority populations. Creating a safe harbor and clarifying Beneficiary Inducements CMP exceptions, with sufficient guardrails to protect against fraud and abuse, will provide more

[1] See the following for an overview of research on barriers to participation in clinical trials: Edgardo Rodríguez-Torres, Margarita M. González-Pérez, Clemente Díaz-Pérez, Barriers and facilitators to the participation of subjects in clinical trials: An overview of reviews, Contemporary Clinical Trials Communications, Volume 23, 2021, 100829, ISSN 2451-8654, https://doi.org/10.1016/j.conctc.2021.100829.

opportunities for research sponsors and others to offset costs that prevent people from considering participation in clinical trials or occur as a result of participating in research.

*2. Please explain whether you view the Federal anti-kickback statute or the Beneficiary Inducements CMP as barriers to offering and providing appropriate remuneration to clinical trial participants and if so, why. In your answer, please describe any other identified barriers to offering and providing appropriate compensation/remuneration to clinical trial participants and how those barriers relate to any barriers created by the Federal anti-kickback statute and Beneficiary Inducements CMP.*

Without an explicit safe harbor or CMP exception for clinical trials, sponsors and research sites may preemptively decline to offer remuneration to reduce costs of research participation to avoid violating (or appearing to violate) the AKS or Beneficiary Inducements CMP. Providing an *a priori* exception for certain types of clinical remuneration would eliminate a) the need for the OIG to issue advisory opinions permitting the waiver or subsidization of certain Federal healthcare program cost-sharing obligations for clinical trial participants on a case-by-case basis (which can delay clinical trials); and b) the uncertainty that sponsors and research sites face when determining what remuneration can be provided.

*3. Please explain what categories of remuneration (including, for example, reimbursement for actual incurred expenses such as travel, lodging, parking, childcare, and meals; stipends; compensation for a participant's time; incentives to encourage enrolling in and completing the trial) and at what levels those categories of remuneration are useful to facilitate participation in clinical trials and why. Similarly, please explain what categories of remuneration are not useful to facilitate clinical trial participation. Please explain the extent to which such categories of remuneration already are offered to clinical trial participants. Please explain whether there are categories of remuneration that may be subject to heightened risks of fraud and abuse. To the extent that there is more uncertainty regarding how the Federal anti-kickback statute and Beneficiary Inducements CMP would apply to certain categories of remuneration, please explain.*

The RFI seeks comment on whether safe harbors are needed for remuneration to clinical trial participants, including reimbursement for documented expenses (travel, childcare, parking, meals), stipends for participant time, effort, and inconvenience, and incentives to encourage enrollment or completion.

Collectively, we support flexibility in the amount and type of remuneration offered to clinical trial participants based on real-world costs due to variability in study commitments and burdens as well as individual participant circumstances (e.g., location as compared to where research procedures occur, income level, insurance status).

OIG should distinguish reimbursement, time and effort compensation, and enrollment incentives to enable equitable research recruitment. We recommend that OIG establish a tiered safe harbor framework that explicitly distinguishes three categories of remuneration:

1. **Reimbursement for Trial-related Expenses**: Remuneration to reimburse participants for actual out-of-pocket expenses directly caused by trial participation, including but not limited to travel, parking, and meals. should be presumptively protected under the anti-kickback statute and excepted from the Beneficiary Inducements CMP definition of remuneration, provided that:

- Expenses are documented and tied to actual trial-related burden (e.g., childcare only for visits, travel reimbursed at documented mileage/transit cost);
- The consent form discloses the reimbursement types and amounts; and
- Reimbursement is not conditioned on trial enrollment, retention, or outcome.

2. **Stipends for Participant Time, Effort, and Inconvenience**: Fixed-amount payments to participants for their time, effort, and inconvenience in participating in a clinical trial should be protected under the anti-kickback statute and excepted from the Beneficiary Inducements CMP definition of remuneration, provided that:

    - The stipend is reasonable in relation to study procedures (e.g., time and burden per visit × reasonable hourly rate for participant time and burden);
    - The stipend is not conditioned on trial enrollment, retention, completion of specific trial arms, or trial outcomes;
    - The consent form explicitly explains the remuneration schedule, including how much compensation is provided for specific visits or procedures, when compensation will occur, and that payments are not contingent on any specific outcome or on completing the entire study.
    - The stipend amount is offered uniformly to all participants in the same study arm.

3. **Incentives for Enrollment or Completion**: Payments or inducements specifically designed to encourage enrollment, retention, or completion (beyond reimbursement and stipends as described above) should not be protected, as they carry elevated risk of undue inducement and selection bias. Any such payments require an individual OIG advisory opinion and careful IRB review.

Safe harbors should explicitly protect reimbursement for lost wages and childcare as documented trial-related costs: Current regulatory ambiguity creates institutional barriers to reimbursing these actual costs that prevent research participation. Institutions routinely reimburse small out-of-pocket expenses (parking, meals, transportation), but do not typically reimburse lost wages or childcare. Therefore, we recommend OIG's safe harbor explicitly clarify that reimbursement for documented lost wages and childcare is presumptively protected as Tier 1 (documented expense reimbursement), provided that:

- Lost wages are documented and treated as make-whole reimbursement for participants (or their caregivers) who suffer a verified loss of income, whether through forfeited hourly shifts or mandatory unpaid leave solely to complete required trial activities. Reimbursing this verified deficit at the participant's documented rate directly prevents research participation from causing an unrecoverable household financial loss.
- Childcare costs are documented (receipt, invoice, or reasonable market rate for informal care) and limited to hours when the participant is in trial activities.
- Reimbursement of this type is disclosed in the consent form: "You may receive reimbursement for lost wages (at your documented hourly rate) and childcare costs directly caused by your participation in this trial."
- Reimbursement is not conditioned on trial enrollment, retention, study completion, or outcomes.

We acknowledge the inherent tension in classifying lost wages as an out-of-pocket reimbursement rather than general compensation. However, it is important to note that, any participant (whether an

hourly worker missing a shift or a salaried worker forced into unpaid leave after exhausting their paid time off) suffers a direct, quantifiable financial deficit identical to paying an out-of-pocket expense. Whether OIG classifies wage replacement as a Tier 1 expense reimbursement or establishes it as a distinct fourth category of protected remuneration, expressly excluding it from Tier 2 (stipends) or Tier 3 (incentives) to avoid unintended undue inducement risks, a functional AKS safe harbor must recognize this deficit to prevent structural barriers that penalize individuals for the time-intensive burdens of trial participation.

Finally, as OIG considers these categories of remuneration, we strongly urge close interagency coordination to address the compounding effect of research compensation on means-tested benefit eligibility. Currently, clinical trial payments are generally treated as taxable gross income, creating a systemic barrier where low-income individuals must weigh the benefits of research participation against the immediate risk of losing Medicaid or Supplemental Security Income (SSI) coverage. While narrow statutory exceptions have historically protected compensation for participants in specific disease categories, the broader clinical research community remains exposed to the risk of sudden disqualification from vital support programs. Aligning an AKS safe harbor with coordinated Federal efforts across HHS, the Internal Revenue Service, and the Social Security Administration to exclude reasonable trial remuneration from gross income determinations would significantly safeguard vulnerable populations and genuinely expand equitable representation in clinical research.

*6. Please explain the role of an Institutional Review Board ("IRB") in reviewing the provision of remuneration to clinical trial participants and whether an IRB's review of the type, amount, and frequency of remuneration provided to clinical trial participants and the advertising of that remuneration is a meaningful safeguard against the harms resulting from fraud and abuse. If so, please specify the rationale and the standards the IRB should use.*

The IRB focuses on whether remuneration to research participants is ethical; we believe this ethical review function should remain central to any new safe harbor. For example, IRBs focus on whether remuneration is reasonable in relation to the study procedures and burden (time, study procedures, visits, etc.) associated with participation. IRB review serves as a key safeguard to help ensure that research participants are informed of the availability and limitations of remuneration that trial enrollment is voluntary, and that they may discontinue participation at any time without penalty or loss of benefits to which they were otherwise entitled.

Additionally, the IRBs assess whether remuneration represents coercion or undue influence, based on its type, amount, and timing. While this is an important assessment IRBs make, IRB review of remuneration in and of itself is insufficient to safeguard against the harms resulting from fraud and abuse as contemplated by the AKS and Beneficiary Inducements CMP. For example, IRBs are not experts on or privy to information about medical billing, physician compensation, or insurance costs, which could factor into assessments of whether a form or amount of remuneration would meet the conditions of a safe harbor under the AKS. Consequently, institutions will need to rely on other expertise (e.g., medical billing personnel) to determine compliance.

Of note, IRBs vary significantly in how they assess remuneration and what level of remuneration might constitute undue influence. Additional evidence-based guidance for IRBs from Federal agencies could be helpful, such as distinguishing between reimbursement, compensation, and incentives, identifying acceptable approaches to participant compensation and incentives (the forms of remuneration that

tend to present more concern to IRBs), and providing data on the harms of not providing any or sufficient remuneration to research participants.

*7. Please enumerate any safeguards that should be in place to ensure clinical trial participants who receive remuneration to participate in a clinical trial are not inappropriately steered to items or services offered by the individual or entity offering the remuneration outside the clinical trial.*

Any changes to Federal laws and regulations surrounding clinical trial remuneration should clearly distinguish between remuneration that facilitates participation in a clinical trial, which would be acceptable, and inappropriate remuneration that is conditioned upon a participant using a drug or device, service (e.g., health care provider, pharmacy, clinic), or other item outside the trial or after trial participation is complete.

Of note, remuneration that is limited to costs incurred related to participation, i.e., reimbursement, in a clinical trial does not carry with it apparent risks of increasing inappropriate Federal healthcare program costs or reward health care providers or professionals for ordering items or services unrelated to the specific trial.

Aside from IRB review of any participant remuneration, which is already required by Federal regulations, another safeguard would be to require sponsors that provide support to keep and retain detailed records of any remuneration (e.g., purpose, amount, date, and method of each payment), which can be audited by the relevant Federal authority to guard against fraud and abuse.

*10. Please explain whether there should be advertising limitations relating to remuneration to clinical trial participants to protect the integrity of the clinical trial and guard against the harms resulting from fraud and abuse.*

For any safe harbor or Beneficiary Inducements CMP, the update should generally limit information about remuneration that can be included in an advertisement to whether the trial will offer reimbursement, compensation, or incentives to participate. Additional details should be available from the research team at the site where the potential participant will enroll, within informed consent documents, and other participant-facing documents (e.g., an information sheet that describes availability of remuneration, the forms it may take and any limits on it). Advertising requirements should disallow remuneration to be used for marketing purposes (e.g., product promotion) for any entity that provides or is involved with the remuneration or describing remuneration as a study benefit.

*11. Please identify what, if any, additional or modified safe harbors to the Federal anti-kickback statute or exceptions to the definition of "remuneration" under the Beneficiary Inducements CMP may be necessary to protect remuneration to clinical trial participants and any arrangements necessary to offer and provide such remuneration. Please explain any key provisions that should be included in any additional or modified safe harbor or exception. Specifically, and to the extent that you did not do so in response to the questions above, please describe what conditions would be appropriate to include in a safe harbor or exception to protect against the harms resulting from fraud and abuse in the context of such arrangements, including what, if any, disclosures should be required by such safe harbors or exceptions. Additionally, please identify which criteria for modifying and establishing safe harbors under section 1128D(a)(2) of the Act (42 U.S.C. 1320a-7d(a)(2)), listed in section II.A above, would be impacted and how.*

We support the OIG creating a safe harbor specifically for clinical trial remuneration that can offset the financial costs research participants encounter described in response to question 3. This safe harbor could leverage existing regulatory processes to help guard against fraud and abuse, such as expectations that sponsors disclose details about research payments in protocols, which could be extended to require the description of all remuneration offered to participants, including form and timing of remuneration and any limits on it; Good Clinical Practice expectations for study documentation available for external audits, which could include details of remuneration provided to participants; IRB evaluation of whether remuneration supports the equitable selection of participants and is not unduly influential; and IRB review of advertisements and the informed consent process to ensure remuneration is disclosed and described appropriately.

*13. Please discuss any potential broader impacts or implications—and in particular, as they relate to the criteria set forth in section 1128D(a)(2) of the Act ( e.g., an increase or decrease in access to health care services, an increase or decrease in costs to Federal health care programs)—that may result from the provision of remuneration to clinical trial participants, additional or modified safe harbors to the Federal anti-kickback statute, or exceptions to the definition of "remuneration" under the Beneficiary Inducements CMP. For instance, if remuneration would result in higher participation rates of federal health care program enrollees in clinical trials, could that lead to improved health care for individuals in those programs?*

Eliminating or mitigating economic burdens can increase the number of people who participate in research and expand representation in research, such as populations from rural communities, with low incomes, or who are uninsured or underinsured. A larger potential research population can, in turn, ensure clinical trials can be completed, reduce how long it takes to meet recruitment requirements, strengthen generalizability of the findings, and support more rapid scientific advancement that leads to better health for more Americans.

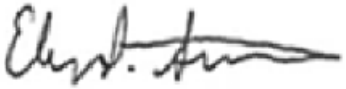
*14. Are there opportunities where OIG could clarify its position through guidance as opposed to regulation? For example, would a Special Advisory Bulletin, an FAQ response, or other guidance offer sufficient protection in some instances? If so, please elaborate.*

Ultimately, additional or modified safe harbors to the Federal anti-kickback statute or exceptions to the definition of "remuneration" under the Beneficiary Inducements CMP would better clarify for sponsors and research sites what financial support for research participants the Federal government deems permissible (e.g., reimbursement for study-related expenses, such as travel). Because regulations often take years to create and implement, a Special Advisory Bulletin, an FAQ response, or other guidance, could be helpful in the interim and beyond. FAQs and other guidance documents, supported by concrete examples and case scenarios, can provide sponsors and IRBs with practical clarity on what constitutes reasonable and ethical remuneration (e.g. guidance or parameters around what constitutes a reasonable expense to support consistent IRB review). This would help to reduce barriers to participation and support broader clinical trial enrollment.

Further, we request OIG to clarify the scope of research covered by any new safe harbor. The RFI focuses on "clinical trial participants," but much federally funded human subjects research, such as observational studies and registries, may not meet the NIH or FDA definition of a clinical trial. We request that OIG clarify whether a safe harbor would apply only to research meeting that definition of "clinical trial," or more broadly to other federally funded research involving similar participant burden.

This clarification would help ensure the safe harbor does not extend its scope to unintentionally exclude other legitimate forms of participant remuneration.

We appreciate the opportunity to comment and welcome the chance to provide additional information to assist HHS on this matter.



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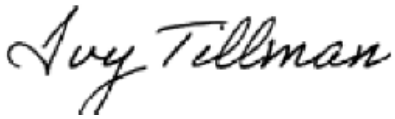

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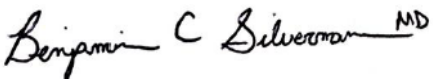

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