Deadline Approaching: OIG Seeks Input on Anti-Kickback Safe Harbors for Clinical Trial Participant Remuneration

On June 24, 2026, the Office of Inspector General ("OIG") of the Department of Health and Human Services ("HHS") issued a **Request for Information** ("RFI") seeking stakeholder input on payments received by individuals in connection with clinical trial participation. Specifically, OIG is seeking to identify ways it might: (i) modify or add new safe harbors to the Federal anti-kickback statute ("AKS") or exceptions to the civil monetary penalty provision prohibiting inducements to beneficiaries (the "Beneficiary Inducements CMP"); or (ii) issue or revise guidance addressing arrangements intended to facilitate clinical trial participation while safeguarding against fraud and abuse.

The RFI follows on the heels of HHS's Operation TrialBlazer initiative, which has identified patient access and engagement as a priority area for revitalizing U.S. clinical research. That initiative has already acknowledged that trial participation imposes real financial burdens on patients (i.e. things like cost-sharing, unplanned tax consequences from trial-related payments, and potential effects on program eligibility (e.g., Medicaid)). Accordingly, OIG appears to be leveraging this RFI to explore whether the fraud and abuse rules themselves serve as a form of barrier or burden to Americans' – and especially government beneficiaries' – ability to access clinical research.

Current OIG Thinking and Issue at Hand

- The AKS and the Beneficiary Inducements CMP were both written broadly, and neither statute carves out an exception for remuneration tied to clinical trial participation. As a result, OIG currently treats remuneration provided to clinical trial participants, including cost-sharing waivers, transportation, childcare expenses, and stipends, as potentially falling within the broad reach of the AKS and the Beneficiary Inducements CMP, meaning such payments may be considered presumptively suspect unless they fit within an existing safe harbor or exception.
- OIG has issued 10 favorable advisory opinions over the past two decades allowing for certain forms of cost-sharing waivers for clinical trial participants, but has not addressed other forms of remuneration to clinical trial participants. Further, while these opinions establish that OIG is comfortable with cost-sharing relief in the right circumstances, the advisory opinions themselves are fact-specific and binding only on the requesting party.

OIG's Request

Rather than proposing specific regulatory text, OIG has opted to cast a wide net. The RFI poses 14 questions spanning from whether remuneration works as an enrollment tool in the first place to the

mechanics of a potential safe harbor (i.e. value caps, permissible payors, IRB oversight, and clinical research phase-specific distinctions). OIG has asked that commenters back their positions with data, studies, or concrete examples where possible. In other words, a generalized comment expressing support for "more flexibility" is unlikely to carry the same weight as specifics tied to actual trial experience.

The RFI poses 14 specific questions to stakeholders, and OIG asks that commenters support claims with relevant data, studies, analyses, and other citations.

Topics covered include:

- Whether offering Federal health care program enrollees remuneration actually facilitates clinical trial participation;
- Whether the AKS or Beneficiary Inducements CMP are perceived as barriers to providing appropriate remuneration;
- What categories and levels of remuneration (e.g., travel, lodging, childcare, stipends, time compensation) are useful to facilitate participation, and which carry heightened fraud and abuse risk;
- What value caps, limits, or restrictions on who may provide remuneration would guard against fraud and abuse;
- The role of Institutional Review Boards (IRBs) as a safeguard over the type, amount, and frequency of remuneration;
- Whether remuneration considerations differ across trial phases (Phase 1–4) and types of trials (e.g., government-sponsored vs. industry-sponsored);
- Whether safeguards are needed to prevent participants from being steered toward non-trial items or services offered by the party providing the remuneration;
- Whether limitations on advertising remuneration are needed to protect trial integrity;
- What additional or modified safe harbors or CMP exceptions may be necessary, and what key provisions they should include; and
- Whether OIG could address some issues through guidance (e.g., Special Advisory Bulletins, FAQs) rather than formal regulation.

Stakeholder Considerations

OIG has signaled openness to addressing some issues through a Special Advisory Bulletin or FAQ rather than formal rulemaking. Given the length of the rulemaking process, stakeholders may consider advocating for interim guidance as the most pragmatic path to near-term certainty for sponsors currently designing or enrolling trials.

This RFI is a particularly timely opportunity for rare disease-focused sponsors, sites, and patient advocacy organizations. For example, qualified treatment centers for certain rare disease therapies are often limited to a small number of sites nationally (or globally), and participants frequently face significant travel and lodging burdens, caregiver support needs, and other questions about remuneration that OIG can squarely address through this guidance. Rare disease stakeholders may be best positioned to give OIG concrete, data-supported input on categories like qualified-treatment-center travel support and caregiver assistance that general commentary from more geographically distributed therapeutic areas may not capture.

Next Steps

Stakeholders wishing to submit comments must do so no later than **August 24, 2026 at 5:00 p.m. ET** (60 days from the Federal Register publication date of June 24, 2026).

Interested stakeholders should reach out to Matt Wetzel (**mwetzel@goodwinlaw.com**) and Amelia Nell (**anell@goodwinlaw.com**) with any questions or assistance with preparing and submitting a response to OIG's RFI.