UNFAVORABLE

OIG WATCH

24-06

Gene therapy manufacturer covering $70K fertility services for eligible patients

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What OIG Said

OIG said this counts as remuneration, and raised flags on value, defensibility, and inducement risk.

- ⚠ A gene therapy company proposed covering up to $70,000 in fertility-related services for patients prescribed its FDA-approved therapy, including Federal program patients whose insurance didn't cover those services.
- ⚠ OIG said this is remuneration: patients get valuable non-covered services, and hospitals may get therapy revenue from patients who otherwise wouldn't proceed.
- ⚠ OIG flagged the lack of valuation support, documentation, or commercial necessity evidence for the $70K benefit, and said this could improperly influence purchase and steerage decisions.
- ⚠ Because payments weren't tied to work, were high dollar, and lacked FMV support, OIG said no safe harbor applied and declined to offer protection.

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Diligence Checklist

What you need to be ready to show in diligence

- ✓ Prove any patient-facing benefit or support has clear scope, medical necessity, and a documented clinical rationale.
- ✓ Have an independent FMV opinion for all support or access programs with economic value, including non-claim-based services.
- ✓ Show support payments don't correlate with product selection, therapy volume, or financial benefit to providers.
- ✓ Document that support services are patient-directed, not routed through providers or commercial teams, and not used as marketing leverage.
- ✓ Ensure any vendor-administered services don't mask hidden steerage or backdoor referral incentives.

If you're doing this and you can't prove commercial need, FMV support, and independence from referral volume, this is the profile OIG said will draw fire.

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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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