FAVORABLE

OIG WATCH

22-22

Free trial units of antipsychotic drug offered to hospitals

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What OIG Said

OIG said this still counts as remuneration but allowed it due to tight controls and no link to referrals, billing, or continued use.

- ✓ OIG reviewed a manufacturer's plan to let hospitals request limited free doses of a long-acting antipsychotic for inpatient use. Doses were capped per hospital and per patient per year.
- ✓ OIG confirmed these free trial units are "remuneration," so the Anti-Kickback Statute applies, even though no one gets paid and the product isn't billed.
- ✓ The structure passed because: (a) prescribers had no financial incentive, (b) participation didn't require ongoing use, (c) use had to be clinically appropriate and tracked, and (d) hospitals couldn't bill for the drug or its administration.
- ✓ OIG noted there was no obligation to continue prescribing the drug post-discharge, and the hospital couldn't sell, trade, or seek reimbursement for free doses, helping reduce risk of disguised referral incentives.

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Diligence Checklist

What you need to be ready to show in diligence

- ✓ Show how any free or discounted drug/product is tracked, capped, and non-billable.
- ✓ Prove prescriber decisions are independent, clinically appropriate, and not tied to product incentives.
- ✓ Require certifications that prescribing is not conditional on continued use, payment, or referral volume.
- ✓ Keep documentation that no patient, payer, or program was billed, and that the product wasn't resold or distributed.
- ✓ Ensure marketing and enrollment don't resemble inducement or steerage, especially when multiple therapeutic alternatives exist.

If you're offering anything of value, even a sample, you need proof it's clinically driven, not commercially motivated.

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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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