

**WHAT MAKES A  
COMPLIANCE PROGRAM EFFECTIVE?**

**4<sup>TH</sup> ANNUAL HEALTH CARE COMPLIANCE ASSOCIATION  
HEALTHCARE ENFORCEMENT COMPLIANCE CONFERENCE  
NOVEMBER 7, 2018**

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**GOALS OF SESSION**

- **REVIEW** RECENT DEVELOPMENTS DEMONSTRATING THE CONVERGENCE OF COMPLIANCE AND ENFORCEMENT
- **HIGHLIGHT** SIGNIFICANT ESCALATION IN GOVERNMENT'S EXPECTATIONS FOR COMPLIANCE PROGRAM INFRASTRUCTURE, OPERATIONS, RISK MITIGATION EFFORTS AND POTENTIAL CONSEQUENCES OF FALLING SHORT
- **EXPLORE** VARIOUS STRATEGIES TO EVALUATE CRITICAL COMPLIANCE INFRASTRUCTURE AND RELATED PROCESSES TO DETERMINE SUFFICIENCY AND EFFECTIVENESS

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## CHANGING COMPLIANCE LANDSCAPE

- RECENT ENFORCEMENT AND OTHER DEVELOPMENTS HAVE IMPACTED THE HEALTHCARE INDUSTRY, INCLUDING:
  - ENFORCEMENT AGENCIES WIDENING THE COMPLIANCE LENS
    - COMPLIANCE 1.0 VS. COMPLIANCE 2.0
    - REGULATORY DEFENSE VS. PROACTIVE OPERATIONAL MACHINE
    - SIGNIFICANTLY ENHANCED EXPECTATIONS FOR ENTERPRISE WIDE COMPLIANCE PROGRAMS AND SUPPORT AT ALL LEVELS
      - BOARD
      - LEADERSHIP
      - MANAGEMENT

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## CHANGING COMPLIANCE LANDSCAPE (CONTINUED)

- INCREASED FCA PENALTIES
- AGGRESSIVE RELATOR STRATEGIES
- FOCUS ON INDIVIDUAL ACCOUNTABILITY
- ENHANCED OIG COMPLIANCE PROGRAM EXPECTATIONS
  - AS EVIDENCED BY RECENT CIA'S

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## INTERSECTION OF REGULATORY ENFORCEMENT AND COMPLIANCE PROGRAM EFFECTIVENESS

*"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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### FCA PENALTIES - THE STAKES ARE HIGH

- INCREASED FALSE CLAIMS ACT (FCA) FINANCIAL PENALTIES FOR NON-COMPLIANCE

\*01/29/18 - DOJ ADJUSTED MAX FROM \$21,916 TO \$22,363

Defense Contractor 12 claims / year		Healthcare Provider 2,000 claims / year	
Triple Damages	\$300,000	Triple Damages	\$300,000
Penalty (2x, \$16 x 12)	\$262,992	Penalty (2x, \$16 x 2,000)	\$43,832,000
Total Recovery	\$562,992	Total Recovery	\$44,132,000

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### YATES MEMORANDUM

- ON SEPTEMBER 9, 2015, FORMER DEPUTY ATTORNEY GENERAL, SALLY QUILLIAN YATES, ISSUED A MEMORANDUM (THE YATES MEMO) REGARDING INDIVIDUAL ACCOUNTABILITY FOR CORPORATE WRONGDOING.
  - PROVIDES GUIDANCE FOR BOTH CIVIL AND CRIMINAL INVESTIGATIONS.
- EMPHASIZES THE NEED TO HOLD INDIVIDUALS WHO PERPETRATED CORPORATE WRONGDOING ACCOUNTABLE, "PARTICULARLY IN THE AFTERMATH OF THE FINANCIAL CRISIS."
- ALTHOUGH SALLY YATES IS NO LONGER WITH DOJ, THE YATES MEMO CONTINUES TO BE DOJ POLICY.

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### RECENT EXAMPLES OF INDIVIDUAL LIABILITY

- RECENT EXAMPLES OF THE INDIVIDUAL ACCOUNTABILITY:
  - FORMER CEO OF TUOMEY HEALTHCARE SETTLED ALLEGED STARK VIOLATIONS FOR **\$1 MILLION**
  - FORMER CFO OF PACIFIC HOSPITAL ENTERED A **PLEA AGREEMENT** WITH DOJ FOR HIS INVOLVEMENT IN A FRAUD SCHEME
  - CARDIOLOGIST AND HIS PRACTICE PAID **\$2 MILLION** AND RELEASED CLAIMS TO AN ADDITIONAL **\$5.3 MILLION** IN SUSPENDED MEDICARE FUNDS TO SETTLE ALLEGATIONS OF FRAUD AND KICKBACKS TO PATIENTS

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**OIG PERMISSIVE EXCLUSION AUTHORITY**

• ON APRIL 18, 2016, OIG ISSUED A REVISED POLICY STATEMENT CONTAINING THE NEW CRITERIA THAT OIG INTENDS TO USE IN IMPLEMENTING ITS PERMISSIVE EXCLUSION AUTHORITY UNDER 42 U.S.C.A. § 1320A-7(B)(7) (REVISED POLICY).



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**OIG PERMISSIVE EXCLUSION AUTHORITY**

• **COMPLIANCE PROGRAM**

- THE EXISTENCE OF A COMPLIANCE PROGRAM THAT INCORPORATES THE SEVEN ELEMENTS OF AN EFFECTIVE COMPLIANCE PROGRAM DOES NOT AFFECT THE RISK ASSESSMENT
- THE ABSENCE OF A COMPLIANCE PROGRAM THAT INCORPORATES THE SEVEN ELEMENTS OF AN EFFECTIVE COMPLIANCE PROGRAM INDICATES HIGHER RISK
- IF THE ENTITY HAS DEVOTED SIGNIFICANTLY MORE RESOURCES TO THE COMPLIANCE FUNCTION, THIS INDICATES LOWER RISK

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**FOCUS ON SELF-DISCLOSURES**

• DANIEL LEVINSON – HHS, INSPECTOR GENERAL, REMARKS AT HCCA ANNUAL COMPLIANCE INSTITUTE (MARCH 2017):

"THE SELF-DISCLOSURE PROTOCOL HAS ALWAYS BEEN A VERY IMPORTANT PART OF DEMONSTRATING THAT WE'RE REALLY ON TOP OF OUR COMPLIANCE WORK AND THAT WHEN A FIRM SEES A PROBLEM IT DOESN'T WAIT IN THE HOPES THAT IT CAN JUST BE AVOIDED, BUT IT COMES FORWARD AND MAKES WHOLE THE TAXPAYER AND INSURES THAT THE FIRM IS ABLE TO MOVE FORWARD ETHICALLY AND LEGALLY."

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**EMPHASIS ON CORPORATE GOVERNANCE IN SETTLEMENTS**

- ON JANUARY 17, 2017, A TENNESSEE FEDERAL JUDGE APPROVED A \$60 MILLION SETTLEMENT AGREEMENT BETWEEN CHSI AND CERTAIN DIRECTORS AND EXECUTIVES WITH THE CLASS OF CHSI STOCKHOLDERS
- THE SETTLEMENT ALSO REQUIRES THAT CHSI **"ADOPT MEANINGFUL CORPORATE GOVERNANCE REFORMS,"** INCLUDING:
  - THE APPOINTMENT OF TWO NEW MUTUALLY ACCEPTABLE INDEPENDENT DIRECTORS TO THE BOARD
  - THE ESTABLISHMENT OF A HEALTHCARE LAW COMPLIANCE COORDINATOR, SUBJECT TO THE APPROVAL OF OIG
    - THE COMPLIANCE COORDINATOR WILL WORK WITH THE CHIEF COMPLIANCE OFFICER TO COORDINATE AND OVERSEE IMPLEMENTATION OF THE COMPANY'S COMPLIANCE PROGRAMS, WITH PARTICULAR EMPHASIS ON MEDICARE AND MEDICAID COMPLIANCE PROGRAMS

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**IG'S REMARKS AT HCCA COMPLIANCE INSTITUTE**

**DANIEL LEVINSON – HHS, INSPECTOR GENERAL, REMARKS AT HCCA ANNUAL COMPLIANCE INSTITUTE (MARCH 2017):**

"TODAY IS VERY MUCH PREVENTION DAY AND WE'RE TALKING ABOUT CORPORATE INTEGRITY AGREEMENTS AND BECAUSE OF THE RECENT DEVELOPMENTS WITH CIA'S AND THE WAY THAT WE'RE NOW ABLE TO FOCUS ATTENTION IN A MUCH MORE LASER-LIKE WAY, I THINK THE EVOLUTION OF CIA'S FROM A BROADER TOOL TO UNDERSTAND WHETHER A SYSTEM IS OPERATING REASONABLY WELL, TO BEING ABLE TO FOCUS ON PARTICULAR AREAS OF VULNERABILITY IS A REAL STEP FORWARD WHEN IT COMES TO CIA'S . . ."

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**IMPORTANCE OF CIA TRENDS TO NON-CIA OBLIGATED PROVIDERS**

- OIG USES CIA'S TO COMMUNICATE PRUDENT APPROACHES TO COMPLIANCE PROGRAM DESIGN AND COMPLIANCE-RELATED INITIATIVES
- EMERGING TRENDS IN CIA'S REFLECT OIG'S ESCALATING COMPLIANCE EXPECTATIONS FOR ENTITIES PARTICIPATING IN FEDERAL HEALTHCARE PROGRAMS
- WHY MONITOR AND ADDRESS EMERGING COMPLIANCE TRENDS?
  - FORTIFY COMPLIANCE INFRASTRUCTURE
  - A COMPANY'S PROACTIVE EFFORTS TO MONITOR AND ADDRESS SUCH EMERGING COMPLIANCE TRENDS OFTEN BENEFITS THE COMPANY WHEN EVALUATED BY GOVERNMENT ENFORCEMENT AGENCIES

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**COMPLIANCE PROGRAM EXPECTATIONS  
ARTICULATED IN CIAS**

**• CORPORATE (OR INDIVIDUAL) INTEGRITY AGREEMENTS**

- AGREEMENT WITH HHS-OIG IN CONNECTION WITH CIVIL HEALTHCARE FRAUD SETTLEMENT
- REQUIRES ENTITY OR INDIVIDUAL TO IMPLEMENT, ENHANCE, OR CONTINUE CERTAIN INTEGRITY OBLIGATIONS
- CIA: DURATION = 5 YRS (40+-59 PGS) / IIA: DURATION = 3 YRS (30+ PGS)

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**EMERGING CIA TRENDS**

- USE OF INDEPENDENT MONITORS
- COMPLIANCE EXPERTS
- MANAGEMENT CERTIFICATIONS AND INCREASED STIPULATED PENALTIES FOR FALSE CERTIFICATIONS
- RISK ASSESSMENT AND MITIGATION
- HEIGHTENED IRO QUALIFICATIONS

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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

- OIG, DOJ, CMS, AND OTHER THIRD PARTIES ARE EVALUATING THE EFFECTIVENESS OF COMPLIANCE PROGRAMS

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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 IMPLEMENTING CORRECTIVE ACTIONS

**"8TH ELEMENT" – REGULAR COMPLIANCE PROGRAM EFFECTIVENESS ASSESSMENTS**

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### DOJ COMPLIANCE EFFECTIVENESS GUIDANCE

- ISSUED IN FEBRUARY 2017 WITHOUT THE TYPICAL FANFARE THAT OFTEN ACCOMPANIES DOJ ISSUANCES
- THE PURPOSE OF THE DOCUMENT IS TO PROVIDE "SAMPLE QUESTIONS THAT THE FRAUD SECTION HAS FREQUENTLY FOUND RELEVANT IN EVALUATING A CORPORATE COMPLIANCE PROGRAM"
- APPLIES TO ALL INDUSTRIES – **NOT JUST HEALTHCARE**
- UNDERSCORES THAT DOJ IS ACTIVELY EVALUATING COMPLIANCE PROGRAM EFFECTIVENESS DURING INVESTIGATIONS

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### DOJ'S ELEVEN EVALUATION TOPICS

<b>Analysis and Remediation of Underlying Conduct</b> <ul style="list-style-type: none"> <li>• Root cause analysis</li> </ul>	<b>Senior and Middle Management</b> <ul style="list-style-type: none"> <li>• Tone at the top and middle</li> </ul>	<b>Autonomy and Resources for Compliance Dept.</b> <ul style="list-style-type: none"> <li>• Independent, high-ranking CCO</li> <li>• Well funded</li> </ul>	<b>Policies and Procedures</b> <ul style="list-style-type: none"> <li>• Interdisciplinary development</li> <li>• Widely communicated</li> <li>• Current</li> <li>• Designed to cover risk areas of commensurate expected behavior</li> <li>• Enforce accountability</li> </ul>
<b>Risk Assessment</b> <ul style="list-style-type: none"> <li>• Identify and prioritize risks</li> <li>• Use of technology</li> <li>• Use of benchmarks</li> <li>• Flexible</li> </ul>	<b>Training</b> <ul style="list-style-type: none"> <li>• Targeted to risks and relevant persons</li> <li>• Tracked participation</li> <li>• Available</li> <li>• Feedback mechanism</li> </ul>	<b>Confidential Disclosure Program Reports</b> <ul style="list-style-type: none"> <li>• Thoroughly assessed</li> <li>• Objectively investigated</li> <li>• Appropriately documented/reported</li> <li>• Remediated/mitigated</li> </ul>	<b>Incentives and Disciplinary Actions</b> <ul style="list-style-type: none"> <li>• Ensure accountability</li> <li>• Apply consistent discipline without regard to organizational rank</li> <li>• Offer appropriate incentives</li> </ul>

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### DOJ'S ELEVEN EVALUATION TOPICS

Continuous Improvement, Testing, and Review	Third Party Management	Mergers and Acquisitions
<ul style="list-style-type: none"><li>• Implement internal controls</li><li>• Determine frequency of assessment and training on controls</li><li>• Involve relevant stakeholders</li><li>• Report to management</li><li>• Encourage periodic third-party assessment</li></ul>	<ul style="list-style-type: none"><li>• Evaluate the risk vendors pose</li><li>• Assess the need for the vendor</li><li>• Integrate the vendor/service line into compliance program</li><li>• Audit the vendor's work</li><li>• Validate contracts and payments</li><li>• Document actions against vendors</li></ul>	<ul style="list-style-type: none"><li>• Conduct thorough compliance due diligence</li><li>• Integrate new acquisition into compliance culture</li><li>• Remediate known or newly identified compliance issues</li></ul>

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### DOJ COMPLIANCE GUIDANCE

- **APPROACH ASSUMES INVESTIGATIVE POSTURE**
  - INCLUDES QUESTIONS PERTAINING TO INFRASTRUCTURE
  - INCLUDES QUESTIONS SPECIFIC TO ISSUE UNDER INVESTIGATION
- **PRACTICAL USE**
  - ROADMAP TO APPROACH DOJ WILL TAKE IN THE CONTEXTS OF INVESTIGATIONS
  - PROVIDES INSIGHT AS TO WHAT DOJ CONSIDERS CRITICAL
- **VALUABLE TOOL**
  - CONSIDER YOUR MOST RECENT INTERNAL INVESTIGATION....

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### “MEASURING COMPLIANCE PROGRAM EFFECTIVENESS: A RESOURCE GUIDE”

- PUBLISHED IN MARCH 2017 BY HCCA AND OIG
- DEVELOPED FOLLOWING A ROUNDTABLE INCLUDING INDUSTRY AND GOVERNMENT REPRESENTATIVES IN JANUARY 2017
- DESIGNED TO HELP ORGANIZATIONS WITH POTENTIAL APPROACHES TO MOVE BEYOND BASIC COMPLIANCE PROGRAM DEVELOPMENT

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**“MEASURING COMPLIANCE PROGRAM EFFECTIVENESS: A RESOURCE GUIDE”**

- PROVIDES BENCHMARKING AND TRACKING OF SPECIFIC COMPLIANCE PROGRAM ELEMENTS TO DETERMINE THE EXTENT TO WHICH THEY ARE SUFFICIENTLY DEVELOPED AND EFFECTIVE
- THE RESOURCE GUIDE LISTS INDIVIDUAL PROGRAM METRICS, NOTING THAT **“THE PURPOSE OF THIS LIST IS TO GIVE HEALTH CARE ORGANIZATIONS AS MANY IDEAS AS POSSIBLE, BE BROAD ENOUGH TO HELP ANY TYPE OF ORGANIZATION, AND LET THE ORGANIZATION CHOOSE WHICH ONES BEST SUIT ITS NEEDS”**

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**“MEASURING COMPLIANCE PROGRAM EFFECTIVENESS: A RESOURCE GUIDE”**

- THE RESOURCE GUIDE EMPHASIZES THAT THIS PUBLICATION IS **NOT** A “CHECKLIST” THAT SHOULD BE “APPLIED WHOLESAL TO ASSESS A COMPLIANCE PROGRAM”
- THE GUIDE IS STRUCTURED TO PROVIDE TOOLS REGARDING BOTH “WHAT TO MEASURE” AND “HOW TO MEASURE”

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**REMARKS AT HCCA COMPLIANCE INSTITUTE**

DANIEL LEVINSON – HHS, INSPECTOR GENERAL, REMARKS AT HCCA ANNUAL COMPLIANCE INSTITUTE (MARCH 2017):

“BUT I TALK ABOUT COMPLIANCE 2.0. I WANT TO FOCUS ON THE **HUMAN FACTORS** THAT HAVE REALLY DEVELOPED OVER THE LAST FEW YEARS AS MORE AND MORE PEOPLE HAVE THOUGHT ABOUT WHAT IT MEANS TO HAVE A CORPORATION, A COMPANY AND ENTERPRISE REALLY DEVOTED TO BEING ABLE TO MAXIMIZE THE RESOURCES AT ITS DISPOSAL . . . WE NEED TO HAVE AN IDEA WHAT THE TONE AT THE TOP IS. OIG FOCUSES ON THAT - **WHAT'S THE TONE AT THE TOP** WHEN WE'RE LOOKING AT CIAS AND TRYING TO UNDERSTAND WHAT THE **INTERNAL CULTURE** OF THE ENTERPRISE IS. AND SURE ENOUGH, EVERYBODY SEEMS TO AGREE WITH IT. SO IT'S AN EXTREMELY IMPORTANT PART OF HOW WE'RE THINKING ABOUT **CULTURE** AND THAT'S THE **HUMAN COMPONENT**”

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DESIGNING YOUR COMPLIANCE PROGRAM /  
ENHANCING YOUR COMPLIANCE INITIATIVES

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**ASSESS CCO'S REPORTING RELATIONSHIP**

- LEVEL OF POSITION (VP, DIRECTOR, MANAGER, ETC...) WILL VARY BY ORGANIZATION'S SIZE AND OPERATIONS
- CONSIDER HAVING CCO REPORT DIRECTLY TO THE BOARD WITH AN ADMINISTRATIVE ("DOTTED LINE") REPORTING RELATIONSHIP TO THE ORGANIZATION'S CEO
  - ALLOWS FOR INDEPENDENCE/BOARD MUST APPROVE HIRING/FIRING
- CCO SHOULD NOT REPORT TO CFO OR COUNSEL

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**"BEST-PRACTICE" COMPLIANCE PROGRAM**

- MODEL YOUR PROGRAM AFTER RECENTLY EXECUTED CIA'S
- EVALUATE COMPOSITION OF COMPLIANCE COMMITTEE(S)
  - ENSURE THAT COMMITTEE MEMBERS UNDERSTAND THEIR ROLE
- ALLOW "SUFFICIENT" TIME FOR COMPLIANCE TRAINING
  - CONSIDER A SERIES OF SHORT SESSIONS VS LENGTHY SESSION
  - TRACK ALL COMPLIANCE TRAINING THAT IS CONDUCTED IN-HOUSE
- VOLUME OF REPORTS OF POTENTIAL COMPLIANCE ISSUES SHOULD CORRELATE TO THE SIZE OF THE ORGANIZATION
  - HOTLINE REPORTS MIGHT DECREASE AS DIRECT REPORTS INCREASE

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**“BEST-PRACTICE” COMPLIANCE PROGRAM**

- MONITOR RESULTS OF SANCTION SCREENING IF PERFORMED BY A THIRD-PARTY VENDOR
  - UNDERSTAND VENDOR'S ACKNOWLEDGEMENT OF RESPONSIBILITY
  - MEMORIALIZE THE AGREEMENT/INDEMNIFICATION IN WRITING
- EFFECTIVELY MANAGE CONFLICT OF INTEREST DISCLOSURES
- REGULAR SIGNED ATTESTATIONS BY SENIOR LEADERS

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**SAMPLE OIG REVIEW OF COMPLIANCE PROGRAM ELEMENT**

- **WHAT TO MEASURE:**
  - COMPLIANCE CULTURE AND SUPPORT
  - INVOLVEMENT OF BOARD MEMBERS AND SENIOR LEADERSHIP
- **HOW TO MEASURE:**
  - BOARD INTERVIEWS
  - QUALIFICATIONS OF COMPLIANCE OFFICER
    - CERTIFICATION IN HEALTHCARE COMPLIANCE., ETC.
  - AUTHORITY OF COMPLIANCE OFFICER TO:
    - ENGAGE OUTSIDE LEGAL COUNSEL
    - INITIATE A WORKING GROUP
    - IMPLEMENT A BILL HOLD

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**OIG'S REVIEW OF CIA COMPLIANCE COMMON MONITORING AND SITE VISIT INQUIRIES**

- ASSESS “PLACEMENT” OF COMPLIANCE WITHIN THE ORGANIZATIONAL STRUCTURE
- VALIDATE COMPLIANCE OFFICER'S STANDING AND AUTHORITY WITHIN ORGANIZATION
- EVALUATE COMMUNICATION BETWEEN COMPLIANCE OFFICER AND BOARD
- EVALUATE RESOURCES DEDICATED TO COMPLIANCE PROGRAM
- COMPLIANCE COMMITTEE MEETING MINUTES
- REVIEW DISCLOSURE LOG AND UNDERLYING INVESTIGATION / REPORTS
- HISTORY OF DEVELOPMENT/IMPLEMENTATION OF CORRECTIVE ACTION PLANS

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QUESTIONS?

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