Avoiding Anti-Kickback Liability Under the Part D Program

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Overview of Presentation

- Overview of the Anti-Kickback Statute (AKS)
- Potential application of AKS to Part D
- Discussion of scenarios
- Questions
When is Anti-Kickback Statute (AKS) Violated?

- A person knowingly and willfully
- Offers, pays, solicits or receives
- Any form of direct or indirect remuneration
- In return for:
  - the referral of patients; or
  - purchasing, leasing, or arranging or recommending the purchase or lease
- Of items or services reimbursable by Medicare or any other “federal health care program”
Challenges in Evaluating AKS Issues

- Exceptionally broad scope of statute
- "One purpose" test
- Intent-based inquiry
- Multiple policy goals underlying law:
  - Prevent over-utilization
  - Preserve patient-centric referral decisions
  - Maintain level playing field among competitors
AKS Penalties

- Criminal penalties: felony punishable by up to 5 years imprisonment and $25,000 fine
- Civil monetary penalties of up to $50,000 per violation and three times the amount of the improper remuneration
- Exclusion from Medicare
- False Claims Act liability
  - Treble damages
  - CMPs of up to $11,000 per claim
Safe Harbors Most Relevant to Part D

- Personal services and management contracts
- Discounts and rebates
- Group purchasing organizations
- Electronic prescribing (proposed)
- Managed care arrangements
- Increased coverage/reduced cost-sharing
**Key Part D Financial Relationships**

- **Pharmaceutical Manufacturers**
  - Consulting fees
  - Grants
  - Entertainment
  - Conferences
  - Meals

- **PDP**
  - Commissions
  - Administrative fees
  - Shared rebates
  - Mail order claims

- **PBM**
  - Claims
  - Discounts
  - Rebates
  - Administrative fees

- **Retail Pharmacies**

- **Mail Order Pharmacy**

- **Physicians**
  - Consulting fees
  - Grants
  - Entertainment
  - Conferences
  - Meals

- **Brokers**
Step-by-Step AKS Analysis

Referral or purchase/lease arrangement? Yes → Remuneration flowing in opposite direction? Yes → Items or services covered by Medicare? Yes → Remuneration in safe harbor? Yes → Favorable advisory opinion

No → Potential AKS liability

Remuneration flowing in opposite direction? Yes → No AKS Violation

No → No AKS Violation

Items or services covered by Medicare? Yes → Remuneration in safe harbor? Yes → Favorable advisory opinion

No → No AKS Violation

Remuneration in safe harbor? Yes → Favorable advisory opinion

No → No AKS Violation

Knowing and willful inducement? Yes → No AKS Violation

No → No AKS Violation
Scenario 1: PDP Marketing

- PDP sponsor pays broker to market PDP to Medicare beneficiaries
- Broker paid commissions based on a percentage of premium
- Broker subcontracts in one service area with independent marketing agents who are paid fixed fee for each “lead” that leads to an enrollment
Scenario 2: PBM Finder’s Fee

- PBM pays finder’s fee to person who assists PBM in obtaining pharmacy benefits management contract with self-insured employee health benefit plan
- Benefit plan includes drug coverage for employer’s retirees
- Employer receives Part D tax subsidy for retiree drug coverage
Scenario 3: Manufacturer Payments to PBM

- Pharmaceutical manufacturer pays PBM:
  - Fixed annual amount for de-identified pharmacy claims data
  - Up-front advance as offset against future rebates
- Year-end adjustment of rebates based on market share movement
- Several drugs sold by the manufacturer are included in the PBM’s formulary
Scenario 4: Switching Fees

- Generic Drug X is a substitute for Brand Drug Y
- PDP sponsor pays pharmacies an education fee for informing enrollees of the financial benefits of using Generic Drug X over Brand Drug Y
- Education fee consists of a base fixed amount plus a year-end bonus linked to the generic substitution rate for Generic Drug X
Scenario 5: Specialty Pharmacy Fees

- Specialty pharmacy supplies chronically ill patients with maintenance drugs by mail order
- Drug manufacturer pays specialty pharmacy to:
  - Provide enhanced education to patients about the proper use of the manufacturer’s drugs
  - Provide consulting services relating to the marketing of drugs to chronically ill individuals
Scenario 6: Long Term Care Pharmacy

- Nursing home chain creates long term care (LTC) pharmacy company to serve its facilities
- Nursing home chain sells LTC pharmacy company to another entity
- As part of transaction, nursing home chain extends term of contract under which LTC pharmacy company serves as chain’s exclusive pharmacy