



HCCA Audit & Compliance Conference

Fundamentals of Health Care Compliance

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Compliance Programs

- Background
- Regulatory Standards
- Roles & Responsibilities
- Effective Compliance Oversight

Comprehensive Crime Control Act of 1984

- Created United States Sentencing Commission
- Development of Organizational Sentencing Guidelines
 - Corporations
 - Partnerships
 - Labor unions
 - Pension funds
 - Trusts
 - Non-profit entities
 - Governmental units

Background

- Two Key Purposes “just punishment” & “deterrence”
- Incentives offered for organizations to detect and prevent crime
- Culpability score
- Chapter 8 Part B – Remedying Harm from Criminal Conduct and Effective Compliance and Ethics Programs
(Come back to this later)

University of Pennsylvania

- December 12, 1995
- \$30 million clinical practices settlement
- Various claims and allegations under False Claims Act
- Placed hospitals, physicians and other health care providers on notice
- Followed by many other enforcement actions

Fraud Statistics 10/1/86-9/31/05

- New Matters
 - Non qui tam 537
 - Qui tam 2,745
- Settlements & Judgments
 - Non qui tam \$2.526B
 - Qui tam \$6.618B
 - Relator share \$1.091B
 - Total \$9.145B

HIPAA – Health Insurance Portability and Accountability Act

- PL 104-191, effective August 21, 1996
- Improve health insurance coverage and portability
- Reduce administrative costs
- Privacy and security standards

Background



- Reduce fraud
 - Appropriated \$548 M to FBI over 7 years
 - Each year thereafter \$114 M
- Defines “Federal Health Care Offense”
 - Expanded reach of federal enforcement activity to include fraud related to any “health care benefit program”, rather than simply federally funded

Caremark Case

Delaware Chancery Court case in which the court concluded that a director's fiduciary obligation included:

- (1) a good faith effort to assure that an adequate compliance program exists; and
- (2) that information regarding the organization's compliance with laws be brought to the board's attention in a regular and timely manner.

In re: Caremark International Inc. Derivative Litigation. 619 A2d 959 (Del. Ch. 1996)

§8B2.1 Effective Compliance and Ethics Programs (attached)

- “To have an effective compliance and ethics program,... an organization shall –
 - Exercise due diligence to prevent and detect criminal conduct; and
 - Otherwise promote an organizational culture that encourages ethical conduct and a commitment to compliance with the law.”
 - “7 Elements”

1. Establish Standards

- Code of Conduct
- Conflict of Interest policy
- Structural (program operation) policies and procedures
- Substantive (high risk areas) policies and procedures

2. High Level Oversight

- Board must be knowledgeable about content & operation and exercise reasonable oversight of implementation and effectiveness of compliance program
- Responsibility for program assigned to a specific high individual (emphasis added)
- Person(s) involved in day-to-day operation shall be given adequate resources, appropriate authority and direct access to board or board committee.

3. Screening

“Reasonable efforts not to include within the substantial authority personnel ... any individual whom the organization knew or should have known ...has engaged in illegal activities or other conduct inconsistent with an effective compliance and ethics program.”
(emphasis added)

4. Training & Education

- “To communicate in a practical manner its compliance standards and procedures”
- “... conducting effective training ... appropriate to such **individuals** respective roles and responsibilities”

“Individuals” means board, management, employees and, as appropriate, agents”

5. Monitoring, Auditing & Reporting

- Monitoring and auditing to detect criminal conduct
- Evaluate the effectiveness of the compliance & ethics program
- Maintain a system for reporting potential violations without fear of retaliation and that allows for anonymous reporting

6. Aligned Incentives

“The organization's compliance and ethics program shall be promoted and enforced consistently throughout the organization through

- (A) appropriate incentives to perform in accordance with the compliance and ethics program; and
- (B) appropriate disciplinary measures for engaging in . . . and for failing to take reasonable steps to prevent or detect criminal conduct”

7. Respond appropriately

- Prompt remediation (including repayment of overpayments)
42 U.S.C. 1320a - 7(b)(A) 3
- Process or procedure changes
- Education or re-education

The Challenge

- People don't view themselves as unethical
- Boards & Management don't know what they need to do
- Incentives are skewed

Ethics

- Perception:
- Reality:
 - Cheating
 - high school
 - college
 - MBA
 - Resumes
 - Workplace



- "What's one man's kickback is another man's marketing approach." *Then one man's jail cell is another man's condo.*
- "It's tough to deal with someone who has their hand held out."

"Note: "Title firm settles over kickbacks, Neil Roland, Bloomberg News, appearing in Aug. 29, 2007 San Ramon Valley Times".



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Role of the Board

- Define scope of the program
- Align incentives
- Approve key policies and procedures
- Require periodic, substantive reporting by management
- Ask questions! ! !

Tip: Add compliance expertise to board or appropriate committee.

Role of Management

- Actively promote/support program
- Ensure implementation of program
- Create culture that permits questions
- Hold subordinates accountable

Tip: It's management's job to implement the program and ensure compliance. The role of the compliance officer is to ensure management has the tools & resources.

Role of Compliance Officer

- Design (and redesign) program with input from management (operations), employees, peers and experts
- Develop policies and procedures
 - Structural → OSGs
 - Substantive → high risk areas
- Develop/acquire educational programs applicable to targeted job functions

Role of Compliance Officer (Cont.)

- Simplify complex, clarify ambiguous
- Respond to environmental changes
- Monitor and report on execution
- Have the difficult conversations

Role of Employees

- Participate in program – complete education, follow P & Ps
- Seek advice when there are questions
- Bring issues of non-compliance to attention of appropriate people
 - Internal
 - Anonymous
- Cooperate in investigating/fixing identified problems

Keep the Program Simple

- Tackle highest risks first
- Give management/employees clear direction
 - Ambiguity paralyzes
 - Specificity enables accountability
- Work within limits of organization's resources

Align Incentives

- Incentive compensation
- Transparency
- Performance evaluation
- Recognition
- Keeping promises

Properly Positioned Compliance Officer

- Reports to board (committee) and/or CEO
- Regular executive sessions
- Reasonable severance package
- Minimize conflicting/untamable responsibilities
- Educated compliance officer

Specific, Measurable Objectives

- **Structural (program operation)**
- P & Ps - orientation to program and P&Ps; development or review of P&Ps, adherence to P&Ps
- High Level Oversight – Board Oversight, Sr. Mgmt participation in meetings, audit exit conferences, compliance meetings, compliance officer member of Sr. Management, etc
- Education - completion of compliance and ethics education, completion of job specific education programs, ethics scenario discussions in staff meetings, etc
- Screening – background checks, exclusion checks

Specific, Measurable Objectives

■ Structural (program operation) (cont.)

- Investigation/Reporting - documentation of employee complaints and hotline calls, prompt investigation and response to complaints/hotline calls
- Monitoring/Auditing - completion of audit/monitoring activities, scores on audits (accuracy of process), completion of reports, tracking & submission of data, etc
- Remediation – correction of identified mistakes (refunds, data/reporting errors, etc), completion of corrective action plans (training, P&P development/modification, implementation of new/different control processes, etc)

- **Risk Assessment Process**

- How are risks identified (new laws/ rules, settlements, case law, management questionnaires/ interviews, audit findings, etc.)
- How are risks rated/evaluated

See attached sample risk assessment tools.

Effective Board Oversight

- **Substantive**

- **General**

- Tax, FLSA, Environmental, Antitrust, etc.

- **Healthcare Specific**

- anti-kickback, Stark, false claim, (including documentation, medical necessity, coding & billing, quality of care standards), licensure & certification, HIPAA, tax-exemption (charity care, billing & collection, intermediate sanctions, lobbying and political activity, loss of bond tax-exemption)

- Tip: Develop a compliance scorecard for key business unit executives that addresses structural components and key substantive risks. These objectives must be specific, objectively measurable and will be most effective if it has a material impact on the performance evaluation and/or incentive compensation process. See attached example.**

Management & Board Reporting – Written Reports

- Written Reports – purpose is to inform, report and educate
 - Issues
 - Investigations (internal & external)
 - Annual work plan progress
 - Key metrics
 - Recent developments

Management & Board Reporting – Oral Reports

- Oral Reports
 - Highlight
 - new investigations/issues
 - new reports/tools
 - Key messages
 - Respond to management/board questions
 - Ask management/board if they have questions

Management & Board Reporting – Minutes

➤ Purpose: To reflect topics, deliberations and actions in meeting and demonstrate that participants are effectively fulfilling their role

➤ Outline

- General topic area
- Issues
- Questions/deliberations
- Action

See [Corporate Minute-Taking: A General Counsel's Guide](http://www.mwe.com/info/pubs/HLN_Analysis0106.pdf) by Michael Peregrine & Russ Hayman
[http://www.mwe.com/info/pubs/HLN Analysis0106.pdf](http://www.mwe.com/info/pubs/HLN_Analysis0106.pdf)

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Q& A

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