

# 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



#### 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

16

### 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

17

### Metrics:

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




---

---

---

---

---

---

---

---

## Enforcement, Incentives and Discipline

18

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

19

- 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

20

- 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

21

#### 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



**Introduction**  
The Division of Corporate Compliance and Ethics is pleased to announce the release of the report, *Evaluation of Corporate Compliance Programs*. This report provides guidance to companies on how to design, implement, and maintain an effective compliance program. The report is based on the findings of the Division's ongoing research and is intended to serve as a resource for companies and their legal counsel.

#### OIG Measuring Compliance Program Effectiveness: A Resource Guide



**Measuring Compliance Program Effectiveness: A Resource Guide**  
This guide provides information on how to measure the effectiveness of a compliance program. It includes a checklist of key factors to consider when evaluating a program's performance and offers practical advice on how to improve it.

---

---

---

---

---

---

---

---

---

---

### Next Steps

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

---

---

---

---

---

---

---

---

---

---

### Questions and Comments

Contact Information:

Lynda Hilliard, MBA, RN, CHC, CCEP

---

---

---

---

---

---

---

---

---

---