FAVORABLE

OIG WATCH

16-13

Waiving cost-sharing and paying stipends to clinical trial participants

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What OIG Said

OIG said participant payments can be okay if the amounts are reasonable, documented, benchmarked to accepted practices, and not coercive.

- ✓ A university-led cancer prevention study waived all participant cost-sharing (copays, coinsurance, deductibles) and paid stipends of $100 per high-resolution anoscopy visit and $25 per swab-only visit.
- ✓ OIG acknowledged this is remuneration that could trigger Anti-Kickback concerns, but concluded the arrangement presents minimal fraud risk because amounts were neither excessive nor coercive.
- ✓ Study leadership documented their methodology: they considered time burden, lost wages, travel expenses, procedure invasiveness, and need to maintain five-year participant retention. They consulted the Study's Community Advisory Board and benchmarked to accepted reimbursement practices in other HIV studies.
- ✓ Critical protection: The study had NCI approval for using grant funds this way, and an independent monitor with no financial interest in study outcomes provided government oversight.

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Diligence Checklist

What you need to be ready to show in diligence

- ✓ Document your methodology for setting stipend amounts: time commitment required, lost wages, travel costs, procedure burden, and retention needs.
- ✓ Benchmark your amounts to accepted practices in comparable studies, don't just pick numbers. Show that amounts are "neither excessive nor coercive."
- ✓ Have independent oversight: institutional review board approval, sponsor approval if grant-funded, and documentation that no party has financial interest in enrollment volume.
- ✓ Prove the research is non-commercial: not product-specific, not designed to benefit a particular commercial entity, and unlikely to induce unnecessary self-referrals.
- ✓ Keep contemporaneous records showing how your Community Advisory Board or ethics committee reviewed and approved the compensation structure.

If your trial stipends can't pass that reasonableness test with documented methodology and independent review, you're potentially at risk of inducement scrutiny.

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Structure not diligence-ready?

Cabra Consulting helps healthcare organizations make sure compensation and transaction structures are independently valued, clearly scoped, and defensible in diligence.

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