FAVORABLE

OIG WATCH

# 24-11

Free meningococcal vaccines tied to high-risk infusion therapy

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# What OIG Said

*OIG acknowledged this is "remuneration," but approved it due to low risk, no provider kickbacks, and FDA-driven patient safety concerns.*

- ✓ Requestor (a pharma company) offered free meningococcal vaccines to patients prescribed high-risk infusion therapies, due to a known black box risk and FDA REMS program requirements.
- ✓ OIG said the vaccines count as "remuneration" under Anti-Kickback, and the ability to bill an admin fee also qualifies, but found the overall arrangement low risk.
- ✓ OIG emphasized: no vaccine costs were billed to Medicare or other payors, and prescribers didn't receive payment beyond possibly billing a ~$20 admin fee.
- ✓ The program addressed FDA-identified gaps in REMS execution, particularly for specialists less familiar with stocking/administering meningococcal vaccines.



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# Diligence Checklist

*What you need to be ready to show in diligence*

- ✓ Show that any free services or goods (e.g. vaccines, devices) are tied to REMS/safety compliance, not marketing or patient inducement.
- ✓ Prove that no provider received financial gain (e.g. payments, rebates, off-books support) beyond nominal admin fees.
- ✓ Have documentation that no vaccine or drug cost was billed to Federal programs or commercial payors.
- ✓ Keep records showing the support is available regardless of provider choice or prescriber participation.
- ✓ Confirm the offering is narrowly tailored to reduce a regulatory or clinical barrier, not drive product uptake.

*If your patient support program offers free items or services, and you can't show FMV alignment and compliance rationale, this is the kind of arrangement that could be flagged.*



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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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