August 24, 2026

Department of Health and Human Services
Office of Inspector General

RE: Docket No. RIN 0936-AA16. Medicare and State Health Care Programs: Fraud and Abuse; Request for Information Regarding the Federal Anti-Kickback Statute and Beneficiary Inducements CMP

Dear Sir or Madam,

On behalf of the Pediatric Inclusion Alliance, we are pleased to submit comments on HHS's Office of Inspector General's Request for information on "Medicare and State Health Care Programs: Fraud and Abuse; Request for Information Regarding the Federal Anti-Kickback Statute and Beneficiary Inducements CMP". We appreciate the opportunity to respond to these important questions regarding remuneration provided to individuals participating in clinical trials. Our comments focus on the questions most relevant to patients and families, particularly those affected by pediatric diseases.

About the Pediatric Inclusion Alliance

The Pediatric Inclusion Alliance (Alliance) is devoted to full, active collaboration among all stakeholders committed to achieving earlier inclusion of children in clinical trials across all diseases and conditions without compromising safety. For far too long, children have had to wait years for access to safe, effective therapies, often already approved for adult populations. These therapies might well have been even more effective for younger patients if administered at the best time for them.

By combining a deep understanding of the needs of pediatric patients and their families, technical expertise, real-world experience in medical research and therapy development, knowledge of regulatory guidance and processes, and public policy experience, the Alliance is a united collaborative of stakeholder groups committed to ensuring that children have the earliest opportunity to access safe and effective therapies when those therapies are most likely to have maximum benefit to them. This is especially true for early onset genetic disorders, the affected

populations for which could benefit profoundly from inclusion of children in clinical trials earlier, at the point of maximum impact for them.

General Considerations for Early Pediatric Inclusion

For many participants in rare pediatric disease research, clinical trials are not simply optional opportunities; they represent the most beneficial, and sometime only, available treatment option. We believe appropriately structured remuneration should remove the financial and logistical costs of research participation, support voluntary and informed decision-making, and include safeguards against fraud, abuse, and undue influence. Policies that reduce unnecessary financial barriers to clinical trial participation can improve equitable access while supporting higher-quality evidence generation and more efficient clinical research. This may be particularly important for clinical trials involving children since participation often impacts the entire family.

Question 1: Whether Remuneration Facilitates Clinical Trial Participation

Without question, appropriate remuneration facilitates clinical trial participation primarily by neutralizing the direct and indirect costs imposed on participants and their families. Clinical trial participation can require expenditures for travel, lodging, parking, meals, childcare, and other household or logistical support. Participants, parents, and caregivers may also lose wages or exhaust vacation, and family leave to attend study visits or care for a participant experiencing illness or treatment-related effects. In lengthy, decentralized, or high-burden trials, these costs can accumulate substantially over the course of a study and may disproportionately affect lower-income households and families managing serious chronic or rare pediatric diseases. As such, it is important to consider how much of the cost of trial participation families can reasonably be expected to bear. When participation creates significant financial hardship, individuals may be unable to make decisions based on the scientific merits of the study, medical considerations, and their personal preferences. Appropriate remuneration can restore the practical ability to make a voluntary and informed choice.

Remuneration is likely to be most effective when it is:

- Adequate to cover reasonable participation-related expenses;
- Available promptly or in advance, so participants are not required to carry substantial costs while awaiting reimbursement;
- Proportionate to the time, inconvenience, and effort required;
- Inclusive of necessary caregiver expenses and burdens;
- Clearly disclosed before enrollment; and
- Administered consistently across participants, sites, and sponsors.

Effective formats may include documented expense reimbursement, prepaid travel and lodging, transportation assistance, childcare support, and per-visit compensation proportionate to the family's burden.

Ensuring that families are made financially whole can remove unnecessary barriers to enrollment, promote enrollment of participants from a wide range of socioeconomic backgrounds, and allow families to make participation decisions based on medical considerations rather than financial hardship. This is especially important in rare pediatric diseases, where each clinical trial participant may be critical to advancing therapeutic development.

Question 3: Categories and Levels of Remuneration

The HHS OIG should distinguish among three categories of participant support: reimbursement of expenses, compensation for time and burden, and modest recognition of study retention or completion. Each serves a different purpose and may warrant different safeguards.

1. Reimbursement of Reasonable Expenses

Reimbursement of actual expenses should be treated differently from an incentive. Its purpose is to prevent the participant from suffering a financial loss as a consequence of contributing to research. Comprehensive reimbursement is particularly important for rare pediatric disease trials, in which participation may require substantial family involvement because the patient population is children and where each eligible participant may be important to advancing therapeutic development because rare diseases are often very small in numbers. Participants should be reimbursed on a one-to-one basis for reasonable, documented expenses incurred because of trial participation. These expenses may include:

- Travel and local transportation;
- Lodging;
- Parking;
- Meals;
- Childcare and eldercare;
- Other necessary household or support services; and
- Lost wages attributable to required study visits.

In-kind provision of transportation, lodging, childcare, and related support should also be permissible.

2. Compensation for Time, Effort, Inconvenience, and Burden

Additionally, participants should be permitted to receive reasonable compensation for the time, inconvenience, and effort associated with participation. Flat per-visit stipends may not adequately account for lengthy visits, invasive procedures, repeated assessments, travel time, post-visit activities, or the varying burdens imposed on families by different trial protocols. Compensation should therefore reflect the reasonably anticipated demands of the study rather than relying exclusively on an across-the-board nominal amount. Moreover, current stipend levels may be especially inadequate for hourly workers who lose income to attend study visits. Inadequate compensation can disproportionately affect individuals with fewer financial resources and may limit the socioeconomic diversity and representativeness of trial populations. The impact of limited

clinical trial participation can have significant unintended consequences, such that participation rates and demographics can in turn can limit evidence generation which can impact the regulatory approval decision.

3. Modest recognition of study retention or completion

Acknowledging a participant's retention in, or completion of, a study should be allowable through modest gestures or tokens of recognition. For example, this could include a "thank you" note for participants in a study, or a blanket a participant could use to keep warm during an infusion session. We recognize the risk of inducement if a significant financial award were to be offered for study completion, and are not suggesting this be allowed. However, especially for children, we believe it is appropriate and motivational to allow study sponsors to recognize research participants' bravery and commitment to research through such modest means. We have intentionally not used the word "incentive" here, as we believe these tokens of recognition should be of little monetary value and therefore would not, themselves, serve as an incentive (or conversely, a disincentive to disenroll if that is the research participant's desire).

Question 4: Value Caps, Financial-Need Limits, and Other Guardrails

The HHS OIG should avoid imposing a single fixed dollar cap across all forms of remuneration. Fixed per-visit limits may fail to reflect the substantial variation in clinical trials in terms of travel requirements, visit duration, protocol intensity, and other participation burdens. Such caps may particularly disadvantage participants with high disease burden, lower incomes, or substantial travel requirements.

Financial-need testing should not be required for reimbursement of legitimate study-related expenses. Similar to how a government employee receives reimbursement of out-of-pocket expenses incurred during work travel, clinical trial participants should receive reimbursement for personally incurred expenses because of the research, not whether the individual can demonstrate poverty or financial hardship. Need-based eligibility requirements may also stigmatize participants and create additional administrative barriers.

At the same time, reasonable remuneration ranges could improve consistency in interpretations of permissible reimbursement requirements across studies while putting in guardrails to protect against fraud, waste, and abuse. This in turn could help reduce the inequities and confusion that result when individual sponsors, institutions, sites, and IRBs reach different conclusions about comparable participant burdens. The HHS OIG guidance could address acceptable valuation methodologies and reasonable compensation ranges without establishing inflexible across-the-board caps.

Participants should receive a written disclosure before enrollment explaining:

- Which expenses will be reimbursed;
- How and when reimbursement will occur;
- How compensation for time and burden will be calculated;
- Whether caregiver support is available;

- The terms of any retention or completion payment; and
- Any potential effect of payments on means-tested public benefits.

Question 11: A Safe Harbor for Clinical Trial Participant Remuneration

To ensure reimbursements and remuneration for participation in clinical trials are permitted and protected under the law, a clinical trial participant remuneration safe harbor should protect:

1. Reimbursement of reasonable, documented study-related expenses;
2. In-kind transportation, lodging, meals, and childcare;
3. Reasonable compensation for participant time, inconvenience, effort, and burden;
4. Prompt or prepaid support that prevents participants from having to advance substantial out-of-pocket costs; and
5. Modest, prospectively disclosed retention or completion payments.

Appropriate safeguards could include:

- Written remuneration policy established before participant enrollment;
- Clear separation of expense reimbursement, compensation, and retention payments;
- Reasonable relationship between compensation and the activities or burdens required by the protocol;
- Prospective disclosure in recruitment and informed-consent materials;
- Consistent application of the remuneration methodology to similarly situated participants;
- Documentation sufficient to substantiate reimbursed expenses, using practical requirements that do not themselves create a barrier;
- Oversight of the remuneration plan through the study's established review processes;
- Prohibition on conditioning remuneration on the participant's use of items or services outside the clinical trial;
- Prohibition on requiring participants to obtain unrelated care from a specified provider, practitioner, or supplier;
- Prorated payment so that participants retain compensation earned before withdrawal; and
- Prohibition on misleading advertising or materially overstating compensation.

These protections would recognize the important difference between making a participant financially whole and paying a participant to select a particular provider, practitioner, supplier, item, or service outside the study.

Question 14: Guidance and Rulemaking

Both formal rulemaking and near-term interim guidance are needed. Near-term guidance on lower-risk arrangements like clarification on reimbursement of documented participation costs and examples of appropriate remuneration practices could reduce uncertainty and inconsistency while OIG develops a comprehensive regulatory framework. However, regulations are needed to establish durable, nationally consistent protections on which sponsors, sites, institutions, and other stakeholders can rely when designing studies and developing multi-year budgets. Guidance alone

may not fully cover certain legal issues, for example study-related cost-sharing, lost-wage payments to federal health care program beneficiaries, and post-trial access to investigational products.

Conclusion

Children deserve timely access to evidence-based therapies that are scientifically developed and tailored to pediatric patients. To achieve this, clinical trials are essential, however, participants and their families should not be expected to absorb substantial financial losses. Appropriate remuneration should be designed to remove participation barriers, recognize participant and family burdens, improve equitable access, and preserve voluntary and informed decision-making.

Thank you for the opportunity to comment on this request for information. If you have any questions or would like to discuss this further, please contact Sara Singleton at Sara.Singleton@Leavittpartners.com.

Sincerely,

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