

# Compliance 202



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# Agenda

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- U.S. Sentencing Guidelines – 2004 changes & developments; 2005 OIG Supplemental Guidance for Hospitals
- Risk Assessment
- Creating a Culture of Compliance
- Compliance Program Evaluation
- Board & Management Roles
- Internal Investigations
  - When to involve legal counsel
  - Disclosure to outside entities
- Emerging Focus Areas



# U.S. Sentencing Guidelines

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- **Elements of an effective compliance plan**
  - Compliance standards and procedures
  - Compliance officer and committee
  - Due care in the delegation
  - Education and training
  - Monitoring and reporting systems
  - Consistent enforcement of standards
  - Response to offenses; prevention of reoccurrences



# U.S. Sentencing Guidelines

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- **Corporate Compliance and Ethics Programs**
  - April 8, 2004, the U.S. Sentencing Commission voted unanimously to:
    - Make compliance and ethics standards more rigorous
    - Put greater responsibility on boards and executives for compliance oversight and management including taking an active leadership role for program content and operations



# 2004 Amendments-Federal Sentencing Guidelines for Orgs.

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- In addition to “due diligence” (1990), organization must “promote a culture that encourages ethical conduct”
- Organization’s governing authority must be “knowledgeable about the content and operation of the program”
- Training is made mandatory, including for board and upper management



# 2004 Amendments-Federal Sentencing Guidelines for Orgs.

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- “Reasonable steps to achieve compliance” is expanded to specifically require auditing and monitoring designed to detect criminal conduct.
- Periodic evaluation of the effectiveness of the program is added as a requirement
- In addition to an avenue for reporting concerns, employees must have an avenue for “seeking guidance regarding potential or actual criminal conduct.”



# 2004 Amendments-Federal Sentencing Guidelines for Orgs.

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- Requires that incentives be used to promote (previously limited to discipline.)
- Requires that periodic risk assessments be conducted.



# Compliance Guidance (OIG)

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- **Sarbanes Accountability**
- **Focus on Culture & Leadership**
  - “.....an organizational culture that values compliance are more likely to have effective compliance programs . . . .”
  - Evidence of the formal commitment to compliance by the government body and senior management should include active involvement by these leaders in fostering an “organizational culture that values, and even rewards, the prevention, detection, and resolution of problems.”

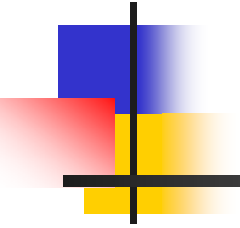


# Compliance Guidance (OIG)

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- **Recent Corporate Integrity Agreements**
- **Annual assessment of implementation and operation of program 2005 OIG Supplemental Compliance Guidance for Hospitals**
  - Outcomes measures (billing & coding, amount of overpayments, audit results, etc.)
  - Focus is on efforts measures

# RISK ASSESSMENT





# U.S. Sentencing Guidelines

(commentary) as amended November 1, 2004

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*The organization shall . . .*

*(A) Assess periodically the risk that criminal conduct will occur, including assessing the following:*

*(i) The nature and seriousness of such criminal conduct . . .*

*(ii) The likelihood that certain criminal conduct may occur because of the nature of the organization's business . . .*

*(iii) The prior history of the organization . . .*



# Compliance Guidance (OIG)

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“Has the hospital developed a risk assessment tool, which is re-evaluated on a regular basis, to assess and identify weaknesses and risks in operations?”

“Does the risk assessment tool include an evaluation of Federal health care program requirements, as well as other publications, such as the OIG’s CPGs, work plans, special advisory bulletins, and special fraud alerts?”

**Supplemental CPG for Hospitals, 70 Fed. Reg. 7858, 7875, January 31, 2005**



# Compliance Guidance (OIG)

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“Is the audit plan re-evaluated annually, and does it address the proper areas of concern, considering, for example, findings from previous years’ audits, risk areas identified as part of the annual risk assessment, and high volume services? ”

**Supplemental CPG for Hospitals, 70 Fed. Reg. 7858, 7875,  
January 31, 2005**



# What is Risk Assessment?

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Risk assessment is the identification, measurement and prioritization of likely relevant events or risks that may have a material consequence on an organization's ability to achieve its objectives.



# Committee of Sponsoring Organizations of the Treadway Commission (COSO)

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- First widely accepted general model of internal control
- Published *Internal Control – Integrated Framework* in 1992



# Internal Control – COSO Definition

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*Internal Control* is broadly defined as a process, effected by an entity's board, management and other personnel, designed to provide reasonable assurance regarding the achievement of objectives in the following categories:

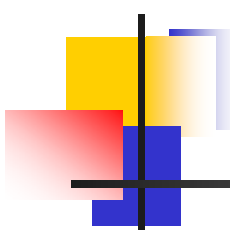
- Effectiveness and efficiency of operations
- Reliability of financial reporting
- Compliance with applicable laws and regulations



# Risk Identification – How?

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- Interviews
- Document review
  - Internal (e.g., audit reports, hotline logs, etc.)
  - External (e.g., OIG Workplan, industry newsletters, third party litigation)
- Employee surveys
- Other?



# Conference Board Report -- Methods Utilized to Identify Risks

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- Internal Document Review (e.g., hotline reports, internal audit reports) 81%
- Interviews of Leadership and Employees 79%
- Workforce Surveys 39%
- External Document Reviews (e.g., newsletters, third-party litigation) 33%
- Focus Groups 23%

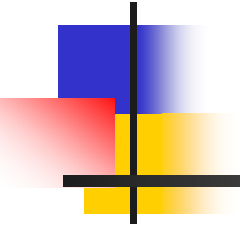
***2006 Compliance Program and Risk Assessment Benchmarking Survey, Corpidia, Inc and The Conference Board***

# Does Your Organization Have an Appetite for Risk?



# **CULTURE OF COMPLIANCE**

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# Role of Ethics/Culture

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“Experience suggests that good ethics programs and good compliance programs are interdependent; each is incomplete without the other. A good compliance program must emphasize values and moral responsibility, because this increases the program’s effectiveness among employees. A good ethics program must help employees to know and obey the law if it is to have any relevance to the company in its actual environment.”

Joe Murphy et. al., *Business Ethics and Compliance: What Management is Doing and Why*, 1999 *Bus. Soc’y Rev.* 35, 39.



# Role of Ethics/Culture

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“It is questionable whether a compliance program can be truly effective if it does not have an ethics component.”

Diana E. Murphy, *The Federal Sentencing Guidelines for Organizations: A Decade of Promoting Compliance and Ethics*, 87 Iowa L. Rev. 697, 716 (2002)



## Eric Holder Memo, Bringing Criminal Charges Against Corporations (June 16, 1999)

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“ . . . the critical [factor in evaluating any compliance program is] whether corporate management is enforcing the program or is tacitly encouraging or pressuring employees to engage in misconduct to achieve business objectives . . . .”



# What is an Ethics Focus?

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- Organizational values
- Decision making in the breach or the "grey zone"
- Deciding between two competing interests or two rights



# **COMPLIANCE PROGRAM EVALUATION**

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# Developing a Compliance Measurement Tool

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- Measures Efforts and Outcomes in Each Business Unit or Department
- Use as Benchmark Between each Business Unit and from Year to Year
- Graphical Representations Create Healthy Competition and Assist in Achieving Compliance Goals



# Possible Efforts Measures

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- Distribution of Code of Conduct to Workforce
- Completion of Training
- Hotline Calls Follow-up and Log Maintenance
- Distribution of Organizational Policies
- Employee Discipline for Misconduct
- Workforce Screening Processes



# Possible Outcomes Measures

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- Coding/billing audit results
- Surveys of employee awareness, understanding, trust in compliance systems
- Results of systems reviews
- Others?



# Compliance Program Objectives Measurement Tool

	Possible Points	Total Points
<b>1. Written Standards of Conduct</b>		
New compliance policies are communicated to all affected members of the facility's workforce within 60 days of the policy's effective date. (Score is equal to the percentage of completion).	100	
Code of Conduct acknowledgement cards are collected from each workforce member and are stored in an accessible place (in the members employee file if employed.) (Score equal to percentage of compliance as confirmed by audit).	100	
<b>2. High Level Leadership</b>		
25 points for each facility compliance committee meeting (quorum of committee members required) at which Facility Compliance Liaison and facility president, CEO or administrator are in attendance and for which minutes are timely forwarded to Chief Compliance Officer (maximum 100 points awarded).	100	
25 points each for attendance of Facility Compliance Liaison at regional compliance committee meeting (maximum, 200 points).	200	



# **BOARD/MANAGEMENT OVERSIGHT ROLE**

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# Duty of Care Concept

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- **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



# Board Obligations with Respect to Duty of Care

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- **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



# Board Communication

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- **The relationship between the Board's fiduciary care and its compliance program oversight responsibilities include:**
  - Asking a series of questions to assist the Board and the oversight committee in developing its structure for the oversight of the compliance program
  - Identifying the existing operational components of a compliance program.
  - Identifying key elements for routine communication with the board



# Control Obligations Under COSO Guidance

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## ■ **Board of directors**

- Provide guidance and oversight to management
- Through selection of management, helps define expectations for integrity and ethical values
- High-level objectives setting and strategic planning
- Investigates any issues they deem important



# Control Obligations Under COSO Guidance

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## ■ **Audit Committee**

- Investigates how senior management is carrying out its financial reporting responsibilities
- Requires corrective action for internal control and financial reporting deficiencies
- Identifies and takes action when senior management overrides or otherwise seeks to misrepresent reported financials



# Audit, Compliance, and Finance Committee

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

- ✓ Ensure that appropriate policies and procedures are in place to preserve and safeguard the organizations' 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



# Senior Management's Oversight

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- **The effectiveness of Senior Management's oversight is typically limited because:**
  - Limited linkage between governance and control activities
  - Existing internal control structures do not address the full range of risks
  - Key risks are managed by separate groups (e.g., security by IT, Sarbanes by Finance, marketing by Marketing)



# Senior Management (cont)

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- **Communication about**

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



# Senior Management (cont)

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- **Create an environment (culture) which**
  - Encourages open discussion of errors and concerns raised by associates
  - Allows for prompt reporting of compliance concerns
  - Designs systems and processes that
    - Ensure compliance
    - Contain adequate controls (compliance, quality, and safety)
    - Are supported by detailed policies and procedures



# Senior Management (cont)

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- **Accountable, at all levels, 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



# Senior Management (cont)

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- **Internal controls**
- **Quality of care**
- **Adherence to applicable defined standards**
- **Member, Patient and/or Employee**
  - Safety
  - Privacy
  - Satisfaction



# Internal Investigations

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*“An inevitable consequence of an effective compliance program is the identification of practices that warrant an internal investigation, and when appropriate, disclosure to the government.”*



# Internal Investigations

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- **Identifying regulatory exposure**
  - OIG compliance program guidance, special fraud alerts, advisory opinions, work plan & semi-annual report
  - Special fraud alerts, bulletins & other guidance
  - CMS advisory opinions & program guidance
  - Law enforcement initiatives & FCA settlements

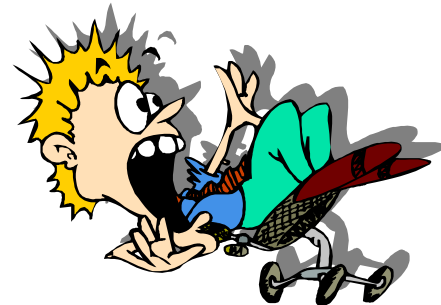




# Internal Investigations

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- **Triggers—Becoming aware of a problem**
  - Reports/Allegations by—
    - Employees
    - Contracted or Delegated Professionals
    - Third parties (i.e., billing consultants, vendors, etc.)
    - Beneficiaries
  - Internal hotline calls
  - Department referrals
    - Noted errors, noncompliant activity, etc.





# Internal Investigations

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- **Triggers—Becoming aware of a problem**
  - Monitoring, ie: new physicians
  - Unexplained increase in reimbursement
  - Substantial caseload jump for a specific service
  - Spot audits (prospective reviews)
  - Statistical audits (retrospective reviews)
  - Legal audits



# Internal Investigations

- **Triggers—Becoming aware of a problem**
  - Discovery of faulty billing advice
  - Inquiries by third party payors
  - Increase in denied claims
  - Government investigation
  - Whistle-blower actions
  - Statistics





# Internal Investigations

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## ■ **Prioritizing multiple compliance issues**

- Could the issue have a significant impact on payment?
- Does the issue present credible evidence of ongoing misconduct that may violate the law & should be reported immediately?
- Has the organization established (and followed) its own standards for the amount of time allotted to address incoming compliance concerns?





# Internal Investigations

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- **Prioritizing multiple compliance issues**
  - Does a CIA require focus on certain items?
  - Does the problem pertain to a discontinued practice?
  - Can certain software be used to perform a preliminary review?
  - Can the suspect practice be suspended or ceased until a review can be completed?



# Internal Investigations

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- **Systems review**

- **Purpose** = identify any problems or weaknesses
- **Process** = 'walk through' of the systems(s) & process(es) that generated the sampling unit in error
- **Goal** = identify at what point the error that resulted in the problem & determine why





# When to Involve Legal Counsel

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- **Privileges**

- What is a “privilege”?
  - Rule of evidence barring communications from admission in legal proceeding
  - Examples: marital communications privilege, patient-physician privilege & psychotherapist-patient privilege
- Corporate clients
  - No 5<sup>th</sup> Amendment rights against self-incrimination for corporations – makes attorney-client privilege especially important



# When to Involve Legal Counsel

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## ■ Privileges (cont.)

### ■ Policy

- Encourage full and frank communication between an attorney and his or her client
- This communication is generally more important than the need for evidence in litigation

### ■ Whose privilege is it?

- The client holds the privilege (not the attorney)
- The corporate client (and not its employees or agents) holds the privilege

# When to Involve Legal Counsel

- **In confidence**

- Expression of confidentiality
- Generally not in confidence if:
  - In presence of third party (non-privileged person)
  - Intention that information will be subsequently disclosed



# When to Involve Legal Counsel

- **When can privilege be waived?**
  - Implied waiver
  - Involuntary disclosure
  - Voluntary disclosure
    - Disclosure to third parties
    - Disclosure to governmental agencies
  - Careless disclosure



# When to Involve Legal Counsel

## ■ Practical considerations

- How to decide whether to bring an internal investigation under privilege
  - Ordinary-course auditing and monitoring vs. privileged audits and investigations
  - Risk analysis
  - Varies by organization, risk area and potential exposure to organization





# When to Involve Legal Counsel

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- **Practical considerations (cont.)**

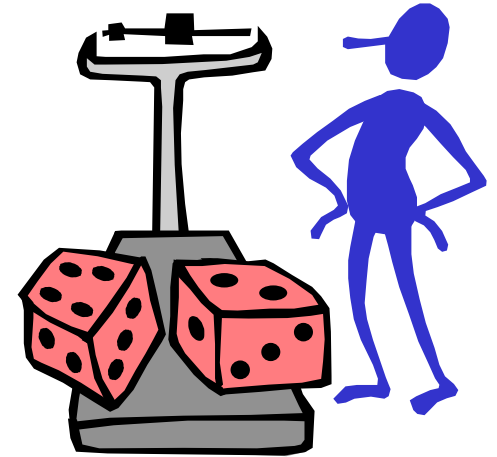
- Timing is everything

- Get attorney involved with investigation early
- Attorney can assist client in evaluating risk of conducting investigation outside of privilege
- Attorney should render advice after non-lawyer advisor delivers work product

# Disclosure to Outside Entities

## ■ Potential risks & benefits

- Favorable treatment
- Less rigorous CIA
- Resolve exclusion remedy
- Minimize potential disruption
- Minimize excessive damages
- Preclude whistle-blower action by requesting Contractor or OIG to “investigate” disclosed facts
- Other considerations





# Emerging Areas

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- Medicaid Fraud Enforcement
- Open Letter – Stark Enforcement
- McNulty Memorandum
- HP Settlement & Board Roles
- Merging Ethics w/Compliance – Creating a Culture



# Medicaid Fraud Enforcement

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- **Total Medicare & Medicaid Spending 2007:  
\$790 Billion**
  - Medicare: \$443 Billion
  - Medicaid: \$347 Billion



# Medicaid Fraud Enforcement

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## ■ **DRA – 2005**

- . . . “takes CMS’ partnership with and oversight of States to a new level . . . .”
- . . . “unique opportunity to identify, recover and prevent inappropriate Medicaid payments . . . .”
- “MIP provides CMS with the ability to more directly ensure the accuracy of Medicaid payments . . . .”



# Medicaid Fraud Enforcement

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- **Section 6034 of the DRA:**

- CMS-MIP gets \$50 million in 07 and 08, \$75 million annually thereafter, with unspent retention authority.
- HHS-OIG Program Integrity Group receives enhanced funding for Medicaid fraud efforts: \$25 million annually.
- National expansion of the Medi-Medi pilot project: \$12 million to start; \$60 million annually by 2010.



# Medicaid Fraud Enforcement

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- **Bottom line on NEW money spending by three Federal enforcement agencies (OIG, CMS-OFM, CMS-MIP) to enforce Medicaid payment integrity:**
  - 2007 = \$87 million
  - 2008 = \$99 million
  - 2009 = \$136 million
  - 2010 = \$160 million



# Medicaid Fraud Enforcement

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- MIP – Strategic use of contractors to conduct audits and support States' program integrity efforts.
- “MIP expects to identify significant overpayments through a carefully crafted audit program.”



# Medicaid Fraud Enforcement

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- **PERM- page 14 Strategic Plan targeted vulnerabilities:**
  - Nursing and personal care facilities/agencies
  - Prescription drugs
  - Durable medical equipment
  - Improper claims for payment



# Medicaid Fraud Enforcement

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- PERM Audits will result in error rates for each program
- States will be required to develop corrective action plans that target major causes of error identified by the PERM reviews
- **Under the new Federal rules states MUST recover any overpayments identified in the PERM audits**



# Open Letter – Stark Enforcement

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- **OIG will consider the lesser CMP penalty (3x amount of remuneration) for Stark violation self-disclosures in appropriate circumstances**
  - What implicates CMP authority?
  - Only available when both Stark and AK in play?
  - Is the amount of overpayment still relevant?



# McNulty Memorandum

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- Timely self-disclosure
- Cooperation with government's investigation
- Waiver of privileged materials
- Shielding of culpable employees & agents
- Obstruction of investigations



# McNulty Memorandum

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- **Corporate Compliance Programs: two key questions**
  - Is the CP well designed?
  - Does the CP work?



# McNulty Memorandum

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## ■ **Factors**

- Comprehensiveness of the CP
- Extent & pervasiveness of the misconduct
- Number & level of employees involved
- Seriousness, duration & frequency of misconduct
- Remedial actions taken (restitution, discipline, revision of the CP)
- Promptness of self-disclosure



# McNulty Memorandum

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- **Factors—Effectiveness of Governance:**
  - Do directors exercise independent review or merely ratify recommendations of management?
  - Are directors given adequate information to allow independent judgment/oversight?
  - Are internal audit adequately funded?
  - Have directors established adequate internal reporting mechanisms?



# McNulty Memorandum

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## ■ **Factors:**

- Is CP a “paper program” only, or has it been adequately implemented?
- Are CP resources adequate?
- Are employees adequately informed about the CP? Do they have confidence in the corporation’s commitment to the CP?



# HP Settlement & Board Roles

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- **Offers compliance related governance protocols worthy of consideration by health care**
  - Identification of a new independent director to serve as the board's "watchdog" on legal and ethical matters
    - Specific responsibilities in effecting oversight & report violations to the Board, HP officials, AG



# HP Settlement & Board Roles

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- Expand oversight and reporting duties of the Chief Ethics and Compliance Officer(CECO) to include investigative practices
- Expand duties of chief privacy officer to review investigative protocols to ensure privacy protection & comply with ethical requirements



# HP Settlement & Board Roles

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- **Establish a “Compliance Council”**
  - Chaired by CEO, include privacy officer, general counsel, internal audit, compliance liaisons
  - Purpose: develop and maintain policies and procedures governing the ethics/compliance program
  - Periodically report to the CFO & Audit Committee



# HP Settlement & Board Roles

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- **Redesign ethics and conflicts of interest components of the training program**
  - So as to be supervised by CECO, compliance council, independent director & chief privacy officer
- **Create separate code of conduct addressing privacy and ethics concerns**
  - For use by outside investigators



# HP Settlement & Board Roles

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- **“HP scandal”**

- Little direct application to healthcare
- Two concepts of absolute relevance to health care
  - Duty of directors to preserve the confidentiality of proprietary corporate information
  - Legal and ethical parameters of privacy matters and internal investigations



# HP Settlement & Board Roles

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- **Emphasizes coordination of all internal components of an organization's compliance effort**
  - Much emphasized goal in health care

Source: AHLA Corporate governance task force



# Emerging Focus Areas

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- **Quality of care**

- Standard of care enforcement actions
  - Administrative sanctions
    - Civil monetary penalties
    - Termination of provider agreement
    - Provider exclusion
- Medically unnecessary procedures





# QUESTIONS

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# Presenter Contact Information

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