

---

# Compliance 101

Debbie Troklus, CHC, CCEP  
AVP Health Affairs/Compliance Officer,  
University of Louisville Health Sciences  
Center

---

---

# Why Compliance Programs Are Essential

- Raise Awareness
- Reduce Risk of Probation and Court-Imposed Programs
- Communicate Organization's Commitment
- Avoid CIA
- Reduce Risk of Exclusion
- Reduce Threat of Qui-Tams
- Public Image

---

# Compliance Programs

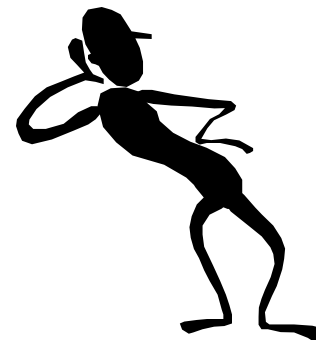
## How Comprehensive Should They Be?

- Billing Compliance (Medicare vs. All Payers)
- Employment/Labor Law
- EMTALA
- Stark
- HIPAA
- Research
- Other Federal &/or State Laws

---

# How to Prevent Qui Tam Suits

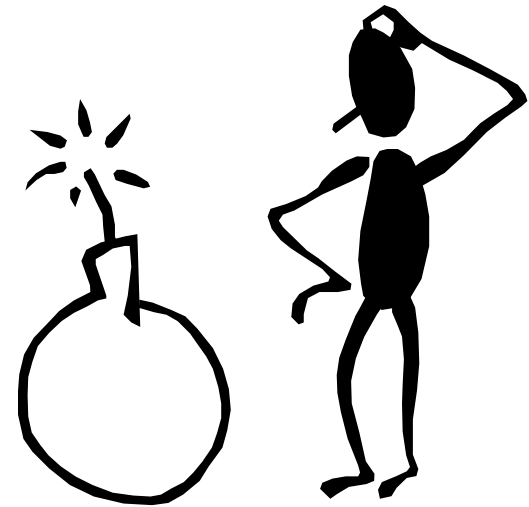
- Create an atmosphere that encourages compliance
- Set up a hotline
- Listen to employees
- Treat each potential issue seriously



---

# A Compliance Program Provides:

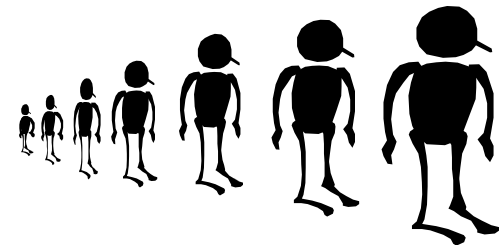
- Education
- Prevention
- Early Detection
- Collaboration
- Enforcement



---

# What Is a Compliance Program?

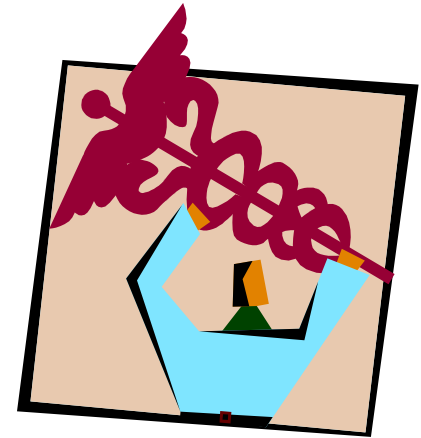
- Recommended by the Government
- Ethical and proper way to do business
- Commitment
- Encourage problems to be reported
- A process with constant monitoring
- A process which prevents, detects or deters non-compliant behavior



---

# Who Needs a Compliance Program?

- Physician Practices
- Hospitals
- Laboratories
- Teaching Institutions
- DME Distributors
- Home Health Agencies/ Hospices
- Others



---

# Basis for all Compliance Programs

- Federal Sentencing Guidelines
  - Amended in Nov. 2004 (chapter 8)
- Applicable to all industries
- 7 elements of an effective program
  1. Oversight
  2. Policies and Standards
  3. Communication and Reporting
  4. Education and Training
  5. Monitoring and Auditing
  6. Enforcement, Discipline and Incentives
  7. Investigation, Response and Prevention

---

# **Organizational Steps to an Effective Compliance Program**

---

# Gain Support / Commitment

- Board
- Management
- Providers
- Staff
- Critical to the effectiveness of the Compliance Program

---

# Financial Support

- Development/Start-up
- Educational Materials
- Staffing
- Ongoing Operations

---

# Develop Code of Conduct

- Organizations ethical attitude
- Address weak areas
- Letter of endorsement
- Chain of command
- Keep it simple

---

# Identify Staffing Needs

- Appoint compliance officer
- Develop job descriptions for staff
  - Auditors, educators, analysts, etc.
  - Supply vs. demand
- Oversight Committee
- Counsel

---

# Conduct Internal Assessment

- What is an assessment?
  - (employee interviews/Focus groups)
- Employee interviews
- Identify risk areas
  - What is currently occurring?
  - Who is responsible?
  - What is the information flow?
  - What are areas for concern?
- Prioritize Risks



---

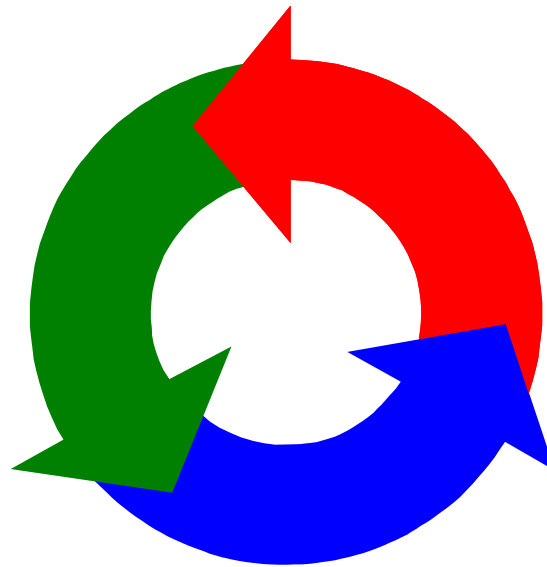
# Develop Mission and Goals

- Achievable
- Measurable
- Communicate



---

# Continuous Improvement



---

# Seven Essential Elements of a Compliance Plan

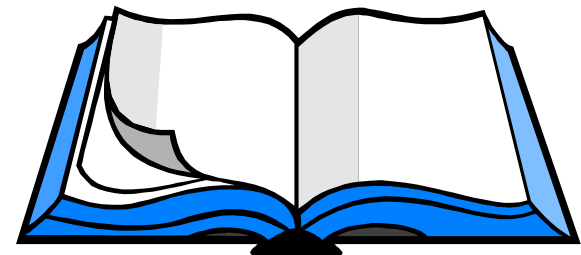
- Standards and Procedures
- Oversight
- Education and Training
- Monitoring and Auditing
- Reporting
- Enforcement and Discipline
- Response, Prevention & Incentives
- (Risk Assessment)



---

# Standards and Procedures

- Code of Conduct
  - Keep It Simple
  - Outline specific legal duty
  - Attestation
- Policies and Procedures
- Continuous Evaluation



---

# Compliance Oversight (Appropriate Authority and Resources)

- Board
- Compliance Officer
- Oversight Committee
- Other Committees
- Field Compliance Positions
- Subject Matter Experts
- Management



---

# Management Responsibilities

- Communication About
  - ❑ Ethics and compliance as a part of each employee's job description
  - ❑ Specific department compliance risk areas
  - ❑ Specific regulatory requirements for each employee's job responsibilities, including quality of care
  - ❑ Following the rules as a condition of employment

---

# Management Responsibilities

- Create an environment (culture) which:
  - Encourages open discussion of errors and concerns raised by employees
  - Allows for prompt reporting of compliance concerns
- Design systems and processes that:
  - Ensures compliance
  - Contains adequate controls
  - Are supported by detailed policies and procedures

---

# Accountability

- Directors and Managers are accountable for:
  - ❑ Failure to detect and report issues of non-compliance
  - ❑ Any retaliation or retribution against individuals who report compliance concerns
  - ❑ Compliance as an element of their performance evaluations
  - ❑ Conducting exit interviews

---

# Management Skills vs. Compliance

## ■ Compliance

- ❑ Risk Identification
- ❑ Education
- ❑ Communication
- ❑ Policies and Procedures
- ❑ Monitoring and Auditing
- ❑ Prevention
- ❑ Early Detection
- ❑ Reporting

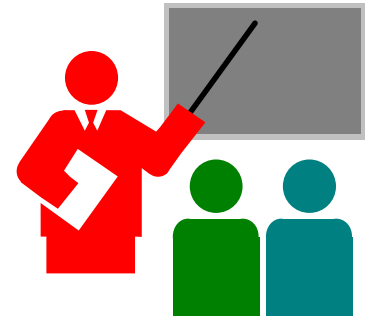
## ■ Management

- ❑ Oral and Written Communication
- ❑ Managing Employees
- ❑ Sound Decision Making
- ❑ Organizing, Coordinating and Planning Activities
- ❑ Critical Thinking
- ❑ Financial Management

---

# Education and Training

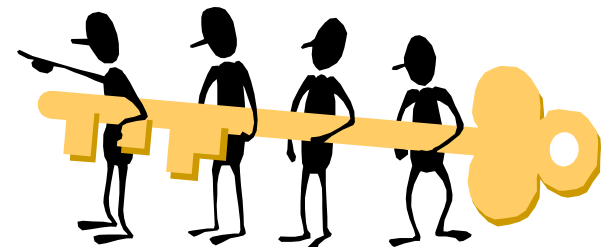
- Communication Process
- Internal vs. External
- Mandatory vs. Voluntary
- General vs. Specific
- Method for Training
- Sanctions
- Attestations



---

# Monitoring and Auditing

- Evaluate Program Effectiveness
- Audit Plan and Methodology
- Internal “Audits”
- Compliance “Reviews”
- Outline Audit Procedures
- Staff Training
- Results Reporting



---

# Monitoring and Auditing

- Auditing is...
  - Independent, objective look at an area for the purposes of reporting factual results
  
- Monitoring is...
  - Day to day look at an area for the purposes of “self” reviewing and assuring processes, systems, etc. are on track and compliant. Monitoring is not usually independent and can be subjective (due to the nature of looking at your own area with your own resources)

---

# Reporting and Investigation

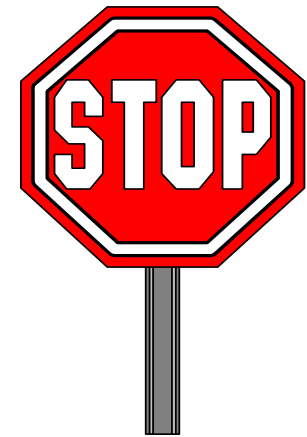
- Anonymous
- Triaging and handling investigations from concerns
- Hotline
  - Policies and Procedures
  - Internal vs. External
- No Retribution for Reporting
  - Privacy and confidentiality



---

# Enforcement and Discipline

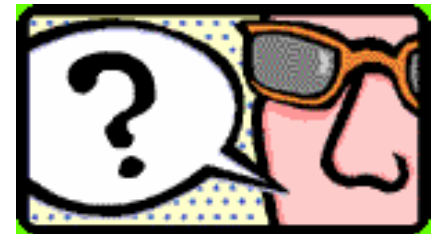
- Appropriate and Consistent Responses
- Sanctions for non-compliant behavior
- Stand firm
- Background Checks (OIG, GSA and others)
- Incentives



---

# Response and Prevention

- Internal Investigation
  - Is it really a problem?
  - How serious is it?
  - Are there enough facts to investigate?
  - What are the areas for concern?
- Contact Counsel
- Interview
- Create Policy



---

# Government Released Programs

[www.dhhs.gov/oig](http://www.dhhs.gov/oig)

Laboratory

Home Health

Hospice

Medicare + Choice

Physician Offices

Third Party Billing

Hospital

DME

Nursing Facilities

Pharma

Ambulance

---

## Health Care Fraud Efforts Continue

- Enforcement environment -- heightened scrutiny
- Enforcement activity – Recoveries
- Enforcement weapons

---

# Questions?????

---