FAVORABLE

OIG WATCH

15-07

Paying Medicare copays and post-sham access in a device clinical trial

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What OIG Said

OIG said this subsidy structure can be okay if payments are fair market value, commercially necessary, and not tied to referrals.

- ✓ A device manufacturer funded patient copays for Medicare beneficiaries participating in a CMS-approved randomized trial, and also covered the procedure post-trial for control-arm patients who qualified and opted in.
- ✓ OIG acknowledged this was remuneration, which means it could implicate Anti-Kickback and beneficiary inducement rules.
- ✓ OIG accepted the arrangement because all clinical site payments were FMV for research services, the subsidies were necessary to preserve the trial's blinding and design integrity, and there were no side deals or referral expectations.
- ✓ OIG emphasized that the structure operated entirely within the CMS-approved protocol, with informed consent, IRB oversight, and no inducement to use the product outside the trial.

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Diligence Checklist

What you need to be ready to show in diligence

- ✓ Have clear third-party FMV support for all investigator and site payments tied to research services.
- ✓ Show that patient copay subsidies and post-sham procedures are CMS-consulted, protocol-driven, and disclosed via informed consent.
- ✓ Prove there are no parallel marketing, referral, or volume-based arrangements with investigators or institutions.
- ✓ Document how subsidy logic supports study integrity (e.g., blinding, enrollment, protocol adherence), not product adoption.
- ✓ Ensure all support flows through the formal IRB-approved trial structure with no off-protocol financial arrangements.

If your study support package isn't tied directly to protocol needs, FMV services, and research integrity, OIG is signaling 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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