

Compliance 101



“Any ... entity which does
not have a compliance program is
‘institutionally nuts’.”

Karen Morrisette
Deputy Chief of the Criminal Division
Division Fraud Section of the
U.S. Department of Justice

Why Develop a Compliance Program?

- Communicate Organization's Commitment
- Avoid the Government's "Help" – Imposed Compliance Programs
- Astronomical Fines/Penalties
- Exclusion from Governmental Programs
- Provides "safe" way to report suspected wrong doing
- Raises Awareness
- Good Business Sense/competitive edge
- Public Image
- **IT'S THE LAW! PPACA Section §6102(b) – March 23, 2013**

Enforcement Overview (high level)

- 1970's - Savings and Loans/Political corruption/Banking Compliance Programs
- 1980's - Defense fraud/Defense Industry Initiative
- 1990's - Health care fraud/OIG Focus
- 1991 - Federal Sentencing Guidelines
- 2000's - Financial Fraud/Governance Accountability emphasis/Sarbanes Oxley Act
- 2010 – Health Care Reform

Regulatory Compliance Drivers

- Federal Sentencing Guidelines (USSC, Chapter 8, Part B Remediating Harm From Criminal Conduct , and Effective Compliance and Ethics Program)
- Sarbanes Oxley Act (Pub.L.No. 107-204, 116 Stat. 745)
- Government Agencies/Regulations, e.g.,: FAR (Federal Acquisition Regulations 48 CFR Parts 2, 3, and 52), NIH (effort reporting, etc.), NSF, DOE (Contract Performance Measures for labs), EH&S, etc.

OIG Work Plan Issues

- Medicare Part A billing by skilled nursing facilities;
- Questionable Part B billing for nursing home stays – non Part A;
- State Survey verification of deficiencies correction;
- National background checks for long term care employees;
- Hospitalization of nursing home patients for manageable and preventable conditions.

7 Elements of an Effective Compliance Program



1. Standards and Procedures
2. Oversight/Compliance Officer/Committee
3. Education and Training
4. Reporting/Communication
5. Monitoring and Auditing
6. Enforcement and Discipline
7. Response and Prevention

Organization “Drift”



- Failure to define the issues properly
- We always have a noble cause when we cross the line.
- Circumstances beyond your control will cause bad acts to be discovered.

Anonymous

Five Principle Strategies to Combat Fraud, Waste, and Abuse

Daniel R. Levinson IG - DHHS – Testimony – 5/11

1. Scrutinize prior to accepting
2. Reasonable and responsive payment methods
3. Assist in adopting practices promoting compliance, including quality and safety
“...recommend ..should be required to adopt compliance programs as COP in the Medicare and Medicaid programs.”
4. Vigilantly monitor for fraud, waste and abuse
5. Respond swiftly, impose punishment, and promptly remedy program vulnerabilities

Oversight and Accountability

- Governing Authority – Knowledgeable about compliance program with reasonable oversight (*Board of Directors*)
- Ethics & Compliance Officer – high level individual
 - Reporting structure clearly defined
 - “direct to the top”, no buffers
 - Strong leader – Independent, empowered, effective
 - Shall have adequate resources and authority
 - Access to Board with periodic reporting responsibilities
- Compliance Committees, Program Staff,

Standards and Procedures

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Code of Conduct

- Keep It Readable
- Tailored to the organization's culture, ethical attitude, business, and corporate identity
- Attestation
- Address weak areas by providing guidance/guiding principles
- Scenarios and FAQs
- Letter of endorsement by President, CEO, Board Chairman
- Chain of command
- Primary language – watch translations

Standards and Procedures

- Controls – steps to prevent misconduct (inhibit or limit)
- Structural
- Substantive
- Collaborate with other Departmental Policies and Procedures
- Not repetitive/Duplicative



Training & Communications

- Communication Process
- Internal vs. External
- Mandatory vs. Voluntary
- General vs. Specific
- Training Methods
- Attestations
- Other Communications Media



Monitoring & Auditing

- Essential for effectiveness – assists in detecting criminal conduct
- Audits – independent/objective
- Monitoring – management tool usually, can be objective but not always
- Audit & monitoring plan is based on risk assessment and is scalable to the organization's risks and resources

Conduct Compliance Risk Assessment

➤ Identify Risk Areas

- What "Activities" Are Currently Occurring?
 - Education
 - Auditing & Monitoring
 - Management Focus On Remediation/Corrective Action

➤ Prioritize Risks

- Who Is Responsible?
- Subject Matter Experts
- What Is The Information Flow?
- What Are Areas For Concern?



Annual Compliance Plan Development

- Prioritize issues identified in compliance risk assessment
- Develop plan to address and mitigate key issues
 - Use 7 elements as foundation for structure to address issues, for example:
 - ✦ Communication strategy
 - ✦ Development of metrics to evaluate progress
 - ✦ Policy/procedure review and update
 - ✦ Systems review and revision as appropriate
 - ✦ Admin/faculty education/training
 - ✦ Monitoring plan, if needed

Reporting

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Hotline/Helpline

- Essential program resource for reporting wrong-doing and/or seeking help and guidance
- Consider differing country laws, etc., if global organization
- Anonymous & confidential to extent allowed by law
- Policy on non retaliation/ non retribution important to have
- Fear of retaliation and perceived inaction-top 2 reasons people don't call back
- Address matters in a timely and consistent way



Reporting

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Metrics:

- Use hotline metrics to improve program:
- Follow up initiated within defined timeframe,
- Timely resolution of matters substantiated, etc.



Enforcement, Incentives and Discipline

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Reasonable steps to prevent or deter criminal are important.

Two areas can assist in prevention and deterrence:

1. Incentives

- Should be aligned with being compliant
- Performance reviews & compensation should have compliance metrics identified



2. Consistency in enforcement

- Support from Sr. Mgmt; Board
- Understanding by all members of organization as to disciplinary measures, fairness and consistency

Response and Prevention

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- Timely response
- Are there enough facts to investigate?
- Process for handling investigations should be defined clearly for consistency:
 - Investigators should be trained
 - Triaging and handling investigations
 - Reports – decide before you start as to report format and who will receive it
 - Decision making on outcomes



Response and Prevention

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- Counsel for advise and/or attorney client privilege
- Preventative measures (sometimes becomes remedial measures as well)
 - ✦ Resolution of issues – root cause analysis
 - ✦ Education and Awareness
 - ✦ Policies and Procedures



Measuring Effectiveness

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Evaluating Effectiveness:

- Program metrics (hotline calls, incidents, etc.)
- Surveys
- Focus Groups
- Testing
- Self Assessments
- Exit Interviews
- Periodic risk assessment, Internal Audit reports, etc.

Measuring Effectiveness

DoJ Evaluation of Corporate Compliance Programs



U.S. Department of Justice
Criminal Division
Fraud Section
[Evaluation of Corporate Compliance Programs](#)

Introduction

The Principles of Federal Prosecution of Business Organizations in the United States Attorney's Manual describe specific factors that prosecutors should consider in conducting an investigation of a corporate entity, determining whether to bring charges, and negotiating plea or other agreements. These factors commonly known as the "Filip Factors" include "the existence and effectiveness of the corporation's pre-existing compliance program" and the corporation's remedial efforts "to implement an effective corporate compliance program or to improve an existing one."

Because a corporate compliance program must be evaluated in the specific context of a criminal investigation that triggers the application of the Filip Factors, the Fraud Section does not use any rigid formula to assess the effectiveness of corporate compliance programs. We recognize that each company's risk profile and solutions to reduce its risks warrant particularized evaluation. Accordingly, we make an individualized determination in each case.

There are, however, common questions that we may ask in making an individualized determination. This document provides some important topics and sample questions that the Fraud Section has frequently found relevant in evaluating a corporate compliance program. The topics and questions below form neither a checklist nor a formula. In any particular case, the topics and questions set forth below may not all be relevant, and others may be more salient given the particular facts at issue.

Many of the topics below also appear in the [United States Attorney's Manual](#) ("USAM"), in the [United States Sentencing Guidelines](#) ("USSC"), in [Fraud Section corporate resolution agreements](#), in [A Resource Guide to the U.S. Foreign Corrupt Practices Act](#) ("FCPA Guide") published in November 2012 by the Department of Justice (DOJ) and the Securities and Exchange Commission (SEC), in the [Good Practice Guidance on Internal Controls, Ethics, and Compliance](#) adopted by the Organization for Economic Co-operation and Development ("OECD") Council on February 18, 2010, and in the [Anti-Corruption Ethics and Compliance Handbook for Business](#) ("OECD Handbook") published in 2013 by OECD, United Nations Office on Drugs and Crime, and the World Bank.

OIG Measuring Compliance Program Effectiveness: A Resource Guide

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[HCCA-OIG Compliance Effectiveness Roundtable
Roundtable Meeting: January 17, 2017 | Washington, DC](#)



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Introduction

Next Steps

- Re-invigoration of Compliance Program;
- Leadership support and commitment to an effective and comprehensive compliance program;
- Education and training of all staff (general) on general compliance and (specific) on job-specific functions, especially those in positions deemed potentially “high risk”;
- Review of processes to ensure compliance with applicable rules and regulations.
- Staff review of the Code of Conduct and anonymous reporting system;
- STAY TUNED!

Questions and Comments

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