Compliance Program Start Up: What are the Basics Needed for your Infrastructure?

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Why are Compliance Programs Important?

- Raise Awareness
- Mitigation Factor
- Communicate Commitment
- Reduce Threat of Qui-Tams (Whistleblower)
- Makes Good Business Sense
- Minimizes impact of CIA

How Comprehensive Should a Compliance Program Be?

- Medicare Billing Compliance
- Medicaid
- Third Party Payors
- Employment/Labor Law
- Therapy Centers
- Safety
- EMTALA (Emergency Medical Treatment & Active Labor Act)
- HIPAA Privacy & Security
- Research
- Stark
- Anti-kickback
- Sarbanes-Oxley
- Quality
- Accreditation
- Other Federal &/or State Laws

OIG Guidance

- Voluntary Disclosure
- Hospital & Supplement
- Laboratory
- Home Health
- Third Party Billing
- DME
- Hospice
- Medicare + Choice
- Nursing Facilities & Supplement
- Ambulance
- Pharma
- Research (draft)
- Physician Practice

Compliance Program Development

What are the top 3 obstacles to Effective Compliance Program Implementation?

What is a Compliance Program

A program which:

- Utilizes tools to prevent and/or detect violations of law or policy
- Defines expectation for employees for ethical and proper behaviors when conducting business
- Demonstrates the organization's commitment to "doing the right thing"
- Encourages problems to be reported
- Provides a mechanism for constant monitoring
- Promotes an ethical culture

Untied States Sentencing Guidelines

- 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”

Untied States Sentencing Guidelines

Determining Culpability Score – 8C2.5

BASE OFFENSE LEVEL 5 points

Credit and or points added (+/-) to sentencing for:

Involvement, prior history, violation of an order, obstruction of justice, self-reporting, cooperation and acceptance of responsibility AND

Effective Program to Prevent and Detect Violations of the Law -3 points

Nov 2004: FSG Amendment 673*

- Expressly joined Ethics and Compliance functions, emphasizing importance of Organizational Culture
- Emphasized importance of Risk Assessments
- Established express Governing Authority Responsibilities
- Strengthened all program elements

*A Basic Introduction to the Organizational Guidelines: Annual National Seminar, New Orleans, LA, September 18, 2015

Nov. 2010: FSG Amendment 744

- 1st: the organization must respond appropriately to the criminal conduct, including restitution to the victims, self-reporting and cooperation with authorities.
- 2nd: the organization must assess its program and modify it to make the program more effective. They seem to encourage the use of an independent monitor to ensure implementation of the changes.

Nov. 2010: FSG Amendment 744

You can get credit for having an effective 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.

Organizations Steps to an Effective Compliance Program

Organizational Relationships and Support

- Board
- Senior Leadership
- Management
- Providers
- Staff
- Budget

Seven Essential Elements of a Compliance Program

"The Seven Elements of a compliance program are important individually, but are most effective on an interdependent basis." CMS

Seven Elements of an Effective Compliance Program

1. Standards and Procedures
2. Education and Training
3. Oversight
4. Monitoring and Auditing
5. Reporting
6. Enforcement and Discipline
7. Response and Prevention

Risk Assessment and Effectiveness Assessments are not considered part of the elements for FSG but are critical to a program's success

Standards and Procedures

- Code of Conduct
  - Simple, short and separate from policies and procedures
  - Provide to all new employees, staff and vendors and during annual compliance training
  - Outline employee expectations in 'plain' English
  - Post prominently – posters and/or intranet
  - Use of attestations
  - Consider putting code in other languages

Standards and Procedures

- Policies and Procedures
  - Assure that you are not writing policies that should be in the management arena
  - Senior leadership endorsed/approved including Board
  - Follow institutional template
  - Periodically reviewed and revised
  - Responsible party is defined. COMPLIANCE DOES NOT OWN ALL POLICIES
  - Education is provided to all affected staff
  - Ongoing evaluation/revision
  - Do not duplicate what might be already in place

Oversight (Authority and Resources)

- Board's Role
- Governing Board Committee, ie: Audit and Finance, Compliance and Audit (whatever is appropriate title)
- Compliance Officer
- Compliance Committee
- Other Committees
- Distributed Compliance Positions
- Subject Matter Experts

OIG: Practical Guidance for Health Care Governing Boards on Compliance Oversight

- **The Compliance Function** – prevention, detection, and assuring resolution of actions.
- **The Legal Function** – advises the organization on legal and regulatory risks, defends the organization.
- **The Internal Audit Function** – provides an objective evaluation through the existing risk and internal controls and framework.
- **The HR function** – manages recruiting, screening, and hiring, provides training and development.
- **Quality Improvement** – promotes consistent, safe, and high quality practices.

Education and Training

- Role of Compliance Officer in developing
- Specific to roles and responsibilities
- Use training to focus on key risk areas
- Mandatory vs. Voluntary
- General annual education
- Focused/specific education
- Physician training most effective with timely, personal approach
- Essential to reinforcing importance of your compliance program

Group Discussion

- Describe what is currently being done in your organization related to Oversight, Reporting Structure, Structure for Compliance Program and Education and Training.
- Identify 3 practices from the discussion which you thought would be good ideas for implementation and report these back to the session participants.

Monitoring and Auditing

- Define for your institution the difference between auditing and monitoring
- Leverage existing resources on auditing and monitoring activities
- Annual Plan is developed from a risk assessment and includes reviewing previous audits, monitors and other pertinent internal and external information
- Addition of “ad hoc” projects
- Concurrent vs. Retrospective
- Sharing results across the organization

Group Discussion

- Discuss your risk assessment process.
- Discuss how your risk assessment process helps identify auditing and monitoring plan.
- Discuss budget you have specifically for this process.

Reporting and Investigation

Mechanism to report matters anonymously, ie: hotline

- Internal vs. external
- Caller knows how to receive updates and information related to their matter
- Tracking of investigations and results
- Reporting to leadership
- Non-retaliation and participation in investigation policies
- Confidentiality and Anonymity
- Use of performance reviews and exit interviews for identifying potential areas of concern

Reporting and Investigation (cont)

- Process for triaging investigations should be defined
- Considerations for attorney client privilege should be given to high risk and/or sensitive matters
- Team to conduct investigations should be defined
- Investigators should be trained in procedures related to interviews, objective methodologies and forensics, where applicable
- Investigations are confidential
- Tracking of investigations and results
- Reporting to leadership

Response and Prevention

- Internal Investigation
  - Are their enough facts to investigate?
  - Consider "fact finding" as a first step before deciding to investigate
- Consult appropriate area for potential methodologies, ie: audit, legal, etc.
- Contact Legal Counsel if fact finding warrants advice and/or privilege

Considerations:

- Who will conduct interviews?
- Discovery possibilities
- Determine from facts as to substantiation of allegations
- Monitor management's actions to resolve issue
- Possible follow up audit
- Document retention/destruction policy

Group Discussion

- How do you decide when an investigation should be done?
- Who conducts the investigation.
- Share 3 practices with the session participants on ideas to implement at your home organization.

Enforcement and Discipline

- Sanctions for non-compliant behaviors
- Fair and Consistent
- OIG Sanctions
- SAM/GSA Sanctions
- SDN Sanctions
- Incentives

Attorney Client Privilege

- Protect process and initial data gathering
- Provides for internal assessment before determining actions
- "Waiver of the privilege for the government acts as a waiver for all purposes"

Evaluating for Success

- Annual review of written program
- Continual review of policies and procedures
  - Are policies being followed?
  - Revisions necessary?
  - Awareness
  - Who is responsible?
- On-going risk assessment
- Effectiveness assessment

Key Points for a Compliance Officer to Remember

1. It is important that the program be scalable to the resources available to your organization
2. Risk Assessments are your "help" in identifying the organization's vulnerabilities and prioritizing them.
3. The program will be in evolution from day 1 so each key element of the program will mature based on the time, skill and effort given as you go.
4. Rome was not built in one day…compliance programs are also not built in one day.
5. Build your framework and design, before responding to issues (which incidentally were probably around long before you were).
6. DON'T DO THIS ALONE. Find an organization champion to be the management voice to support your efforts.
7. Network for "sanity"….Identify peers in the profession who can be safe and independent sounding boards for you.

In summary….

- Independence for the Compliance Officer Role is critical to the success of the role.
- Current models of compliance programs vary but regardless of design, it is important that you have a direct reporting structure to the governing board and/or CEO.
- The Federal Sentencing Guidelines and the 7 elements are a good start for developing compliance programs. However, it is important to conduct a risk assessment which is the basis for your focus within each of the elements, ie: education and training, auditing and monitoring
- Measures for success for the new compliance program in the first 2 years are mainly related to your process and design…is it working as it should be. As the program evolves, outcome measurements will be able to be obtained.

Questions