

HCCA's Managed Care Compliance Conference

Interrelationship Among the Compliance Officer, Legal Counsel and Board of Directors

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Agenda

- **Introductions**
- **Scenario #1: Day to Day Operations**
 - Daily roles in compliance for the 3 key Compliance Program players: Compliance Officer, Legal Counsel and the Board
- **Scenario #2: When Potential Non-Compliance is Discovered**
 - Roles of the Compliance Officer, Legal Counsel and Board in conducting internal reviews and investigations
 - “Best Practices” in conducting internal reviews and investigations
- **Scenario #3: Government Agency Audit/Inquiry/Investigation**
 - Roles of the Compliance Officer, Legal Counsel and Board in preparing for and responding to government audits, inquiries and investigations
 - “Best Practices” for getting ready for and responding to government audits, inquiries and investigations
- **Conclusion/Next Steps for Your Company**



Scenario #1: Day-to-Day Operations

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It's a typical Monday morning at a managed care company:

- What is the **Compliance Officer** doing?
- What is the **General Counsel** doing?
- What is the role of the **Board of Directors** on a day-to-day basis?
- How do their activities overlap?
 - How do they differ?

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MCOs have mandatory compliance program obligations

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- Managed care organizations (MCOs) with federal health care program (FHCP) participation agreements are **required to have effective compliance programs**
 - Medicare Advantage (MA)
 - Medicare Part D
 - Federal Medicaid and some state Medicaid Programs (e.g., NY)
- Most other health industry companies have voluntary compliance programs
 - Except where they are subject to a government CIA

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The Compliance Officer's Responsibilities

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- The Compliance Officer's responsibilities can be broken down into 3 integral areas: "DRS"
 - **Daily Oversight of the Compliance Program ("D")**
 - Oversee the development and implementation of the 7 legally required elements of the Corporate Compliance Program
 - **Reporting/Communications ("R")**
 - Effectively report to and between senior management, the Board, the Compliance Committee and other compliance program stakeholders (e.g., department heads, employees, vendors)
 - Central communications liaison with outside agencies
 - **Skill Sets ("S")**
 - People skills
 - Communications skills
 - Organizational skills

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Daily Duties of the Compliance Officer

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- The Compliance Officer is responsible for overseeing the development and implementation of the Compliance Program
- **Effectiveness is the benchmark for corporate compliance**
 - Not just policies and procedures, training
- The role of governance in compliance is the current focus
 - Not just "tone at the top" lip service that compliance is important
 - Board and senior management are responsible for understanding the Compliance Program
 - They also are responsible for knowingly ensuring that the proper infrastructure for effective compliance is in place
- Compliance Officer's job is to effectuate these governance objectives for the Compliance Program

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Daily Role of the Compliance Officer

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- Oversee the development of **written policies and procedures**
 - Written standards are designed to promote the company's commitment to compliance with applicable state and federal standards
- Ensure the provision of effective **training/education**
 - Board/Compliance Committee
 - Senior and "line" management
 - Employee training
 - Vendor training if necessary
- Establish and monitor mechanisms for effective **lines of communication** about compliance
 - *E.g.*, a compliance hotline

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Daily Role of the Compliance Officer

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- Ensure the **enforcement of standards**
 - Publicized disciplinary standards and disciplinary actions
- Develop an appropriate **monitoring and auditing** program
 - Risk areas are a function of business operations
- Oversee the implementation of **prompt responses** to detected offenses
 - Includes processes for investigation, corrective action and possible reporting

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Effectiveness of the Compliance Program

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- What reference materials should be used to inform the design of an **effective** compliance program?
 - U.S. Sentencing Guidelines
 - OIG industry guidances
 - Not just the M+C guidance
 - Look at hospital, billing company and other industry guidance recommendations from the OIG
 - OIG workplan
 - Published DOJ settlements, CIAs
 - Managed care investigations
 - Also look at other targeted industry segments, *e.g.*, pharma
 - MA and Part D FWA guidance
 - CMS/MEDIC and OIG audit initiatives

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Reporting/Communications Responsibilities of the Compliance Officer

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- Reporting and communications are a central element of the Compliance Officer's responsibilities
 - Report regularly to the Board of Directors
 - Status of Compliance Program projects
 - Key internal reviews concerning potential non-compliance
 - Significant government inquiries/investigations
 - Adequacy of Compliance Program resources
 - Sufficiency of reporting relationships
 - Communications with Compliance Committee
 - Set agendas for Compliance Committee meetings – see areas above
 - Training and education schedules for employees
 - Communications with Senior Management and Department heads
 - Inform about specific risk areas
 - Educate about the Compliance Program

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How often should the Compliance Officer report to the Board?

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- Medicare Part D guidance supports reporting at least on a quarterly basis, or more frequently as necessary
- Recent corporate integrity agreements (“CIAs”) with health care companies require 4 times per year
- AHLA/OIG jointly published resource for health care boards of directors supports “regular” reporting
 - The actual frequency to be determined based on circumstances
- U.S. Sentencing Guidelines refer to at least annual reporting
- Medicaid compliance program guidance is silent on the required frequency for reporting

What is the right frequency for Board reporting for your organization?

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Skill Sets for an Effective Compliance Officer

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- Strong “people” skills
 - Proven ability to work effectively with employees at all levels of the company
- Able to use effective problem-solving skills in addressing compliance program matters
- Acts with effective communication skills
 - Both verbal and written
- Establishes reputation
 - Trustworthy
 - Knowledgeable
 - The “go to” person about compliance matters
- Able to set priorities and meet or supervise deadlines
- Able to organize complex projects

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Should the Compliance Officer report to the GC or CFO?

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- OIG believes that:
"[T]here is some risk to establishing an independent compliance function if that function is subordination [sic] to the hospital's general counsel, or comptroller or similar hospital financial officer."
- OIG views freestanding compliance functions as:
"designed to help ensure independent and objective legal reviews and financial analyses of the institution's compliance efforts and activities."
- By separating the compliance function from the key management positions of general counsel or chief financial officer (where feasible) -
"a system of checks and balances is established to more effectively achieve the goals of the compliance program."

Source: OIG's Compliance Program Guidance for Hospitals (Feb. 1998), footnote 35.

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Daily Role of Legal Counsel in Compliance

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What is Legal Counsel's role in the Compliance Program?

- Substantive
 - Identify major risks areas from Company's operations and ensure that they are appropriately reflected in the Compliance Program
 - Monitor enforcement activities by federal and state regulatory agencies
 - Advise on government regulations and implications of non-compliance
 - Participate in Compliance Program training
 - Report to the Board on the areas within the counsel's responsibility

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Daily Role of General Counsel

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- Assess the Compliance Program effectiveness:
 - Whether Compliance Program processes are targeting the key risk areas and providing required training in those areas
 - Whether Compliance Program is assuring the confidentiality and non-retaliation principles for persons who report potential non-compliance
 - Whether the Company is auditing and monitoring the risk area in a meaningful way
 - Whether the Company's procedures for taking disciplinary measures against persons engaged in non-compliant conduct are
 - Publicized and effective in serving as a deterrent to others, particularly re: criminal conduct
 - Being used in a non-discriminatory manner
- Ensure that the Board has been properly educated about its role in the Compliance Program

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The Board's Role in Compliance

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"[The Court is] of the view that a director's obligation includes a duty to attempt in good faith to assure that a **corporate information and reporting system, which the board concludes is adequate, exists**, and that failure to do so under some circumstances may, in theory at least, render a director [personally] liable for losses caused by noncompliance with applicable legal standards . . . (emphasis added)"

Caremark International Inc. Derivative Litigation, 698 A.2d 959 (Del.Ch. 1996)

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The Board's Role in Day-to-day Compliance

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- Exercise reasonable oversight of compliance program
 - To ensure that the Company's day-to-day business operations are carried out in compliance with applicable laws
 - Requires Board to have a fundamental understanding of the Company's Compliance Program
 - Board has the "ultimate responsibility" for meeting federal program participation requirements
- Exercise the legal "duty of care"
 - Make inquiries of management about Company's operations and required compliance infrastructure

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The Board's Role in Day-to-day Compliance (cont)

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- Confirm that corporate information and reporting systems exist
 - Systems should be adequate to bring compliance issues to the Compliance Program and where appropriate to the Board's attention
- Ensure that Compliance Program has adequate resources
 - Appropriate authority
 - Direct access to the Board
- Ensure that Company does not allow persons with substantial authority to remain in place if such persons engaged in significant non-compliance
 - Or if they should have known about significant non-compliance being carried on in their business unit(s)
 - Criminal activity is a special concern here

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Scenario #2: When Potential Non-Compliance is Reported

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An employee reports to the Compliance Officer that the price being paid by the MCO to a health clinic, which is an affiliate of the MCO, is being increased by fifty cents (.50) pmpm; however, the cost of living increase provided for in the contract would justify thirty cents (.30) pmpm.

Also, the employee says, because the clinic is an MCO affiliate, Company policies are being ignored in that there is no executed BAA between the MCO and clinic and PHI is being shared by the parties by email and other channels without being adequately protected.

The employee just wants the Compliance Officer to know.

What do the three parties do?

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The Role of the Compliance Officer in Internal Reviews/Investigations

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What is the Compliance Officer's role in internal reviews and investigations?

- Identify the internal and external team members and/or necessary areas of expertise to review the matter at hand
 - Work with counsel to engage needed outside expertise (legal, consulting, accounting, public relations, etc.)
 - Confirm the team members' professional time commitment to the review
 - Determine and articulate the goals of the internal review

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The Role of the Compliance Officer in Internal Reviews/Investigations (cont)

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- Formulate the work plan for carrying out the internal review
 - Assign responsibilities
 - Establish appropriate interim and final deadlines for assignments
 - Get approval from counsel, Compliance Committee and Board, as appropriate, for the scope of the work plan, time frames and commitment of resources
 - Coordinate regular status meetings/calls among the review team members

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The Role of the Compliance Officer in Internal Reviews/Investigations (cont)

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- Maintain the “chron” and “master file” for the Company’s review activities
 - Obtain any requested written reports from the team
- Keep counsel and Board informed of status of the review activities
 - Seek additional resources promptly as necessary to conduct the review
- Oversee that an appropriate team is assembled to review preliminary and final reports/findings
 - *E.g.*, Legal, HR, operations

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The Role of the Compliance Officer in Internal Reviews/Investigations (cont)

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- Ensure that the review team makes recommendations to the Board or Compliance Committee about resolution strategies
 - Consider impact of the non-compliance and potential resolution strategies on:
 - Members
 - Any implicated government program data
 - Any possible affect on government program payments (past or future)
 - Ensure that consideration is given to whether self-disclosure is required or recommended in the matter

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The Role of the Compliance Officer in Internal Reviews/Investigations (cont)

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- Ensure that a going-forward plan for operational modifications is established:
 - To reduce the likelihood that the non-compliant behavior will occur again
 - Are additional staff or resources needed in the unit to perform the operations?
 - Are specific personnel changes required in the operating department?
 - Does the management or reporting structure for the operational unit need to be reorganized?

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The Role of the Compliance Officer in Internal Reviews/Investigations (cont)

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- Obtain clear direction from counsel, Board, and/or Compliance Committee about what steps are to be taken to address or resolve the matter
 - Carry out or oversee execution of the approved resolution steps
 - Serve as primary Company representative, or co-representative with counsel, in communications with enforcement agencies
- Report back to the Board/Compliance Committee on status of resolution steps, any new issues or areas of concern, etc.

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The Role of the Compliance Officer in Internal Reviews/Investigations (cont)

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- Consider modifications to the Company's Compliance Program to reduce the likelihood that the non-compliance will re-occur
 - New or modified p&p?
 - Additional or new training?
 - More auditing and monitoring of the underlying activities?

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The Role of Legal Counsel in Internal Compliance Reviews/Investigations

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What is the role of Legal Counsel in internal compliance reviews/investigations?

- Participate on review team
 - Protect attorney-client privilege
 - Engage and oversee activities of outside counsel/consultants
- Determine if/when any Company employees should be informed to obtain their own personal counsel

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The Role of Legal Counsel in Internal Compliance Reviews/Investigations (cont)

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- Analyze the review findings to determine scope of potential Company exposure
 - Inform the Board/Compliance Committee of nature of risks to the Company arising from the non-compliance activities
 - CMS or Medicaid agency intermediate sanctions or contract remedies exposure? False Claims Act (FCA) exposure (treble damages)? Criminal exposure? Board liability? Litigation exposure? PR impact?
 - Consider the FERA amendments to FCA regarding “overpayments”

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The Role of Legal Counsel in Internal Compliance Reviews/Investigations (cont)

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- Participate in developing recommendations to the Board/Compliance Committee about resolution strategies
- Advise the Company on the merits/risks and responsibilities for possible self-disclosure
- Participate in the assessment and delivery of any disciplinary measures
- Ensure that approved operational and Compliance Program modifications are implemented

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The Board's Role in Internal Compliance Reviews/Investigations

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What is the Board's role in internal compliance reviews/investigations?

- Obtain clear information on a timely basis about the nature and scope of the potential non-compliance
- Ensure that sufficient resources are made available to properly investigate the issues
- Obtain timely advice from counsel regarding the potential civil and/or criminal exposure for the Company arising from the non-compliance
- Consider any immediate steps required to mitigate the Company's potential exposure

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The Board's Role in Internal Compliance Reviews/Investigations (cont)

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- Solicit Senior management's input regarding whether any operational modifications are required to reduce the likelihood of re-occurrence
- Solicit the Compliance Officer's recommendations for modifications to the Compliance Program to reduce the likelihood of re-occurrence
- Consider the impact of the incident(s) on the Company's long-term relationship with affected government agencies, key customers and significant business partners
- Give serious attention to potential self-disclosure

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The Board's Role in Internal Compliance Reviews/Investigations

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- Make the business judgments required to establish the steps that the Company will take to resolve and remedy the matter
 - Ensure that proper resources are available to carry out such directives
- Obtain confirmation that its directives have been carried out

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Responding to Potential Non-Compliance relating to a Government Healthcare Program

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- CMS is showing increasing willingness to exercise sanction authority
 - E.g., contract termination, CMPs, non-renewal of contracts
- Other government agencies (OIG, GAO) have been critical of CMS's oversight of plans so far
 - Also critical of the Plans' compliance programs
 - OIG's 2010 workplan includes specific list of MA and Part D review areas
- Other federal health care fraud initiatives are underway
 - Reorganization of CMS includes joint resources focused on Medicare and Medicaid Program Integrity activities
 - HEAT (DOJ and HHS joint anti-fraud initiative)

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Scenario #3: Outside Audit or Investigation

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The State has engaged an independent auditor to audit the Plan. Before the State sets the date for the audit, the State asks the Plan to provide initial training to the auditor who has not audited a Medicaid MCO before. The Plan agrees to assist and spends 2 weeks providing an orientation to the auditors about Medicaid managed care operations. The auditor then conducts the audit and provides a draft report of his findings, which raises questions regarding the Plan's charitable donations, the Plan's categorization of certain administrative expenses as medical expenses (*i.e.*, the administrative portion of the pharmaceutical expenses) and the Plan's payments to its parent company as not directly related to Medicaid healthcare services and Plan payments to related health centers with a friendly PC and managed by Parent. State informs Plan that it contemplates filing an action alleging FCA violations.

What do the three parties do?

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Role of Compliance Officer in Responding to Government Inquiries

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What is the role of the Compliance Officer in responding to government audits and inquiries?

- In consultation with senior staff:
 - Discuss and decide implications of the State's request to be trained
 - For example, consider whether to coordinate training with audits on-site or off-site
- Discuss and document scope of audit
 - Also define the standards to be used in the audit up front
- Provide notification of the audit to Board through appropriate reporting channels
- Establish and enforce protocol for staff interactions with auditors; identify persons to serve as Plan liaisons with the state auditors
 - Record violations of protocols

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Role of Compliance Officer in Responding to Government Inquiries (cont)

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- Receive report from state auditors or appropriate liaison staff
- Assess implications of audit report on Compliance Program
 - What p&p are implicated?
 - Are audit issues addressed as existing risk areas; what recommendations?
 - If conduct inconsistent with p&p, report on staff involved in the conduct (including senior staff)
 - Implications on training and communication
 - Implications for incentives and discipline
 - Implications for auditing and monitoring
 - Propose any modifications to Compliance plan

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Role of Legal Counsel in Responding to Government Inquiries

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What is the role of Legal Counsel in responding to government inquiries?

- Participate in discussions and decisions regarding implications of audit
- Participate in pre-audit discussions with the state regarding standards and scope
 - Use the pre-audit discussions as an opportunity to explain the Company's compliance program and its effectiveness
- Participate in Board notification if appropriate
- Review audit report to assess potential Company liability
 - Consider FERA/FCA implications
 - Assess merits of any rebuttals/defenses
 - Communicate with counsel for the state
- Receive staff analysis of state's audit report
- Review and report on implications for risk areas

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Role of Legal Counsel in Responding to Government Inquiries (cont)

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- Receive draft report from Compliance Officer
- If criminal implications, provide an assessment on the effectiveness of the recommended modifications to the Compliance Program
 - Recommend any needed modifications
- Assess basis of legal action and make recommendations regarding next steps, including possible engagement of outside counsel
- Work with senior management regarding litigation strategy

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Role of the Board/Board Committee in Responding to Government Inquiries

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- Receive notification regarding audit
- Discuss implications and protocols for reporting to Board on an ongoing basis
- Receive audit report
- Receive staff's report regarding audit issues
 - Provide feedback on areas covered by the report
- Review recommendations from staff regarding Compliance Program revisions
- Have management make presentation regarding Compliance Program recommendations
- Review strategy regarding potential litigation
- Assess whether employees are held accountable under the Compliance Program

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Compliance Program Effectiveness

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- Federal sentencing guidelines expressly require that:
 - Each organization periodically evaluate the effectiveness of its Compliance Program
 - The Governing board exercise oversight of implementation and effectiveness of the Compliance Program
- Government recognizes that failure to prevent and detect non-compliance does not necessarily mean that the program is not generally effective
- Consider utilizing external experts to conduct the effectiveness review
 - Independent assessment of Program effectiveness is stronger evidence than an internally-generated assessment
- Effectiveness review findings should be presented to the Board for discussion
- Frequency and scope of effectiveness review assessment should be determined by the Board and documented

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EpsteinBeckerGreen

EPSTEIN BECKER GREEN was founded over 35 years ago as a law firm dedicated to the health care industry. Today, among its approximately 350 attorneys, more than 100 attorneys practice health law full-time. EpsteinBeckerGreen has been consistently ranked as one of the nation's largest health care law firms by *Modern Healthcare*. Attorneys with EBG's Health Care and Life Sciences Practice serve a wide spectrum of health care organizations, in capacities from general counsel to special counsel on particular complex issues. The firm's representation of its health care clients covers all aspects of the law affecting their business. By utilizing its extensive experience at the leading edge of the health industry, as well as access to the focused knowledge of attorneys in all of the Firm's other core practice areas, EpsteinBeckerGreen's Health Care and Life Sciences practice is able to serve as a solutions provider to clients with respect to general corporate matters (including acquisitions and reorganization), tax matters (including tax-exempt issues), labor and employment matters, real estate and facility construction matters, capital finance and reimbursement issues and federal and state health regulatory matters.

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CLIFF BARNES is a Shareholder at EpsteinBeckerGreen in the firm's Health Care and Life Sciences Practice in Washington, DC. Cliff's practice focuses on represents providers, including hospitals, hospital systems, nursing homes, ancillary service companies; managed care companies, concentrating in Medicare and Medicaid managed care companies; non-profit associations; and contract research organizations. Mr. Barnes counsels health care providers on issues related to mergers, acquisitions, joint ventures, and various forms of contracting, including risk arrangements, international transactions, antitrust issues, fraud and abuse, compliance programs, and federal and state regulations, serves as general counsel for nursing home clients, serves as general and special counsel for managed care companies, including Medicare and Medicaid health plans. He serves as general and special counsel for non-profit associations, including Medicaid Health Plans of America ("**MHPA**") and the National Medical Association, among others. He also counsels contract research organizations on issues related to clinical trial agreements, protocols, and informed consent, represents providers in JCAHO accreditation appeals and counsels clients on compliance program effectiveness.

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