FAVORABLE

OIG WATCH

23-11

Clinical trial subsidies for Medicare cost sharing + site/investigator payments

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What OIG Said

OIG said this structure can be OK if site and investigator compensation is FMV and the patient subsidies are capped, not advertised, and applied consistently.

- ✓ A device manufacturer paid Medicare cost-sharing obligations (up to $2,000) for clinical trial participants and paid sites/investigators for trial-related services.
- ✓ OIG said this constitutes remuneration to both patients and providers, meaning Anti-Kickback and CMP risk was in play.
- ✓ OIG accepted the structure as FAVORABLE because the payments were capped, not advertised, not expected to generate downstream use, and were certified as fair market value for necessary trial work.
- ✓ Subsidizing cost-sharing helped preserve trial blinding and reduce socioeconomic barriers, which OIG saw as legitimate, non-referral-related reasons.

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Diligence Checklist

What you need to be ready to show in diligence

- ✓ Have a certified third-party FMV basis for all site and investigator payments tied to trial activities.
- ✓ Document that participant subsidies (e.g., cost-sharing coverage) are not advertised, not volume-linked, and capped.
- ✓ Prove payments to providers are not contingent on enrollment or referral targets.
- ✓ Show clear, written site agreements detailing responsibilities, capped compensation, and IRB oversight.

If your trial support model can't show FMV, capped subsidies, and a non-promotional purpose, OIG says you're in risky territory.

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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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