FAVORABLE

OIG WATCH

24-04

Refunds + price protection discounts on ultra-rare one-time therapy

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What OIG Said

OIG said this structure avoids kickback risk if pricing terms are clearly scoped, pre-approved, and documented, and if risk shifts aren't used to steer volume.

- ✓ Requestor offered two financial protections to a treatment center for a one-time, high-cost drug: (1) a full refund or waiver if payers deny coverage, and (2) a price-lock discount if WAC increases after the insurer signs off but before the drug is delivered.

- ✓ OIG said this counts as remuneration, but allowed it due to tight constraints: small patient universe, required pre-approval from insurers, and no marketing to referring physicians or patients.

- ✓ The structure was backed by advance insurer contracts, documentation of pricing terms, and transparency in invoices and cost reports, all of which reduced fraud risk.

- ✓ OIG highlighted that commercial necessity (not patient steerage) drove the refund offer, and that the discount met safe harbor conditions, including arms-length terms and appropriate cost reporting.

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Diligence Checklist

What you need to be ready to show in diligence

- ✓ Show full documentation of any refund, waiver, or price adjustment logic, including insurer pre-approval, contracts, and patient coverage status.
- ✓ Prove that refund terms are not tied to volume or referrals, and that they are applied consistently regardless of payer type.
- ✓ Maintain evidence that cost reporting and invoicing reflect the true economic impact of any refund or discount.
- ✓ Confirm the structure is commercially necessary, not just a way to shift risk and capture volume.
- ✓ Document that pricing terms (including WAC lock-ins) are negotiated at arms length and apply uniformly across payors.

If you can't defend your refund and discount mechanics as commercially necessary, pre-approved, and FMV-aligned, OIG says that's the profile they will scrutinize.

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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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