Bloomberg BNA

BNA's
Health Care Fraud Report™

What the OIG's New Compliance Guidance Means for Health-Care Organizations' Boards of Directors

NICHOLAS MERKIN

Health-care organization boards of directors have long been a focus of OIG scrutiny and have been the subject of OIG guidance statements in 2003, 2004 and 2007.[1]

On April 20, 2015, the OIG issued yet another set of practical guidance advice specifically targeting a board's oversight of compliance program functions.[2]

This guidance encompassed and set forth expectations regarding:

- the roles of, and relationships between, health-care organizations' audit, compliance and legal departments;
- the mechanism and process for issue-reporting within health-care organizations;
- an approach to identifying regulatory risk; and
- methods of encouraging enterprise-wide accountability for achievement of compliance goals and objectives.

The result of these heightened expectations—coupled with increased regulatory enforcement and plaintiffs' attorneys looking for deep-pocketed targets—may mean that health-care organization directors have even greater responsibility and potential liability than those of non-health-care entities.

In this environment, it is crucial for health-care organization boards of directors to understand the new OIG guidance and the investment time and resources necessary to execute properly their corporate responsibilities and duties.

It is crucial for health-care organization boards of directors to understand the new OIG guidance and to invest the time and resources to execute their corporate responsibilities.

A closer look at the OIG's recent statement reveals that its guidance is fairly opaque.

So what does the new OIG guidance mean in practical terms? What are its real-life implications to a health-care entity and its board?

Set forth below is a summary of the relevant aspects of the OIG's recent guidance statement, as well as suggestions for renewed ''best practices'' and practical sug-

[1] OIG and AHLA, Corporate Responsibility and Corporate Compliance: A Resource for Health Care Boards of Directors (2003); OIG and AHLA, An Integrated Approach to Corporate Compliance: A Resource for Health Care Organization Boards of Directors (2004); and OIG and AHLA, Corporate Responsibility and Health Care Quality: A Resource for Health Care Boards of Directors (2007).

[2] OIG, AHIA, AHLA, and HCCA, Practical Guidance for Healthcare Governing Boards on Compliance Oversight (2015).

Nicholas Merkin is the chief executive officer of Compliagent, a health-care regulatory compliance firm. He can be reached at nmerkin@compliagent.com

 ISSN 1092-1079

gestions for effectively incorporating the OIG's directives into health-care organizations' compliance plan oversight.

Health-Care Organizations' Audit, Compliance and Legal Departments

According to the OIG, the compliance function in health-care organizations is generally shared among the audit, compliance and legal departments. The OIG views the relationships, reporting lines and divisions of responsibility among those stakeholders to be properly the subject of internal policies and procedures and direct board scrutiny.

The OIG's guidance, however, is fairly silent about the manner in which the board's oversight obligations should be discharged.

The OIG admits there is no ''one-size-fits-all'' solution here that would fit all health-care entities and that elements such as organizational size and resources will dictate the practical application of these requirements.

Despite this, the OIG speaks with clear and unequivocal instruction in one regard: in demanding that the compliance, legal and audit functions be independent of one another.

An entity's compliance officer or staff should never be the same its legal counsel or department, nor be subordinate to it. In the OIG's view, legal and compliance are separate functions, with different scopes of responsibility.

The same is true for the audit department. In the OIG's framework, the compliance function ''promotes the prevention, detection, and resolution'' of activities that are inconsistent with legal, policy or business standards, while the legal function advises management and the board with respect to ''relevant laws and regulations.''

The audit department, in contrast, responsible for evaluating ''existing risk and internal control systems.''[3]

Issue-Reporting Within Healthcare Organizations

The next—and related—area of the new guidance is a focus on the board's access to an adequate spectrum of information and data necessary to properly engage in compliance oversight.

The OIG, while again giving little instruction as to the specifics, recommends an internal organizational reporting structure that ensures that the board receives regular compliance and risk reports.

The OIG proposes separate and independent reporting from the principal personnel responsible for the audit, compliance, human resources, legal, quality and information technology functions.

These lines of reporting, according to the OIG, should be addressed in internal policies, procedures, and protocols, as well as by the organization's compliance plan.

Part of this process should be the development of objective metrics and measures by which the compliance health of an organization may be effectively assessed and evaluated.

More specifically, in connection with proper information flow within a health-care organization, the OIG's guidance charges the board with ensuring the existence of infrastructure and processes effecting timely reporting of suspected compliance violations and responding with remedial measures.

Identifying Regulatory Risk

The OIG recognizes that the health-care industry presents an acute set of oversight challenges demanding a heightened level of oversight, including referral relationships and arrangements, billing issues, privacy breaches and quality and outcome matters.

The OIG's guidance emphasizes the board's role in the identification of the risks associated with these areas and that such risks must be addressed though detection tools, such as compliance hotlines and internal audits.

Three emerging areas of particular interest are discussed in the context of board responsibilities in this area:

1. an increased emphasis on quality;
2. changes in insurance coverage and reimbursement; and
3. new forms of reimbursement (including value-based purchasing and bundled and global payments).

Encouraging Enterprisewide Accountability

The last area addressed in the OIG's guidance statement is the board's role in enforcing internal accountability for the compliance program.

The OIG's perspective is that all employees within an organization should be held accountable for an entity's compliance conduct—not only those members of the audit, compliance or legal divisions.

Moreover, health-care boards should set organizationwide compliance goals and measure and communicate progress, as well as compliance successes and failures.

In this area, the OIG provides specific guidance as to fulfilling these requirements, such as compensation-related rewards and penalties for compliance attainments and breakdowns.

The OIG also emphasizes the need for adequate self-disclosure protocols and the reporting of compliance violations, as appropriate.

Best Practices and Recommendations for Meeting the OIG's Expectations

Understanding and digesting the OIG's recent guidance for health-care boards of directors, while an important first step, is only the beginning of a continuing process of building and refining compliance infrastructure for all health-care organizations.

Moving forward into implementation requires translating recommendations into actions in some of the ways described below.

Modified Policies and Procedures Written policies and procedures are imperative for addressing compliance risk within an organization.

[3] Id. at pp. 6-7.

  HFRA ISSN 1092-1079

Health-care organizations, in light of the new guidance discussed above, should revise their policies and procedures in connection with the strict relationships, reporting lines, and divisions of responsibility among the audit, compliance and legal departments desired by the OIG.

Revised policies and procedures should lay out the lines of independent, regular reporting to the board from the audit, compliance, human resources, legal, quality and information technology areas of an entity, as well as effective tools to be used to identify compliance risk.

The new policies and procedures should also lay out the design of internal disciplinary and accountability structures, including how compliance goals will be set, communicated organizationally, and monitored by the board.

Additional Education and Training All staff should educated as to the revised organization's policies and procedures, as well as the mechanisms by which the policies and procedures are revised and kept current.

Specifically, director training should focus on, in addition to the recent OIG guidance, the various fiduciary duties directors have in connection with the compliance function, as well as the primary regulations that relate to organizational compliance, such as the False Claims Act, Stark and anti-kickback laws, exclusion screening requirements, HIPAA and other privacy laws, as well as applicable state laws.

Internal and External Auditing and Reporting Renewed internal and external auditing and reporting mechanisms should be planned and implemented to focus on the areas of concern highlighted by the OIG.

All health-care organizations should conduct a yearly compliance effectiveness review and risk analysis, preferably conducted by an independent third-party. This analysis should lead to modifications and risk prioritization in their enterprise-wide compliance plans and programming.

Reports made to directors arising from newly-conducted audits and an organization's compliance hotline should be substantive and result clear instructions as to remediation and change.

Maintenance and Validation The information stream arising from truly effective corporate compliance programs can be overwhelming. In order to realistically discharge the oversight obligations underscored by the OIG, it is crucial for organizations to be able organize and present such data in a meaningful way to directors and management.

The manner in which this information is communicated must, by necessity, vary by organizational type, size, and the resources available. At the very least, however, whether compliance-focused dashboards, software, or more low-tech methods, directors must be able to track their organizations' incidents of non-compliance and how these incidents were addressed.

More optimally, directors should have easy and real-time access to evolving procedures and protocols, educational materials, reports related to audits, ongoing litigation, employee background screening, discipline and training, as well as the evolving corporate compliance plan and areas of focus.

Conclusion

Health-care entities are among the most complex organizations to manage and oversee from both a business and compliance perspective.

Directors charged with such oversight responsibility face formidable challenges. Recognizing this, the OIG has provided several guidance statements, the most recent of which was issued in April 2015.

Simply put, the OIG and other regulatory bodies have set the bar high and imposed demanding expectations upon health-care boards of directors.

Although compliance with these burdens requires much in terms of attention and resources, it is not impossible. Understanding the OIG's guidance in this area is crucial, as is implementation of the OIG's recommendations.

Although, as the OIG has stated, there is no ''one-size-fits-all'' way in which to address compliance, the implementation of the suggestions set forth above may be advisable way in which health-care boards of directors can discharge their various duties and obligations.