

Compliance 101

Debbie Troklus, CHC-F, CHRC, CCEP-F, CHPC,
CCEP-I
Managing Director, Aegis Compliance & Ethics Center
Sheryl Vacca



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



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



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

3

OIG Guidance

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



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

4

Compliance Program Development

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



HCCA
HEALTH CARE
COMPLIANCE
ASSOCIATION

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

5

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



HCCA
HEALTH CARE
COMPLIANCE
ASSOCIATION

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

6

Who Needs a Compliance Program?

You do!



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

7

United 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”



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

8

Nov 2004: FSG Revisions

- “culture” of compliance
- defining compliance standards & procedures
- spelling out compliance obligations
- adequate resources
- clarifying employee screening practices



HCCA
HEALTH CARE
COMPLIANCE
ASSOCIATION

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

9

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



HCCA
HEALTH CARE
COMPLIANCE
ASSOCIATION

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

10

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.



HCCA
HEALTH CARE
COMPLIANCE
ASSOCIATION

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

11

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.



HCCA
HEALTH CARE
COMPLIANCE
ASSOCIATION

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

12

Organizations Steps to an Effective Compliance Program



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

Organizational Relationships and Support

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



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

14

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



HCCA
HEALTH CARE
COMPLIANCE
ASSOCIATION

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

15

Seven Elements of an Effective Compliance Program

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

(Keep in mind that Risk Assessment and Effectiveness Assessments are also important)



HCCA
HEALTH CARE
COMPLIANCE
ASSOCIATION

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

16

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 in 'plain' English
 - Post prominently – posters and/or intranet
 - Use of attestations
 - Consider putting code in other languages



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

17

Standards and Procedures

- Policies and Procedures
 - Assure that you are not writing policies that should be the management arena
 - 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



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

18

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



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

19

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 timely, personal approach
- Essential to reinforcing importance of your compliance program
- Required, ie: Deficit Reduction Act, Federal Acquisition Regulations, etc.



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

20

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



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



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
- Tracking of investigations and results
- Reporting to leadership



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

23

Enforcement and Discipline

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



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

24

Response and Prevention

- Internal Investigation
 - Are there 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



HCCA
HEALTH CARE
COMPLIANCE
ASSOCIATION

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

25

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

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

26

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



HCCA
HEALTH CARE
COMPLIANCE
ASSOCIATION

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

27

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



HCCA
HEALTH CARE
COMPLIANCE
ASSOCIATION

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

28

Compliance Paradigm Shift

rFROM ~~oom~~ FROM

- Ad Hoc. Occasional activity
- Limited/Centralized Oversight
- Informal or No Policies/Procedures
- Inspect, Detect, React
- Unknown Risks

TO

- Planned, Continuous Activity
- Oversight by Everyone
- Formal, Written Policies and Procedures
- Anticipate, Prevent, Monitor
- Risk Mitigation and Prevention



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

29

Enforcement Fads

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



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

30

Escaping the Spotlight

- Maintain Commitment
- Be Vigilant in Latest Areas of Enforcement Agency interests



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

31

OIG: FY 2012 HHS OIG Semiannual Report

- Accomplishments reported to Congress
 - \$8.5 B in savings (2011- \$5.2B in savings)
 - 3,131 exclusions of individuals and entities from participation in Federal health care programs (2011 - 2,662)
 - 723 criminal actions (2011 – 778)
 - 382 civil actions (2011 – 367)



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

32

Questions



HCCA
HEALTH CARE
COMPLIANCE
ASSOCIATION

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

33