

## Outside Looking In: In-House and Outside Counsels' Perspectives on Compliance & Enforcement Investigations

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- HCCA'S CLINICAL PRACTICE COMPLIANCE CONFERENCE
- **PHOENIX, ARIZONA**
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## Overview

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- Enforcement Agencies and Landscape
- Applicable Statutes
- Understanding Government Procedure
- Working with Counsel
- Leading Practices in Conducting and Responding to Investigations
- Outcomes and Negotiated Resolution



## U.S. Department of Justice (DOJ)

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- Prosecution of healthcare fraud
  - Criminal/Civil/Antitrust Divisions
  - Consumer Protection Branch
  - Healthcare fraud coordinators within 94 United States Attorneys' Offices
  - Federal Bureau of Investigation
  - Drug Enforcement Agency
  - Partnerships with private payors
- Distinct funding sources

## Other Enforcement Players

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- Local District Attorneys
- Offices of Inspector Generals - Federal and State
- Medicaid Fraud Control Units
- Centers for Medicare and Medicaid Services
- Medicaid State agencies
- Tricare Management Authority
- Federal/State contractors
- Commercial payor "Special investigative units"
- Licensing boards
- Whistleblowers



The graphic features a central, bold title 'Enforcement Agenda' set against a background of a stylized, grayscale cityscape. The buildings are depicted with a grid-like pattern of lines, creating a sense of depth and perspective. The overall aesthetic is professional and modern.

## Enforcement Agenda

## Enforcement Outlook in 2017

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- Federal and State healthcare budget shortfalls
- Perception that fraud is rampant
- More state and federal enforcement officials
- New reimbursement models increasing referral “tensions”
- Greater collaboration DOJ, CMS, and private payors
- Use of data analytics will continue to drive enforcement
- Increased focus on individual actors

## Recent DOJ Activity

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- DOJ recovered more than \$4.7 billion in FY 2016
  - Up from FY 2015 \$3.8 billion recovery
  - ROI for the Health Care Fraud and Abuse Control Program \$6 returned for every \$1 expended
- Continues 4-year record of recoveries over \$3 billion
- Of \$4.7 billion –
  - \$2.5 billion from healthcare industry, including \$330 million from hospitals
  - \$2.9 billion (more than half) from cases filed by whistleblowers under FCA
- Number of qui tam suits exceeded 700
  - Up from FY 2015 600
  - But way up from 1987's 30
  - Whistleblowers received \$519 million

## DOJ's Yates Memorandum

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- Yates Memo (9/9/2015): “Individual Accountability for Corporate Wrongdoing”
- Emphasizes DOJ's commitment to combat fraud “by individuals.”
- Recommends:
  - Not to give cooperation credit unless company provides facts re: individuals
  - To focus investigations on individuals “from the inception”
  - Not to release “culpable individuals” from liability absent “extraordinary circumstances”
  - Not to settle with company without “clear plan to resolve related individual cases”

## HHS-OIG's General Policy on Exclusion

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- Exclusion only apply to misconduct from the past 10 years
- Early Reinstatement Process
- Aggravating Factor Threshold Elevated
  - Amount will have to be at least \$50,000 in several scenarios
- Mitigating Factor for Exclusions
  - Patient access to care significantly harmed by exclusion
- Audit Obstruction Policy



## Health Care Fraud Statute

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- Federal criminal statute for public AND private health care fraud, 18 U.S.C. § 1347
- Knowingly and willfully execute/attempt a scheme or artifice to:
  - Defraud health care benefit program; or
  - Obtain by false or fraudulent pretenses property under custody/control of program in connection with delivery or payment for items or services
- 10-year imprisonment, restitution, and fine
- New norm of relying on private payor losses

## The Federal Anti-Kickback Statute

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- **Criminal statute, 42 U.S.C. § 1320a-7b(b)**
  - Remuneration is anything of value
  - *One Purpose Test*
  - Must be commercially reasonable
- **Recommend or arrange for items/services under federal programs**
  - Includes non-clinicians
- **Greater compliance with safe harbor generally means less risk**
  - Advisory Opinions address industry concerns
- **Forms basis for civil liability**
- **Commercial bribery statutes limit remuneration in cash/private plans**

## Remember the ACA

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- **Patient Protection and Affordable Care Act**
  - Enacted March 23, 2010
- **Amendments to Anti-Kickback statute**
  - Rejects stringent definition of knowledge
  - Violations result in falsity under the False Claims Act (FCA)
    - FCA violations can occur even if claim was submitted by an "innocent" third-party
- **Clarification of sentencing guidelines**
  - Presumption intended loss is value of claim, not actual payment

## FCA

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- **A false claim or statement for payment to the United States, 31 U.S.C. § 3729(a)**
  - Conspiracy
  - “Reverse” false claims is the knowing retention of a known overpayment
- **Claim must be submitted "knowingly"**
  - Actual knowledge
  - Deliberate ignorance
  - Reckless disregard
  - No specific intent to defraud required
- **Other state/federal law violations may be bases for liability**

## FCA, cont'd.

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- **Six-year statute of limitations**
  - Three years from date material facts are known or reasonably should be known by responsible official
    - DOJ is the official, not agent
  - Not more than 10 years after the violation
- **Remedies**
  - Damages not required
  - If found liable, mandatory treble damages and penalties
  - Attorneys' fees and costs
- **Increased penalties for violations after Nov. 2, 2015**
  - Minimum per claims penalties: \$10,781 from \$5,500
  - Maximum per claim penalties: \$21,563 from \$11,000



## FCA *Qui tam* Provisions

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- *Qui tam* actions brought by private individuals (“relators” a.k.a. whistleblowers) on behalf of the Government
- Procedure
  - Relator must file a complaint, under seal, in a U.S. district court that has jurisdiction over the case
  - Relator must also serve written disclosures on DOJ describing “substantially all material evidence and information the person possesses”
  - DOJ has 60 days to investigate and decide whether to intervene,
  - but extensions are liberally granted. 31 U.S.C. § 3730(b)(2).
  - Trend is to limit extensions

## *Qui tam*, cont'd.

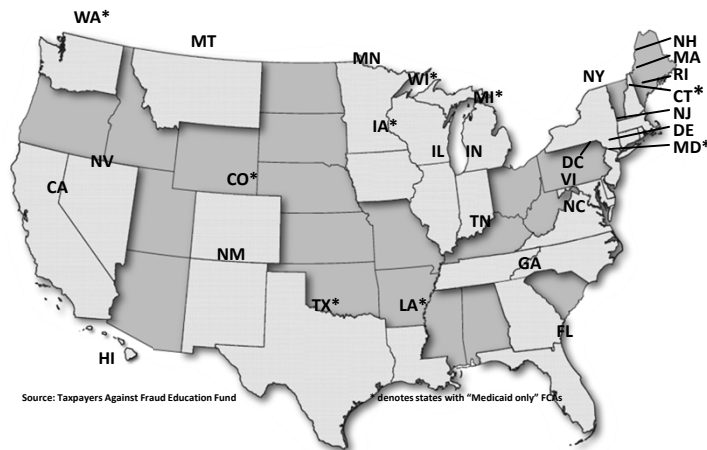
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- After the Government fully investigates, it can:
  - Intervene in the case, assuming primary responsibility for the litigation
  - Decline to intervene, which allows the relator to carry on without the Government
  - Move to dismiss the case (even if the relator objects)
  - Seek to settle the case
- Bars to *qui tam* suits include:
  - Public disclosure (anyone could have filed this suit)
  - First-to-file rule (someone already filed)
  - Previous Government action (U.S. is already involved)

## Escobar: Key Supreme Court Case

- *Universal Health Servs., Inc. v. U.S. ex rel. Escobar*, 136 S. Ct. 1989 (2016)
  - Allowed implied certification BUT relied on whether material to payment
  - Unanimous decision
  - Implied certification can be a basis for liability under certain circumstances
  - Courts continue to parse Escobar regarding materiality requirement

## State False Claims Acts



## Stark Law

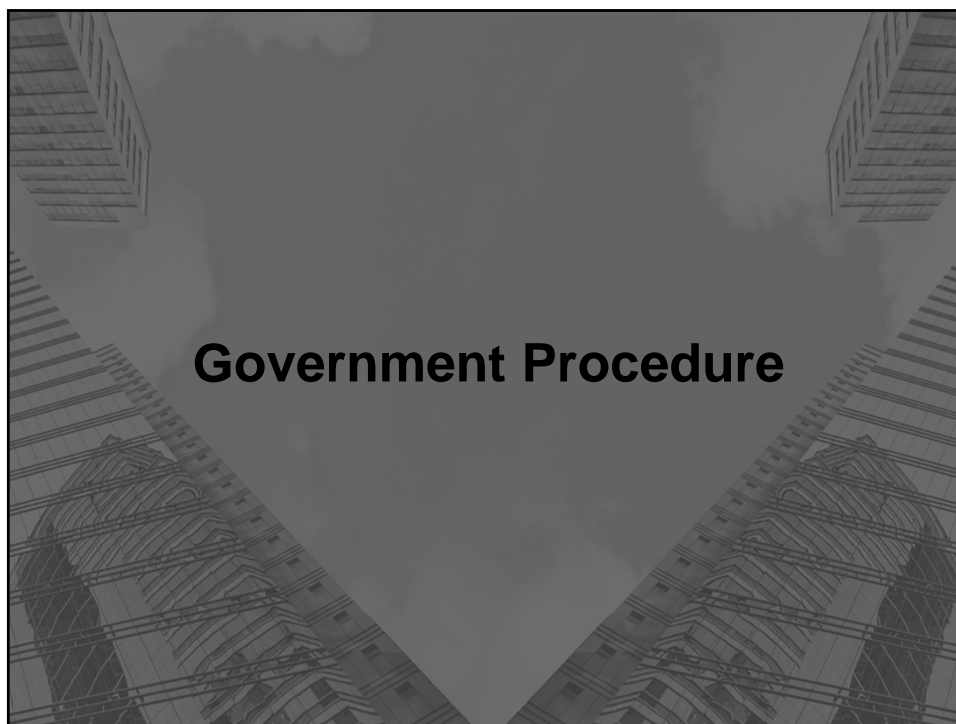
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- Prohibits self-referrals for federal business, 42 U.S.C. § 1395nn
  - Must involve physician referral
  - Designated health services
  - Medicare and Medicaid only
  - Ownership interest or compensation arrangement
  - Generally must be commercially reasonable and fair market value
  - State law may limit non-Medicare business agreements
- Strict liability
  - Must fully satisfy statutory or regulatory exception
- Remedy is payment disallowance
  - Exclusion and CMP liability
  - May be violation of FCA

## Civil Monetary Penalties Law

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- HHS-OIG administrative remedy, 42 U.S.C. § 1320a-7a(a)
  - Permissive exclusion and money damages for specific violations like payment or receipt of illegal kickbacks
- Mirrors FCA but not governed by civil rules of procedure or evidence
  - Limited discovery
  - Hearsay admissible
- OIG usually releases this authority in exchange for compliance obligations



## Sources of Investigative Cases

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- Partnering by enforcement agencies
- Data mining
- Initiatives, working groups, and task forces
- Competitor complaints
- Patient/family complaints
- Self-disclosures
- Whistleblowers
- Social media
- Traditional media

## Common Risk Areas

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- **False/fraudulent claims**
  - Billing for items or services not rendered
    - Upcoding and product substitution
  - Misrepresenting nature of items or services
    - Seeking reimbursement for unallowable costs
- **Retention of overpayments**
  - Refusal to return erroneous payments
- **Improper financial relationships/referrals**
  - Sham compliance with safe harbor or exception
  - Excessive payments
  - Percentage based compensation
- **Insufficient documentation of work performed**

## Government Investigations

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- **Parallel proceedings are simultaneous civil/criminal /administrative investigation of same defendants**
  - Usually jointly handled
  - Can be federal and State/local or multi-district
- **Examples**
  - Procurement fraud
  - Financial frauds
  - Healthcare fraud
  - Asset forfeiture actions
  - Drug diversion
  - SEC and antitrust investigation

## Investigations, cont'd.

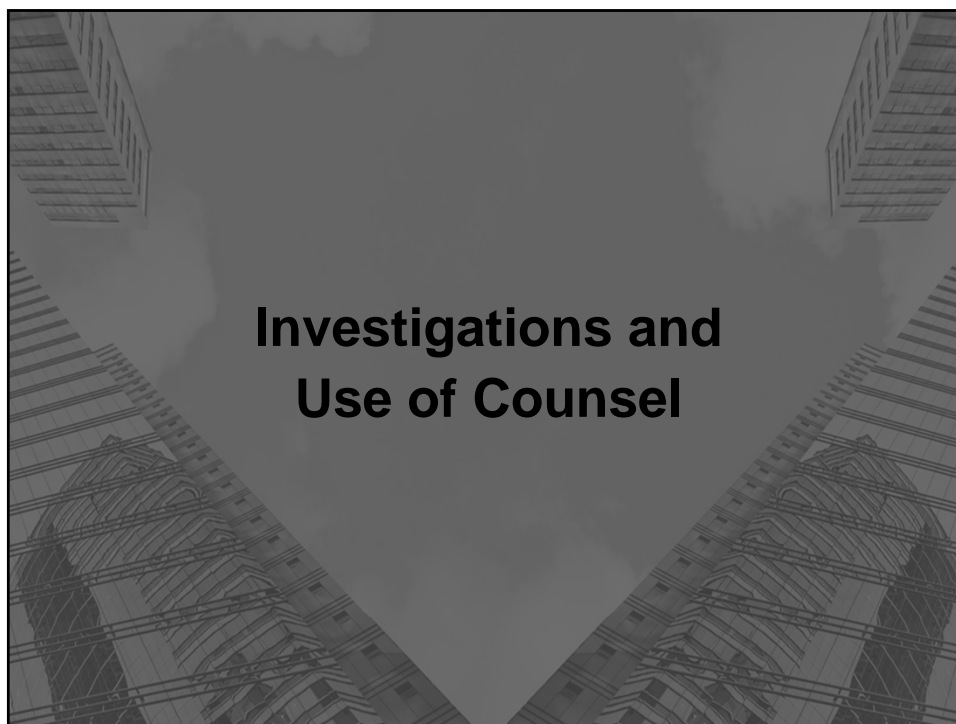
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- Surveillance
- Consensual monitoring
- Qui tams
- Data analytics
- Interviews
- Search warrants
- CIDs
- Subpoenas
  - Grand jury
  - Inspector General
  - AID (HIPAA)
- Requests for information

## Investigations, cont'd.

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- Obtain information
  - Claims/contracts/payments
  - Interview
- Issue warrant, subpoena, or request
  - Internal/external correspondence/e-mails
  - Policies/practices
  - Specific claims/patient files
- Review information gathered
  - What is knowledge/intent?
- Determine how to proceed
  - Civil/criminal/administrative or parallel



### Internal Investigations 101

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- Tracking all reports/assessments
- Documenting investigation plan
- Preservation of information
- Protections to ensure confidentiality
- Conducting investigation
- Determining scope of disclosure
- Reporting of conclusions/findings to appropriate parties
- Corrective actions for responsible persons/departments
- Discipline of bad actors
- Non-retaliation reinforcement
- Taking remedial measures (repayment or disclosure)

## Common Internal Investigation Triggers

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- Hotline calls
- Reports to management or compliance
- Vendor communications
- Departing employees
- Industry rumors
- News articles
- Subpoenas or other government requests
- Government interviews of employees or related parties
- Private litigation

## Risk Areas, cont'd.

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- Conflicts of interest
- Out of network billing
- Collection policies
- Referrals to ancillaries
  - pharmacy and laboratories
- Physician-owned entities
- Space and equipment rentals
- Medical director positions
- Practice acquisitions
- Locum tenens and leased/temporary staff



## Preliminary Assessment

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- Have an initial discussion of the issues with the point of contact and other relevant individuals
- Goals should be to get information on the background and context of the issue, the identity of individuals with relevant information, and the business concerns of the client
- Recognize that the information received likely is incomplete and inaccurate
- Scope should be dynamic dependent upon findings, needs to be consistently reassessed

## Hire Counsel or Stick With Internal?

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- Criminal or civil
- Attorney/Client privilege
- Lawyers for Executives or Board
- Nature of the problem
  - Overpayment
  - False billing
  - Stark Law
  - Anti-Kickback Statute
  - Whistleblower retaliation
  - Survey/compliance issues

## Hiring Counsel, cont'd.

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- Time sensitivity
- Cost
- Leadership perception
- Seriousness of allegations
- Ethical and conflict considerations
- Ability to offer a fresh perspective
- “Cover”
- Engaging outside counsel
- Preserving privilege and protections
- Handling deliverables

## Working to Develop an Investigative Plan

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- Identify potential misconduct
  - Factual vs. legal
- Leverage internal/external resources
- Locate responsible individuals
  - Initial targets
  - May change
- Steps to be taken:
  - Document preservation and collection
  - Gather information
  - Review and research deadlines and projects
- Reassess if know government action or timelines
- Implementation and monitoring of corrective and remedial actions

## Issuing the Preservation Notice

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- Necessary to protect yourself and your client
- Differences how notice will be received:
  - Litigation holds routine for some
  - For others cause significant concern and can result in departures
- Nature of inquiry will determine scope and recipients of litigation hold
  - Whether broad or narrow will determine cost

## Who is the Point of Contact

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- Determine the appropriate contact (company, owner, employee, or combination of the above)
- Where the client is a company, clearly establish a point of contact (in writing), with authority to receive information and give direction
  - Where possible, the primary point of contact should be uninvolved in the conduct at issue
- Discuss with the company client its hierarchy and which entity has ultimate authority
  - Investigations make employment inherently unstable
  - The point of contact today can be unemployed or adverse to the company tomorrow (Yates Memo)

## Explaining Rights and Obligations

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- **Example reminders:**
  - Company is/intends to cooperate
  - Government requests directed to the company must be forwarded to counsel
  - Do not lie or mislead government or its agents
  - Obey hold notices and preserve evidence
  - Right to counsel if the government wants to interview you
    - *The company may provide such assistance upon request*
  - Most interviews are voluntary – even during raids
  - If compelled to testify, notify company and legal
  - Understand implications of invoking 5<sup>th</sup> Amendment right

## Conducting Interviews

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- Should in house lawyer be present?
- Before or after document review?
- Employees (*Upjohn warning*) and third-parties
- Notification whether separate counsel may be prudent
- Sequencing is important
  - Typically begin with those who will be most forthcoming/those with the least to lose
- May need to get support from organization for some interactions
- Some interviews may need to all be done on same day to minimize noise & cover-up potential
- Often lead to other persons needing to be interviewed

## Selling the Corrective Action

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- Who best can communicate the plan
- Target high-risk areas
  - Monitoring vs. auditing
- Disciplinary actions
- Training
- Policy revisions
- Corrective communications
- Culture adjustments
- Monitoring and implementation
- *Evidence of the Above?*

## Handling Repayment and Disclosure

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- FIRST fix any problems
- Federal law requires repayment of known Medicare/Medicaid overpayments within 60 days
  - CMS issued final rule at 77 Fed. Reg. 9179 (Feb. 16, 2016)
- Disclosure to DOJ
  - Possible non-prosecution of business entity
    - *See USAM § 9-28.000, et seq.*
  - Limited civil FCA multiplier
    - *See False Claims Act § 3729*
- HHS-OIG Self-Disclosure Protocol
  - Lower damages/no integrity obligations
- CMS Voluntary Self-Referral Disclosure Protocol
  - Do not disclose both to CMS and OIG
  - Use OIG protocol if implicates other laws

## Leading Practices for Effective Collaboration

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- Implement an effective compliance program
- Assess status - target, witness or subject
- Get ahead of government's investigation
- What is scope of representation
  - Does anyone need separate counsel (Yates Memo)
  - Has anyone talked to the government
  - Seek insurance coverage
- Evaluate ALL liability - criminal, civil, admin, state, licensure, and private
- Strategy has implications for parallel case

## Leading Practices, cont'd.

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- Preserve documents
  - Scope of hold notice
  - Beware of ramifications of company-wide notices
- Protect privileges/protections
  - Critical given current case law
- Compile right team
  - Consultants
  - Clinical and billing
  - Statisticians
- Client counseling
  - Early and often

## Resources for Enforcement Information

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- Advisory opinions
- Published cases
- OIG Compliance program guidance publications
- State and federal work plans/audits/evaluations
- Settlement/integrity agreements
- Press releases
- GAO reports
- Comments/preambles to safe harbors/exceptions



## Responding to Enforcement Actions and Resolutions

## Settlements

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- **Global settlements if requested by defendant**
  - Criminal and Civil each negotiate own agreements
  - DOJ cannot address administrative remedies
- **Settlement parameters**
  - Loss/issues determine level of DOJ involvement
  - Most terms are non-negotiable
    - No confidentiality clauses
  - Covered conduct and released parties are narrow
    - Reservation of claims against individuals
  - Gov't does not resolve relator's claims/fees
    - Relators/defendants directly discuss

## Settlements, cont'd.

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- **Global settlements**
  - Invoke only when appropriate
  - Early contact with administrative agencies
- **Settlement Issues**
  - Covered conduct
  - Released parties and claims
  - Interplay between corporation and principals
  - Inability to pay
  - Administrative concerns
  - Collateral consequences



## Possible Outcomes

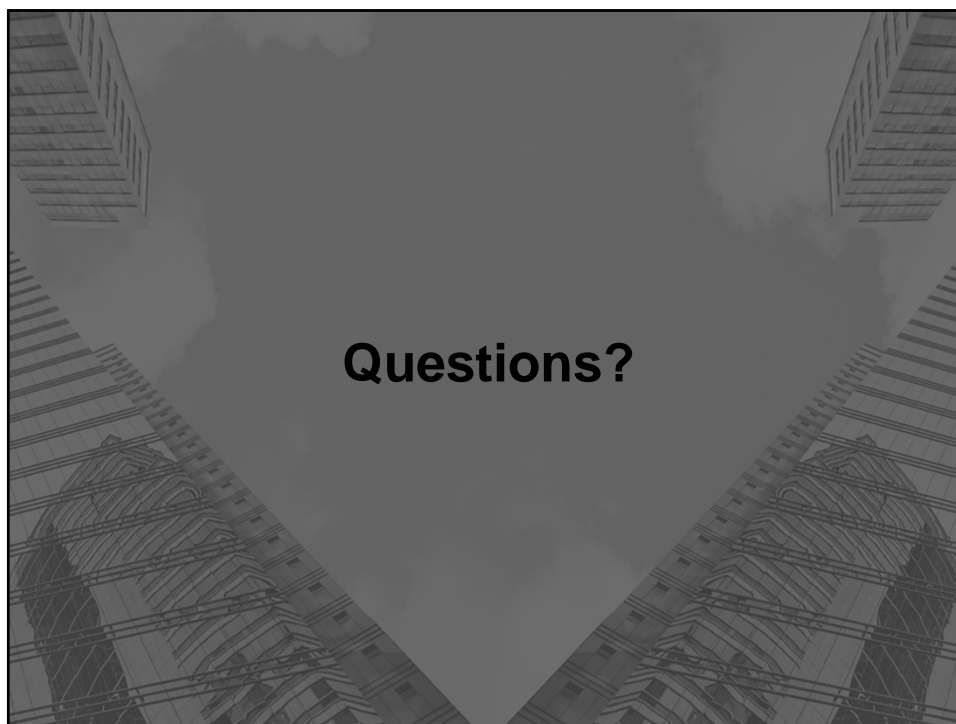
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- Suspension of payments
- Termination from gov't programs
- Civil recoveries from responsible parties
- Criminal convictions and restitution
- Exclusion/debarment/revocation
- Licensing board action
- Compliance or integrity obligations
- *Cost of responding*
- *Loss of business/goodwill/morale*

## Compliance Matters

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- If an organization is found guilty of a violation of state or federal laws, the government may offer a reduction in penalties if an effective compliance program is in place



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