

ADVANCED COMPLIANCE STRATEGIES: CORPORATE GOVERNANCE AND CORPORATE COMPLIANCE

By

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Overview. The Office of Inspector General (OIG) for the U.S. Department of Health and Human Services (DHHS) has issued compliance guidance for various sectors of the health care industry, including the Pharmaceutical Industry. The OIG guidance is labeled as “voluntary”. However, the most potent force for the development of compliance programs came as the result of the creation of the United States Sentencing Commission in the 1980s. This Commission developed “Compliance Guidelines for Organizations” (“Guidelines”) that are mandated in the sentencing process. These Guidelines have been followed by the OIG in their compliance guidance documents. The Guidelines apply to all organizations in all business sectors and represent a very serious set of standards for organizations that come under investigation by the Federal government. They call for compliance programs that are “top-down”, beginning with the Board and Senior Management. This document focuses on and highlights some of the Board level responsibilities. More recently the Sarbanes-Oxley Act of 2002, mandates many of the features of these programs for all covered entities (i.e. publicly traded companies).

Corporate Responsibility and Corporate Compliance. The DHHS Office of Inspector General (OIG), in conjunction with the American Health Lawyers Association (AHLA) published a new guidance document entitled “Corporate Responsibility and Corporate Compliance: A Resource for Health Care Boards of Directors”. There are a number of questions being raised about the significance of this document. Much can be answered in the words of the introduction section where it is noted that the headlines of papers have been filled in recent months with reports about increased scrutiny of corporate directors as result of scandalous behavior by some companies. There have been a number of legislative and regulatory actions taken to improve governance oversight of business activities. Among the most heralded actions was the enactment of the Sarbanes-Oxley Act that calls for, among other things, a hotline directly from employees to the oversight function on the Board.

Although the events driving the development of this new guidance document from the OIG are relatively new, the expectations of the OIG for strong involvement and responsibility by Boards are not. For years, the OIG has noted in their compliance guidance documents that the compliance efforts of any organization begin at the top, the top meaning the Board. They have noted that their compliance program guides were designed to assist governing bodies (e.g., Boards of Directors or Trustees) in the proper management and operation of an organization and called upon corporate officers to provide ethical leadership to the organization and to assure that adequate systems are in place to facilitate

ethical and legal conduct. The OIG has further noted that the adopting and implementing an effective compliance program requires a substantial commitment of time, energy and resources by the governing body. In response to this, many organizations have expanded their traditional Audit Committee into an Audit and Compliance Committee to include compliance oversight.

The OIG has repeatedly stated that case law suggests that the failure of a corporate director to attempt in good faith to institute a compliance program in certain situations may be a breach of a Director's fiduciary obligation. They cite the Caremark case as an example of that (In re Caremark International Inc. Derivative Litigation, 698 A.2d 959 (Ct. Chanc. Del. 1996).

It is also important to note that the OIG encouraged Congress to increase their authority in dealing with Boards and Board members who were derelict in their oversight responsibilities. The passage of the Health Insurance Portability and Accountability Act (HIPAA) was a response to this plea (Public Law 104-191—AUG. 21, 1996, 110 STAT. 2005). Section 213 of that act is entitled, "Permissive Exclusion of Individuals with Ownership or Control Interest in Sanctioned Entities". It states that "Any individual who has a direct or indirect ownership or control interest in a sanctioned entity and who knows or should know...of the action constituting the basis for the conviction or exclusion...; or "(ii) who is an officer or managing employee...of such an entity. Thus, the OIG has the authority to exclude members of the Board from the health care industry if they knew or should have known about the activity that gave rise to a conviction or exclusion in the company. This is the gross negligent standard and the OIG has the authority to administratively impose the sanction within the Department of Health and Human Services (DHHS). It does not require judicial determination in the federal courts.

The "Corporate Responsibility and Corporate Compliance" document is a resource designed to assist health care organization directors to ask knowledgeable and appropriate questions related to health care corporate compliance. The document focuses on the "duty of care" and again cites the Caremark case noted above. They note the duties that Directors have in both the development and oversight of compliance programs. The OIG identifies two distinct contexts for this, (a) decision-making functions and (b) oversight functions and then offers a list of suggested questions that Board members should ask in each arena.

The significance of all of this recent activity is not only the willingness of the OIG to assist Boards in carrying out their fiduciary obligations, but a warning that the OIG is willing to hold Boards to these standards. This is not a hollow threat in that the HIPAA authorities are there to give the OIG teeth in taking action against Board members who forget their fiduciary responsibilities.

- The Board should be the apex of any effective compliance program and be ultimately responsible for the proper implementation and continued operation of a compliance program.

EFFECTIVE COMPLIANCE PROGRAMS

1. Can dramatically reduce penalties, if violations occur
2. Improve internal communication and feedback to management
3. Provide useful intelligence actual operations environment
4. Reduce the likelihood of civil and criminal wrongdoing
5. Ensures legal/policy changes are disseminated quickly to all employees
6. Reduce vulnerability and liability exposure to "whistle blowing"
7. Improve crisis response capabilities
8. Permit quickly and positively to emerging lawsuits and investigations
9. Reassures Board/community that improper conduct is being addressed
10. Promotes good business by having everyone adhere to the same rules
11. Avoid having one imposed by enforcement agencies

Under Sarbanes-Oxley, the Board must take on greater responsibility and accountability. The Board should have financially-literate members, appointed for long terms. The key to compliance is the proper establishment and operation of the Audit Committee of the Board.

The Sentencing Commission and the OIG stress the seven basic elements of an effective compliance program. The following outlines a few key steps in developing and implementing such a program. It is designed only to give flavor to what is needed for effective programs. The focus is on Corporate Governance.

STEP 1. ENSURE TOP-DOWN COMPLIANCE OVERSIGHT

An effective Compliance Program must be a "top-down" program; the top being the Board, followed by the Chief Executive Officer, President, Chief Operating Officer, and so on through the executive and management structure of the organization down to the lowest echelon of employees. Often the most difficult step in developing an effective compliance program is achieving a consensus among the management team and the Board of Directors or Governing Board. It is important they understand that a commitment to building an effective compliance program is not based upon a negative decision to do it simply because the government wants it done. The initial "buy-in" at the Board level can make all the difference between developing a functioning compliance program

and a sterile one that is created by “painting by the numbers”. It also can spell the difference between a “sham” compliance program and an effective one. The positive benefits of a compliance program should be stressed.

The Department of Justice and the Office of Inspector General (OIG) at DHHS have stressed the importance they place on having the Board intimately involved in providing ongoing oversight of compliance efforts. The OIG notes in the various compliance guidance documents that a comprehensive compliance program should include the designation of appropriate bodies, e.g., a corporate compliance committee, charged with the responsibility of operating and monitoring the compliance program, and who report directly to the CEO and the governing body.

The OIG, in conjunction with the American Health Lawyers Association (AHLA) published a new guidance document entitled “Corporate Responsibility and Corporate Compliance: A Resource for Health Care Boards of Directors”. It addresses the importance of strong involvement and responsibility by Boards in providing compliance oversight. For years, the OIG has noted in their compliance guidance documents that the compliance effort of any organization begins at the top, the top meaning the Board. This is consistent with a long history of legal expectation for Boards arising from (a) fiduciary duties, (b) derivative suits, (c) good faith standards, etc. They have noted that their compliance program guides were designed to assist governing bodies (e.g., Boards of Directors or Trustees) in the proper management and operation of an organization and called upon corporate officers to provide ethical leadership to the organization and to assure that adequate systems are in place to facilitate ethical and legal conduct. The OIG has further noted that adopting and implementing an effective compliance program requires a substantial commitment of time, energy and resources by the governing body. In response to this, many organizations have expanded their traditional Audit Committee into an Audit and Compliance Committee to include compliance oversight.

The OIG has repeatedly stated that case law suggests that the failure of a Corporate Director to attempt in good faith to institute a compliance program in certain situations may be a breach of a Director’s fiduciary obligation. They cite the Caremark case as an example of that in re: Caremark International Inc. Derivative Litigation, 698 A.2d 959 (Ct. Chanc. Del. 1996). A case was brought against the Board of Directors of Caremark alleging that the directors breached their fiduciary duties by failing to monitor effectively the conduct of employees who violated various state and federal laws regarding payments to health care providers that ultimately led to the organization pleading guilty to criminal charges and paying substantial penalties. The Chancellor in the case concluded that a director does have a general duty to ensure that there is an effective compliance and control system and that the failure to do so could, under some circumstances “render a director liable for losses caused by non-compliance with applicable legal standards.”

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The Board of Directors must be considered the apex of any effective compliance program and is ultimately responsible for the proper implementation and continued operation of a compliance program. Many privately held companies and nonprofit organizations do not have any truly independent directors. Consideration should be given to adding such independent directors to the Board, not only for purposes of the audit committee, but also for service on a compensation committee that deals with management compensation (including bonuses and options to management shareholders).

Federal regulators and the public see the Board as having major responsibilities in assuring the existence of adequate internal controls of the corporation. This includes the accounting and financial systems, as well as proper auditing oversight of the Corporation. To be viewed as effective, board members must demonstrate that they are objective, capable and inquisitive, as well as evidence a working knowledge of the entity's activities and environment. Board members are expected to commit the time necessary to fulfill their Board responsibilities. The Board is responsible for holding management accountable through its governance, guidance and oversight activities. By selecting management, the Board has, in effect, defined what it expects in regards to integrity and ethical values, and must confirm its expectations through its oversight role. To do less, or to discharge these activities poorly, invites stockholder suits and investigations that may target board members.

STEP 2. CREATE BOARD LEVEL COMPLIANCE COMMITTEE

The Office of Inspector General (OIG) has been issuing compliance guidance for over a decade. They have adopted and elaborated upon the seven compliance steps outlined in the Federal Sentencing Guidelines. Program Guidance documents are designed to clarify expectations as they relate specifically to the health care industry. The OIG believes that every effective compliance program must begin with a formal commitment by the organization’s governing body to include all of the applicable elements identified by them. The OIG position is that

it is of critical importance for the Board and senior management to assume lead in developing compliance programs in order to avoid fraud and abuse and promote compliance with all applicable laws and regulations. They note it is incumbent upon a Board, corporate officers and managers to provide ethical leadership to the organization and to assure that adequate systems are in place to facilitate such conduct. The OIG guidance calls for “as a first step, a good faith and meaningful commitment on the part of the ... administration, especially the governing body and the CEO, should substantially contribute to a program’s successful implementation.” They also see that effective Board oversight of compliance as one of their critical fiduciary responsibilities.

BOARD OVERSIGHT RESPONSIBILITIES

- Compliance with applicable laws, regulations and policies
- Accurate and reliable accounting, auditing and claims processing
- Compliance Program development and implementation
- Adherence to high business standards, legal and personal ethics
- Adequate compliance education/training and communication
- Development, approval, and dissemination of a Code of Conduct
- Compliance policies/procedures developed and disseminated

The Board should ensure the Audit Committee (“Committee”) has been charged with the responsibility of providing oversight of Compliance of the organization and ensuring the organization has adopted and implemented policies and procedures that should ensure compliance with all applicable laws, regulations, and policies. It should be directly responsible for the appointment, compensation, retention and oversight of the work of any registered public accounting firm engaged for the purpose of preparing or issuing an audit report or performing other audit, review or attest services for the issuer, and each registered public accounting firm must report directly to the Committee.

The primary goals of the Committee should be to (a) assist the Board in fulfilling its fiduciary responsibilities relating to the legal and financial compliance with applicable laws, regulatory requirements, industry guidelines, and policies; (b) ensure that all applicable accounting and auditing reporting practices are proper and accurately reflect the condition of the organization, (c) provide a vehicle for communication between the Board and management with regards to proper operations, and (d) present to the Board recommendations to assist the organization in conducting its activities in full compliance with all applicable laws, regulations, policies, and the Code.

Among their responsibilities, the Committee should:

- Act independent of management.

- Provide oversight of accounting/financial reporting, accounting services and approve all contracted non-audit services.
- Assist legal and financial compliance with applicable laws, regulatory requirements, industry guidelines, and policies
- Ensure the organization has adopted and implemented compliance policies and procedures.
- Provide oversight to the internal audit function including reporting obligations, the proposed annual audit plans and the coordination of such plans with the independent auditors.
- Review and recommend to the Board the independent auditors to be selected to audit the financial statements of the organization.
- Provide oversight to the implementation of the Compliance Program, and ensure adherence to the Code of Conduct and government rules/regulations.
- Review the activities of management and its employees in light of the Code of Conduct and the Compliance Program to ensure that policies and procedures are properly understood and followed.

STEP 3. PROVIDE STRUCTURE TO THE COMPLIANCE PROGRAM

As pharmaceutical organizations begin to develop and/or enhance their corporate compliance program, the first step has to be establishing a framework for the individual(s) responsible for the oversight and operation of the program. Furthermore, once the compliance program begins functioning within the organization, policy statements should be issued to the organization related to areas of compliance risk.

Compliance policy/procedures should address

- Government expectations
- Establishing a framework for the compliance program
- Establishing an infrastructure for the compliance program
- Providing guidance on critical compliance related areas
- Explaining compliance office duties and responsibilities
- Providing specific guidance on areas of specific compliance risk

It is important that an organization be able to evidence that development and implementation of the compliance program had the active involvement at the Board level. The easiest and best way to evidence this is in compliance policy development.

BEST PRACTICE

. Gain Board level involvement in policy development and consider having them

Before any policy development, it is advisable to establish the protocols for how they are to be developed; including defining what goes the header, purpose and procedure sections. The process for developing, approving and dissemination the policies should also be described.

WRITTEN COMPLIANCE DATE AND COMPLETE.

It is important to make must have current written procedures that address compliance with applicable their areas and all affected

BEST PRACTICE

. Make the first policy one that describes how compliance policies and procedures

STEP 4. ENSURE GUIDANCE IS UP TO

sure all departments policies and issues related to laws and regulations in parties have ready

access to them. All departments should annually review and identify all areas of compliance risk within their area of responsibly and determine if:

- An existing policy and procedure addresses those issues
- Revision of existing policy is needed to better address an issue area
- New policy document is needed to minimize the risk of non-compliance

The Chief Compliance Officer (CCO) and Compliance Committee should review all compliance policies and update those that require it and ensure all compliance policies are approved by the Chief Executive Officer and the Board of Directors. When developing or revising a policy, begin with a statement of purpose that defines the intent and objectives. If it is in response to legal or regulatory authority, that authority should be noted along with a list of supporting and source documentation used to validate the policy and procedure. The CCO, in consultation with the Compliance Committee and as required legal counsel, should coordinate development of all draft compliance policies and be responsible for submitting them to appropriate management and executives for review and comment; and thereafter for approval by the Chief Executive Officer and Board of Directors. In submitting the draft policies for approval, the CCO should include with the proposed policy and procedure a presentation of the compliance issues in question, a description of how the policy and procedure proposes to address such issues, and a plan for implementation (including any

training required). The proposed policy and procedure, with justification, should be distributed to the CEO and Committee members prior to the scheduled committee meeting where approval should be sought.