



HCCA's 12TH ANNUAL COMPLIANCE INSTITUTE

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**CORPORATE LIABILITY, GOVERNANCE AND
COMPLIANCE IN THE HEALTH CARE INDUSTRY**

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Corporate Liability, Compliance and Governance

- HIPPA '96 and Corporate Scandals
- The New Era of Corporate Responsibility
- Sarbanes-Oxley Act of 2002
- Department of Justice Principles of Federal Prosecution of Business Organizations of 2003
- United States Sentencing Guideline Amendments of 2004



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Corporate Liability, Governance and Compliance

- Eliminate conflicts of interest and promote independent decision-making in the best interests of the business organization
- Self governance, self reporting and acceptance of responsibility are building blocks of the organizational culture expected from reordered enforcement priorities



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Sarbanes-Oxley and the Sentinel Effect on Business Organizations

- Public companies – governance and integrity of financial information
- Private companies – fiduciary obligations of Board of Directors and shareholder derivative liability
- Not-for-profit organizations – fiduciary obligations and Attorney General oversight
- Caremark Decision – all organizations
 - Duty of compliance oversight enters the Boardroom – fiduciary obligation of individual Board members



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Caremark Decision (Cont'd.)

- Oversight and responsibility of the Board of Directors and high level personnel of the organization
- Board knowledge about the content and operation of the organization's compliance program to prevent and detect violations of the law
- Board exercises reasonable oversight with respect to implementation and effectiveness of the compliance program.



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Sarbanes-Oxley Act (Cont'd.)

- Corporate scandals resulted in quick legislative action in 2002
- Attempt to foster change in the way business organizations act and assign greater responsibility to executives for failures in the accuracy of financial statements.



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Sarbanes-Oxley Act (Cont'd.)

- Increased accountability of corporate executives and board members and improved self governance
- Accuracy and full disclosure of corporate financial information
- Elimination of internal and external conflicts of interest
- Foster compliant corporate culture by protecting reports of misconduct.



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Department of Justice Principles of Federal Prosecution of Business Organizations "Thompson/McNulty Memo"

- Voluntary disclosure and self-reporting as quasi mandatory function of cooperation
- Cooperation in investigating business organization's own wrongdoing
- Affects charging decision against business organization
- Affects sentence under United States Sentencing Guidelines
- Business organizations cannot run the risk of failing to have an effective compliance program
- Failure to detect and prevent wrongful conduct will result in consequences for any business organization in current compliance environment
 - Deferred Prosecution Agreements and Corporate Integrity Agreements.



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What Changed?

- More consistent, nationwide law enforcement response to corporate fraud
- Proactive approach and faster prosecutions encouraged
- Greater uniformity in case disposition with potentially grave consequences for business organizations



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What Changed?

- New emphasis on completeness of cooperation
- Did business organization, while purporting to “cooperate”, engage in conduct that actually impeded investigation, e.g.:
 - Overly broad assertions of legal representation (organization and employees)
 - Directions not to meet/cooperate with government agents
 - Incomplete or delayed document production
 - Failure to promptly disclose illegal conduct known to corporation
 - Continued financial or other support of culpable employees: Modified by impact of McNulty Memo
 - Joint defense agreements with culpable employees.



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What Changed?

- Complete cooperation includes full disclosure of key facts
- May require waiver of attorney-client and work product protections
- Substantially modified by McNulty Memo
 - Limited to factual internal investigation
 - Routine requests for waiver has been controversial and subject to abuse by prosecutors.



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What Does the Government Expect from Business Organizations

- Partnership with Federal and State governments in detecting and preventing misconduct and promoting an ethical corporate culture
- Organizations which fail to ferret out wrongful conduct and non-compliant activity will likely suffer the consequences of not doing so
- Cooperation in investigating an organization's own wrongdoing.



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Sentencing Guideline Amendments of 2004

- Sentencing guidelines for organizations introduced concept of compliance program to reduce criminal culpability for business organizations in 1991
- Sarbanes-Oxley Act required United States Sentencing Commission to review and amend guidelines to enhance compliance program effectiveness
- Amendments encourage business organizations to partner with Federal government and promote self policing, reporting and cooperation in investigations of its own wrongdoing.



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Sentencing Guideline Amendments of 2004 (Cont'd.) The United States Sentencing Commission's Original Essential Elements for a Compliance Program

- **Standards of Conduct and Policies and Procedures**
 - **Developed and distributed to all employees to promote a commitment to compliance**
- **Compliance Officer**
 - **Focal point for compliance activities**
- **Education and Training**
 - **Continued education and training essential for an effective compliance program**
- **Monitoring and Auditing**
 - **Process for continuing evaluation for a successful compliance program**



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Sentencing Guideline Amendments of 2004 (Cont'd.)
The United States Sentencing Commission's Original Essential Elements for a
Compliance Program

- **Reporting and Investigation**
 - **Communication to detect and prevent misconduct with ability to investigate and implement corrective action**
- **Enforcement and Discipline**
 - **Discipline for failure to adhere to compliance standards and procedures**
- **Response and Prevention**
 - **Ability to respond to and correct non-compliant activity and conduct.**



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Sentencing Guideline Amendments
(Cont'd.)

- Amendments continue to emphasize prevention and detection of criminal conduct, but further emphasize promotion of organizational culture which encourages compliant and ethical conduct
- Amendments stress organizational responsibility, risk assessment and ethical behavior
- Strict legal compliance must be accompanied by a strong commitment to proactive governance and management of risk and ethical behavior
- Compliance with law, but also implement "best practices."



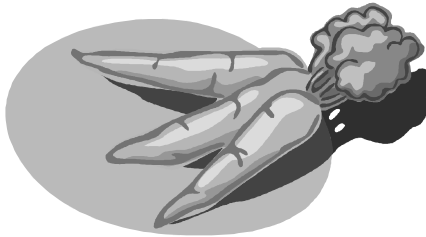
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Sentencing Guideline Amendments

(Cont'd..)

- Amendments adopt “**carrot and stick**” approach regarding criminal penalties for business organizations
- Sustained effective compliance program can mean difference between survival and demise of business organizations.



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Content of Sentencing Guideline Amendments

- Establishment of compliance standards and procedures and creation of code of conduct reasonably capable of reducing misconduct and promoting ethical behavior
 - Focus on areas of high risk and adopt procedures to reduce non-compliant activity
- Assigning oversight and responsibility to high level personnel and governing authority for organizational compliance program
 - Knowledgeable about content and operation of compliance program
 - Ensure implementation and effectiveness of program
 - Compliance professionals provided with adequate resources and authority and reporting responsibility to governing authority.



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Content of Sentencing Guideline Amendments (Cont'd.)

- Compliance Responsibilities Should Not Be Delegated to Individuals Who Have Engaged in Misconduct
 - Organizational Screening Process Required for Hiring and Promotion
- Training of Upper Level Management and Employees and Agents Addressing Specific Risk Areas



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Content of Sentencing Guideline Amendments (Cont'd.)

- Auditing and Monitoring to Detect Violations of the Law
 - Procedures for Allowing Anonymous Reporting
 - Expanded Focus of Reporting to Include Potential Misconduct and Seeking Guidance on Compliance Matters
- Expand Enforcement of Compliance Program by Disciplinary and Incentive Measures with Employees
- Responsiveness to Misconduct Through Investigation, Corrective Action and Possible Voluntary Disclosure.



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Ongoing Risk Assessment of Likely Risks for Business Organization

- Amendments expect more than creation of compliance program – compliance program must actually be effective in detecting and preventing misconduct
 - Offense by high level personnel creates rebuttable presumption of ineffectiveness



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“Cooperation” or “Unconditional Surrender”

- Cooperation taken into consideration in charging decisions by Department of Justice
 - Organization's ability to make witnesses available
 - Disclosure of organization's internal investigation, including waiver of attorney/client privilege when necessary, to identify individuals responsible and scope of conduct:
Substantially modified by McNulty Memo
 - Disclosure in a timely and complete manner before facts become stale and to better enable recovery of losses



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“Cooperation” or “Unconditional Surrender”
(Cont’d.)

- Powerful incentives involved in business organization’s decision to cooperate in investigation of own wrongdoing
- Department of Justice views self-reporting as a quasi mandatory function of cooperation
- Drives wedge between organization and its employees
 - Undermines fundamental employer/ employee relationship.



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“Cooperation” or “unconditional Surrender”
(Cont’d.)

- Cooperation evaluated on case-by-case basis
- Deferred prosecution agreement – survival of business organization – corporate integrity agreement with Department of Health and Human Services
- Circumstances literally coerce business organizations into cooperation and the United States Sentencing Commission and the courts have taken notice



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Deferred Prosecution Agreements ("DPA")

- **Deferred Prosecution Agreement – creature of Department of Justice – consequence of enforcement of corporate culpability**
 - **Organization commits to "best practices" for effective governance and promotion of ethical culture of compliance**
 - **Chief Compliance Officer reporting directly to Board**



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Deferred Prosecution Agreements ("DPA") (Cont'd.)

- **Extensive training and education programs**
- **Hotline reporting of non-compliant conduct**
- **Appointment of monitor to oversee obligations under deferred prosecution agreement.**



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Corporate Integrity Agreements (“CIA”)

- Creature of Office of the Inspector General (“OIG”) of the United States Department of Health and Human Services
 - Obligations in return for continued participation in Federal health programs/waiver of permissive exclusion
- A part of global criminal and/or civil settlement
- May represent OIG’s opinion on the effectiveness of an organization’s compliance program



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Corporate Integrity Agreements (“CIA”) (Cont’d.)

- Adopts and adheres to seven essential elements of an effective compliance program, including:
 - Education and training
 - Focused audit and monitoring
 - Independence of compliance officer
- Reporting requirements to OIG.

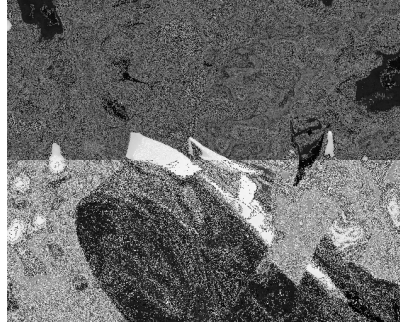


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Independence of the Compliance Officer

- Dual responsibility of compliance officers are suspect to the OIG at large organizations
- Concern with sufficient commitment of resources
- Reporting to Board of Directors/Trustees
- Independent CCO.



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OIG Expectations: Compliance Training

- Broad Based Compliance Program Training
- Extensive and Specific Training for Risk Areas
- Document training
- Efforts made to train physicians
- Technology training
- Essential for Effective Compliance Programs



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Board of Directors Duty of Care

Duty of care involves determining whether the directors acted:

- In good faith
- With the level of care that an ordinarily prudent person would in like circumstances
- In a manner that they reasonably believe is in the best interest of the corporation



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Director's Obligations

- **Decision-making function**
 - Applying duty of care principles to a specific decision or board action
- **Oversight function**
 - Applying duty of care principles with respect to the general activity in overseeing the day-to-day business activities of the corporation



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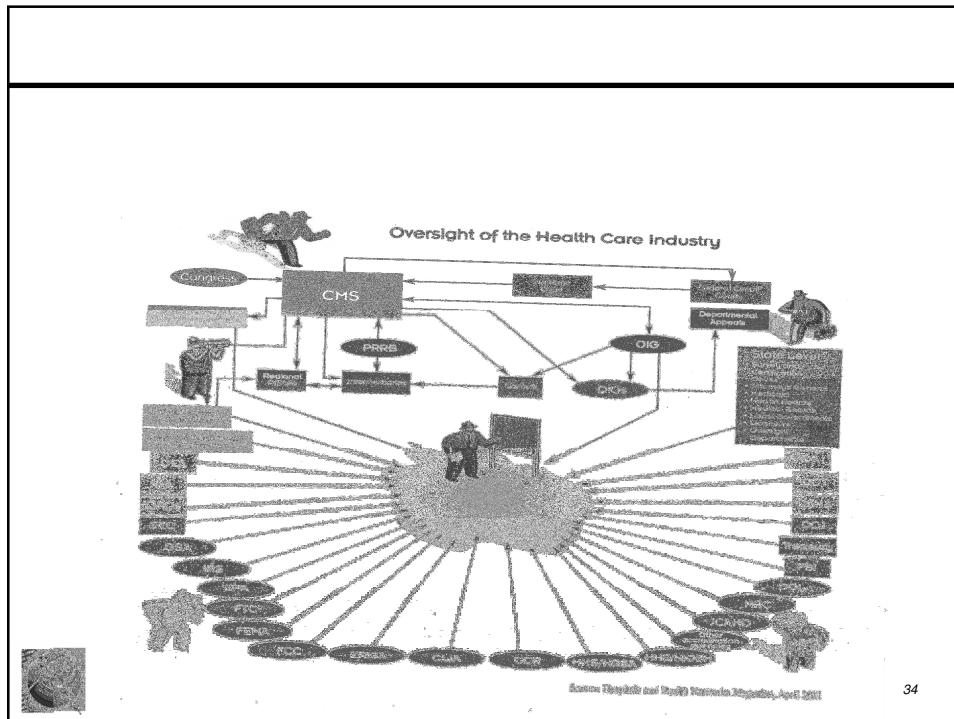
Why Corporate Compliance Programs?

- Risks associated with non-compliance have grown dramatically
- Board compliance program oversight responsibility is an ongoing element of the duty of care
- Compliance programs are designed to mitigate risks to health care organizations in a heavily regulated industry



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Audit and Compliance Committee

Committee's Compliance Functions **(as defined by Board Policy)**

- Ensure that appropriate policies and procedures are in place to preserve and safeguard the System's assets
- Ensure proper ethical and legal standards are present and maintained in meeting all applicable laws, rules and regulations
- Monitor compliance with applicable laws, rules and regulations



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Committee's/Board's Focus on Compliance

Two Categories

- Structural – the Board's understanding of the scope of compliance program
- Operational – the Board's understanding of the operations of compliance program



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Structural Questions

- How is Board structured to oversee compliance issues?
- How is the compliance program structured and who are the key employees responsible for its implementation and operation?
- How does the compliance reporting system work?
- How frequently does the Board receive reports about compliance issues?



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Structural Questions (Cont'd.)

- What are the goals of the compliance program?
- Does the compliance program address the significant risks that may apply to our organization?
- How were those risks determined and how are new compliance risks identified and incorporated into the program?
- How has management determined the adequacy of the resources dedicated to implementing and sustaining the compliance program?



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What are the Goals of the Compliance Program (Cont'd.)

- Develop annual auditing and monitoring work plans
- Effectively communicate regulatory changes to include accountability for implementation
- To create a culture that promotes:
 - Integrity
 - Open Communication
 - Responsiveness to concerns.



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Program Evaluation

- Compliance Scorecard

Measurement Framework:

Structure x Process x Outcome =
Effectiveness



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Measurement Framework

- **Structure** measures refer to the *capacity* of a health care organization to ensure compliance.
- **Process** measures refer to the *manner* in which an organization actually provides compliance coverage.
- **Outcome** measures refer to *observable, measurable* compliance outcomes.



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Measuring Effectiveness

Quarterly Compliance Scorecard -- ___ Quarter 2008

Date:	Hospitals	Clinics	Transportation	Homecare
Compliance Structure:				
Compliance Education				
• CIA Obligations				
Standards and Procedures Review				
Business Unit Reporting Mechanism				
Business Unit Program Oversight				
Compliance Awareness				
Compliance Process:				
Risk Assessment				
Risk Prioritization				
Response and Prevention				
• CAP Timely Filed				
• Ongoing Monitoring Effective				
Internal Investigations				
• Key Compliance Indicators				
HIPAA Compliance				
• Education				
• Business Associates				
• Other				
Compliance Outcome:				
Compliance Audit Error Rate				
Total:				
Rating				

Compliance Audit Error Rate Point Key	
0 – 5%	50 Points
6 – 9%	40 Points
10 – 15%	30 Points
16 – 20%	20 Points
21 – 25%	10 Points
25% +	0 Points

Evaluation Key	
80 and above	Green
60 and above	Yellow
59 and below	Red



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Fulfilling the Commitment

- Employee responsibility and accountability
- Policy development
- Code of Conduct
- Education, training, and communication
- Reporting
- Integrity Line
- Monitoring
- Auditing
- Ongoing evaluation and reporting



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Accountability

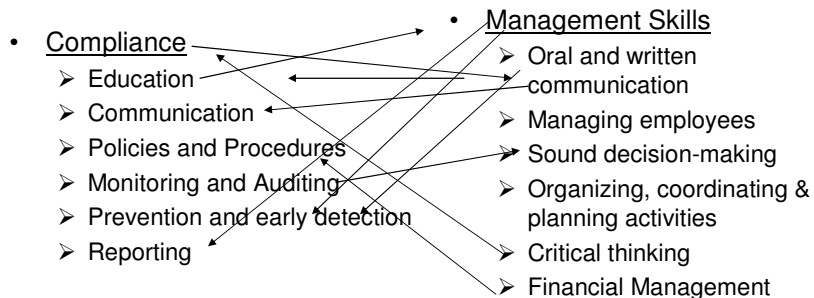
- Directors and Managers are accountable for:
 - Failure to detect and report non-compliance issues
 - Any retaliation or retribution against individuals who report compliance concerns
 - Compliance as an element of our performance evaluations



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Management Skills v. Compliance



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Deficit Reduction Act (Effective January 1, 2007)

- Impact on enforcement of the health care fraud and abuse laws under state law and under state Medicaid programs.
- Provisions:
 1. Required states to pass false claims statutes which are consistent with the Federal False Claims Statute, including a whistleblower provision and gives the states significant economic incentives to obtain recoveries under the statute.
 2. Medicaid provider who receives in excess of \$5 million annually is required to implement compliance measures or face the prospect of denied reimbursement for Medicaid services.



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Deficit Reduction Act
(Effective January 1, 2007) (Cont'd.)

3. Disseminate information to employees and agents about whistleblower provisions of False Claims Act and retaliation prohibitions for reporting fraud and misconduct.
 4. Appropriations for Medicaid fraud enforcement in unprecedented amounts.
- The impact of these changes are designed to parallel the impact which the Federal HIPAA statute and the whistleblower provisions of the Federal False Claims Act has had on enforcement in Medicare fraud over the last 10 years.



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?? Questions ??

Have we ever:

1. had any Compliance issues?
2. returned money received in error?
3. been investigated by an outside agency related to any compliance issues?



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THE END



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