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**

**Mature**
- "Planning" mentality
- Adopting more open approach with government regulators
- Flexible enough to withstand and learn from regulatory situations
- More integrated with other operational units
- Technical and business tools are used to enhance competitive advantage
- Maximizes budgeted resources because tasks are better planned and coordinated
- Maximum flexibility: "Anticipatory"
- Participates with government regulators setting standards and policies

**Evolving**
- "Put out fires" mentality
- Minimum level of compliance
- Inflexible
- Technical and business tools are used to enhance competitive advantage
- Adopting more open approach with government regulators
- Flexible enough to withstand and learn from regulatory situations
- More integrated with other operational units

**Emerging**
- No corporate-wide compliance process and systems

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**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

Untied 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.

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)

<table>
<thead>
<tr>
<th>Board</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is your Board aware of the compliance program?</td>
</tr>
<tr>
<td>Is there commitment and buy-in?</td>
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<tr>
<td>Is there proper delegation of authority and accountability?</td>
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</table>

<table>
<thead>
<tr>
<th>Compliance Officer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Can the CO make decisions?</td>
</tr>
<tr>
<td>Is the CO leading the effort?</td>
</tr>
<tr>
<td>Is there timely response to newly developed rules and regulations?</td>
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</table>

<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>

<table>
<thead>
<tr>
<th>Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does Management encourage open discussion of errors and concerns raised by employees?</td>
</tr>
<tr>
<td>Is a culture of compliance created?</td>
</tr>
</tbody>
</table>
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?

**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

<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

**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>Percentage</td>
<td>5.7%</td>
<td>0.0%</td>
<td>0.0%</td>
<td>18.9%</td>
<td>26.4%</td>
<td>49.1%</td>
</tr>
</tbody>
</table>

### How to Evaluate the Effectiveness of Your Compliance Program

**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>Stark/Anti-Kickback Violations</td>
<td>4</td>
<td>Regulatory</td>
<td>1) Decrease in reports of potential violations&lt;br&gt;2) Decrease in attorney fees related to Stark issues&lt;br&gt;3) Decrease in fines paid for violations</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Reputational</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Financial</td>
<td></td>
</tr>
<tr>
<td>Data privacy and security breaches</td>
<td>4</td>
<td>Regulatory</td>
<td>1) Decrease in number of reportable breaches&lt;br&gt;2) Notification and remediation costs&lt;br&gt;3) Decrease in costs for remediation of breach</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Reputational</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Financial</td>
<td></td>
</tr>
<tr>
<td>Oversight (Governing Body, Compliance Structure and Compliance Officer)</td>
<td>2</td>
<td>Regulatory</td>
<td>1) Governing Body Committee minutes reflect discussion of compliance risks and mitigation activities on a periodic basis</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Reputational</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Financial</td>
<td></td>
</tr>
<tr>
<td>No Governing Body oversight and knowledge of compliance risks and mitigation activities</td>
<td>2</td>
<td>Regulatory</td>
<td>1) Increase in conflict of interest reporting and resolution&lt;br&gt;2) Decrease in attorney fees related to resolution of conflict issues</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Reputational</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Financial</td>
<td></td>
</tr>
<tr>
<td>Education and Training</td>
<td>3</td>
<td>Regulatory</td>
<td>1) Increase in conflict of interest reporting and resolution&lt;br&gt;2) Decrease in attorney fees related to resolution of conflict issues</td>
</tr>
<tr>
<td>Unresolved Conflicts of Interest (AMCs)</td>
<td>3</td>
<td>Regulatory</td>
<td>1) Increase in conflict of interest reporting and resolution&lt;br&gt;2) Decrease in attorney fees related to resolution of conflict issues</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Reputational</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Financial</td>
<td></td>
</tr>
<tr>
<td>Inaccurate Bills Submitted to Government Payers</td>
<td>3</td>
<td>Regulatory</td>
<td>1) Decrease in denials and government reimbursement payback</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Reputational</td>
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<td>Financial</td>
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### 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?