HealthCare Compliance Association
Compliance Institute
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Academic Medical Center Compliance Program:
Strategies for Developing an Effective Program

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Lynda Hilliard, CHC, CCEP
Compliance Professional

Session Agenda

1. "Nuts and Bolts" - The Basics 1:30-2:45
   • Key elements of a comprehensive program
   • Challenges to implementation

   Break 2:45-3:00

2. Key AMC compliance program risks 3:00-4:15
   • Prioritizing risks
   • Mitigation Strategies

3. Summary/Questions and Answers 4:15-5:00

The Nuts and Bolts of an Effective Compliance Program
Measures of Effectiveness

The Federal Sentencing Guidelines (Section 8) outline the following steps to achieving compliance program effectiveness:

1. Exercise due diligence to prevent and detect criminal conduct;
2. Otherwise promote an organizational culture that encourages ethical conduct and a commitment to compliance with the law.

• Such compliance and ethics program shall be reasonably designed, implemented, and enforced so that the program is generally effective in preventing and detecting criminal conduct. The failure to prevent or detect the instant offense does not necessarily mean that the program is not generally effective in preventing and detecting criminal conduct.

Key Elements of a Comprehensive Compliance Program

☑ Established structure and processes that address the following:
  • Seven Elements of an Effective Compliance Program – Section 8, Federal Sentencing Guidelines (FSG), United States Sentencing Commission (USSC);

Translation: 7 Elements into Action

<table>
<thead>
<tr>
<th>Standards of Conduct/Policies and Procedures</th>
<th>Governing Body/Compliance Office</th>
<th>Employee Screening</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approved Code of Conduct</td>
<td>Resolution from GB</td>
<td>Establish systems to background check new hires in high risk positions.</td>
</tr>
<tr>
<td>Compliance-related policies and procedures</td>
<td>Appointment of Compliance Officer</td>
<td>Establish periodic screening to ensure no employees have been sanctioned/excluded from federal participation.</td>
</tr>
<tr>
<td>Approved Compliance Plan</td>
<td>Resources Allocated to Compliance Function</td>
<td>Monitor and report on screening activities.</td>
</tr>
<tr>
<td></td>
<td>Operational Compliance Committee established</td>
<td></td>
</tr>
</tbody>
</table>
**Translation: 7 Elements into Action**

**Education and Training**
- General Training/Orientation to the Program
- Job-specific training on high compliance risk areas
- Tracking attendance – incorporate attendance into performance standards

**Audit/Monitoring – Anonymous Reporting/Measuring Effectiveness**
- Periodic risk assessments
- Establishment of department – specific ongoing monitoring
- Implementation of comprehensive audit and monitoring plan
- Confidential, anonymous Hotline – timely follow-up and reporting of trends
- Annual review of program to determine effectiveness

**Translation: 7 Elements into Action**

**Consistent Discipline and Enforcement**
- Consistent discipline across organization
- Use of incentives for staff to comply with Program
- Reporting and communication of activities

**Response and Prevention**
- Process for staff to comply with government investigations
- Appropriate protocols for preservation of documents
- Processes in place to address newly identified compliance risks

**OIG Model Guidances**
   - Supplemental (2005)
5. Durable Medical Devices...Industry (1999)
   - Supplemental (2008)
12. DRAFT for Public Health Service Grant Recipients
Key Elements of a Comprehensive Compliance Program

- Governing Body and senior leadership demonstrate positive commitment to the Program
  - Sufficient resources to build and sustain Program;
  - Communication to subordinates to support and “live” the Program;
  - Receive, and act upon, reports submitted by the Compliance Officer;
  - Periodically evaluate effectiveness of Program and make improvements.

Key Elements of a Comprehensive Compliance Program

- Staff awareness of compliance program, compliance officer and how to report issues;
- Issues are being identified and reported appropriately;
- Improved processes are the outcomes of issue resolution;
- Compliance is an integral part of the business planning process;

Primary Challenges to Implementation

1. Lack of Governing Body/Senior Leadership respect and support for the program
2. Ineffective compliance program structure
3. Lack of sufficient resources
4. Lack of compliance integration and relationship building with other operational departments
5. Poor or non-existent cultural “buy-in”
I. Garner Senior Leadership Support

Management, financial and governance support are essential for sound compliance programs

1. Management: "C" level positions: CEO, CMO CFO, CIO, COO, CLO, etc.
2. Finance: Financial support of the Compliance Department and Compliance Program
3. Governance: Board of Trustees, Board of Directors

Need engagement at all three levels of an organization

Evidence of Engaging Senior Leadership

☑ Understanding strategic focus areas
  • Patient Care
  • Employee Engagement
  • Financial Health

☑ Aligning compliance goals with organizational strategies
  • Integration within Organization
  • Compliance Active in Advancing the Long-Term Strategy
  • Integral Part of the Strategic Planning
  • Communication of Enforcement Trends is Acted Upon

Evidence of Engaging Senior Leadership

☑ Leading and providing briefings to the Governing Body on new developments in the law and related legal implications.

☑ Interacting with the Governing Body and Senior Leadership as they seek assurance that the compliance program and other legal controls are in place to monitor the associated legal and compliance risks.
II. Ineffective Program Structure

- All 7 elements have NOT been implemented fully
  - Standards of Conduct approved, but NOT disseminated to all staff
  - LEIE screening occurring, but results not analyzed and acted upon;
  - Audits are conducted but management is not held responsible for fixing identified problems;
  - Credibility and respect of CO and compliance office is undermined.
  - Others

III. Insufficient Funds/Resources

Lack of funds and/or resources constrain the Program’s ability to be effective in detecting, preventing and deterring instances of fraud, waste and abuse.

1. Lack of a concerted, consistent effort to market and communicate the program to staff and applicable agents of the organization.
2. Inability to establish and manage a confidential, anonymous reporting line;
3. Lack of sufficient education and training of employees in high risk positions;
4. Compliance risks are identified, but investigation and mitigation resources are unavailable;
5. Inability of the CO to monitor industry issues and react proactively for the organization
IV. Collaboration & Building Relationships

Know Your Customer

- Schedule “meet and greet” meetings with all key leadership (clinical and administrative)
  - Assess their knowledge of a compliance program and their role in it;
  - Share the concept of compliance program oversight and commitment by the Governing Body;
  - Provide assurance that you are not going to take over their operations;
  - Stress your role as a support to meeting organization goals in an efficient manner;

Establish Trust and Credibility

- Develop ability to affect change,
- Do not over-promise results,
- Overcome having responsibility without authority,
- Conduct in-person compliance training for Governing Body and senior leadership.

Ongoing “Face Time”

- Attend leadership and middle management events;
- Schedule periodic, but ongoing meetings with key collaborators, e.g., CMO, OGC, HR, Education, Business Development, Contracting etc.

Tools to Measure Effectiveness: Start at the Beginning

1. MAP your Program – structure and processes (see next slide)
2. Develop Compliance Risk Dashboard
   - Specific risk areas to monitor outcomes or mitigation activities
   - Determine appropriate process or outcomes and related indicator thresholds
   - Identify and prioritize compliance risks based upon mission, risk exposure and resources to mitigate
Compliance Program Mapping Grid

<table>
<thead>
<tr>
<th>Program Element</th>
<th>Regulatory Requirement</th>
<th>Citation</th>
<th>Internal Control</th>
<th>Control Owner</th>
<th>Process Owner</th>
<th>Confirmation/Reconciliation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Education</td>
<td>If mandated by law or CFR or other regulations</td>
<td>What is required, e.g., all staff will be educated on code of conduct</td>
<td>Division Leader</td>
<td>HR/Governance Leader</td>
<td>Compliance to confirm records, support all staff attendance</td>
<td></td>
</tr>
<tr>
<td>And so on</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Sample Dashboard Formats

Effectiveness Measures - Examples

*Healthcare Services are compliant when they are:*

- Documented, charged and billed correctly;
- Provided in an approved facility;
- Promoting patient rights;
- Reimbursed correctly;
- Provided without financial incentives;
- Medically necessary;
- Provided by qualified physicians/staff;
- Conforming to quality standards;
Reporting Effectiveness Measures

Governing Body and Senior Leadership Reporting

- Standardize reporting tools;
- Summarize outcomes;
- Highlight successes and risk areas.

### Compliance Effectiveness Outcome Measures

<table>
<thead>
<tr>
<th>Identified Risk</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>4</td>
<td>Regulatory</td>
<td>Increase in minutes of required education or training, decrease in time for validation, decrease in time for fee validation.</td>
</tr>
<tr>
<td>Data privacy and security breaches</td>
<td>4</td>
<td>Regulatory</td>
<td>Prevent financial costs, reduction in invasion of patient privacy, reduction in loss of corporate reputation.</td>
</tr>
<tr>
<td>Oversight (Governing Body, Compliance Structure and Compliance Officer)</td>
<td>2</td>
<td>Regulatory</td>
<td>Increase in minutes of required education or training, decrease in time for validation, decrease in time for fee validation.</td>
</tr>
<tr>
<td>Risk tolerance and decision making</td>
<td>1</td>
<td>Regulatory</td>
<td>Increase in minutes of required education or training, decrease in time for validation, decrease in time for fee validation.</td>
</tr>
<tr>
<td>Monitoring and tracking</td>
<td>1</td>
<td>Regulatory</td>
<td>Increase in minutes of required education or training, decrease in time for validation, decrease in time for fee validation.</td>
</tr>
<tr>
<td>Conflict of interest</td>
<td>2</td>
<td>Regulatory</td>
<td>Increase in minutes of required education or training, decrease in time for validation, decrease in time for fee validation.</td>
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<tbody>
<tr>
<td>Financial and Regulatory Reporting</td>
<td>2</td>
<td>Regulatory</td>
<td>Increase in minutes of required education or training, decrease in time for validation, decrease in time for fee validation.</td>
</tr>
<tr>
<td>Enforcement and Learning</td>
<td>2</td>
<td>Regulatory</td>
<td>Increase in minutes of required education or training, decrease in time for validation, decrease in time for fee validation.</td>
</tr>
<tr>
<td>Policies for appropriate non-financial screening.</td>
<td>2</td>
<td>Regulatory</td>
<td>Increase in minutes of required education or training, decrease in time for validation, decrease in time for fee validation.</td>
</tr>
<tr>
<td>Built and Maintaining Effective Compliance Programs</td>
<td>2</td>
<td>Regulatory</td>
<td>Increase in minutes of required education or training, decrease in time for validation, decrease in time for fee validation.</td>
</tr>
<tr>
<td>Special emphasis areas</td>
<td>2</td>
<td>Regulatory</td>
<td>Increase in minutes of required education or training, decrease in time for validation, decrease in time for fee validation.</td>
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</tbody>
</table>
Compliance Risks for Academic Medical Centers

Usual and Unique

Usual Suspects

- Stark and Anti-Kickback
- Affordable Care Act
- Procurement Requirements
- State Employment Laws
- RAC, MAC, and ZPIC Audits
- 2015 OIG Work Plan
  - Duplicate Graduate Medical Education payments
  - Indirect medical education payments
General Mitigation Strategies

• Compare wRVUs (work resource value units) across and among clinical disciplines and explore outliers or irregularities;
• Educate billing and coding staff about clinical trials, research protocols, and grant requirements;
• Work with Principal Investigators (PI).

Unusual Suspect for AMCs

☑ Clinical Research Billing
  • Balancing ICD-09 (or ICD-10)
  • Research protocols
  • Bundled payments

Clinical Research Billing

Challenges
1. Ensuring insurance is not charged for services that should be covered by research study funds
2. Unique Needs:
   a. Double billing
   b. Proper controls
   c. Missed opportunities
   d. Billing for unallowables

Mitigation Activities
• Implement coding reviews
• Engage outside consultant to review charges
• Conduct regular, random audits of pro and technical fees
• Provide physician education and feedback
• Invest in coding/audit software
Slide 31

1  David - I would pick several "key" risks from the usual list and add them here with some strategies to mitigate, e.g., Stark - contract audits, education of physician recruiters, etc. We need a little more meet with the identification of the risks
Lynda Hilliard, 3/3/2015

Slide 33

2  David - I re-formatted this so that you could add some of the activities that UC is doing, e.g., inventorying compliance processes, re-education, audit etc.
Lynda Hilliard, 3/3/2015
Clinical Research Billing

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Mitigation Activities

- Require a formal coverage analysis before contract is signed.
- Hold first 10 claims for review for accuracy (against the study budget).
- Educate the principal investigators, research coordinators, contract negotiators, and IRB staff about the requirements.

Audience-Identified Risk Areas

- Audience survey of entity specific high risks
- Mitigation Strategies

Unique Financial Pressures

- Research Projects
- Educational Mission
- Clinical Activities
- Conflicts of Interest
David - I re-formatted this so that you could add some of the activities that UC is doing, e.g., inventorizing compliance processes, re-education, audit etc.

Lynda Hilliard, 3/3/2015
Mitigating Conflicts of Interest and Related Financial Pressures

✓ Establish process to review and manage financial disclosures and possible conflicts.
✓ Target and train industry-funded PI’s and their research coordinators about FCOI (financial conflicts of interest) http://grants.nih.gov/grants/policy/coi/.
✓ Educate contract and grants officers, IRBs (institutional review boards), Tech Transfer offices about FCOI.

Mitigating Other Financial Risks

✓ Conduct regular reviews of 3rd party agreements for appropriate terms and conditions.
✓ Establish real-time processes for the evaluation of affiliation agreements, professional service agreements for consistency with mission.
✓ Establish a broad-based oversight committee to review and manage difficult or complicated agreements.

Association of American Medical Colleges (AAMC) Top Initiatives

1. Improving Health Equity
2. Integrating Quality
3. Managing Talent
4. Redesigning Care Delivery
5. Transforming Medical Education
Maybe you could elaborate on what would be compliance's role in each of these areas. Maybe a few of the compliance risks associated with each item?? If you want, I could help you with these slides - we just need to make them more applicable to daily operations for the CO.

Lynda Hilliard, 3/3/2015
Increase Oversight Activities

- Tighten up physician recruitment process
  - Fair Market Value (FMV) analysis
  - Aligning physician needs to research and patient care needs
- Develop compliance, research, quality integration committees
  - Remove “silo” mentality
  - Integration across traditional areas critical

New Sources of Financial Pressure

- AMCs must identify new funding sources due to:
  - NIH Cuts
  - Sequestration
  - Loss of General Medical Education (GME) funding
- Managing third-party agreements, affiliation agreements, and other arrangements that challenge existing regulatory and policy frameworks

Addressing Emerging Financial Risks

- Align margins to fuel the mission
- Focus relentlessly on achieving and measuring quality
- Reconsider “conventional wisdom”
- Plug holes and pick low hanging fruit

Source: Athena Health 2014 White Paper
David - these strategies sounds very management focus vs what the compliance officer would do. Could you elaborate a little more on each of the areas about what the CO would do? Thanks

Lynda Hilliard, 3/3/2015
Overall Advice

“...AMCs need to move quickly in the areas where they do have differentiated core competencies, differentiated core assets, and more control. The only way to avoid disruption will be if the AMC leaders pro-actively drive accountability and results throughout their organizations.”

Athena Health 2014 White Paper

Summary

Questions and Answers

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Lynda Hilliard lynda.hilliard@hotmail.com