FAVORABLE

OIG WATCH

25-07

Pharma-funded companion diagnostic testing for eligible patients

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What OIG Said

OIG said a free companion diagnostic can be acceptable if it expands access to clinically required testing without steering referrals or letting the sponsor harvest targeting value.

- ✓ OIG reviewed a program where a drug manufacturer pays a lab a fixed fee per test so eligible patients receive an FDA-approved companion diagnostic at zero out-of-pocket cost, including Medicare beneficiaries.
- ✓ OIG acknowledged this is remuneration to both patients (waived cost-sharing) and providers (they can offer the test without cost and may bill follow-up visits), so it squarely raises Anti-Kickback risk if used to induce prescribing.
- ✓ OIG was comfortable because the test is required to determine whether the drug is indicated, and about half of patients will test negative, meaning the program does not reliably drive drug utilization and can just as easily point to a competitor therapy.
- ✓ The manufacturer cannot receive patient- or provider-identifiable data, field reps can't discuss the drug in connection with the program, and the lab is barred from promoting the arrangement, limiting any ability to turn "free testing" into a sales funnel.

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Diligence Checklist

What you need to be ready to show in diligence

- ✓ Have a written program with objective, clinical eligibility criteria that do not vary by payer, income, or prescribing history.
- ✓ Show the subsidized item/service is clinically necessary to access covered care (here, a required companion diagnostic), not a discretionary sweetener.
- ✓ Prove no provider remuneration: no payments for ordering, no free staff time, no subsidized collection/handling, and clear attestations that providers won't bill third parties for the free service.
- ✓ Lock down data flow: no identifiable utilization reporting, no sales-force access, and explicit prohibitions on using program data for targeting or incentive comp.
- ✓ Ensure payments to third parties (labs/vendors) are fixed, per-service, and not volume-tiered in a way that mimics rebates for utilization.

If your "free" access program can't show clinical necessity, independence from referral volume, and tight data/firewall controls, it will read like steerage in diligence, even if the intent is access.

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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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