FAVORABLE

OIG WATCH

22-05

Paying FMV site fees and patient cost-sharing in a CMS-approved device trial

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What OIG Said

OIG said this setup can be okay if site payments are FMV, patient subsidies aren't marketed, and nothing is tied to referrals or future use.

- ✓ OIG reviewed a device company running a CMS-approved clinical trial. The sponsor paid sites and investigators, and subsidized Medicare patient cost-sharing (~$1,300) to encourage enrollment and retention.
- ✓ OIG said these payments do count as remuneration, which could trigger Anti-Kickback or Beneficiary Inducements scrutiny.
- ✓ But they accepted the structure because site payments were certified as fair market value, and the company wasn't using subsidies to steer referrals or lock in future use.
- ✓ OIG also noted the therapy was a one-time treatment, not expected to drive downstream utilization, which reduced seeding concerns.

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Diligence Checklist

What you need to be ready to show in diligence

- ✓ Have written FMV certification for all investigator and site payments, no volume linkage or side deals.
- ✓ Prove that patient cost-sharing subsidies weren't advertised or selectively offered and were clearly disclosed only in the IRB-approved consent.
- ✓ Show CMS approval of the trial and Category B IDE status under Medicare rules.
- ✓ Document that the product has no anticipated downstream reimbursement tail or re-use trigger.
- ✓ Confirm all sites were selected using objective, non-referral-based criteria (e.g. IRB timeline, staffing, enrollment capacity).

If your cost-sharing subsidies or site payments look like selective inducement, you'll face serious defensibility questions if scrutinized.

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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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