Strategies to Evaluate the Effectiveness of Your Compliance Program

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Compliance Program “Check-up”

- In many respects, a compliance program is a corporate wellness program

- When was the last time your compliance/wellness program had a check-up?

- Delaying a compliance program check-up until a problem/illness arises is akin to delaying an annual physical/wellness check-up until a health issue arises

  - May be too late to address an otherwise preventable problem
We have a Compliance Program, but. . .

- Are we focused on the right issues?
- Is the program identifying our principle risks?
- Are we getting value/return for our investment (effort)?
- Are we investing time, money and resources where we should?
- How do we evaluate the quality and effectiveness of our program (outcome)?

Evaluating Compliance Program Effectiveness

- What does compliance “effectiveness” look like?
- How do you assess compliance effectiveness in your organization?
- What is the government looking for to demonstrate effectiveness?
## Compliance Program Maturity Determination: Effectiveness Indicators

<table>
<thead>
<tr>
<th>Compliance</th>
<th>Managing Compliance Risks</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mature</strong></td>
<td>• Technical and business tools are used to enhance competitive advantage</td>
</tr>
<tr>
<td></td>
<td>• Maximizes budgeted resources because tasks are better planned and coordinated</td>
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<tr>
<td></td>
<td>• Maximum flexibility: &quot;Anticipatory&quot;</td>
</tr>
<tr>
<td></td>
<td>• Participates with government regulators setting standards and policies</td>
</tr>
<tr>
<td><strong>Evolving</strong></td>
<td>• &quot;Planning&quot; mentality</td>
</tr>
<tr>
<td></td>
<td>• Adopting more open approach with government regulators</td>
</tr>
<tr>
<td></td>
<td>• Flexible enough to withstand and learn from regulatory situations</td>
</tr>
<tr>
<td></td>
<td>• More integrated with other operational units</td>
</tr>
<tr>
<td><strong>Emerging</strong></td>
<td>• &quot;Put out fires&quot; mentality</td>
</tr>
<tr>
<td></td>
<td>• Minimum level of compliance</td>
</tr>
<tr>
<td></td>
<td>• Inflexible</td>
</tr>
</tbody>
</table>

- No corporate-wide compliance process and systems

### Relax, this Won’t Hurt a Bit. . .
### Where Do We Start?

- Every organization is different
- No one size fits all answer for compliance programs or evaluating the effectiveness of the same
- But, investigative and enforcement agencies have consistently stated that the effectiveness of a compliance program should be judged, at least in part, by how it compares to programs of similarly situated organization

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### United States Sentencing Commission
Federal Sentencing Guidelines (FSG)

- Common ground for **all** compliance programs, both in and outside of health care
- Effective November 1, 1991
- Revised November 2004 and 2010
- Control sentencing of organizations for most federal criminal violations
- Sentencing credit for “effective programs to prevent and detect violations of law”
**FSG Revisions (Nov. 2010)**

- First, the organization must respond appropriately to the criminal conduct, including restitution to the victims, self-reporting and cooperation with authorities.

- Second, the organization must assess its program and modify it to make the program more effective.
  - Seems to encourage the use of an independent monitor to ensure implementation of the changes.

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**FSG Revisions (Nov. 2010)**

You can get credit for having an effective compliance program, provided you meet the new criteria:

- the head of the compliance program must report directly to the governing authority or appropriate subgroup,
- the compliance program must discover the problem before discovery outside the organization was reasonably likely,
- the organization must promptly report the problem to the government, and
- no person with operational responsibility in the compliance program participated in, condoned or was willfully ignorant of the offense.
FSG (Seven) Essential Elements/Indicators of a Compliance Program

- Standards and Procedures
- Oversight/High-Level Responsibility
- Education and Training
- Monitoring and Auditing
- Reporting
- Enforcement and Discipline
- Response and Prevention
- (Risk and Effectiveness Assessments)

Standards and Procedures

- Code of Conduct
  - Is it understandable for all staff?
  - Is it tailored to the organization’s culture, business, and corporate identity?
  - Have employees signed attestations that they have reviewed the Code?

- Policies and Procedures
  - Is there continuous evaluation?
  - Does someone have assigned responsibility?
  - Does your policy mirror your practice?
### Compliance Oversight (Appropriate Authority and Adequate Resources)

**Board**
- Is your Board aware of the compliance program?
- Is there commitment and buy-in?
- Is there proper delegation of authority and accountability?

**Compliance Officer**
- Can the CO make decisions?
- Is the CO leading the effort?
- Is there timely response to newly developed rules and regulations?

<table>
<thead>
<tr>
<th>Oversight Committee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do they ensure that appropriate policies and procedures are in place to preserve and safeguard the organization’s assets?</td>
</tr>
<tr>
<td>Do they ensure proper ethical and legal standards are present and maintained in meeting all applicable laws, rules and regulations?</td>
</tr>
<tr>
<td>Do they should monitor compliance with applicable laws, rules and regulations?</td>
</tr>
</tbody>
</table>

**Management**
- Does Management encourage open discussion of errors and concerns raised by employees?
- Is a culture of compliance created?
Education and Training

- Communication Process
  - Are employees aware of the compliance program?

- Education and Training
  - Are employees trained on compliance related topics on an annual basis?
  - Is new hire training provided within 30 days of employment?
  - Is training mandatory?
  - Is all training tracked?
  - Are there sanctions in place for those that do not attend the training?

Monitoring and Auditing

- Evaluate Program Effectiveness
  - Have you conducted an effectiveness assessment of your compliance program?

- Audit Plan and Methodology
  - Have you completed and prioritized your organizational risk
  - Do you have an annual audit plan?
  - Do you monitor on an on-going basis?
  - Is feedback given on audit/review findings?
  - Are corrective action plans developed on non-compliant audit findings?
  - Do you make (regular) reports to the Board?
## Reporting and Investigation

- **Reporting System**
  - Is it anonymous?
  - Are all calls triaged?
  - Are concerns addressed in a timely manner?
  - Is there a non-retaliation/non-retribution policy communicated to all employees?
  - Is confidentiality maintained to the extent of the law?

- **Investigations**
  - Are they conducted in a timely manner?
  - Are all issues investigated?

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## Enforcement and Discipline

- **Enforcement**
  - Are responses appropriate and consistent?
  - Are policies and procedures enforced?
  - Are background checks conducted on a regular basis?

- **Disciplinary Measures**
  - Is there a discipline policy?
  - Is it communicated?
  - Is it fair and consistent?
Response and Prevention

- Response
  - Do you respond in a timely manner?
  - Do you have the trust of your organization to handle issues appropriately?
  - Is counsel involved?

- Prevention
  - Are corrective actions put into place?
  - Are re-audits conducted to assure the issue is resolved?

How to Evaluate the Effectiveness of Your Compliance Program

Benchmarks:

- FSG 7 Elements of Compliance Program
- OIG Model Guidances (e.g., Hospital, DME, SNF)
- Industry Benchmarks – National/Regional
- Your Organization – Comparison of Performance from Year-to-Year
- Related Outcomes (e.g., repayment costs for inaccurate billing/coding)
How to Evaluate the Effectiveness of Your Compliance Program

Methodology

- Document reviews
- Interviews
- Surveys

How to Evaluate the Effectiveness of Your Compliance Program—Interviews (example)

<table>
<thead>
<tr>
<th>QUESTION</th>
<th>Positive Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Does your organization have a compliance officer?</td>
<td>67%</td>
</tr>
<tr>
<td>2. Do you know who the compliance officer is?</td>
<td>53%</td>
</tr>
<tr>
<td>3. Do you know how to contact the compliance officer?</td>
<td>84%</td>
</tr>
<tr>
<td>4. Are you obligated by your organization to report improper or unethical conduct?</td>
<td>100%</td>
</tr>
</tbody>
</table>
How to Evaluate the Effectiveness of Your Compliance Program—Surveys (example)

Survey Question: ABC Medical Center is an Ethical Company?

<table>
<thead>
<tr>
<th></th>
<th>Totally Disagree</th>
<th>Strongly Disagree</th>
<th>Disagree</th>
<th>Agree</th>
<th>Strongly Agree</th>
<th>Totally Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.7%</td>
<td>0.0%</td>
<td>0.0%</td>
<td>18.9%</td>
<td>26.4%</td>
<td>49.1%</td>
<td></td>
</tr>
</tbody>
</table>

Scoring:

- How do you score in regard to those benchmarks?
- Identification of best practices, findings and recommendations
## Compliance Program Outcome Metrics

<table>
<thead>
<tr>
<th>Identified Risks</th>
<th>Risk Ranking*</th>
<th>Type of Compliance Risk</th>
<th>Outcome Measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standards of Conduct and Policies and Procedures</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stark/Anti-Kickback Violations</td>
<td>4</td>
<td>Regulatory Reputation</td>
<td>1) Decrease in reports of potential violations</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Financial</td>
<td>2) Decrease in attorney fees related to Stark issues</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>3) Decrease in fines paid for violations</td>
</tr>
<tr>
<td>Data privacy and security breaches</td>
<td>4</td>
<td>Regulatory Reputation</td>
<td>1) Decrease in number of reportable breaches</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Financial</td>
<td>2) Decrease in regulatory fines</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>3) Notification and remediation costs</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>4) Decrease in costs for remediation of breach</td>
</tr>
<tr>
<td>Oversight (Governing Body, Compliance Structure and Compliance Officer)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No Governing Body oversight and knowledge of compliance risks and mitigation activities</td>
<td>2</td>
<td>Regulatory Reputation</td>
<td>1) Governing Body Committee minutes reflect discussion of compliance risks and mitigation activities on a periodic basis</td>
</tr>
<tr>
<td>Education and Training</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unresolved Conflicts of Interest (AMCs)</td>
<td>3</td>
<td>Regulatory Reputation</td>
<td>1) Increase in conflict of interest reporting and resolution</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Financial</td>
<td>2) Decrease in attorney fees related to resolution of conflict issues</td>
</tr>
<tr>
<td>Inaccurate Bills Submitted to Government Payers</td>
<td>3</td>
<td>Regulatory Reputation</td>
<td>1) Decrease in denials and government reimbursement payback</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Financial</td>
<td></td>
</tr>
</tbody>
</table>

## Benefits of an (Effective) Compliance Program

- Demonstrates organization’s commitment to good corporate conduct
- Identify and prevent criminal and unethical conduct
- Create a centralized source of information on industry regulations
- Develop a methodology that encourages employees to report potential problems
Benefits of an (Effective) Compliance Program (con’t.)

- Develop procedures that allow the prompt, thorough investigation of alleged misconduct
- Initiate immediate and appropriate corrective action
- Reduce the organization’s exposure to civil damages and penalties, criminal sanctions, and administrative remedies, such as program exclusions

QUESTIONS?