

How to Communicate With the Board of Directors About Your Compliance Program

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The statements made by the presenters during this session represent their individual views and should not be construed to represent the views of their respective organizations.

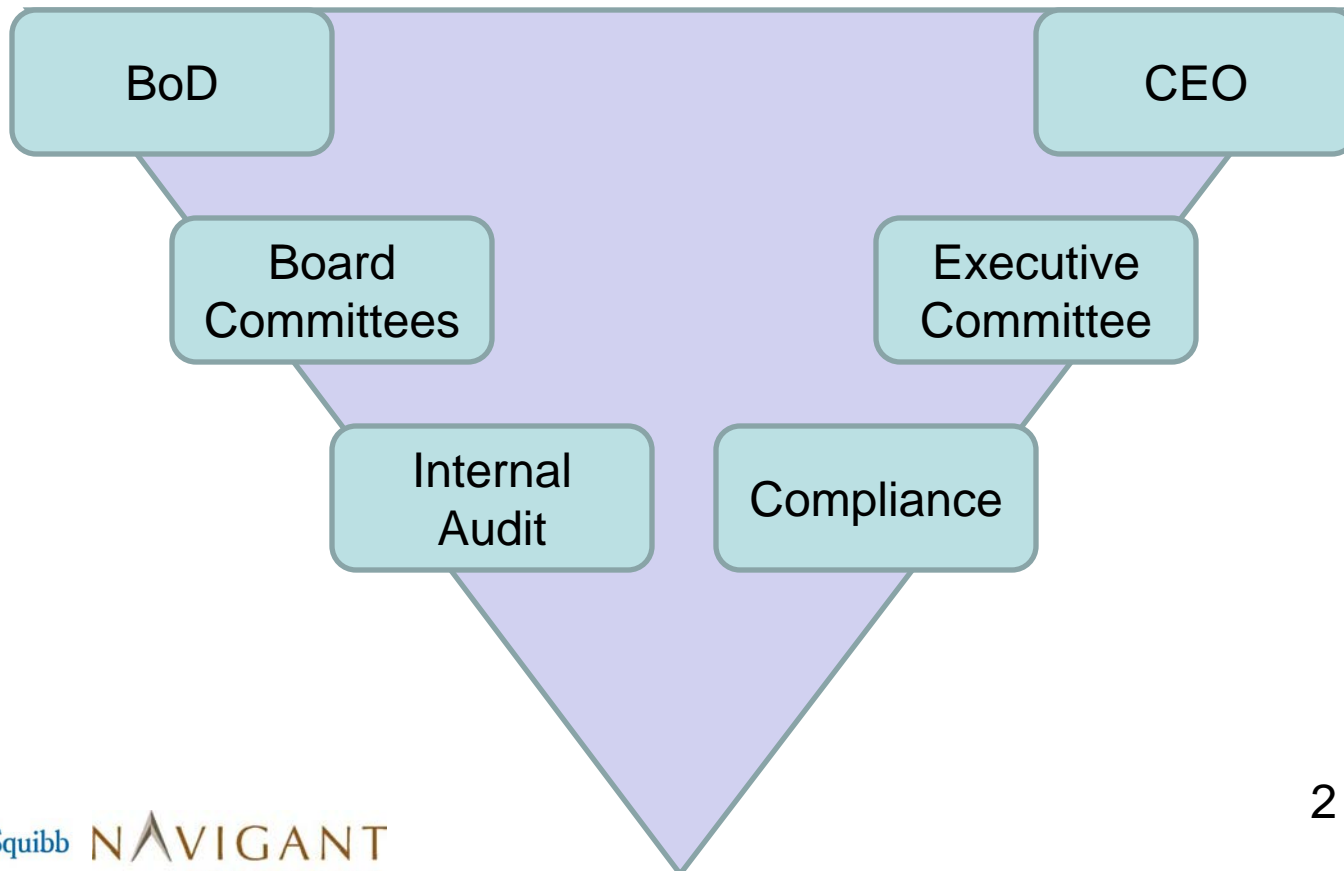


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Board of Directors

Oversight and Governance



Board Presentations Are An Important Element of an Effective Health Care Compliance Program

- Federal Sentencing Guidelines
 - The organization's governing authority shall be knowledgeable about the content and operation of the compliance and ethics program and shall exercise reasonable oversight with respect to the implementation and effectiveness of the compliance and ethics program.
- OIG Guidance on Board Responsibilities
 - Directors have a fiduciary responsibility to exercise a reasonable duty of care in overseeing a company's compliance program

Topics to Present to the Board

- Scope of the Compliance Program
 - Structure of the compliance organization
 - Reporting relationships of the compliance organization
 - Delegation of compliance-related responsibilities outside the compliance organization
 - Objectives of the compliance program
 - Limitations that may impact those objectives
 - Compliance risks faced by the organization
 - Plans to address those compliance risks
 - Resources needed to develop or maintain the compliance program

Topics to Present to the Board (continued)

- Operation of the Compliance Program
 - Code of Conduct
 - Policies and Procedures
 - Training
 - External Current Events
 - Monitoring and Auditing
 - Remedial measures in response to deficiencies
 - Receiving reports of and responding to potential compliance violations

Helpful Hints

- Time is precious
- Less paper and more talking versus more paper and less talking
- Present consistent sets of data and information at each meeting
- Don't be timid about reminding the Board what you told them before
- Remember that Board Members have diverse backgrounds and business experiences, and are not involved in the day-to-day activities of a health care company
- Read the newspaper
- Leave plenty of time for questions
- Be comfortable saying that you don't have an answer but will look into it and follow up

Recent CIA Requirements

Organization	CIA Date	Independent Compliance Advisor	Annual Compliance Program Effectiveness Review	Annual Compliance Program Effectiveness Resolution
Tenet	September 2006	X	X	X
Cephalon	September 2008	X	X	X
Bayer	November 2008	X	X	X
Lilly	January 2009		X	X
Quest	April 2009	X	X	X
Pfizer	August 2009		X	X
Biovail	September 2009		X	X
UMDNJ	September 2009		X	X

Board Implications

- Expanded remit for oversight
- More than just public policy, or ethics
- Personal implications
- Need for independent review

Board Resolution

The Risk and Compliance Committee of Biovail's Board of Directors (Risk Biovail's Compliance Committee) has made a reasonable inquiry into the operations of Biovail's Compliance Program, including the performance of the Chief Compliance Officer and the compliance department. Based on its inquiry, the Risk Committee has concluded that, to the best of its knowledge, Biovail has implemented an effective Compliance Program to meet the Federal health care program requirements, FDA requirements, and the obligations of the CIA.

Board Resolution

The Board of Directors has made a reasonable and due inquiry into the operations and effectiveness of Quest's Compliance Program for the period, including the performance of the Compliance Officer, the Compliance Committees, and the compliance department. In connection with its inquiry, the Board of Directors has **retained an independent and objective** Compliance Expert with expertise in health care compliance programs to support the Board of Directors' responsibilities. The Board of Directors has arranged for the Compliance Expert to perform a Compliance Program Review to (i) assess the **effectiveness** of Quest's Compliance Concerns Process and (ii) provide the Board of Directors with **recommendations** with respect to the Compliance Concerns Process. The Board of Directors has reviewed the Compliance Program Review Report and has adopted the recommendations of the Compliance Expert set forth in the Compliance Program Review Report. Based on all of these steps, the Board has concluded that, to the best of its knowledge, Quest has implemented an effective Compliance Program."

Thirteen Questions That Support Compliance Effectiveness Assessments

OIG Element	Question	Answer	Tested?
Oversight	Does the compliance officer have direct access to the governing body, the president or CEO, all senior management, and legal counsel?	Y / N	Y / N
	Does the compliance officer make regular reports to the BoD and other management concerning different aspects of the organization's compliance program?	Y / N	Y / N
Written Standards	Have the standards of conduct been distributed to all directors, officers, managers, employees, contractors and vendors?	Y / N	Y / N
	Has the organization developed a risk assessment tool, which is re-evaluated on a regular basis, to assess and identify weaknesses and risks in operations?	Y / N	Y / N
Training and Education	Has the organization evaluated the appropriateness of its training format by reviewing the length of the training sessions; whether training is delivered via live instructors or computer-based training programs; and the need for general and specific training sessions?	Y / N	Y / N
Open lines of Communication	Has the organization established a well publicized, anonymous hotline or similar mechanism so that employees, contractors, and other individuals can report potential compliance issues?	Y / N	Y / N
	Are the results of internal investigations shared with the governing body and relevant departments on a regular basis?	Y / N	Y / N
	Do you evaluate the 'Tone From The Top' on a regular basis (e.g. annually)?	Y / N	Y / N
Auditing and Monitoring	Is the compliance audit and monitoring plan re-evaluated annually, and does it address the proper areas of concern, considering, for example, findings from previous year's audits, risk areas identified as part of the annual risk assessment, and high risk areas?	Y / N	Y / N
	Have you built into the formal compliance audits a degree of independence?	Y / N	Y / N
Responding to Detected Deficiencies	Has the organization created a response team, consisting of representatives from compliance, audit and any other relevant functional areas, which may be able to evaluate any detected deficiencies quickly?	Y / N	Y / N
Enforcement of Standards	Are employees, contractors and vendors checked routinely (e.g., at least annually) against government sanctions lists, including the OIG's list of excluded individuals/Entities (LEIE) and the General Services Administration's Excluded Parties Listing System?	Y / N	Y / N
	Are disciplinary standards established which describe disciplinary action (up to and including termination) for compliance-related violations?	Y / N	Y / N

Helpful Hints

- Meet quarterly with a Compliance Committee of the BoD
- Prepare with concise pre-reads, highlighting areas for discussion
- Use a Dashboard
- Repeat critical items if necessary
- Educate the BoD on Health Care Compliance
- Remain current on OIG, DoJ activity
- Be prepared for basic and complex questions
- Leverage experts and seasoned advisors to the BoD

Presenters

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