

**Morgan Lewis**

***FAST BREAK:***

**WHAT A FEDERAL PROSECUTOR  
REALLY THINKS ABOUT YOUR  
COMPLIANCE PROGRAM**

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# Agenda

- Federal health care spending and efforts to curb fraud, waste & abuse
- Industries and areas of concern to HCF prosecutors
- Elements of an effective compliance program
- Evaluating a compliance program through the eyes of DOJ
- Case studies of effective and deficient compliance programs

# Health Care Spending & Monetary Recoveries

- U.S. spent an estimated \$3.2 trillion in FY 2015, of which \$325 billion was spent on prescription drugs
- The federal spend on health care in FY 2015 was more than \$9,990 per person
- CMS anticipates 5.8% growth each fiscal year through FY 2025
- Government Health Care Fraud and Prevention Efforts recovered \$3.3 billion in FYI 2016; \$2.4 billion in 2015; and \$3.3 billion in FY 2014 (ROI equals \$5.00 for every \$1.00 spent during 2014-16)
- Since 1997, the Government's Health Care Fraud and Abuse Control (HCFAC) Program has recovered more than \$31 billion

# No Health Care Industry Sector is Immune from Fraud

- Pharmaceutical Companies
- Medical Device Manufacturers
- Durable Medical Equipment Suppliers
- Pharmacies
- Medical Laboratories
- Ambulance Service Companies
- Hospitals
- Health Clinics
- Nursing Homes
- Hospice Providers
- Doctors
- Nurses
- Therapists
- Chiropractors
- Other Health Care Professionals

# Areas of Concern

- Independence of Medical Advice Rendered to Patients
- Off-Label Use of Drugs and Medical Devices
- Patient Safety
- Overutilization
- Unnecessary Procedures
- Unperformed Procedures
- Costs to Taxpayers

# Examples of Fraud, Waste & Abuse

- Kickbacks being paid to doctors and other health care providers
- Misleading marketing and promotional schemes
- Improper use of grants and Continuing Medical Education (CME) programs
- Improper pricing arrangements
- Improper price reporting and rebate reporting
- Improper billing practices
- Improper coding of diagnoses and procedures
- Billing for medically unnecessary services
- Billing for unperformed services
- Manipulating clinical data

# Principles of Federal Prosecution of Business Organizations “The Filip Factors”

- Nature and Seriousness of the Offense
- Pervasiveness of Wrongdoing
- History of Similar Conduct
- Willingness to Cooperate
- Existence and Effectiveness of Pre-Existing Compliance Program
- Timely and Voluntary Disclosure of Wrongdoing
- Remedial Actions Taken
- Collateral Consequences
- Adequacy of Civil or Regulatory Enforcement Actions
- Adequacy of Prosecution of Individuals

# Benefits of a Compliance Program

- The existence of a working compliance program, as referenced in Section 8 of the Sentencing Guidelines, can help you mitigate potential civil and criminal liability
- Credit available where a high level person (without a direct compliance monitoring role) engages in wrongdoing, but program detects problem, its reported, and compliance officials report to board or subset of board (audit committee)
- Government recognizes that one-size does not fit all in terms of compliance programs (large, medium, small companies and businesses)
- Compliance matters for both first time and repeat offenders



# Recent DOJ Compliance Guidance

- DOJ and SEC issue Foreign Corrupt Practices Act (FCPA) Resource Guide in November 2012, and revised in June 2015
- DOJ Fraud Section hires Hui Chen as “Full-Time Compliance Expert” in November 2015
- DOJ Fraud Section issues “Evaluation of Corporate Compliance Programs” Guidance on February 8, 2017  
(<https://www.justice.gov/criminal-fraud/page/file/937501/download>)

# Eleven Areas of Evaluation for Corporate Compliance Programs

- Analysis and Remediation of Underlying Misconduct
- Senior and Middle Management
- Autonomy and Resources
- Policies and Procedures
- Risk Assessment
- Training and Communication
- Confidential Reporting and Investigation
- Incentives and Disciplinary Measures
- Continuous Improvement, Periodic Testing and Review
- Third-Party Management
- Mergers & Acquisitions

# Compliance Program Questions

- Historically, does the company have a track record of a “Culture of Compliance”?
  - High-level commitment to compliance where “tone [is set] from the top”
  - Ethical behavior from the “lowest ranking employee through upper management”
- Does the company have clear, well written policies that are easily understood by employees?
  - Foreign operations: policies should be translated into languages spoken by the employees and third-party vendors in those countries
- Does the company have a compliance officer with actual authority to investigate and address compliance issues?
  - Adequate resources to investigate and remediate problems
  - Unfiltered line of communication to upper management, CEO, Board, etc.

# Compliance Program Questions (cont.)

- Does the company proactively investigate and address potential compliance issues?
  - Anonymous hotlines and other reporting mechanisms
  - Remedial steps taken currently and in the past to address identified problems
- Does the company actively train and educate management and its employees as to all legal, regulatory and ethical requirements?
  - One and done compliance and ethics training is not acceptable
  - Training given and updated regularly to address new business risks
- Does the company's compliance program actually encourage employees to report suspected wrongdoing without fear of retribution?
  - Indifference and retaliation through isolation and demotion as the corporate response
  - Qui tam relators can be created if company ignores relator's effort to work within the compliance framework to create ethical environment

# Compliance Program Questions (cont.)

- Does the company actually discipline employees who engage in unlawful or unethical conduct?
  - High-level employees often formulate, approve, and implement the business plans that caused the problem
  - Both low-level and high-level employees need to be accountable for bad behavior
  
- Does the company take steps to regularly review and evaluate the effectiveness of its compliance program?
  - Risk assessment is an ongoing process
  - Regular reviews designed to assess and respond to changing business activities, geographic markets, and third-party providers

# Case Examples

- The story of Dr. Joseph Kubacki and a local hospital
- Voluntary disclosures by hospitals and health networks
- Creative compliance solution involving a nursing home
- The billion dollar pharma settlements focused on compliance

# Thanks!



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Please join us for next month's webinar:

["E/M Coding for Non-Coders"](#)

Featuring Jake Harper

➤ Thursday April 20, 2017 3:00 PM (EST)