

# Defining, Quantifying and Measuring Effectiveness

*Lynn Shapiro Snyder, Esq.*

Epstein Becker & Green, P.C.

Washington, DC

# Elements Of An “Effective” Compliance Program

## The Federal Sentencing Guidelines

United States Sentencing Commission Guidelines,  
Guidelines Manual, 8A1.2, comment. (N.3(k))

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### OIG Model Guidances

- Clinical Laboratories
- Hospitals
- Home Health Agencies
- Third Party Billing Companies
- DMEPOS
- Medicare+Choice Organizations
- Hospice
- Nursing Facilities
- Individual Physicians and Small Group Practices

# FSG: Standards and Procedures

1. “The organization must have established compliance standards and procedures to be followed by its employees and other agents that are reasonably capable of reducing the prospect of criminal conduct.”

# OIG: Written Standards Of Conduct And Other Written Policies

- Easily understandable code of conduct provided to all employees
- Policies addressing specific risk areas
- Retooled and tested for effectiveness
- Emphasis on accurate claim submission, billing processes and quality of care

# FSG: Responsible Oversight Personnel

2. “Specific individual(s) within high-level personnel of the organization must have been assigned overall responsibility to oversee compliance with such standards and procedures.”

# OIG: Designation of A Compliance Officer

- High level authority -- but not CFO or general counsel
- Direct access to governing body, president or CEO, senior management and legal counsel
- Establishment of a compliance council/committee
- Responsible for coordination and communication

# FSG: Compliant Work Force

3. “The organization must have used 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.”

# OIG: Due Care With Delegation Of Discretionary Authority

- Criminal background checks
- Reference checks
- Employee certifications
- OIG's Cumulative Sanctions List
- GSA's List of Excluded Individuals
- Health Integrity Protection Data Bank  
(Health Plans only)



# FSG: Training Programs

4. “The organization must have taken steps to communicate effectively its standards and procedures to all employees and other agents, *e.g.*, by requiring participation in training programs or by disseminating publications that explain in a practical manner what is required.”

# OIG: Education And Training

- Mandatory, regular, and ongoing
- Officers, managers, directors, employees, contractors, and other significant agents
- Federal and state statutes, regulations, rules, guidelines, and the policies of private payors
- Condition of employment

# OIG: Education And Training

- General, Specialized and Informal Training
- Tailored to level of comprehension of employees
- Different training sessions for employees with different levels of responsibility

# FSG: Monitoring and Auditing Systems

5. “The organization must have taken reasonable steps to achieve compliance with its standards, *e.g.*, by utilizing monitoring and auditing systems reasonably designed to detect criminal conduct by its employees and other agents and by having in place and publicizing a reporting system whereby employees and other agents could report criminal conduct by others within the organization without fear of retribution.”

# OIG: Audits And Monitoring

- Development of an ongoing evaluation process
- Regular, periodic compliance audits by qualified personnel
- Focus on areas with substantive exposure to government enforcement actions
- Establishment of baselines and subsequent use of “benchmarking”
- Periodic reviews of whether the program’s compliance elements have been satisfied

# OIG: Effective Lines of Communication

- Open lines of communication between compliance officer and personnel
- Hotlines and other forms of communication
- Confidentiality and non-retaliation policies
- Source of clarification to questions or problems
- Documented and dated responses

# FSG: Disciplinary Actions

6. “The standards must have been consistently enforced through appropriate disciplinary mechanisms, including, as appropriate, discipline of individuals responsible for the failure to detect and offense. Adequate discipline of individuals responsible for an offense is a necessary component of enforcement; however, the form of discipline that will be appropriate will be case specific.”

# OIG: Enforcement

- Written policy statement setting forth degrees of discipline that may be imposed for failure to comply with applicable laws and regulations and/or the compliance program
- Appropriately and consistently applied
- Discipline for “foreseeable failure of their subordinates”



# FSG: Corrective Actions

7. “After an offense has been detected, the organization must have taken all reasonable steps to respond appropriately to the offense and to prevent further similar offenses - - including any necessary modifications to its program to prevent and detect violations of law.”

# OIG: Response and Correction

- Prompt investigation of alleged violations of the compliance program or any violations of applicable laws or regulations
- Where problems are identified, initiate a corrective action plan, which may include referral to law enforcement, voluntary disclosure, and submission of any overpayments

# OIG: Self-Reporting

- Credible evidence of misconduct
- Reason to believe that the misconduct may violate criminal, civil or administrative law
- Recommends disclosure to the appropriate governmental authority not more than 60 days after determining that there is credible evidence of a violation.

# Recent Developments Regarding The Quantification of Effectiveness

- April 15, 1999 GAO Report, “Early Evidence of Compliance Program Effectiveness Is Inconclusive” (HEHS 99-59)
- April 2, 1999 OIG/HCCA Joint Report, “Building a Partnership for Effective Compliance”
- October 28, 1999 Draft OIG Compliance Guidance for Nursing Facilities

GAO Report:  
“Early Evidence of Compliance  
Program Effectiveness Is  
Inconclusive”

April 15, 1999 (HEHS 99-59)

# 1999 GAO Report

“The principal measure of a compliance program’s effectiveness is its ability to prevent improper Medicare payments.”

# 1999 GAO Report

Continued...

The GAO acknowledged that it is difficult to measure compliance program effectiveness because of the lack of comprehensive baseline data and the existence of many other factors that could affect measurement results.

# 1999 GAO Report

Continued...

- Other potential indicators for measuring compliance program effectiveness:
  - the amount and frequency of refunds of overpayments identified by the provider and
  - the frequency of self-disclosures of potential provider misconduct
  - frequency of disciplinary actions taken against noncompliant employees
  - increased employee awareness of proper billing rules and other compliance policies



# 1999 GAO Report

Continued...

- In response to the GAO's report, June Gibbs Brown, the Inspector General, stated that other important objectives and benefits of compliance programs include:
  - increasing employee awareness of federal health program requirements
  - centralized source of information
  - thorough investigation procedures
  - improving the quality of patient care

OIG/HCCA Joint Report:  
“Building a Partnership for  
Effective Compliance”

April 2, 1999

# 1999 OIG/HCCA Report

- Roundtable participants stressed the importance of compliance audits including:
  - baseline audits
  - proactive audits
  - issue-based

# 1999 OIG/HCCA Report

Continued...

- Participants also recommended that the following types of documentation be maintained to demonstrate program effectiveness:
  - Audit results;
  - Logs of hotline calls and their resolution;
  - Corrective action plans;
  - Due diligence efforts in business transactions;
  - Disciplinary action;
  - Modification and distribution of written P&Ps;
  - Disclosures and refunds;
  - Records of employee education; and
  - Annual reports and web sites.

# 1999 OIG/HCCA Report

Continued...

- Other indicators cited by the OIG to determine a program's effectiveness:
  - Funding and support provided to the program
  - Sufficiency of training and availability of guidance
  - Evidence of open lines of communication
  - Documented practice of refunding overpayments and self-disclosing incidents

# Draft OIG Compliance Guidance for Nursing Facilities:

“Assessing The Effectiveness of a  
Compliance Program”

October 28, 1999

# Assessing The Effectiveness of a Compliance Program

- The OIG recommends that organizations should evaluate all elements of a compliance program through “employee surveys, management assessments, and periodic review of benchmarks established for audits, investigations, disciplinary action, overpayments, and employee feedback.” *Draft OIG Compliance Guidance for Nursing Facilities*

# Assessing Policies and Procedures

- Do employees:
  - experience recurring pitfalls because issues not adequately covered?
  - flagrantly disobey standards because they observe no sincere buy-in from management?
  - have trouble understanding the policies?
- Does the organization routinely experience systematic billing failures?



# Assessing the Compliance Officer/Committee

- Do compliance personnel:
  - have sufficient professional experience working with billing, clinical records, documentation, and auditing principles?
  - have adequate funding, staff and authority?
  - compromise the goals of the program by virtue of their other responsibilities in the organization?

# Assessing Training

- Are employees trained enough?
- Do employees fail post-training tests?
- Do the training materials adequately summarize important aspects of the program?
- Are the training instructors qualified and experienced to field questions?

# Assessing Communication

- Do compliance officers receive appropriate inquiries from employees?
- Do P&Ps provide the “whos” and “whens” of reporting?
- Do employees fear retaliation?
- Do employees report through the wrong channels?
- Do employees have bad-faith, ulterior motives for reporting?

# Assessing Discipline

- The OIG states that “[t]he number and caliber of disciplinary actions can be insightful.”
  - Have appropriate sanctions been applied to compliance misconduct?
  - Are sanction applied consistently, regardless of the employee’s level in the corporate hierarchy?
  - Have double standards bred cynicism among employees?

# Assessing Audits and Monitoring

“The hallmark of effective monitoring and auditing efforts is how an organization determines the parameters of its reviews.”

# Assessing Audits and Monitoring

- Do audits focus on all pertinent departments of an organization?
- Does an audit cover compliance with all applicable laws, as well as federal and private payor requirements?
- Are the results of past audits, pre-established baselines, or prior deficiencies reevaluated?
- Are the elements of the compliance program monitored?
- Are auditing techniques valid and conducted by objective reviewers?

# Assessing Audits and Monitoring

“The extent and sincerity of an organization’s efforts to confirm its compliance often proves to be a revealing determinant of a compliance program’s effectiveness”

# Assessing Corrective Action

- When a provider learns of an issue, does it knowingly disregard associated legal exposure?
- Is there a correlation between deficiency identified and the corrective action necessary to remedy?
- Are isolated overpayment matters properly resolved through normal repayment channels?
- Is credible evidence of misconduct that may violate the law promptly reported to the appropriate authorities?



# What is Your Organization's Effectiveness Checklist?