COMPLIANCE 2.0

2019 HCCA COMPLIANCE INSTITUTE
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Goals of Session

☐ **Review** recent developments demonstrating the regulators are focused on Effectiveness in Compliance Programs

☐ **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

Compliance 2.0 - 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
Changing Compliance Landscape

- Increased FCA penalties
- Aggressive Relator Strategies
- Focus on Individual Accountability
- Enhanced OIG and DOJ compliance program expectations as evidenced by:
  - Recent CIAs
  - DOJ’s Evaluation of Corporate Compliance Programs Guidance Document
  - OIG/HCCA Measuring Compliance Program Effectiveness Document

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)
FCA Penalties - The Stakes Are High

Increased False Claims Act (FCA) financial penalties for non-compliance

<table>
<thead>
<tr>
<th>Defense Contractor</th>
<th>Healthcare Provider</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>12 claims / year</td>
<td>2,000 claims / year</td>
</tr>
<tr>
<td>Triple Damages</td>
<td>$300,000</td>
</tr>
<tr>
<td>Penalty (2.86 x 12)</td>
<td>$262,992</td>
</tr>
<tr>
<td>Total Recovery</td>
<td>$562,992</td>
</tr>
<tr>
<td></td>
<td>Triple Damages</td>
</tr>
<tr>
<td></td>
<td>$300,000</td>
</tr>
<tr>
<td>Penalty (2.86 x 2,000)</td>
<td>$43,832,000</td>
</tr>
<tr>
<td>Total Recovery</td>
<td>$44,132,000</td>
</tr>
</tbody>
</table>

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).
- OIG is publishing its fraud risk indicator on its website.
### OIG Assessment of Permissive Exclusion

<table>
<thead>
<tr>
<th>Compliance Program</th>
<th>Impact on Risk Assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>A compliance program that incorporates the seven elements of an effective compliance program</td>
<td>Risk assessment not affected</td>
</tr>
<tr>
<td>Absence of a compliance program that incorporates the seven elements of an effective compliance program</td>
<td>Indicates higher risk</td>
</tr>
<tr>
<td>Entity devoted significantly more resources to the compliance function</td>
<td>Indicates lower risk</td>
</tr>
</tbody>
</table>

### Other Compliance Program Developments

- **2010**
  - ACA Mandates Compliance Programs as a Condition for Enrollment

- **2015**
  - Yates Memo
  - DOJ Compliance Counsel

- **2016**
  - OIG Update to Permissive Exclusion Authority Criteria
  - CMS Issues 60-Day Overpayment Final Rule

- **2017**
  - DOJ Issues “Evaluation of Corporate Compliance Programs” Guidance Document
  - Daniel Levinson’s HCCA Compliance Institute’s Keynote Address where He Coined the Phrase “Compliance 2.0”
Compliance 2.0 – Enhancing Compliance Initiatives and Assessing Risk

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 CIAs and the way that we’re now able to focus attention in a much more laser-like way, I think the evolution of CIAs 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 CIAs . . .”
Qualities of an Effective Compliance Officer

- Integrity and a sense of fairness
- Strength of character and authority
- Attention for detail while maintaining the ability to see the big picture – “seeing the forest through the trees”
- Calm demeanor – no hysteria when problems are identified
- Communication style that may be adaptable to different audiences
- Engaged in continuous learning

Emerging CIA Trends Indicate a Focus on Effectiveness and Accountability

- Use of Independent Monitors
- Compliance Experts
- Management Certifications and Increased Stipulated Penalties for False Certifications
- Heightened IRO Qualifications
- Risk Assessment and Mitigation
Risk Assessment in Healthcare

- All of the organization’s managers generally have areas where they intersect
  - Legal
  - Compliance
  - Finance
  - Risk Management
  - Quality

* A collaborative approach to prioritizing organizational risk can help focus the organization’s resources in the areas of highest risk. In addition, a collaborative approach will help to drive desired behaviors to avoid compliance issues.

Risk Assessment

- Focus on priority areas where multiple areas of risk intersect.
  - Break down of opioid prescribing
    - New regulations and guidance pose compliance risk- How do ensure the right people are aware in your organization?
    - Standards of care and patient safety are drivers for the new rules and guidance- How to ensure patients have access to high quality care from providers that are up to date on emerging guidance and rules?
    - Non-compliance with the new rules/guidance may lead to patient harm and subject your organization to legal risk of enforcement- How do you reduce the risk of harms and financial repayments/penalties?
  - Looking at the spaces of overlap will often lead you to the greatest opportunities for a collaborative and focused effort to develop a compliance plan that can identify and mitigate your highest risk areas.
Legal and Compliance

- Education and Training
  - Resolve Issues
  - Legal Decision Making
- Review and Audit
  - Identify Outliers

Teamwork

- Legal and compliance are just two parts of the greater team that is the enterprise. Like any good team:
  - Everyone should play by the same rules and playbook.
  - Each team member should be striving for the same goals. Success has to have the same meaning for each.
  - A supportive environment of respect and collaboration where everyone knows their role and those role are value add to the entire team and to the teammates.
- Establish roles ➔ Continual communication ➔ Everyone moving towards the goal
Compliance Risk Assessment

- A compliance risk assessment ("CRA") is a process used to identify, assess, and prioritize potential risks.
- CRAs evaluate multiple outputs such as:
  - Financial data (to identify potential impact of the topic);
  - Past performance (to establish a baseline of known information about the topic); and
  - Public data (to ascertain benchmarks).
- Opinions of subject matter experts
- Analysis of existing controls
- Determination of risk tolerance
- The CRA includes documentation of the standard operating procedures.

Risk Assessment Definitions

- Compliance Risk – The potential threat posed to the company’s financial, organizational, or reputational standing resulting from a violation of law, regulation, or organization/industry standards of practice.
- Inherent Risk – Risk posed before internal controls are considered. Inherent risk includes the potential impact of and likelihood of compliance risk.
- Residual Risk – Remaining compliance risk potential after internal controls such as policies, training, and auditing and monitoring are implemented.
Risk Assessment Process Flow

1. Evaluate Sources of Compliance Risk
   - Internally Identified
   - Externally Identified

2. Inherent Risk Analysis
   - SME Controls Analysis
   - Residual Risk Assessment

3. Risk Mitigation Activities
   - Acceptable Risk
     - Schedule Re-assessment
   - No Further Action
   - Unacceptable Risk
     - No Further Action

Rating Inherent Risk

Compliance Risk Assessment - Inherent Risk Scoring Guidelines

**Reputation Risk Factor**
- **HIGH** = National Negative Impact - National Media
- **MEDIUM** = Regional Negative Impact - Regional Media/Specialized
- **LOW** = Localized Negative Impact - Site Specific Media

**Financial Risk Factor (Revenue Dollars at Risk)**
- **HIGH** = > 1 Million Dollars
- **MEDIUM** = < 1 Million and > $50,000
- **LOW** = < $50,000

**Legal/Regulatory (Civil and Criminal Fines or Penalties and Sanctions)**
- **HIGH** = Federal or State Actions / Investigations
- **MEDIUM** = Routine Investigation
- **LOW** = No regulatory or legal actions

**FREQUENCY / LIKELIHOOD**
- **HIGH** = > 1,000 patients / month OR occurs monthly (almost certain)
- **MEDIUM** = < 1,000 and >500 patients / month or occurs twice annually (Likely)
- **LOW** = < 500 patients / month or occurs annually or less frequently (Possible)

**SME**
Please enter the name of the SME as resource / contact for risk item and the designee for completing the Risk Item Control Analysis if applicable.
CRA – Operational Process

- CRA Team compiles Risk Items from Internal and External Sources
- The compiled list is provided to the Compliance Risk Evaluation Team quarterly

- Compliance Risk Evaluation Team:
  - Ranks the top ten Risk Focus Items for the CRA Process
  - Identifies Compliance Risk Focus Team members
  - Requests Volume/Targeted Data Query as applicable to remaining Risk Items

- Compliance Risk Focus Team conducts the Inherent Risk Analysis and designates the Subject Matter Expert (SME) to perform the SME Controls Analysis

- Subject Matter Expert completes the SME Controls Analysis

- CRA Team calculates the Residual Risk Score (Inherent Risk - Controls Analysis = Residual Risk) and provides an update to the Compliance Risk Focus Team

- The Compliance Risk Focus Team reviews the Residual Risk for Risk Determination Outcome:
  - Risk Deemed Acceptable and No Further Action
  - Risk Deemed Acceptable and Scheduled for Re-Review in an upcoming year
  - Risk Deemed Unacceptable and Risk Mitigation activities initiated
  - Risk Determination Outcome reported to Compliance Work Group

Risk Mitigation Operational Flow

- Compliance Risk Mitigation (CRM) Team Leader identifies and assembles team

- CRM Team reviews and evaluates previous Risk Assessment / Analysis scores

- CRM Team develops Risk Mitigation Strategy (Goal) and plans actions accordingly

- CRM Team implements actions as planned

- CRM Team evaluates the effectiveness of implemented actions

- CRM Team:
  - Evaluates the outcome of risk item through re-assessment of Residual Risk
  - Performs Risk Determination
  - Reports Actions taken and Risk Determination Outcome to Compliance Risk Focus Team
  - Reports Action taken and Risk Determination Outcome to Compliance Work Group
### Demonstrating Effectiveness

**Output versus Outcomes**

<table>
<thead>
<tr>
<th>Output</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data</td>
<td>Behavior Change</td>
</tr>
<tr>
<td>Plans</td>
<td>Meaningful Results</td>
</tr>
<tr>
<td>Activities</td>
<td>Quantified Performance</td>
</tr>
<tr>
<td>Methods</td>
<td>Impact of Activities</td>
</tr>
<tr>
<td>Approaches</td>
<td>Indicator of Effectiveness</td>
</tr>
<tr>
<td>Patterns</td>
<td>Subjective in some cases (e.g. ROI for Compliance Programs)</td>
</tr>
<tr>
<td>Tangible</td>
<td>Quantification of performance over time</td>
</tr>
<tr>
<td>Does not describe risk, value, or impact</td>
<td></td>
</tr>
</tbody>
</table>
### Measuring Outcomes = Measuring Effectiveness

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Describe the desired outcome</td>
<td>Admit patients to the appropriate level of care</td>
</tr>
<tr>
<td>Identify the anticipated quantitative measurement</td>
<td>&lt;5% financial error rate</td>
</tr>
<tr>
<td>Confirm the outcome is reasonable based upon outputs (activities)</td>
<td>Data reveals admissions do not meet the two-midnight rule; so mitigation activities are employed</td>
</tr>
<tr>
<td>Implement measurements</td>
<td>Trend over time – Display results in a meaningful manner</td>
</tr>
<tr>
<td>Demonstrate value</td>
<td>Communicate results</td>
</tr>
</tbody>
</table>

#### Example of an Outcome Graph

![Error Trending by Requirement](image-url)

- **Two Midnight Benchmark**
- **Compliant Inpatient Order**
- **Both**

- Q1
- Q2
- Q3
- Q4
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.”

Resources for Evaluating Compliance Program Effectiveness

**DOJ’s Evaluation of Corporate Compliance Program**
- Issued in February 2017 to provide “sample questions that the Fraud Section has frequently found relevant in evaluating a Corporate Compliance Program”
- Underscores that DOJ is actively evaluating Compliance Program effectiveness during investigations
- Outlines 11 “sample topics and questions”
- Includes questions pertaining to infrastructure of the Compliance Program and other questions issued during an investigation
- Roadmap to the approach DOJ will take in the contexts of its investigations and insight into what DOJ considers critical

**OIG/HCCA’s Measuring Compliance Program Effectiveness: A Resource Guide**
- Developed following a roundtable including industry and government representatives in January 2017, and published in March 2017 by HCCA and OIG
- Designed to help organizations with potential approaches to move beyond basic compliance program development
- Provides benchmarking and tracking of specific compliance program elements to determine the extent to which they are sufficiently developed and effective
- The Resource Guide emphasizes this publication is not a “checklist” that should be “applied wholesale to assess a compliance program”
- The Guide is structured to provide tools regarding both “what to measure” and “how to measure”
“Best-Practice” Compliance Program

- Model your program after recently executed CIAs
- 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

“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
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 investigations/reports
- History of development/implementation of corrective action plans

Questions