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OIG Seeks Comment on Clinical Trial Participant Remuneration Under the AKS and Beneficiary Inducements CMP

Health Care Law Brief on **July 1, 2026**

On June 24, 2026, the Office of Inspector General ("OIG") for the U.S. Department of Health and Human Services ("HHS") published a Request for Information ("RFI") seeking public input on whether OIG should add or modify its regulatory safe harbors for the Federal anti-kickback statute ("AKS") or statutory exceptions to the Beneficiary Inducements Civil Monetary Penalties Law ("Beneficiary Inducements CMP") for remuneration provided to individuals in connection with clinical trial participation.

The RFI sits within HHS's broader clinical trial reform initiative. Dubbed "Operation Trailblazer", HHS's initiative seeks to strengthen U.S. leadership in early clinical research and development. To accomplish that goal, HHS created a Roadmap, which identifies the ways to modernize regulatory processes, encourage more efficient trial practices, better leverage existing data and technologies, and improve patient access and engagement in clinical trials. To increase clinical trial participation, HHS proposes expanding decentralized and hybrid trial models, embedding research in community-based settings, using telehealth, remote monitoring, AI-enabled tools, and real-world data. The roadmap also identifies patient financial burdens—including co-payment obligations for standard-of-care services delivered during a trial, tax issues, possible Medicaid eligibility impacts, and geography—as structural barriers to clinical trial access and retention.

In pursuit of HHS's department-wide goals, OIG's RFI asks stakeholders to address:

- Whether remuneration facilitates clinical trial participation;
- Whether the AKS or Beneficiary Inducements CMP operate as barriers to encouraging such participation;
- What types and amounts of remuneration are appropriate, such as cost-sharing support, travel, lodging, parking, childcare, meals, stipends, compensation for time, or completion incentives; and

- What safeguards, including Institutional Review Board ("IRB") review, value caps, advertising limits, and anti-steering protections, should apply.

OIG also requests the public to provide feedback about whether regulatory protection is necessary for stakeholders or whether sub-regulatory guidance, such as a Special Advisory Bulletin or FAQ, would be sufficient. Comments are due by 5:00 p.m. on August 24, 2026.

Legal Framework

The AKS prohibits the knowing and willful offering, paying, soliciting, or receiving of remuneration to induce or reward referrals or other business reimbursable by a Federal health care program. OIG has promulgated certain regulatory safe harbors to protect specified arrangements from AKS sanctions. In developing or modifying safe harbors, HHS may consider factors such as access, quality, patient choice, competition, Federal program costs, overutilization, and fraud-and-abuse risk.

The Beneficiary Inducements CMP separately prohibits the offering or transferring of remuneration to Medicare or State health care program beneficiaries that is likely to influence such beneficiaries' selection of a provider, practitioner, or supplier. While AKS-protected arrangements are excepted from the Beneficiary Inducements CMP, CMP exceptions do not independently protect arrangements under the AKS.

OIG's Existing Advisory Opinion Roadmap

Although clinical trials are not often reimbursed by Medicare (as set forth in the Medicare Secondary Payer ("MSP") rules), Medicare may subsidize certain costs, such as the treatment of trial-related complications, and Medicaid requires coverage of routine patient costs in qualifying clinical trials. Thus, clinical trial participation by Federal health care program enrollees can still heighten risk under the AKS or CMP.

The RFI does not assume that OIG is starting from a blank slate in considering clinical trial incentivization. To the contrary, OIG cites to its two-decades-worth of *favorable* advisory opinions, which permit waiver or subsidization of certain Federal health care program cost-sharing obligations for clinical trial participants. Against this backdrop, OIG also acknowledges that it has not yet opined on other forms of remuneration via advisory opinion, including, for example, transportation costs, childcare costs, or stipends.

Taken together, OIG's advisory opinions have gradually created a fact-specific roadmap for clinical trial cost-sharing support, which has evolved over time. For example, OIG has been more receptive where the remuneration is:

- Tied to protocol-required or study-related items and services;
- Not advertised as a recruitment inducement;
- Disclosed through informed consent;
- Subject to IRB or government oversight;
- Finite in duration, amount, or enrollment; and
- Supported by study-integrity rationales such as enrollment, retention, socioeconomic diversity, blinding, or avoiding differential financial burdens across study arms.[1]

Two recently issued *unfavorable* opinions (AO 24-05 and AO 24-06), which specifically address financial assistance for commercial gene therapy treatment, may be viewed as *cautionary*. However, those opinions turned on the potential influence over treatment centers and physicians, not protocol-bound remuneration to clinical trial participants. OIG's concerns in those opinions—particularly the lack of data to assess access, cost, patient outcome, competition, and steering risks—may nevertheless be raised by stakeholders in RFI commentary.

Structural Limitations

Critically, for those operating in the clinical trial space, OIG's advisory opinions are not available to be relied upon for protection by anyone like the safe harbors—they may be legally relied upon only by the opinion requestor(s).

The MSP rules establish an important financial limitation, as well. Generally, Medicare may not pay as the primary where payment has been made, or can reasonably be expected to be made, by another primary plan. Thus, any AKS regulatory safe harbor or Beneficiary Inducement CMP exception relating to clinical-trial remuneration would likely remain subject to MSP rules.

Takeaways

Stakeholders should consider whether to submit comments addressing the categories of remuneration that may be important to their clinical trial operations and what data they may have available to support such positions.

Proskauer's Health Care Group is knowledgeable and experienced with the public comment process and can assist stakeholders if appropriate. We will continue to monitor developments related to the RFI and other OIG guidance in this area. Subscribe to Health Care Law Brief to remain up-to-date.

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[1] See AO 02-16 (2002), AO 04-01 (2004), AO 08-11 (2008), AO 16-13 (2016), AO 17-02 (2017), AO 21-13 (2021), AO 21-17 (2021), AO 22-05 (2022), AO 23-11 (2023), and AO 26-05 (2026).

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