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Healthcare Fraud Investigation Strategies

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Strategic Decisions Arising in Government Investigations

- Self-Reporting
- Balancing Legal Obligations & Enforcement Priorities
- Settlement vs. Trial

Self-Reporting

- OIG
  - Voluntary Self-Disclosure Protocol
  - Open Letter to Health Care Providers
- U.S. Attorney's Office
- Medicare Contractors

Balancing Legal Obligations & Enforcement Priorities

- Ethical Risks of Advising Clients based on Risk of Enforcement
- Intent-based Laws (AKS & CMPs)
  - Need to Understand Government Priorities to Advise Clients Properly
- Cannot Ignore Enforcement driven by Whistleblower False Claims Act
- Tough Cases – Technical Stark Violations

Settlement vs. Trial

- Amount of Settlement
- Scope of Release (federal/state/administrative)
- Likelihood of Success at Trial
- Risks associated with Trial
  - FCA Liability
  - Exclusion (Economic Death Penalty)

Risks of Trial – False Claims Act Liability

TYPICAL DEFENSE CONTRACTOR

- $100,000 damages X 3 = $300,000
- 12 (# of claims) X $11,000 = $132,000
- Total liability = $432,000

Risks of Trial – False Claims Act Liability

TYPICAL HEALTHCARE PROVIDER

- $100,000 damages X 3 = $300,000
- 2000 (# of claims) X $11,000 =$22,000,000
- Total Liability = $22,300,000

New Areas of Healthcare Activity Under Scrutiny

- Medicare Part D
- Quality of Care
- Medical Device Industry
- Clinical Research
- Off-label Marketing

Part D

- Government Spending Huge Amounts of Money on Prescription Drug Coverage
- Concern about Fraud
- Government and PDP Audits

Quality of Care

- Government challenge to distinguish egregious cases from malpractice
- Information on quality of care is growing
  - Government reporting obligations
  - May see some enforcement based on failure to report
- Uncertain future

Medical Device Industry

- Move Over Pharma – Government Sets Sights on New Target
- Cost of Medical Devices Consume Growing Share of Healthcare Reimbursement
- Relationships with Physicians

Clinical Research

- Government Concerned about Corrupting the Research Process
- Excessive Payments to Physicians
- Failure to Report Adverse Events

Off-label Marketing

- Latest Area of Emphasis on Pharmaceutical Manufacturers
  - January 2007: Schering-Plough Pays $180 Million in Connection with Off-label Use of Temodar.
- Government Concern
  - Corrupting the Physician Decisionmaking Process
  - Avoiding FDA Regulatory Process
- Examining Sales Incentive Plans

Questions?

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