# Using the DOJ Fraud Section Guidance on "Evaluation of Corporate Compliance Programs" to Enhance Compliance Plans

**by Thomas William Baker**[1]

A well-functioning Compliance Program is an absolute best practice for health care providers and suppliers and other entities that involve governmental reimbursement programs. While there are no existing legal requirements for such programs (with the exception of skilled nursing facilities), multiple federal agencies have published guidelines for structuring Corporate Compliance and Ethics Programs for many years. However, until now there has been little guidance on how a Compliance Plan is expected to operate.

On Feb. 8, 2017, the Fraud Section of the U.S. Department of Justice (DOJ) quietly and without any accompanying press release published comprehensive guidance on the "Evaluation of Corporate Compliance Programs" (referred to herein as the "DOJ Compliance Program Guidance") on the "Compliance Initiative" page of the DOJ web site: https://www.justice.gov/criminal-fraud/page/file/937501/download. Rather than state precisely how a Corporate Compliance and Ethics Plan should be constructed, the DOJ presents a series of questions that DOJ internally asks when assessing whether an organization that is under investigation for potential misconduct has effectively implemented its Compliance Program.

## Importance of Implementing an Effective Compliance Program.

Whether an organization has an effective Compliance Program is critically important when allegations of wrongdoing arise because implementation of an effective Compliance Program is potentially exculpatory and is also valuable when an organization is engaged in settlement negotiations with federal agencies. Consequently, when confronted with an allegation of misconduct, the typical initial response from the target organization is "we have a Corporate Compliance Program." However, to the DOJ, merely making that statement or even showing the DOJ a document that appears appropriate is not enough: the DOJ needs to determine whether the Compliance Program is in fact effectively implemented.

## The DOJ Compliance Program Guidance Complements Other Compliance Guidance.

The DOJ identifies eleven topics for a focused Compliance Program review, each of which is followed by a series of specific questions for evaluation of the Compliance Program's effectiveness. Most of these topics and the related questions dovetail neatly with the Federal Sentencing Guidelines as well as Compliance Guidelines promulgated by other governmental agencies such as the United States Department of Health and Human Services, Office of the Inspector General (OIG) and statutory requirements of skilled nursing facility Compliance and Ethics Programs enacted through Section 6102 of the Affordable Care Act of 2010 (which for convenience are collectively described as the "Compliance Program Guidelines").

The Guidelines for Organizational Defendants from the Federal Sentencing Guidelines form the foundation for all Corporate Compliance and Ethics Programs and describe seven specific elements that must be set forth in every Corporate Compliance Plan:

- **Standards of Conduct.** The organization must establish specific ethical standards and policies and procedures to be followed by all of its employees and other agents that are reasonably capable of reducing the prospect of criminal conduct.
- **Responsibilities.** Specific individuals at a high-level within the organization must be assigned overall responsibility to oversee compliance with such standards and procedures.
- **Delegation of Authority.** The organization must use due care not to delegate substantial discretionary authority to individuals whom the organization knew, or should have known through the exercise of due diligence, had a propensity to engage in illegal activities.
- **Communication/Education.** The organization must take steps to communicate effectively its standards and procedures to all employees and other agents by, for example, requiring participation in training programs or by disseminating publications that explain in a practical manner what is required.
- **Monitoring and Auditing.** The organization must take reasonable steps to achieve compliance with its standards by, for example, instituting monitoring and assessment systems reasonably designed to detect misconduct by its employees and other agents and by having in place and publicizing a reporting system through which employees and

other agents can report misconduct by others within the organization without fear of retribution.

- **Discipline.** The standards must be consistently enforced through proper disciplinary mechanisms, including, as appropriate, discipline of individuals responsible for the failure to detect an offense.
- **Response and Prevention.** After an offense has been detected, the organization must take all reasonable steps to respond appropriately to the offense and to prevent future similar offenses, including any necessary modifications to its compliance program to prevent and detect violations of law.

Within the context of these seven elements, the size and complexity of the organization dictates the formality of the Compliance Plan.

In addition, the DOJ Compliance Program Guidance reflects the growing emphasis on identifying individual persons who are involved in the compliance process as first expressed in the "Yates Memo" issued by former Deputy Attorney General Sally Yates that, in essence, directs the DOJ to identify potentially culpable individuals as part of any DOJ investigation of an organization.

To put the DOJ Compliance Program Guidance into perspective, the Compliance Program Guidelines are prophylactic in nature and address what an organization should do to prevent allegations of wrongdoing, and the DOJ Compliance Program Guidance describes how the DOJ determines whether the organization has in fact implemented an effective Compliance Program after an allegation of misconduct arises.

## Summary of DOJ Compliance Program Guidance In the Context of Other Compliance Program Guidelines.

verall, the topics and questions that DOJ uses when evaluating the effectiveness of a Corporate Compliance Program are much more focused and detailed than the seven core requirements of a Corporate Compliance and Ethics Plan as described in the Federal Sentencing Guidelines and much more process oriented than substantive compliance guidance promulgated by agencies like the OIG. The following is a summary of some key points of DOJ emphasis in its Compliance Program Guidance on each of the DOJ's eleven topics within the context of the Compliance Program Guidelines:

- **Analysis and Remediation of Underlying Misconduct.** The questions under this topic relate to the Compliance Program Guidelines requiring organizations to "respond" to allegations of misconduct and take actions to "prevent" further similar offenses and include inquiries regarding the following: the cause of the misconduct and whether the response revealed "systemic issues" (in contrast to an isolated incident); who made the analysis; and whether there were prior opportunities to detect the misconduct, and, if so why the opportunities were missed.
- **Role and Involvement of Senior and Middle Management.** The questions under this topic relate to the Compliance Program Guidelines requiring specific high-level personnel to have overall responsibility for implementing the Compliance Program and include inquiries regarding the following: whether senior leaders have demonstrated leadership in the organization's compliance and remediation effort and what specific actions senior leadership has taken in that regard; what compliance expertise has been available on the board of directors; whether the board of directors have held executive or private sessions with the compliance and control functions; and what types of information the board of directors and senior management examined in their oversight of the area in which the misconduct occurred.
- **Autonomy and Resources.** The questions under this topic relate to the Compliance Program Guidelines requiring communicating compliance standards and procedures to all employees and other agents as well as requiring specific high-level personnel to have overall responsibility for implementing the Compliance Program and include inquiries regarding the following: whether compliance representatives were involved in training and decisions relevant to the misconduct; how the compliance function compares with other organizational functions in stature, compensation, and access to key decision makers; whether compliance personnel were properly qualified; whether the compliance officers had direct reporting lines to the Governing Board; how the organization insures independence of the compliance function; how the organization has responded to prior allegations of misconduct presented to senior management by the compliance officers; whether the compliance department received proper funding and resources; and whether the organization outsourced the compliance function to an external firm or consultant and if so how that decision was both made and managed.
- **Policies and Procedures**. The questions under this topic relate to the Compliance Program Guidelines requiring standards of conduct and communicating the standards of conduct to the organization's agents and include inquiries regarding the following: the process for designing and implementing policies and procedures; how the organization manages accountability for supervisory oversight of performance in accordance with the standards of conduct; how the standards of conduct were communicated to the organization's agents; who was responsible for integrating the standards of conduct into the organization's operations; why the Compliance Program failed to detect and prevent the misconduct; how the misconduct was funded and whether the

organization had effective internal controls; and, if vendors were involved in the misconduct, the process for vendor selection.

- **Risk Assessment**. The questions under this topic relate to the Compliance Program Guidelines requiring a baseline assessment of regulatory risk and include inquiries regarding the following: the methodology that the organization used to identify, analyze, and address its particular regulatory risks; and what information and metrics the organization used to help detect the misconduct in question.
- **Training and Communications**. The questions under this topic relate to the Compliance Program Guidelines requiring effective communication of the Compliance Program standards and procedures to all employees and other agents and include inquiries regarding the following: whether the organization provided tailored training for high-risk and control employees that address the risk in the area where the misconduct arose; how the organization measured the effectiveness of the training; what senior management has done to let employees know the organization's position on the misconduct; what communications are generally made when an employee is terminated for failure to comply with the organization's standards of conduct; what resources are available to employees to provide guidance regarding compliance policies; and if the organization has assessed whether its employees know when to seek advice and if they would be willing to do so.
- **Confidential Reporting and Investigation.** The questions under this topic relate to the Compliance Program Guidelines requiring response to allegations of misconduct and preventing further similar offenses and include inquiries regarding the following: how the organization collected, analyzed, and used information from its compliance reporting mechanisms; how the organization insured that investigations were independent, objective, appropriately conducted, and properly documented; and the process for responding to investigative findings and how high up in the organization the investigative findings are reported.
- **Incentives and Disciplinary Measures.** The questions under this topic relate to the Compliance Program Guidelines requiring consistent enforcement of Compliance Program policies and procedures through appropriate disciplinary mechanisms and include inquiries regarding the following: when and how disciplinary actions in response to the misconduct were taken; whether managers were held responsible and disciplinary measures were considered for misconduct that occurred under their supervision; whether the organization has ever terminated or disciplined any person for similar misconduct; who participated in making disciplinary decisions; whether disciplinary actions have been consistently and fairly applied; and whether the organization has incentivized engaging in compliant and ethical conduct.
- **Continuous Improvement, Periodic Testing and Review.** The questions under this topic relate to the Compliance Program Guidelines requiring monitoring and auditing the effectiveness of the Compliance Program and include inquiries regarding the following: what kind of audits would have revealed the misconduct before it occurred, were those audits conducted, and what were the findings of any such audit; how has audit information been reported to senior management; how often are internal audits generally conducted in high risk area assessments; what control testing has the organization generally undertaken; and how often has the company updated its risk assessments and reviewed its compliance policies, procedures, and practices.
- **Third Party Management.** The questions under this topic relate to the Compliance Program Guidelines requiring delegation of authority for implementing the Compliance Program to qualified persons when an organization's operations have an independent, third party management company and include inquiries regarding the following: how the organization's third party management process has corresponded to the nature and level of the enterprise risk identified by the organization; whether this process has been integrated into the relevant procurement and vendor management process; the business rationale for using a third party management company; what mechanisms the organization used to insure that the third party management company contract terms specifically describe the services to be performed and have appropriate payment terms, the described contractual work is actually performed, and that compensation is commensurate with the services rendered; how the organization analyzed the third party's incentive model against compliance risks; how the organization monitors third party management performance; how the organization has trained the relationship managers about what the compliance risks are and how to manage them; how the organization has incentivized compliance and ethical behavior by third party management companies; whether red flags were identified from the due diligence of the third parties involved in the misconduct and how they were resolved; whether a similar third party has been suspended, terminated, or audited as a result of compliance issues; and how the company has monitored situations to insure that compliance issues related to vendor relationships do not arise again.
- **Mergers and Acquisitions.** The questions under this topic relate to review of the compliance function in a specific setting and do not precisely fall into the requirements identified in the Compliance

Program Guidelines and include inquiries regarding the following: whether the misconduct or risk of misconduct was identified during due diligence; how the risk assessment due diligence was conducted and who individually conducted it; how the compliance function has been integrated into the merger, acquisition, or integration process; what has been the organization's process for tracking and remediating misconduct identified in due diligence; and what has been the organization's process for implementing compliance policies and procedures at new entities.

## Using the DOJ Compliance Program Guidance for Self-Assessment.

Organizations now have a detailed template for understanding how the DOJ assesses existing Compliance Programs when there is an allegation of wrongdoing. It is therefore advisable for all organizations to engage in a self-assessment of the effectiveness of their Compliance Programs using the DOJ Compliance Program Guidance as a baseline for how Compliance Programs are expected to perform.

Reflecting on the content of this analytical framework, we see the following themes:

- **Senior Management Must Be Actively Involved In Supervision of the Compliance Process.** When an allegation of misconduct arises, DOJ can make senior management accountable, even if senior management is not directly involved in the alleged misconduct. This is consistent with both the "Responsible Office Doctrine" that has long been part of federal False Claims Act law and the "Yates Memo" that focuses on making individuals responsible for corporate acts.
- **The Compliance Function Must Have the Ability to Report Directly to the Governing Board.** This addresses the concern expressed in the Compliance Program Guidelines that compliance concerns reported to compliance officers through the organization's internal reporting system might be blocked by senior management (such as the chief financial officer, general counsel, or chief executive officer), whose performance may be implicated in the report.
- **Compliance Expertise Must Be Made Available to the Governing Board.** The Governing Board must actively oversee implementation of the organization's Corporate Compliance and Ethics Plan. This is consistent with the standard of conduct for directors of Delaware corporations established in In re: Caremark International, Inc. which, in essence, provides that directors may be exposed to individual liability for breach of the duty of care if the organization fails to implement a Corporate Compliance and Ethics Plan that satisfies the seven elements described in the Federal Sentencing Guidelines for Organizational Defendants.[2]
- **DOJ Distrusts Independent Contractors.** In general, federal regulatory agencies believe that there is more opportunity for misconduct through independent contractor arrangements than there is through bona fide employees, and the DOJ Guidance is consistent with that belief. For example, it is perfectly permissible for an organization to outsource the compliance function to an independent contractor, but, if so, then how and why that decision was made and how it was managed must be explained. This leads back to informed decision making by the Governing Board. Also, the DOJ dedicates an entire topic to Third Party Management, demonstrating that DOJ perceives third party management as a regulatory vulnerability. Although third party management agreements are also perfectly permissible, they are subject to intensified scrutiny when an allegation of misconduct arises. Once again, responsibility for oversight of the third party management agreement and accountability of third party vendors in general falls on the organization's Governing Board.
- **The Organization Is Expected to Engage in Continuous Self-Critical Analysis and Regulatory Risk Assessment.** A Corporate Compliance and Ethics Plan cannot be a static piece of paper filed in a notebook in the organization's bookcase: it must become a living, breathing part of the organization. Resources must be allocated for active management of the compliance function and periodic assessment to identify potential regulatory risk.

Every organization now has a blueprint for understanding how the DOJ will assess an organization's compliance efforts when there is an allegation of misconduct. How would your Compliance Program hold up to this scrutiny?

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(Endnotes)

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2 *In re Caremark Intern. Inc*. Derivative Litigation, 698 A.2d 959, 2 EXC 21 (Del. Ch. 1996).