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Prosecuting Illegal Kickbacks: The Cost of Noncompliance

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Agenda

- Today's “kickback” risks
- Legal interpretation of Anti-Kickback Statute (“AKS”)
- Balance between tolerable and intolerable legal risk

Today's "Kickback" Risks

- Reimbursement programs, drug assistance
- Contributions to copay foundations
- Nurse educators
- Transportation services
- Assistance to clinics and non-profits (i.e. technology, equipment, etc. for storage and administration of drug)
- Genetic testing programs

Anti-Kickback Statute

[42 U.S.C. § 1320a-7b(b)]

The AKS is a criminal law that prohibits the knowing and willful payment of “remuneration” to induce or reward patient referrals or the generation of business involving any item or service payable by federal health care programs (e.g., drugs, supplies, or health care services for Medicare or Medicaid patients).

Intent

- The One Purpose Test – If one purpose of the payment was made to incentivize the physician to refer patients, then the AKS has been violated. *United States v. Greber*, 760 F.2d 68, 69 (3d Cir. 1985).
- The mere hope, expectation, or belief that referrals may ensue from remunerations designed wholly for other purposes does not amount to an AKS violation. *United States v. McClatchey*, 217 F.3d 823, 834–35 (10th Cir. 2000).

Independent Value

Does the service at issue provide “independent value” to providers apart from your product?

If there is no independent value, the service is “properly considered part of the products purchased” such that the “cost is already included in the product’s price” and does not implicate the AKS.

OIG Advisory Opinion No. 00-10 at 7 (Dec. 28, 2000).

Anti-Kickback Statute & False Claims Act

- Reimbursement claims made pursuant to an illegal kickback constitute a violation of the False Claims Act (“FCA”).
- FCA’s materiality standard under *Escobar* applies when underlying violation is AKS violation.
- “A misrepresentation about compliance with a statutory, regulatory, or contractual requirement must be material... in order to be actionable under the [FCA].”

Universal Health Services v. United States ex rel. Escobar, 136 S. Ct. 1989, 2002 (2016).

Practical Implications - Government

- Government is pursuing public policy initiatives via the AKS
- Illegal conduct versus disfavored activity

Practical Implications - Manufacturers

- Balancing tolerable versus intolerable risk
- Ensuring access to drug
- Application to private insurers
- Illegality versus practicality
- Reputational concerns

Legal Takeaways

- What is intent of program/service?
- What value does service provide to physicians?
- Do you have a good faith belief that your company is trying to comply with the AKS?