Compliance 101

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COMPLIANCE VITALS

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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.
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; and
- Laws protecting the privacy and security of health information

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

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: 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

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...
Chief Compliance Officer

- Responsibility (continued):
  - Ensuring that independent contractors and agents are aware of the organization's 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
Chief Compliance Officer

Causes of Burnout
- Isolation
- Fear of losing job
- Fear of what you don’t know
- Long hours
- No appreciation
- Target is always moving

What can you do?
- Define the compliance program scope
- Establish boundaries
  - Availability 24/7
  - Work smarter not harder
  - Lifeguard vs. Cop
- Personal Health
  - Exercise
  - Meditate
  - Network
- Fear vs. Truth
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.

SCCE Code of Ethics
Compliance & Ethics Professionals

- **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

Education

- **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
Operationalizing the Findings

- 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

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
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
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

Board

Communicate

Risk Identification

Evaluates

Monitor

Control Activities

Establish Priorities

Develop Work Plans

Broad Focus on Compliance Risks

Risk Identification

Surveys

Interviews

Prior audit findings

Prior compliance investigations

Exit Interviews with separating employees

External sources
Risk Identification

- Human Resources
- External Audits
- Risk Services
- Admin.
- Finance
- Internal Audits
- Privacy
- Operations

Compliance

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
Effectiveness Evaluation

How do you measure effectiveness?

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

Developing Yourself and Your Team ...

- Let's talk about skillset:
  - Can you own the room?
  - Do you have courage of conviction?
  - Do you have strong communication skills - especially active listening?
  - Can you change language, tone, pitch to suit audience?
  - Can you read people?
- If you don’t have it – then develop it
  - EQ vs IQ
    - Relationships
    - Strategic Thinking
    - Informal Power
    - Poker Face
    - Humility
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
Lessons Learned

- There is always another move ... continue to experiment, network and learn new skills
- Lead with the value proposition to the business
- Compliance program follows the business model ... embrace the complexity

Questions?