



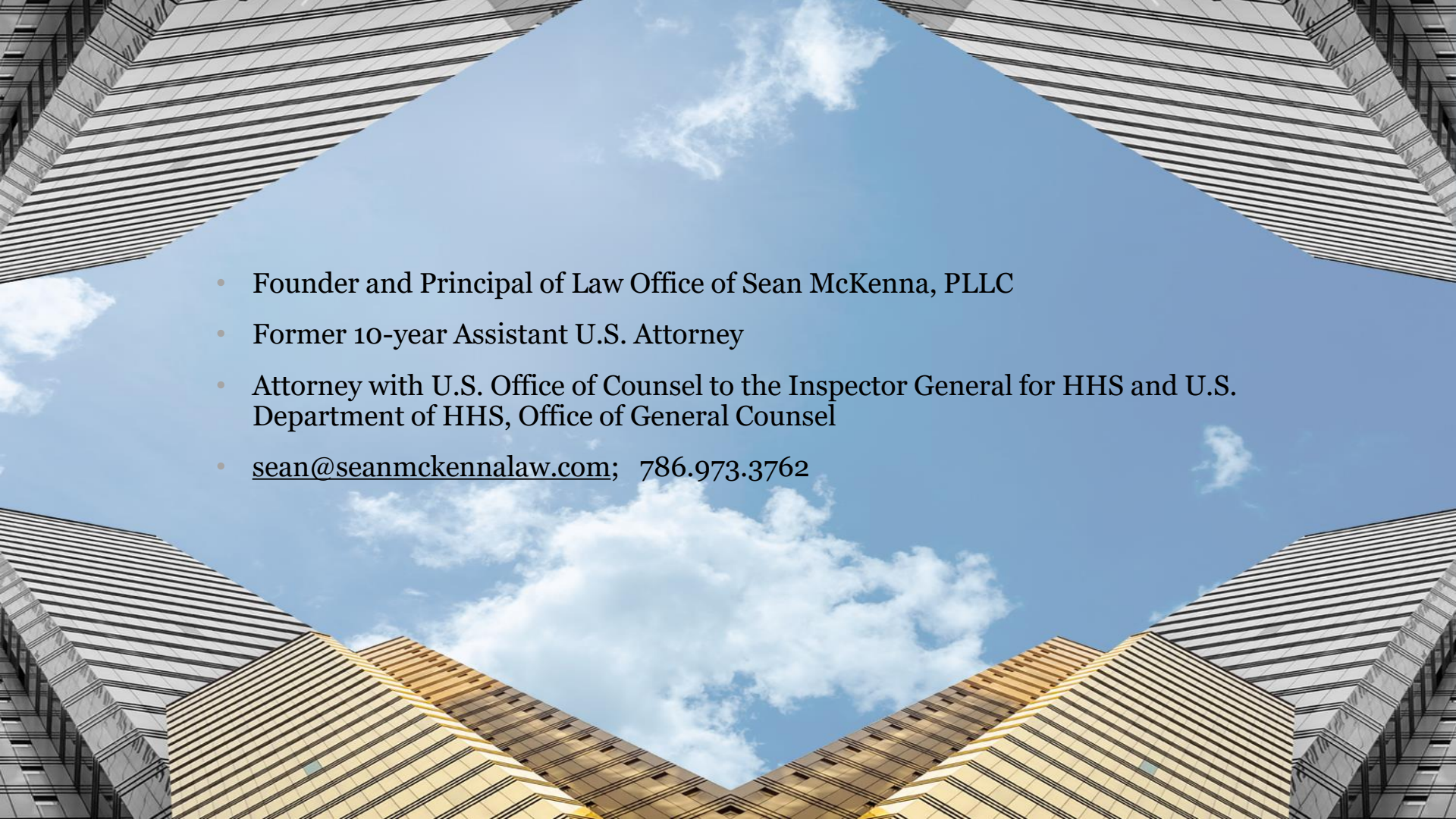
Enforcement Trends – Compliance Investigations

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Today's Agenda

- Enforcement update
- The investigative process as it related to compliance
- What to expect during and after settlement
- Using your compliance program to mitigate compliance risks



Enforcement Update

Enforcement Players

- Department of Justice
 - Fraud
 - Antitrust
 - Environmental
- SEC
- Administrative Agencies
- Federal/State Contractors
- Local District Attorneys
- States Attorneys General
- Offices of Inspector General - Federal and State
- Commercial Payor “Special Investigative Units”
- Licensing Boards
- Whistleblowers
- Private Litigants

Examples of DOJ Activity

- DOJ recovered more than \$4.7 billion in FY 2017
 - Up from FY 2015's \$3.8 billion recovery
 - ROI for the Health Care Fraud and Abuse Control Program \$6 returned for every \$1 expended
 - 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
 - SEC- filed 18 enforcement actions in 2018
 - Antitrust- 35 case filings in 2018
 - Number of *qui tam* suits exceeded 700
 - Up from FY 2015's 600
 - Way up from FY 1987's 30
 - Whistleblowers received \$519 million
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Current Administration Agenda

DOJ has stated it will continue the previous administration's stance on Corporate Misconduct:

- The department will continue to investigate and prosecute individual wrongdoers for corporate misconduct
- The federal government will “not use criminal authority unfairly to extract civil payments”
- BUT new guidance recently issued could limit enforcement
 - *See Granston and Brand memos*

Yates Memorandum

- Issued September 9, 2015
- “Individual Accountability for Corporate Wrongdoing”
- Emphasizes DOJ’s commitment to combat fraud “by individuals”
- Purposes and Benefits:
 - Proper parties are held responsible for their actions
 - Results in a change of corporate behavior
 - Serves as a deterrent to future fraudulent behavior
 - Increases public confidence in the justice system
 - Increases consistency in handling outcomes of federal investigations

Granston Memo

- Leaked and dated January 10, 2018
- Michael D. Granston, Director DOJ Commercial Litigation Branch
- Addressed to all AUSAs handling False Claims Act cases
- Dismissal under FCA section 3730(c)(2)(A)
- Increase in *qui tams*, but not DOJ resources
- 7 “*Granston Factors*”

Brand Memo

- January 25, 2018
- “. . . the Department may not use its enforcement authority to . . . Convert agency guidance documents into binding rules.”
- Example: Definition of “reasonable and necessary”
- *United States ex. Rel. Polukoff v. St. Mark’s Hospital*
- Uncertain future for HHS-OIG Advisory Opinions in FCA and criminal cases



Investigations

Sample Statutes

- False Claims Act
- Travel Act/Anti-Kickback Statute
- Criminal Fraud-related laws
- Licensure issues
- CMP laws

Government Investigations

- Surveillance
- Consensual monitoring
- *Qui tams*
- Data analytics
- Interviews
- Search warrants
- Civil Investigative Demands
- Subpoenas
 - Grand jury
 - Inspector General
 - AID/HIPAA
- Requests for information

Investigations, cont'd.

- 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

- 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)

Investigative Initiators

- 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

Preliminary Assessment

- 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 will be dynamic dependent upon findings, needs to be consistently reassessed

Investigative Plan

- 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

Implementing Corrective Action

- 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?*

Repayment and Disclosure

- FIRST fix any problems
- Federal law requires repayment of known Medicare/Medicaid overpayments within 60 days otherwise FCA violation
 - 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



Settlements

Settlements - Considerations

- Financial
- Regulatory
- Remedial
- Equitable
- Policy/Industry

Possible Outcomes

- Suspension of payments
- Civil recoveries from responsible parties
- Criminal convictions and restitution
- Exclusion/debarment/revocation/termination
- Licensing board action
- Compliance or integrity obligations
- *Cost of responding*
- *Loss of business/goodwill/morale*

Settlements

- Investigations' Influence On Settlement
- Types Of Resolutions
 - Dismissal with No Action
 - Closed Fraud Matter, but Referral to Administrative Agency
 - Deferred Prosecution
 - Non-Prosecution Agreement
 - Negotiated (most common)
 - Self-Disclosures

Settlements


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

Settlements

- Specific Issues
 - Covered conduct
 - Released parties and claims
 - Interplay between corporation and principals
 - Inability to pay
 - Administrative concerns
 - Collateral consequences

You've Settled – Now What?

- Corporate Dissolution
- Private Litigation
- Administrative Liability
- Individual Culpability
- Corporate Integrity/Integrity Agreement
 - What Is It?
 - Fines
 - Penalties
 - Disgorgement
 - Independent Review Organization
- Corporate Monitorship



Compliance Effectiveness: Leading Practices

Seven Elements of the OIG Model Compliance Program as an area to focus your evaluation



Audit/Monitoring – Evaluation

- Looking for improvement
- Be careful – creative people can make audit results look better than they are
 - Must establish **consistent** measurements
- Consider using *Net Dollar Value Error Rate* on consistent universe annually as one review
 - 50 claim randomly selected probe sample – consistent with OIG requirements
 - Five percent or below is an acceptable error rate
 - Great way to have a consistent measurement year after year
- Complement with other planned and focused reviews and trend the results
- How many “for cause” reviews performed annually – comparison

Annual Audit Work Plan

- Based upon approved annual work plan
 - By Compliance/Audit Committee or Board
- How many projects were on original plan?
- How many projects were added during year?
- How many were completed? Not completed?
- Trend to answer resources and accurate planning
- If you are missing either bad budget or operational problem

Compliance Program Evaluations

- Each circumstance is probably different
- General thoughts:
 - Consider an independent external review at some pre-determined interval of time (i.e. – every two or three years)
 - Contract via the Board and include in budget
 - Report to the Board
 - Assure you have someone doing this who is experienced and bring value – interview them
 - Utilize findings for improvement and then review again - good auditing approach, which can pay dividends in long run
 - Develop scorecard of good statistics

Compliance Resources

- 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



Concluding Thoughts

In Sum

- Investigate Yourself- So The Government Won't
- Carefully Consider Options
- Remediate – Begin Early
- Establish and Maintain An Effective Compliance Program

Benefits

If an organization is investigated for violations of state or federal laws, the government may offer a reduction in penalties if an effective, demonstrated compliance program exists.



Questions