Compliance 101

Debbie Troklus, CHC-F, CHRC, CCEP-F, CHPC
Managing Director, Aegis Compliance & Ethics Center
Steven Ortquist, CHC-F, CCEP
Sutter Health

HCCA
HEALTH CARE
COMPLIANCE
ASSOCIATION

www.hcca-info.org | 888-580-8373

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

HCCA
HEALTH CARE
COMPLIANCE
ASSOCIATION   *www.hcca-info.org | 888-580-8373*   *2*

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

HCCA
HEALTH CARE
COMPLIANCE
ASSOCIATION

www.hcca-info.org | 888-580-8373

3

OIG Guidance

- Voluntary Disclosure
- Hospital
- Laboratory
- Home Health
- Third Party Billing
- DME
- Hospice

- Medicare + Choice
- Nursing Facilities
- Ambulance
- Pharma
- Hospital Supplemental
- Research (draft)

HCCA
HEALTH CARE
COMPLIANCE
ASSOCIATION

www.hcca-info.org | 888-580-8373

4

Compliance Program Development

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

What is a Compliance Program

- An effective program that prevents and detects 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
- Recommended by government

Who Needs a Compliance Program?

You do!

HCCA
HEALTH CARE
COMPLIANCE
ASSOCIATION

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"

HCCA
HEALTH CARE
COMPLIANCE
ASSOCIATION

Nov 2004: FSG Revisions

- "culture" of compliance

- defining compliance standards & procedures

- spelling out compliance obligations

- adequate resources

- clarifying employee screening practices

Recommendations, cont.

- Training an essential element

- Mandating means for anonymous reporting

- add, "specifically encourage prevention and deterrence of violations of the law as part of compliance programs"

- "ongoing risk assessments" if credit expected

Nov. 2010: FSG Revisions

- 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 Revisions

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

HCCA
HEALTH CARE
COMPLIANCE
ASSOCIATION   *www.hcca-info.org | 888-580-8373*

Organizational Relationships and Support

- Board

- Senior Leadership

- Management

- Providers

- Staff

- Finance and Budget

HCCA
HEALTH CARE
COMPLIANCE   *www.hcca-info.org | 888-580-8373*   *14*
ASSOCIATION

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

- Standards and Procedures
- Education and Training
- Oversight
- Monitoring and Auditing
- Reporting
- Enforcement and Discipline
- Response and Prevention

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 specific legal duty
  - Post prominently – posters and/or intranet
  - Use of attestations
  - Consider putting code in other languages

Standards and Procedures

- Policies and Procedures
  - Senior leadership endorsed/approved including Board
  - Follow institutional template
  - Periodically reviewed and revised
  - Responsible party is defined
  - 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
- Audit and Compliance Committee
- Compliance Officer
- Compliance Committee
- Other Committees
- Distributed Compliance Positions
- Subject Matter Experts

Education and Training

- Role of Compliance Officer in developing
- Specific to roles and responsibilities
- Use training to focus on key risk areas
- Physician training most effective with personal approach
- Essential to reinforcing importance of your compliance program
- Everyone – 1 hour
- High risk areas – 3 hours or more
- Required, ie: Deficit Reduction Act, Federal Acquisition Regulations, etc.

Monitoring and Auditing

- Leverage existing resources on auditing and monitoring activities
- Define for your institution the difference between auditing and monitoring
- 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

HCCA
HEALTH CARE
COMPLIANCE
ASSOCIATION

www.hcca-info.org | 888-580-8373

21

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
- Electronic tracking of investigations and results
- Reporting to leadership
- Non-retaliation policy
- Confidentiality and Anonymity
- Use of exit interviews for identifying potential areas of concern

HCCA
HEALTH CARE
COMPLIANCE
ASSOCIATION

www.hcca-info.org | 888-580-8373

22

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
- Electronic tracking of investigations and results
- Reporting to leadership

HCCA
HEALTH CARE
COMPLIANCE
ASSOCIATION

www.hcca-info.org | 888-580-8373

23

Enforcement and Discipline

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

HCCA
HEALTH CARE
COMPLIANCE
ASSOCIATION

www.hcca-info.org | 888-580-8373

24

Response and Prevention

- Internal Investigation
  - Is it really a problem?
  - How serious is it?
  - Are their enough facts to investigate?
- Consult Audit
- Contact Legal Counsel

- Interviews and Discovery
- Assess Findings
- Revise/Create Policy/Procedure
- Follow up review

HCCA
HEALTH CARE
COMPLIANCE
ASSOCIATION

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"

HCCA
HEALTH CARE
COMPLIANCE
ASSOCIATION

Would you know what to do if FBI agents knocked on your door at 9:00 PM?

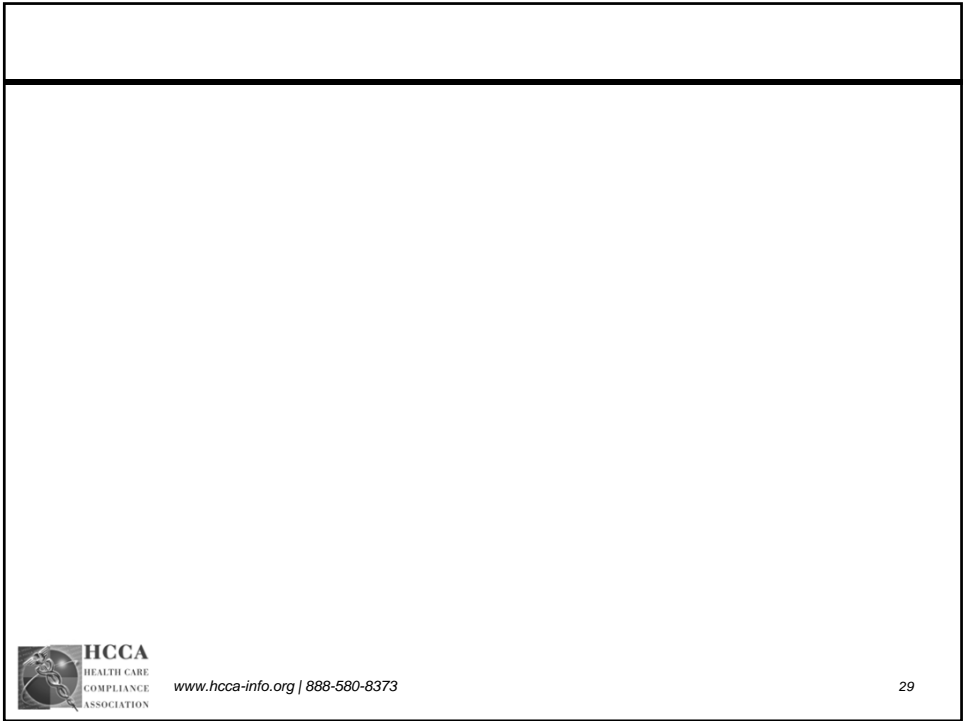## Evaluating for Success

- 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

Compliance Paradigm Shift

rFROMoomFROM	TO
• Ad Hoc	• Planned, Continuous Activity
• Limited/Centralized Oversight	• Oversight by Everyone
• Informal or No Policies/Procedures	• Formal, Written Policies and Procedures
• Inspect, Detect, React	• Anticipate, Prevent, Monitor
• Unknown Risks	• Risk Mitigation and Prevention

Enforcement Fads

- 1970's - Political corruption
- 1980's - Defense fraud
- 1990's - Health care fraud
- 2000's - Corporate governance/accounting fraud

Escaping the Spotlight

- Maintain Commitment

- Be Vigilant in Latest Areas of Enforcement Agency interests

OIG: FY 2011 HHS OIG Semiannual Report

- Accomplishments reported to Congress
  - $5.2B in savings

  - 2,662 exclusions of individuals and entities from participation in Federal health care programs

  - 723 criminal actions

  - 382 civil actions

Questions