

# HCCA ATLANTA REGIONAL COMPLIANCE CONFERENCE

## CRITICAL DEVELOPMENTS TO SHARE WITH LEADERSHIP TODAY

**JANUARY 25, 2019**

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## GOALS OF SESSIONS

- **Analyze the significant authority issued in 2017 and 2018**
- **Explore additional enforcement and compliance developments and dynamics**
- **Discuss enhanced expectations from industry experts in compliance, finance, and insurance to understand broader implications**
- **Identify practical steps, including important messages and other actions, to consider pursuing in light of enforcement and industry developments**

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## SIGNIFICANCE OF 2017 AND 2018

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## IMPORTANT AUTHORITY

- **DOJ** – Evaluation of Corporate Compliance Programs (FEBRUARY 2017) (**DOJ EVALUATION GUIDANCE**)
- **OIG** – Measuring Compliance Program Effectiveness: A Resource Guide (MARCH 2017) (**OIG RESOURCE GUIDE**)
- **DOJ and SEC** – Revised Foreign Corrupt Practices Act (FCPA) Enforcement Policy (NOVEMBER 2017) (**FCPA ENFORCEMENT POLICY**)
- **OIG** – Fraud Risk Indicator (SEPTEMBER 2018) (**FRAUD RISK INDICATOR**)

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## DOJ: FCPA ENFORCEMENT POLICY

- **Crescendo**
  - The FCPA Enforcement Policy builds upon concepts in the joint publication of the DOJ criminal division and the enforcement division of the U.S. Securities and Exchange Commission (SEC), *A Resource Guide to the U.S. FCPA* (NOVEMBER 2012) (**FCPA RESOURCE GUIDE**)
- **Foundation**
  - Even though focused on FCPA issues, the FCPA Resource Guide is a valuable tool for understanding DOJ's views on enforcement and compliance issues
    - Applies across all industries
  - The FCPA Enforcement Policy builds on that foundation but adds information regarding characteristics of an operationalized compliance platform designed and implemented to reduce risk

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### FCPA RESOURCE GUIDE HALLMARKS OF EFFECTIVE COMPLIANCE

- Commitment from senior management
- Written policies
- Oversight, authority and resources
- Risk assessment
- Training and continuing advice
- Incentives and discipline
- Third-party due diligence
- Confidential reporting
- Internal investigations
- Continuous improvement – periodic testing and review
- Due Diligence in transactions

### FCPA ENFORCEMENT POLICY ADDITIONAL EMPHASIS

- **Greater predictability is important to DOJ**
  - **Conditions:** DOJ outlines ranges of outcomes to expect *if* a company can demonstrate patterns of proactive behavior once that company learns of potential misconduct, including:
    - 1) Voluntary Disclosure
    - 2) Significant Cooperation
    - 3) Appropriate and timely remediation
  - **Benefits:** Significant advantages can potentially be achieved:
    - 1) Fine reductions – off of low end of U.S. Sentencing Guidelines fine range
    - 2) Avoidance of corporate monitor
- **Valuable Resource:** Review definitions, etc.

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## DOJ EVALUATION GUIDANCE

- While not limited to the FCPA arena, the DOJ Evaluation Guidance reflects the original hallmarks of effective compliance programs as described in the 2012 FCPA Resource Guide
  - The DOJ Evaluation Guidance is organized around key questions prosecutors should ask to understand whether:
    - The compliance program is truly operationalized
    - The culture supports compliance
    - The organization prioritizes controls that actually work
    - The organization seeks to identify and prioritize risk
    - The organization consistently remedies potential noncompliance and integrates lessons going forward
    - The organization regularly assesses effectiveness; develops benchmarks and pursues improvement

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## OIG RESOURCE GUIDE

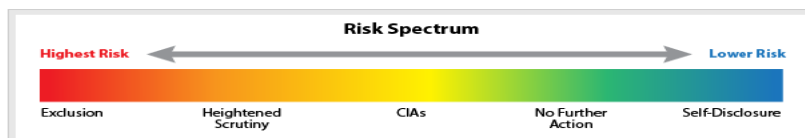
- While far different in nature, the OIG Resource Guide provides ideas for measuring compliance program effectiveness
  - Truly a *resource* – *not* a rule or best practice
  - After a January 2017 meeting involving OIG, HCCA and industry, OIG published the Resource Guide to facilitate benchmarking initiatives and other efforts to measure and track the maturity of various compliance program elements, functions and initiatives
  - Fantastic collaboration between industry and OIG
    - Industry appreciated effort to collaborate and learn from government representatives and peers
    - Government learned more about practical approaches and effort dedicated to compliance

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## ADDITIONAL 2018 OIG POLICY

### Fraud Risk Indicator

OIG assessment of future risk posed by persons who have allegedly engaged in civil healthcare fraud.



- The government's primary civil tool for addressing healthcare fraud is the False Claims Act (FCA). Most FCA cases are resolved through settlement agreements in which the government alleges fraudulent conduct and the settling parties do not admit liability. Based on the information it gathers in an FCA case, OIG assesses the future trustworthiness of the settling parties (which can be individuals or entities) for purposes of deciding whether to exclude them from the Federal healthcare programs or take other action.
- OIG applies [published criteria](#) to assess future risk and places each party to an FCA settlement into one of five categories on a risk spectrum. OIG uses its exclusion authority differently for parties in each category (as described in the criteria and below). OIG bases its assessment on the information OIG has reviewed in the context of the resolved FCA case and does not reflect a comprehensive review of the party. Because OIG's assessment of the risk posed by a FCA defendant may be relevant to various stakeholders, including patients, family members, and healthcare industry professionals, OIG makes public information about where a FCA defendant falls on the risk spectrum.

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## OIG RISK CATEGORIES

### HIGHEST RISK - EXCLUSION

- Parties that OIG determines present the highest risk of fraud will be excluded from Federal healthcare programs to protect those programs and their beneficiaries. Excluded individuals and entities are listed in OIG's [Exclusions Database](#).

### HIGH RISK - HEIGHTENED SCRUTINY

- Parties are in the High Risk category because they pose a significant risk to Federal healthcare programs and beneficiaries. This is because, although OIG determined that these parties needed additional oversight, they refused to enter CIAs sufficient to protect Federal healthcare programs. Parties in the High Risk category that reached settlements finalized on October 1, 2018 or later [are listed here](#).

### MEDIUM RISK - CIAS

- Healthcare providers and other entities in the Medium Risk category have signed CIAs with OIG to settle investigations involving Federal healthcare programs. Under these agreements, parties promise to fulfill various obligations in exchange for continuing to participate in the programs. A list of active CIAs is posted on [OIG's website](#).

### LOWER RISK - NO FURTHER ACTION

- OIG sometimes concludes that parties present a relatively low risk to Federal healthcare programs. As a result, OIG is not seeking to exclude them from those programs or require a CIA. OIG's cases against these parties are closed without evaluating the effectiveness of any efforts the parties have made to ensure future compliance with Federal healthcare program requirements.

### LOW RISK - SELF-DISCLOSURE

- A party may disclose evidence of potential fraud related to Federal healthcare programs to OIG. OIG believes that doing so in good faith and cooperating with OIG's review and resolution process generally demonstrates that the party has an effective compliance program. OIG works to resolve such cases faster, for lower settlement amounts, and with a release from potential exclusion with no CIA or other requirements. More information about [OIG's self-disclosure protocol is here](#).

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## OIG FRAUD RISK INDICATOR – CLASSIFICATION AS HIGH RISK

U.S. Attorneys » Western District of Kentucky » News

Department of Justice  
U.S. Attorney's Office  
Western District of Kentucky

FOR IMMEDIATE RELEASE Tuesday, November 6, 2018

**\$5.1 Million Dollar Settlement Reached With Indiana Dental Firm To Resolve False Claims Allegations**

LOUISVILLE, Ky. – United States Attorney Russell M. Coleman announced today that ImmediaDent of Indiana, LLC (ImmediaDent), which operates nine dental care practices in Indiana, and Kansas based Samson Dental Partners, LLC (SDP), which provides administrative support services to ImmediaDent, have agreed to pay the United States and the State of Indiana \$5.139 million to resolve allegations that they improperly billed Indiana's Medicaid program for dental services; the companies have been determined to continue to be a high risk to the United States health care programs and their beneficiaries.

The Western District of Kentucky is working on behalf of the United States to ensure that the United States and the State of Indiana receive the full amount of the settlement. The settlement is the result of a long and complex process involving the Department of Health and Human Services, and the Office of the Indiana Attorney General, Medicaid Fraud Control Unit.

"Let this be a warning to both companies that the United States will not pay billions of dollars in false claims. The United States and the State of Indiana have agreed to pay \$5,139,276.74 under the settlement. The companies also agreed to pay \$1,782,729.26 to the state of Indiana. In connection with this settlement, OIG determined that the companies needed additional oversight. OIG proposed the companies enter into a Corporate Integrity Agreement that would require compliance measures and monitoring by OIG. The companies refused to agree to this oversight. OIG has determined that in the absence of such oversight, the companies pose a continuing high risk to the Federal health care programs and their beneficiaries.

ImmediaDent's medical professionals and staff by rewarding production, disciplining employees for not meeting production objectives, and directing personnel in a manner which compromised clinical

- References **high risk** more than once in the press release
- Warns** health care organizations that the United States government is watching and will continue to watch for false claims no matter how large or small

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## OTHER ENFORCEMENT AND COMPLIANCE DEVELOPMENTS AND DYNAMICS

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### 2018 RECOVERY METRICS

- In FY 2018, DOJ recovered more than **\$2.8 BILLION** in settlements and judgments in civil cases involving fraud
- Of the \$2.8 billion in settlement and judgments, **\$2.5 BILLION** involved the healthcare industry
  - FY 2018 marked the ninth consecutive year that civil healthcare fraud recoveries have exceeded **\$2.0 BILLION**
- While overall recoveries were less than last year, healthcare industry recoveries increased (**\$2.4 BILLION** in FY 2017 versus **\$2.5 BILLION** in FY 2018)

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## TRENDS IN QUI TAM SUITS

- Insurance and financing may be tougher to obtain as both industries have tracked DOJ guidance closely
- Greater number of hybrid cases (intervened and non-intervened claims)
- Greater number of cases with multiple firms representing relator(s)
  - Can create challenges for coordination
    - Who speaks for Relator(s)?
    - What is the dynamic between multiple firms and government?
- Relator community more aggressive in gathering facts, data and other information
  - Often not clear whether Relator(s) is working with counsel when obtaining such information
- Greater number of serial Relators
- Significant tax law changes involving the ability to deduct FCA settlements

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## INTERSECTION OF FCA AND COMPLIANCE PROGRAM EFFECTIVENESS

FCA Intent Theories:

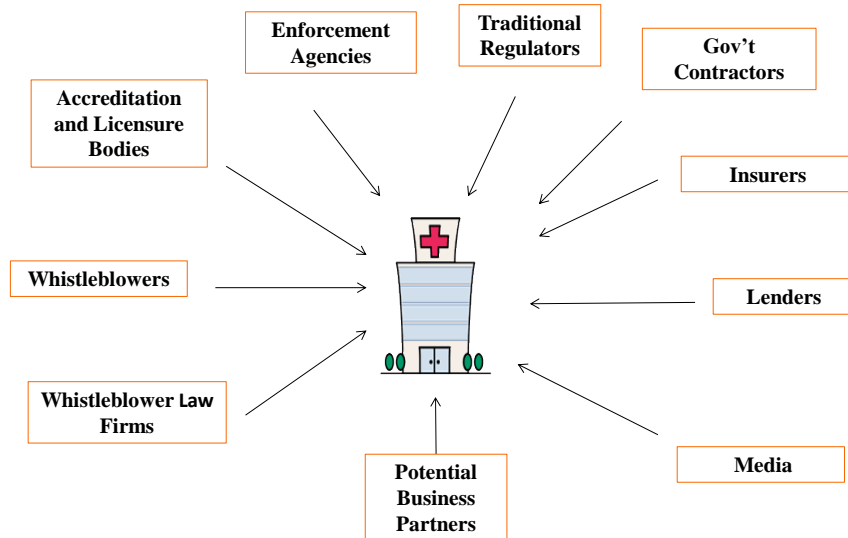
*“The absence of a high-functioning compliance program may be used to establish [FCA] intent.”*

Thomas Beimers (Former Senior Counsel with HHS OIG)

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## EXPANDING UNIVERSE OF EVALUATORS



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## SPOTLIGHT: DOJ DATA ANALYTICS TEAM

- DOJ has become far more sophisticated in its ability to use data to identify investigative and audit targets
  - In 2017, DOJ created a new Data Analytics Team within the Health Care Fraud Unit
  - The Data Analytics Team provides U.S. Attorney's Offices with customized healthcare data analytics training and assistance while investigations and prosecutions are ongoing
- Interesting Impact:
  - For example, from 2016 to 2017, charges against medical professionals increased **89%** for the Health Care Fraud Unit

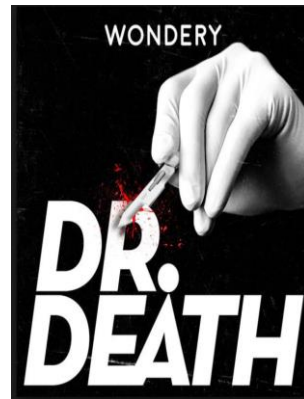
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## SPOTLIGHT ON MEDIA AND ENTERTAINMENT

### Traditional Journalism



### Entertainment



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## POTENTIAL CONSEQUENCES EXPANDING

<b>Corporation</b>	<b><i>Financial</i></b>	<ul style="list-style-type: none"> <li>• Penalties</li> <li>• Settlements</li> <li>• Impact on Ability to Obtain Financing</li> <li>• Impact on Insurance Premiums</li> </ul>
	<b><i>Other</i></b>	<ul style="list-style-type: none"> <li>• Exclusion</li> <li>• Deferred Prosecution Agreement</li> <li>• Corporate Integrity Agreement</li> <li>• Mandatory Divestiture</li> <li>• Impact on Business Partnerships</li> <li>• Reputational Harm</li> </ul>
<b>Individuals</b>	<b><i>Financial</i></b>	<ul style="list-style-type: none"> <li>• Settlements</li> <li>• Penalties</li> <li>• Forfeiture</li> </ul>
	<b><i>Other</i></b>	<ul style="list-style-type: none"> <li>• Jail Time</li> <li>• Exclusion</li> <li>• Reputational Harm</li> </ul>

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## REMEMBER: CHANGES TO FCA DAMAGES AND PENALTY FORMULAS ARE NOW IN EFFECT

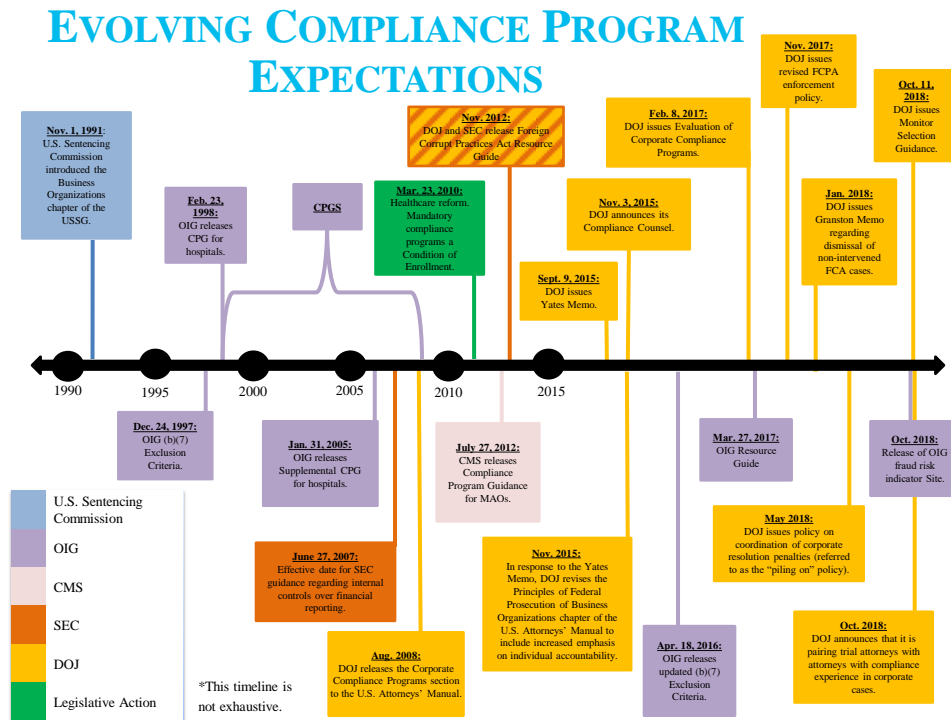
- Increased False Claims Act (FCA) financial penalties for non-compliance
  - In 2018, the *minimum* per claim penalty increased to \$11,181 and the *maximum* increased to to \$22,363
  - Example of damages with new FCA penalties

<b>Defense Contractor</b> 12 claims / year	<b>Healthcare Provider</b> 2,000 claims / year
Triple Damages: \$300,000	Triple Damages: \$300,000
Penalty (\$22,363 x 12): \$268,356	Penalty (\$22,363 x 2,000): \$44,726,000
<b>Total Recovery: \$568,356</b>	<b>Total Recovery: \$45,026,000</b>

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## EVOLVING COMPLIANCE PROGRAM EXPECTATIONS

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## EXPECTATION: EFFECTIVE COMPLIANCE PROGRAMS

- ***"You get no bonus points for having a compliance program"***
  - HHS Inspector General Daniel R. Levinson, remarks at the Health Care Compliance Association's Annual Compliance Institute (Apr. 18, 2016)
- The expectation has shifted from incentivizing the adoption of compliance programs to incentivizing the operation of **effective** compliance programs

## PREVENTATIVE MEDICINE: ROD ROSENSTEIN MAY 2018

- Deputy Attorney General Rod Rosenstein analogized corporate compliance programs to preventative medicine:
  - *“Getting an annual physical doesn’t mean you won’t get sick. But those screenings - just like a robust compliance program - help to ensure that issues will be detected and addressed at an early stage.”*

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## PREVENTATIVE MEDICINE: ROD ROSENSTEIN MAY 2018 (CONT’D)

- These positions reflect the “diffused” nature of some of the most important authority in this arena
- Without adequate risk identification, assessment and other efforts, organizations are less likely to:
  - Uncover a problem at an early stage
  - Be in a position to voluntarily disclose or pursue other important remediation
  - Stop conduct before it becomes pervasive
  - Keep pace with its risk profile as it evolves and grows

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Compliance 1.0	Compliance 2.0
<ul style="list-style-type: none"> <li>• Voluntary (unless CIA obligation)</li> <li>• CCO expected to implement compliance program</li> <li>• Effectiveness gauged by establishment of seven basic elements: <ul style="list-style-type: none"> <li>○ Implementing written policies, procedures and standards of conduct</li> <li>○ Designating a compliance officer and compliance committee</li> <li>○ Conducting effective training and education</li> <li>○ Developing effective lines of communication</li> <li>○ Conducting internal monitoring and auditing</li> <li>○ Enforcing standards through well-publicized disciplinary guidelines</li> <li>○ Responding promptly to detected offenses and undertaking corrective action</li> </ul> </li> <li>• Role of compliance in DOJ investigations and other industry action unclear</li> </ul>	<ul style="list-style-type: none"> <li>• Mandatory condition of enrollment</li> <li>• Compliance Program and compliance issues are a shared responsibility <ul style="list-style-type: none"> <li>○ Tone is set at the top</li> <li>○ Compliance leadership must be demonstrated by executive and operational leaders</li> <li>○ Resources allocated appropriately</li> <li>○ Program led by statured CCO with deep understanding of business process and strategy</li> <li>○ Ongoing process improvement</li> </ul> </li> <li>• Seven elements assumed</li> <li>• Effectiveness gauged on: <ul style="list-style-type: none"> <li>○ Risk based approach</li> <li>○ Sophisticated use of data</li> <li>○ Diligence</li> <li>○ Remediation</li> </ul> </li> <li>• Role of compliance critical in DOJ investigations and other work with industry partners, including finance, insurance and business partners</li> </ul>

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## INDUSTRY RESPONSE:

### INSURANCE

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## INSURANCE MARKETS REACT TO DOJ ACTIVITY

- As DOJ articulated elevated expectations regarding compliance program effectiveness and related concepts, such as individual accountability, insurance markets have taken notice
- These developments are critical to understand and track
- The goal of this portion of the panel discussion is to explore these developments and discuss considerations to share with you leadership team

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## BACKGROUND

- **CONSIDER DEFINITION OF INSURANCE RISK**

- The likelihood that an insured event will occur, requiring the insurer to pay a claim

- Provide overview of insurance market for healthcare organizations, including:

- Insurance coverage options designed for regulatory investigations and *qui tam* law suits
- Director & Officer (D&O) policies

- Discuss

- State of market
- Application and disclosure issues
- Diligence and considerations

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## FOCUS ON *QUI TAM* ACTIONS

- Explore insurance challenges presented in *qui tam* actions, including:
  - Notice to insurers in sealed *qui tam* actions
  - Detail and frequency of reports expected by insurers given confidentiality agreements, etc.
  - Impact of recent tax law changes
    - Deductibility of FCA settlement payments
    - Conflicts with insurance dynamics

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## PRACTICAL CONSIDERATIONS

- Discuss common missteps healthcare organizations make in connection with the submission of insurance claims
  - Regulatory and fraud policies
  - D&O policies
- Explore recent examples of alleged noncompliance or wrongful acts that have surfaced in insurance coverage disputes, including any impact on the insurance claims
- Discuss best practices, tips and other issues
  - Relationship and interactions with insurers
    - Address reservation of rights and denial of coverage letters
  - Important issues to cover with leadership and governing body
  - Reaction to OIG “high risk indicator”

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## INDUSTRY RESPONSE: FINANCE

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### LENDERS APPROACH TO DILIGENCE

- Similar to insurance sector, lending partners have followed enforcement and regulatory developments closely
  - While lenders have historically considered compliance related issues, including maintenance of compliance programs, recent DOJ and OIG activity has resulted in increased scrutiny
    - Prior to new lending arrangements
    - Monitoring existing arrangements
- Some may be unaware of in-house sophistication within lending organizations
  - Explore infrastructure at Capital One
  - Discuss regular training provided to key stakeholders

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## REACTION TO ENHANCED GOVERNMENT EXPECTATIONS

- Explore key areas of heightened Compliance 2.0 expectations:
  - Qualifications and stature of Compliance Officer and Compliance Department
  - Lines of communication and reporting (including relationship between compliance and legal departments)
  - Tone at top and in middle
    - Leadership team
    - Governing body
    - Operational leaders
  - Governing body's compliance expertise
  - Operational metrics / data analytics
  - External audits and investigations

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## REACTION TO ENHANCED GOVERNMENT EXPECTATIONS (CONT'D)

- Key Compliance 2.0 Areas Cont'd
  - Existence of regular risk assessment program and related work plans
    - Expectation of risk based approach to controls and other related effort (e.g., training)
  - Approach to internal investigations and remediation
    - Specific Overpayment/60-Day Rule Controls
    - Evidence of refund activity
    - Dedication to root cause analyses
  - Third-Party Risk Assessments

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## RECENT EXAMPLES AND PRACTICAL TIPS

- Discuss
  - Recent examples of issues discovered through diligence material to lending decisions
  - Address reaction to OIG Fraud Risk Indicator
  - Other tips and practical considerations

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## WHAT CAN YOU DO NOW? PRACTICAL STEPS TO CONSIDER

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## KEY TAKEAWAYS

- DOJ and OIG are aligned; both are active
- While past decade has been focused on substantive developments, scrutiny (heightened) reverts to infrastructure
  - Now, mandatory not voluntary
- Organizations are expected to effectively prove the sophistication of their programs based on detailed authority issued by DOJ and OIG in numerous, complex areas
  - Reviewers are well informed and experienced
  - Superficial descriptions without proof will not work

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## KEY TAKEAWAYS (CONT'D)

- Scrutiny will focus on compliance program operations, culture, continuous improvement and results
  - Scrutiny extends far beyond compliance to executive leadership, management, governing body, operations, legal, human resources, internal audit and other key functions
  - Scrutiny includes specific individual roles and accountability
- Findings will impact numerous key decisions by enforcement, regulators, business partners and others

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## WHAT YOU NEED TO DO

- Understand heightened expectations and new landscape (Compliance 2.0)
- Educate key stakeholders on import
- Develop infrastructural assessment plan
  - Tremendous flexibility in approach
  - Consider controls in key areas
  - Identify opportunities for improvement
  - Develop reasoned action plan
  - Execute and document

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## EXAMPLE: RISK ASSESSMENTS

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## TRADITIONAL SEVEN ELEMENTS OF A COMPLIANCE PROGRAM

1. Designating a Compliance Officer and Compliance Committee
2. Implementing written policies, procedures and standards of conduct
3. Conducting effective training and education
4. Developing effective lines of communication
5. Conducting internal auditing and monitoring
6. Enforcing standards through well-publicized disciplinary guidelines
7. Responding promptly to detected offenses and undertaking corrective actions

*“8th Element” - Risk Assessments*

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## DOJ EVALUATION GUIDANCE

- DOJ guidance instructs prosecutors to probe an organization's risk assessment process in making prosecutorial decisions

**U.S. Department of Justice**  
Criminal Division  
Fraud Section  
*Evaluation of Corporate Compliance Programs*

**5. Risk Assessment<sup>4</sup>**

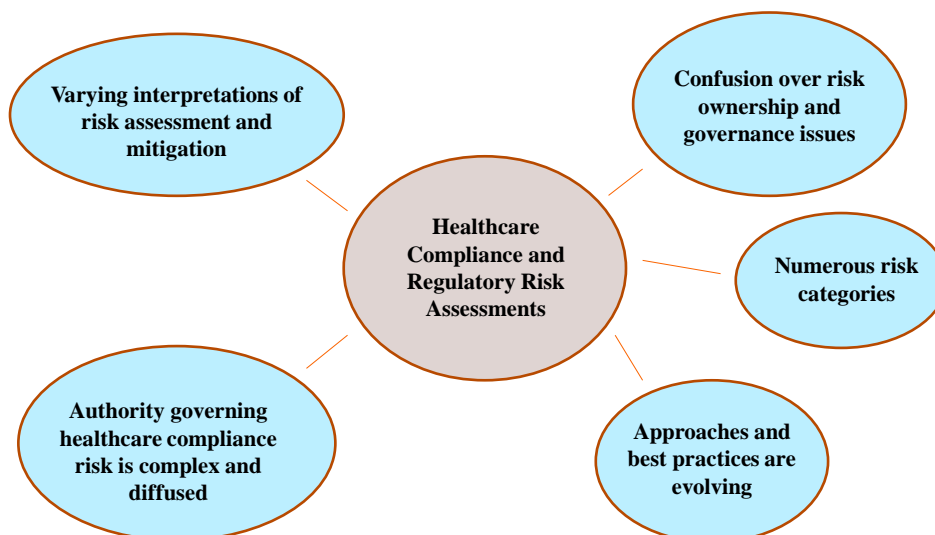
☐ **Risk Management Process** – What methodology has the company used to identify, analyze, and address the particular risks it faced?

**Introduction**  
The Principles of Federal Prosecution of Business Organizations in the United States Attorney's Manual describe (1) the entity, determine commonly known pre-existing corporate compliance programs. Because a company's compliance program is a formula to address the company's risks, we make an assessment of the program. There are, however, no formulas. This document frequently found relevant in evaluating a corporate compliance program. The topics and questions below form neither a checklist nor a formula. In any particular case, the topics and questions set forth below may not all be relevant, and others may be more salient given the particular facts at issue.

Many of the topics below also appear in the *United States Attorney's Manual* ("USAM"), in the *United States Sentencing Guidelines* ("USSC"), in Fraud Section corporate resolution agreements, in a *Resource Guide to the U.S. Foreign Corrupt Practices Act* ("FCPA Guide") published in November 2012 by the Department of Justice (DOJ) and the Securities and Exchange Commission (SEC), in the *Good Practice Guidance on Internal Controls, Ethics, and Compliance* adopted by the Organization for Economic Co-operation and Development ("OECD") Council on February 18, 2010, and in the *Anti-Corruption Ethics and Compliance Handbook for Business* ("OECD Handbook") published in 2013 by OECD, United Nations Office on Drugs and Crime, and the World Bank.

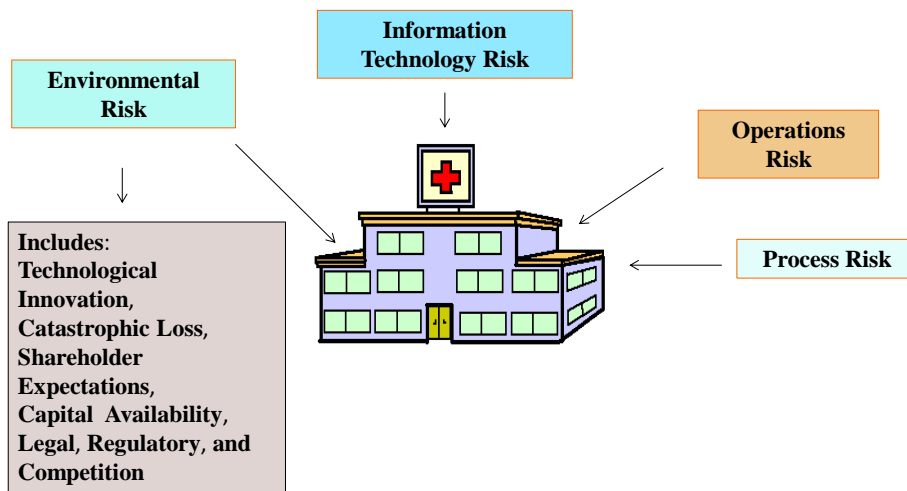
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## ASSESSING RISK: INDUSTRY CONFUSION



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## MULTIPLE SOURCES OF MACRO RISK



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## GENERAL CONSIDERATIONS FOR RISK ASSESSMENTS

- Risk assessments are a critical driver of overall compliance program effectiveness
  - Risk assessments present a key opportunity to build compliance programs
- Organizations vary considerably regarding the sophistication and maturity of their risk assessment programs
- Risk assessments are not “one size fits all” and must be tailored to the organization
  - Flexibility exists within **basic** parameters

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## RISK ASSESSMENT STRUCTURE CONSIDERATIONS

- Critical to develop a formal risk assessment process
  - Risk program, including processes and expectations should be documented and communicated
  - Sufficient resources required
- Senior leadership and governing body should understand elevated expectations and organization's approach
- Sources of potential risk should be continuously evaluated and vetted
  - Healthcare transformation has created numerous new risk areas that are expected to be considered as potential risk sources
- Key stakeholders must be involved at each step

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## RISK ASSESSMENT STRUCTURE CONSIDERATIONS (CONT'D)

- Important to vet external resources if used
- Measuring tools and algorithms should be carefully considered with input from a diverse group of stakeholders including compliance, legal and internal audit
- Work plans generated from annual risk assessments should be practical and executed and clearly identify owners and deadlines
  - Execution and success of work plans should be reviewed objectively and opportunities for enhancements should be communicated and implemented
  - Government inquiries will include baseline questions about these issues

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## ATTORNEY CLIENT PRIVILEGE CONSIDERATIONS

- Privilege issues should be carefully considered
- While not every facet of a risk assessment program needs to be privileged, involvement of counsel is critical when assessing and prioritizing sources of potential risk.
- Important to consider documentation and accurately characterize *potential* risks

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## PITFALLS TO AVOID

- Jumping in without thinking through
  - **Example:** Use of measuring tools that are not understood and that automatically generate sensitive scores that are discoverable
  - **Example:** Approaches that fail to prioritize leaving a record of far too many sensitive potential risks than could be effectively pursued in a reasonable time period
- Failing to include key stakeholders
- Failing to consider aspects of risk assessment and mitigation processes that warrant legal advice
- Failing to keep senior leadership and board updated on changing environment and opportunities afforded by sound risk mitigation program

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## OTHER EXAMPLES TO EXPLORE

- Individual Accountability
  - Leadership Team
  - Governing Body
- Controls
  - Difference between controls and written standards
- Internal Investigations and Remediation
- Third-Party Compliance Expectations

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## QUESTIONS?

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