Assessing the Effectiveness of Compliance Programs

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Overview

➢ Standards for Compliance Programs

➢ Effective Compliance Programs

 – Design

 – Staffing

 – Detection

 – Enforcement

➢ Case Law Developments

➢ Benefits

Guidances

➢ U.S. Sentencing Guidelines for Organizations and the DOJ's <u>Federal Prosecution of Corporations</u> both offer incentives for Corporations to develop effective compliance programs or improve existing programs

– Sentencing guidelines provide general guidance concerning what constitutes an effective program

– DOJ Memorandum provides further concrete guidance regarding standards of effectiveness

U.S. Sentencing Guidelines

An effective compliance program is one that has been reasonably designed, implemented and enforced so that it will generally be effective in preventing and detecting criminal misconduct.

U.S. Sentencing Guidelines - Minimum Criteria

➢ Standards and procedures reasonably designed to reduce prospect of criminal conduct

➢ High-level individuals with overall responsibility for compliance

➢ Due care not to delegate substantial discretionary authority to individuals with a propensity to engage in illegal activities

➢ Effective communication of standards and procedures to employees and agents

➢ Monitoring and auditing systems designed to detect criminal conduct and a non-retaliatory reporting system

➢ Consistent enforcement of standards through appropriate discipline

➢ Remediation after detection to prevent further non-compliance

DOJ: Federal Prosecution of Corporations

➢ Factors to be Considered When Charging a Corporation

 – DOJ lists 8 factors for determining whether to indict a corporation; 2 of these factors deal with compliance programs

 – mere existence of a compliance program is not sufficient to justify not charging a corporation

DOJ: Critical Factors in Evaluating a Compliance Program

➢ Is the compliance program adequately designed for maximum effectiveness to prevent and detect wrongdoing?

➢ Does the Company enforce the program, <u>i.e.</u>, does the program work?

Is the Program Adequately Designed?

➢ Is compliance a priority for senior management?

– Has the Board of Directors endorsed the compliance program?

– Is there a Compliance Officer/Compliance Committee charged to implement, enforce, and investigate? Who is the Compliance Officer?

– Does the Compliance Officer/Compliance Committee report to the Board of Directors?

– Does the CEO participate in the compliance program (e.g., endorse the Code of Conduct, meet with compliance personnel, provide updates on compliance initiatives)?

– Is the compliance program vital and proactive? Has a "culture of compliance" been established? Do employees believe that senior management supports the program?

Is the Program Adequately Designed? (cont.)

➢ Has the Company identified legal/regulatory risks impacting its businesses?

– Is there a formal analysis of the significant legal/regulatory risks impacting the business?

– Does the company review existing and contemplated business activities on a regular basis and update the compliance program as necessary?

– Does the company consider past litigation, compliance risks, current enforcement activities, and emerging areas in the development of the compliance program?

– Does management review the analysis?

Is the Program Adequately Designed? (cont.)

➢ Have the following areas been reviewed for possible incorporation into the compliance program?

- Adverse Events

- Antitrust

- Customs

- Environmental

- Fraud and Abuse

- Foreign Corrupt Practices

- Business Conduct (including ethics, conflict of interest, gifts

- Employment (including sexual harassment and discrimination)

- Immigration

- PDMA

- Pricing

- Promotion/Marketing

- Securities Law

- Trade Embargo/Boycott

- Lobbying, government relations, political contributions

- Manufacturing, Clinical and Laboratory operations

- Wage and Hour Laws

Is the Program Adequately Designed? (cont.)

➢ How much do employees know/think about how the compliance program works?

- Are employees adequately informed about the compliance program and the company's commitment to it?

- Is the code of conduct distributed to all employees? Is it tailored to the company's business? Is it user-friendly?

- Are well-written procedures and policies distributed to employees?

- Are employees trained in those areas impacting their job responsibilities?

- Are training programs effective and timely? Do they target specific audiences (including contractors, agents)? Do they include workshops, videos, seminars, newsletters, and CBT?

- Do management and employees recognize legal and regulatory issues? Do they know when to call counsel?

- Are surveys used to measure employee's understanding of the compliance program?

Is the Program Adequately Designed? (cont.)

➢ Is there an anonymous reporting mechanism for employees to utilize that provides confidentiality and non-retaliation?

– How many calls/letter are received on the hot/help line?

– What is the frequency of compliance-related calls vs. non-compliance?

– Is hot/help line appropriately publicized? Do employees express "surprise" about the existence of hot line?

– Is the hot/help line used to provide compliance advice or as a means for raising concerns about how to deal with situations before they become problems?

– Is senior management advised of hot line matters?

Is the Program Adequately Staffed?

➢ Are the programs adequately staffed to audit, document, analyze, and utilize the results of Corporation's compliance efforts?

   – Are resource needs reviewed by the Compliance Officer and Compliance Committee?

   – Has company assessed the part-time vs. full-time expectations for compliance personnel?

   – Is compliance an "add-on" to a multitude of responsibilities?

➢ Have sufficient auditing resources been allocated to compliance areas?

   – What is the audit frequency for sensitive areas?

   – Are senior management and compliance personnel involved in determining audit frequency?

Does the Program Detect Misconduct?

➢ Do the programs detect the types of misconduct most likely to occur in a particular company's line of business?

- – Has the company implemented oversight systems to monitor compliance programs (e.g., quality control programs)?

- – Does the company use quality assurance audits to provide a snapshot of operations and identify violations?

- – Does the company investigate and remediate problems in a credible way?

➢ Are auditor's findings and recommendations swiftly implemented?

➢ Are audits and investigations reviewed with senior management to assess trends and hot spots?

➢ Are whistleblowers going outside the company to report problems?

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Is the Program Enforced?

➢ Is it a paper program or a real compliance program

- Does the company "let sleeping dogs lie" or "turn a blind eye" to compliance issues?

- Has the company been known to create a "wink and nod" environment where there is tacit encouragement or pressure on employees to do other than the right things?

➢ What are the consequences for non-compliance? Does the program have teeth?

- Are employees aware of disciplinary code and practices?

- Is compliance a significant part of performance criteria for managers and employees?

- Is discipline administered consistently?

➢ Does the Company utilize results of compliance efforts?

- Are records reviewed and maintained in an appropriate way?

- Are management reports issued?

Case Law:
What are Effective Policies?

➢ Define the legal/regulatory risks and prohibited conduct

  – Do's/Don't's

  – Description of prohibited conduct must be sufficiently broad to include all types of covered conduct

  – Consider requiring employees to certify that they "read, understood, and agree to abide by standards"

➢ Provide a variety of means of reporting non-compliance

  – Management chain

  – Human Resources

  – Law and Audits

  – Hot Line

➢ Describe disciplinary measures that Company may employ for non-compliance

➢ Maintain a policy of non-retaliation

  – Give careful consideration to "false report" provisions that may be viewed as discouraging complaint reporting

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Case Law:
What is Effective Communication?

➢ Distribute policies to all affected employees

➢ Train all affected employees

  – maintain training records

Case Law:
What are Reasonable Steps to Achieve Compliance?

➢ Implement reporting systems that allow employees to bypass management and others in the chain of command

➢ Policy must include non-retaliation for good faith reporting of violations

Case Law:
What are Effective Responses to Non-Compliance?

➢ Conduct prompt investigations

➢ Assure consistent, systematic responses

➢ Take prompt and appropriate remedial actions

➢ Conduct investigator training programs

  – how to conduct an investigation

  – appropriate interview techniques

  – documentation

  – remedial actions

  – record retention

Other Standards for Assessing Compliance Programs

➢ Government Standards

  – Fraud Alerts

  – Advisories/Interpretations

  – Speeches by regulators, enforcement officials

  – Voluntary disclosures (EPA, NRC, FTC)

  – Settlements/Consent Decrees

  – HHS OIG Compliance Program Guidances

➢ Benchmarking/Industry Practices

  – Create the minimum standard of effectiveness for compliance

  – Defense, aerospace, and telecommunications industries have set standards as a result of compliance problems

➢ Surveys

Benefits of an Effective Compliance Program

➢ Creates a culture of compliance where wrongdoing is discouraged and employees feel good about the company

➢ Helps company mange its compliance issues and minimize adverse consequences (i.e., intervention by government, criminal sanctions, and civil damages)

➢ Helps company avoid reputational issues that go along with compliance problems

➢ Is cost-effective (i.e., costs of compliance much less than costs associated with government investigation)

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