Compliance 101

SCCE
Compliance & Ethics Institute
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Objectives

- Understand the factors to consider when developing and implementing a compliance program
- Understand the elements of an effective compliance program
- Identify some of the keys to maintaining an effective compliance program
- Introduction of techniques used to assess risk, audit and monitor vulnerabilities, develop work plans and corrective actions, and establish program metrics.
The Rules/Values Dichotomy

- Everyone agrees that rules are important/necessary
- Many ethics programs are oriented around compliance – rules/regulations/laws/policies. They are really (and understandably) compliance programs
- And even the least rule-bound accept the “Thomas Moore argument”:

  “And when the last law was down, and the devil turned round on you – where would you hide…the laws all being flat?”

  (Robert Bolt, A Man for All Seasons)

- Rules establish common understanding of accepted behavior within a social group (country, state, city, company, agency)

The Rules/Values Dichotomy

- But there is common agreement within the ethics field that rules are necessary but not sufficient
- The rule based system is predicated on being able to anticipate each situation and match it to a pre-existing paradigm (rule)
- Viewed this way, the rules based system must ultimately break down – it is not possible to anticipate every situation – or to instruct individuals on an almost infinite set of variables
- This is where value based systems enter
The Rules/Values dichotomy

- Rules based systems are at best reactive – they are aimed at preventing a recurrence of a problem
- Values based systems are intrinsically pro-active – they attempt to equip employees to identify and deal with ethical situations
- For better or worse, we tend to label these systems
  - Rules based systems are “compliance”
  - Values or principles based systems are “ethics”
- In reality organizational ethics must be both
  - Principles-based behavior
  - Rule-based behavior

Some history: Consider the Woolf Committee report

- Concern over business ethics is not new and formal consideration can be traced back to 19th century and the industrial revolution
  - Company founders drew upon their beliefs and social values to guide their approach to business, especially in relation to their employees
  - As businesses recognized as leaders continued to prosper over time, it became increasingly recognized that this was because of, rather than despite, their ethical standards.
- Today stakeholder groups have high expectations of how an organization conducts business
  - Failing to live-up to these expectations can have an impact on the company’s “license to operate”; or
  - the degree of regulation or legislation required. These external standards have become drivers

What conclusion can we draw from these observations? We have moved from internally motivated, values driven cultures to externally controlled, compliance driven programs.
Where are you going?

- Understand where you are going, what do you need to get there, ensure management support and buy-in
- A well planned path is a key to arriving at your intended destination.

What is a Compliance Program?

- Systematic, on-going process aimed at ensuring the organization and its employees comply with applicable laws and regulations
  - Prevention
  - Detection
  - Enforcement
  - Collaboration
What laws?
- Laws prohibiting the submission of false claims;
- Laws prohibiting payments of kickbacks or other payments to induce referrals;
- Laws designed to restrict referrals by a physician or provider to an entity with whom the physician has a financial relationship;
- Laws protecting the privacy and security of health information;
- Export Control laws;
- OSHA and Environmental regulations

Factors to consider
- The regulatory environment is exceedingly complex
- Many laws and rules governing the conduct of heavily regulated entities prohibit conduct which is perfectly acceptable in other settings
- Severe penalties could apply even without any intent to violate the law
- A compliance program is judged by its substance, rather than form
Benefits of a Compliance program

- Safeguards the organization’s legal responsibility to abide by applicable laws and regulations
- Demonstrates to employees and the community the organization’s commitment to good corporate conduct
- Identify and prevent criminal and unethical conduct
- Improve the quality of work

Benefits of a Compliance program (cont.)

- Create a centralized source of information on regulations
- Develop a methodology that encourage employees to report potential problems
- 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.
The Seven Essential Elements

- Policies and procedures, including written standards of conduct
- High level responsibility
- Effective education and training
- Monitoring and auditing
- Reporting process
- Enforcement and discipline
- Response and prevention

We start with a little discussion....

So, why have a code of conduct at all?
Is it necessary?
What purpose does it serve?
Woolf Committee Report: Codes of Conduct

- Express ethical values as an integral part of the company’s core business
- Clearly set the standards of behavior required at every level in the company and of others associated with the company
- Emphasize the positive commercial benefits of high ethical business conduct
- Give a warning to expect disciplinary action if there are breaches of the requirements and a commitment to follow this through
- Use clear and simple non-legalistic language
  - examples of ethical dilemmas
  - key questions to ask
  - where to go for further advice and guidance

Woolf Committee Report: Codes of Conduct

- Include an explanation of how the ethics policies are implemented and embedded into business practice and the organizational culture and how implementation of the policies will be monitored and audited and publicly reported;
- Should be a living document, reviewed regularly with a mechanism for employees to submit their views and suggestions
What are the challenges?

- Tone
- Cultural geographic differences
- Regulatory differences
- Implications of infrastructure
- Language (translation) issues
- Employee acceptance/skepticism outside US
- Cultural myths

Standards/Policies

- Code of Conduct
  - Demonstrates emphasis on compliance with all applicable laws and regulations
  - Pertains to all employees and representatives of the organization
  - Present specific guidelines for employees to follow
  - Provides a process for proper decision-making
  - Ensures all employees understand what is expected of them
Standards/Policies

- Code of Conduct – Best practice
  - Written plainly and concisely so all employees can understand
  - Translate into other languages, as appropriate
  - Is consistent with organization’s policies and procedures
  - Document employee has read and understands the standards
  - Train supervisors to answer questions about the standards
  - Compliance with the standards is an element of every employee performance evaluation

Standards/Policies

- Compliance Policies
  - Address identified risk areas
    - Non-retaliation
    - Internal assessment
    - Record retention
    - Self-disclosure
    - Relationship with referral sources
    - Conflict of interest disclosure
    - Documentation requirements
High Level Responsibility

- **Compliance Officer**
  - Adequate resources and appropriate authority
  - Direct access to the governing authority
  - Size and setting of the organization may influence reporting structure and duties
  - Is an oversight function – accountability rests with business owners

- **Compliance Committee**
  - Advise the compliance officer and assist in the implementation of the compliance program

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Chief Compliance Officer

- **Responsibility includes oversight of:**
  - Implementation and development of strategy of the compliance program
  - Reporting, on a regular basis, to the CEO and governing body
  - Revising the compliance program periodically as appropriate
  - Developing, coordinating, and participating in education and training programs
  - Ensuring that independent contractors and agents are aware of the organizations compliance program requirements
  - Ensuring processes in place for background checks
  - Assisting with internal compliance review and monitoring activities
  - Independently investigating and acting on matters related to compliance
SCCE Code of Ethics Compliance & Ethics Professionals

- **Principle I: Obligation to the Public** – Compliance and ethics professionals should embrace the spirit and the letter of the law governing their employing organization’s conduct and exemplify the highest ethical standards in their conduct in order to contribute to the public good.

- **Principle II: Obligations to the Employing Organization** – Compliance and ethics professionals should serve their employing organizations with the highest sense of integrity, exercise unprejudiced and unbiased judgment on their behalf, and promote effective compliance programs.

- **Principle III: Obligation to the Profession** – Compliance and ethics professionals should strive, through their actions, to uphold the integrity and dignity of the profession, to advance the effectiveness of compliance programs and to promote professionalism in compliance and ethics.

Compliance Committee

- **Role:**
  - Oversight role where escalated issues are reviewed

- **Composition:**
  - Operations
  - Finance
  - Human Resources
  - Audit
  - Legal
  - IT
Education

- General Compliance Education
  - Laws and regulations guiding all compliance activity
  - Organization compliance philosophy
  - Compliance communication within and outside the organization
- High-risk areas
  - OIG Work Plan
  - Industry Guidance and Internal Risks
- Best Practices
  - Vary deployment techniques (Web-based, Lecture, Self-learning)
  - Obtain employee acknowledgement of training
  - On-going review and refresh

Monitoring and Auditing

- One of the seven elements of a comprehensive compliance program
- Assists organizations in determining their strengths / weaknesses / risks
  - Can also assist in determining whether the appropriate resources are in place throughout the organization
- Provides ongoing assurance to management that high-risk areas are operating in accordance with organizational policies and procedures
  - Or...highlights the areas that are not
- Can demonstrate compliance program effectiveness
Selecting Compliance Monitors or Audits

- Monitoring vs. Auditing
- Utilizing a risk-based approach
  - Organization-wide risk assessment
  - Specific risk areas
  - Ongoing significant risk areas
- Consider approach based on an annual planning process
- Address risks related to new or revised regulatory requirements
- As part of the determination of compliance program effectiveness, perform a compliance audit of whether the seven elements have been met / exceeded
- Determine whether the issue should be “monitored” or “audited”

Compliance Auditing Resources

- Internal vs. external resources
- Compliance auditors should have a minimum level of technical competence related to area of audit
  - Qualified in business area auditing
  - CPAs
  - JDs
- Ongoing training and education should be mandatory
  - On-the-job training can be invaluable
- Internal Audit and the Compliance function
- S.W.A.T. team to respond to urgent situations
- Engaging outside specialists when necessary
  - Conducting compliance audit under attorney-client privilege
Operationalizing the Findings

- Monitoring results and audit report findings should be shared with all interested/affected parties with the goal of improving future performance and eliminating compliance exposures.
- Ownership of compliance issues needs to be determined
  - Team leader identified to implement recommendations
- Time frame for implementation should be agreed to
- Team leader charged to implement recommendations
  - Champion identified for support
- Follow-up meeting should be scheduled for status update
- Follow-up audit or limited review should be performed to determine whether findings and recommendations were effectively implemented
- Can reflect on compliance program effectiveness

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Reporting

- **Who Needs to Know?**
  - Employee’s Role in Compliance
  - Management’s Role in Compliance
  - Board’s Role in Compliance
  - Government’s Role in Compliance
    - CMS Pilot Project on Measuring Effectiveness
- **Hotline Reporting**
  - Electronic tracking of investigations and results
  - Confidentiality/Anonymity
  - Non-Retaliation
- **Exit Interviews**
  - Identifying potential areas of concern
HelpLine Program

- 24/7/365 “live” telephonic coverage for incoming calls from any employee. Translation services available on demand
- 24/7/365 web report access available to any employee with access to an Internet café
- All call reports disseminated to Ethics Office for review, triage, and delegation to appropriate internal/external resource for fact finding and resolution
- Case management system, with access privileges controlled by Ethics office
- Capacity to track both requests for ethics advice as well as allegations of unethical behavior or misconduct
- Anonymous or confidential reports accepted
- Internal review of case matters (“one over one” review) prior to closure
- Statistics reviewed by Oversight Committee for trends and concerns; reported regularly to Board of Directors

Enforcement and Discipline

- Sanctions for non-compliant behaviors
- Consistency
- Credentialing/Licensing Sanctions
- Incentives
Response and Prevention

- Action Plans
- Key Compliance Indicators
  - Risk Assessment
  - Moving from a reactive to a proactive program
- Internal Investigations
  - Effectively and timely
- Role of Legal Counsel
- Document, Document, Document

Planning and Conducting Investigations

- Ethics Issues & Your Role
- Standards of Proof
- Meeting the Reporter v. Anonymous Complaint
- Planning and Carrying Out an Effective Investigation
- Interviewing
- Documentation & Drawing Conclusions
- Making a Recommendation
- Other Considerations
- Group Activity
1. Ethics Issues & Your Role

What is an Ethics issue?

ANYTHING

Are Ethics Officers responsible for resolving all Ethics issues?

NO

2. Standards of Proof

What is the standard applicable to internal investigations?

- Beyond a reasonable doubt
- Clear and convincing evidence
- Preponderance of the evidence
- Good faith investigation/Reasonable conclusion
3. Meeting the Reporter v. Anonymous Complaint

What is the purpose of the initial meeting with the Reporter?

- Identify all of the issues
- Gather all material facts from Reporter
- Determine if a formal investigation is needed
- Instill confidence in the system and you

3. Meeting the Reporter

Do you need additional facts to resolve the Reporter’s issue?

**NO**

*No Formal Investigation Required*

1. Provide advice/guidance or
2. Seek assistance from Sector Director and then respond to Reporter

**YES**

*Formal Investigation Required*

1. Begin planning with Sector Director
2. Formulate Strategy
3. Meeting the Reporter

What happens if you hear…?

Now that we’ve talked, I don’t know if you are the right person to handle this issue. Only a Hispanic woman can understand the kind of treatment I’m faced with on a daily basis in this company….

Ask: Is there any reason why you feel I cannot be fair and objective?

3. Meeting the Reporter

The Confirmation Memo:

- Identify (confirm) issues
- Identify facts provided by Reporter
- Confirm there are no additional issues
- Identify investigator and confirm her impartiality/fairness
- Identify roadmap for investigation
- Affirm expectations– this is what we’ll do for you
4. Planning and Carrying Out an Effective Investigation

5. Interviewing: Opening & Closing Statements
   You need standard opening and closing remarks
5. Interviewing: Types of witnesses

What different types of witnesses might you encounter?

- The Non-Cooperative
- The Limelight Seeker
- The Ax-to-Grinder

5. Interviewing: Effective Questioning

Does anyone know what this is?
5. Interviewing: After Questioning

What is the most important thing to do when interviewing any witness?

5. Interviewing: Accused & Witnesses

Some things you should know about interviewing:

Investigation Notes
- Fact #1: Blah, blah, blah
- Fact #2: Blah, blah, blah
- Fact #3: Blah, blah, blah
5. Interviewing: Accused & Witnesses

The accused:

Hey Buddy! I didn't do it!
If the glove does not fit you must acquit.

What if the Accused denies wrongdoing?

Hey Buddy! I didn't do it!
If the glove does not fit you must acquit.
5. Interviewing: Accused & Witnesses

Do you have any ideas why she would make up something like this? No, I sure don't.

Have you had any conflicts or problems with this person in the past? Well, there was that incident a few weeks ago....
5. Interviewing: Accused & Witnesses

Thank you for your time. I'll need to gather some more facts from her.

You're welcome. I just want to help straighten this whole thing out!

Gee, that Ethics Officer was a really nice individual. I'll tell my friends that they should speak up when they face a problem!
5. Interviewing: Assessing Credibility

Who do you trust?

Anyone who considers protocol unimportant has never dealt with a cat.

Unfortunately there is a protocol to an investigation (or any inquiry) and that means (Yuck!) documentation. Document quickly -- as nearly contemporaneously as possible. Take notes and review them before you forget what they meant!
These aren’t my thoughts on the subject – they’re my cat walking on the keyboard!

Document clearly. Don’t assume something, ask the question. If something is an assumption on your part, record it that way.

And for heaven’s sake, write clearly! Remember, other people will have to read and understand what you wrote. Eloquence is not your goal – clarity is.

6. Documentation & Drawing
Conclusions

What are some considerations after all of the facts are gathered?

- Timeliness
- Truthfulness
- Pattern & Practice
  - Don’t be afraid to make mistakes!
  - Motivation
7. Making a Recommendation

What are the choices?

3.1 Progressive discipline: A process for addressing behavior that does not meet expected and communicated standards. This process is established to alert an employee to a perceived conduct problem and to provide an opportunity for improvement. The goal of progressive discipline is to alert the employee of the need to correct specific behavior.

Verbal Warning • Suspension
Written Warning • Termination

Are there any other options to consider to meet the goal of the policy?

8. Other Considerations: Document Retention

Scan
Upload to GCS
Shred

Investigation Notes
8. Other Considerations: Retaliation

Any retaliation or reprisals against participants in an investigation will not be tolerated and is subject to discipline, up to and including termination. Any individual who intentionally misdirects an investigation, whether by falsehood or omission, will be subject to the discipline up to and including termination.

8. Other Considerations: Privilege vs. Work Product

### Attorney-Client Privilege
- Protects confidential communications between attorney & client where legal advice is being sought or provided
- Protects Ethics Investigation communications if EO seeks legal advice from BAE attorney
- Mark items ‘privileged’ only when they potentially are privileged
- “Privileged & Confidential Attorney-Client Communication”

### Attorney Work Product
- Protects materials prepared in anticipation of litigation
- Protects Ethics Investigation documents if EO’s primary motivation for creating the doc is because there is a prospect of litigation
- Mark items ‘attorney work product’ only when they potentially are privileged
- “Attorney Work Product”

Do not mark items when there is no legitimate privilege claim as this is misleading and waters down the claim for truly privileged documents.
Risk Assessment

- Eighth element of an effective compliance program
- Government guidance
  - Federal Sentencing Guidelines
    - “Organizations shall periodically assess the risk of criminal conduct and shall take appropriate steps…”

Why Conduct a Risk Assessment

- Proactive versus reactive
- Supports enterprise risk management
- Cultural integration
- Raises awareness of program value
- Mitigation of penalties
- Continuous program improvement
- Basis for annual work plan
- Identifies needed resources
The risk assessment process

Risk Identification

- Surveys
- Interviews
- Prior audit findings
- Prior compliance investigations
- Exit Interviews with separating employees
- External sources
Risk Tolerance

- Continuum ranging from total avoidance of risk to total acceptance
- Tied to mission and organizational governance and leadership
- Understand that you probably can not address all risks identified
Risk Mitigation

- Identifying and prioritizing risks creates risk if nothing will be done with the information
- Audits are not corrective action!
- Develop work plan – monitor effectiveness of plan
- Understand the root cause
- Resources available

Work Plan Development

- Involve stakeholders
- Communicate
- Monitoring and ongoing periodic assessment
- Re-evaluate and reprioritize at next risk assessment
Effectiveness Evaluation

- Why measure effectiveness?
  - US Sentencing Guidelines
  - American Health Lawyers Association and OIG Resource documents
  - Corporate Integrity Agreements/Settlement Agreements

Effectiveness Evaluations

- What do you measure?
  - Seven elements (plus risk assessment)
    - Authority
    - Policy and Procedures (including Standards of Conduct)
    - Training and Education
    - Reporting
    - Auditing and Monitoring
    - Response and Prevention
    - Enforcement
    - Risk Assessment and Work Plan Development
Barriers to Effectiveness

Compliance Officer

- Lack of authority to enforce standards, policies and procedures
- Lack of support by Board or Executive Management
- Inadequate skills to perform the essential functions of the job
- Lack of resources or commitment from employer

Barriers to Effectiveness

Code of Conduct / Policies and Procedures

- Well written policies or Code that is not available to workforce
- Well written policies that are not enforced
- A poorly written Code or policies that are out-of-date, are not specific to organization, are inaccurate
Barriers to Effectiveness

Training and Education

- Inaccurate training materials
- Limited access to training
- Poor quality of training (e.g., dull, technical, too long)
- Poor quality of delivery of training (e.g., unqualified trainers, boring narration)
- Limited variation in training

Open lines of Communication

- Lack of culture of openness
- Lack of awareness of mechanisms to report violations
- Lack of anonymous reporting mechanism
- Actual or perceived fear of retaliation
- Limited action on reported issues
Barriers to Effectiveness

Disciplinary Guidelines

- Poorly communicated guidelines
- Preferential or limited enforcement of guidelines
- Lack of progressive discipline

Barriers to Effectiveness

Auditing and Monitoring

- Lack of an auditing and monitoring schedule based on organizational risks
- Limited resources to perform function
- Auditors not trained well
- Lack of independence/objectivity or conflict of interest of the auditors
Barriers to Effectiveness

Responding to Offenses

- Lack of thoroughness of investigations
- Response is not timely
- No corrective action taken
- Limited follow up by compliance program
- Lack of monitoring of corrective actions

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<td>Does the compliance program have a clear, well-crafted mission?</td>
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<td>Does the compliance program have sufficient resources (staff/budget), training, authority and autonomy to carry out its mission?</td>
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<td>Is the relationship between the compliance function and general counsel function appropriate to achieve the purpose of each?</td>
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<td>Is there an active compliance committee, comprised of trained representatives of each relevant function department as well as senior management?</td>
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<td>Are ad hoc groups or task forces assigned to carry out special missions, such as conducting an investigation or evaluating a proposed enhancement to the compliance program?</td>
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<td>Does the compliance officer have direct access to the governing body, the Director, all senior management, and legal counsel?</td>
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Effectiveness Evaluation

- How do you measure effectiveness?

### Ministry Integrity Dashboard Report

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Other Methods of Measurement

- Employee Surveys
- Interviews or Focus Groups
- Document Reviews
- Benchmarking against providers
- Denial Management
- Existing Measures
- Compliance Training Quizzes
Board Oversight

- Five reasons board members should be concerned:
  - Right thing to do
  - Fiduciary and legal duty
  - Specific reporting requirements
  - State requirements
  - Board members can face personal exposure

Interview Continued

- Board role to be educated
- Board can be held responsible for neglecting their duty of oversight
- The biggest problem with oversight is failing to ask the tough questions, failing to require and review compliance metrics, and failing to require education for the board and senior managers
Closing the Loop

- Communicate findings with governance and key stakeholders
- Communicating status and effectiveness of actions
- Metrics
  - Structure x Process x Outcomes = Effectiveness

Lessons Learned

- Know the resources you have to commit for both the evaluation processes, corrective action, and work plan
- Start small and build
- Continuous effectiveness – are you addressing the most important risks
Lessons Learned

- Planning and developing a road map is the best way of reaching your destination, but anticipate a few obstacles on your path
- Establish and maintain key relationships to help you be successful
- Courage is developed, not innate, and grows based upon the confidence that success brings

Questions?