

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

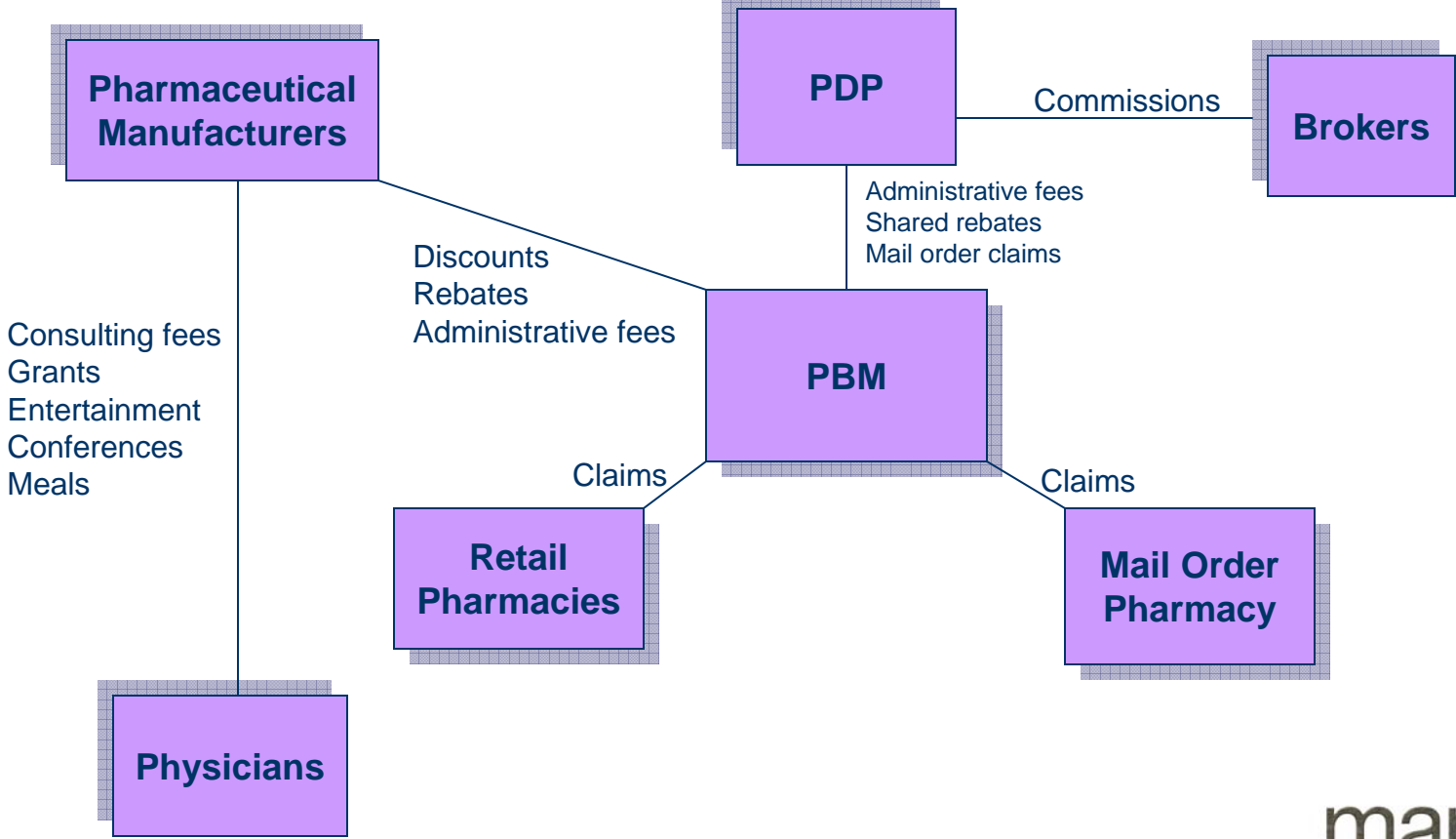
AKS Penalties

- 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

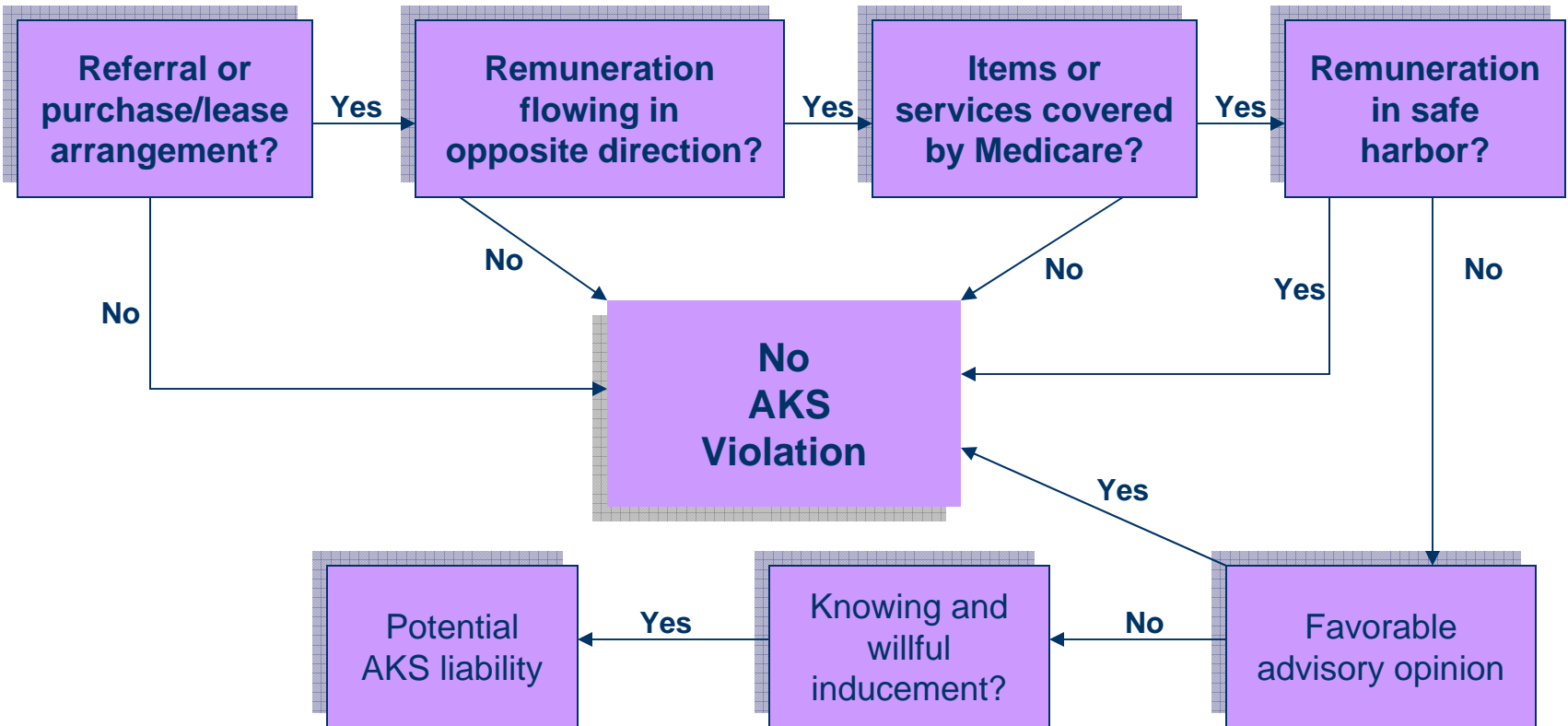
Safe Harbors Most Relevant to Part D

- 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



Step-by-Step AKS Analysis



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