FAVORABLE

OIG WATCH

24-02

Manufacturer-funded rare-disease patient assistance funds

CABRA CONSULTING

What OIG Said

OIG said manufacturer donations to disease funds are risky remuneration, but can be acceptable if the charity is independent and assistance isn't tied to drugs or referrals.

- ✓ OIG reviewed a nonprofit's 12 rare-disease funds, each backed by a single pharma donor, paying patients' cost-sharing, uncovered medical costs, premiums, and emergency relief.
- ✓ OIG said the arrangement implicates Anti-Kickback because donor money subsidizes patients who may use the donor's drug; that financial support is "remuneration" if intent to induce is present.
- ✓ OIG was comfortable not imposing sanctions because funds were defined by recognized disease states (not narrow drug "slices"), patients were approved first-come/first-served based on documented financial and medical need, and the charity didn't ask what drugs patients were taking.
- ✓ Donors had no ability to shape funds or steer spending, received only aggregate/non-identifying reporting, and no fund spent more than ~35% of its outlays on the donor's own products, helping show the charity wasn't a pass-through.

CABRA CONSULTING

Diligence Checklist

What you need to be ready to show in diligence

- ✓ Have written donor agreements explicitly barring donor control over fund creation, eligibility rules, or permitted uses of dollars.
- ✓ Show disease funds are clinically defined and not restricted to specific drugs, stages, symptoms, or severity that map to one product.
- ✓ Prove eligibility is independent of product choice: robust financial-need screening, physician certification of diagnosis, and no collection of drug-specific data at intake.
- ✓ Maintain firewalls on donor reporting: no patient-level data, no drug-level spend detail, and nothing that lets a donor correlate giving to utilization.
- ✓ Track fund spend mix over time; if donor-drug support becomes the dominant use, your risk profile changes fast.

If your PAP can't prove independence from donor influence and product pull-through, OIG could view it as remuneration designed to induce drug utilization.

CABRA CONSULTING

Structure not diligence-ready?

Cabra Consulting helps healthcare organizations make sure compensation and transaction structures are independently valued, clearly scoped, and defensible in diligence.

CABRA CONSULTING