Health Care Compliance Association®

HCCA New Orleans Regional

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Evaluating Your Compliance Program for Best Practice

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INTRODUCTION TO SPEAKERS

Bret S. Bissey, MBA, FACHE, CHC, CMPE

Healthcare Compliance Executive / Consultant, MediTract

- 30 years of diversified healthcare management, operations and compliance experience.
- Former SVP, chief of ethics and compliance officer at UMDNJ.
  - Credited with re-engineering the compliance program of the nation's largest free-standing public health sciences university.
  - Successfully led the compliance program to adhere to CIA with DHHS/OIG that occurred following a Deferred Prosecution Agreement.
- Chief compliance and privacy officer at Deborah Heart and Lung Center.
  - Three-year CIA, first settlement of Voluntary Disclosure Protocol
  - Compliance program recognized by HCCA as a "Best Practice."
- Certified in HCCA and the Medical Group Management Association.
- Author of Compliance Officer's Handbook.

INTRODUCTION TO SPEAKERS

Paul Weidenfeld, Attorney at Law; Co-Founder Exclusion Screening, LLC

- Co-Founder, Exclusion Screening, LLC;
- Private Practice Focus on healthcare fraud investigations and litigation
- Health Care Fraud Coordinator, Department of Justice, Executive Office of United States Attorneys (DOJ EOUSA)
- Asst. United States Attorney, New Orleans, Health Care Fraud Coordinator
- Trial Attorney and State Public Defender
  - Wide range of cases (criminal matters, torts, contract disputes, Maritime Personal Injury cases, etc.)
  - 50 trials and 25 appellate arguments United States Supreme Court, 5th Circuit Court of Appeals, Louisiana Supreme Ct, Traffic and Municipal Courts of N.O.

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OVERVIEW

1. Introduction
2. Evaluating Your Compliance Program & "Effectiveness" – Guidance
3. Elements to Consider in Your Evaluation Efforts
4. How Best to Perform the Compliance Program Evaluation?
5. Q&A

GOALS

- Offer practical suggestions for conducting the assessment of your compliance program to ultimately reduces overall organizational compliance risk.
- Learn how to utilize the elements of the DHHS OIG Model Compliance Program(s) and OIG/HCCA Resource Guide to develop a work plan to perform this assessment.
- Learn how to evaluate whether you can perform this activity with internal resources, external experts or a combination of both.
- Learn the value of regularly performing this activity, including how it can protect against fraud and abuse related fines, penalties and related sanctions.

EVALUATING YOUR COMPLIANCE PROGRAM & EFFECTIVENESS PROGRAM GUIDANCE

Applicable Government Guidance on Compliance Programs

- DHHS OIG Compliance Program Guidance for Hospitals, Home Health, 3rd Party Billers (1998); Hospice, Nursing Facilities (1999); Physician Practices (2000), Supplemental for Hospitals (2005).
- DOJ Compliance Program Guidance on Evaluation of Corporate Compliance Programs (Feb. 2017)
- Resource Guide, Compiled from HCCA-OIG Compliance Effectiveness Roundtable Meeting, January 17, 2017 (Issued March 27, 2017)

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Government Guidance – "Gold" Standard: Effectiveness is the KEY

- Original OIG Compliance Program Guidance for Hospitals the word "effective" is referenced 19 times.
- In the recently published Resource Guide, "effective" or "effectiveness" is used 41 times it the Resource Guide

Do Not Underestimate its Importance!

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Benchmarking – OIG Makes Frequent References

Claims processing evaluation (Audit Function)

- Establish a benchmark for error rates.
  - CIA Standard?
  - True error rate or Net Dollar Value?
  - Sample Size?
  - Consistency of Universe?
  - Prospective or Retrospective?

Reporting, Investigation, Adherence to 60 Day Rule

- Reference to External benchmarking reports

Assessing Your Compliance Plan

- Benchmark your program with similar ones in your industry
- Compare benchmarking data you obtain with data obtained from similar entities

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DOJ Compliance Program Guidance on Evaluation of Corporate Compliance Programs (February 8, 2017)

- Effectiveness of a Compliance Program is an important factor in consideration of corporate prosecution; Intended to provide guidance on evaluating its effectiveness in that context
- Not specific to health care industry, but contains many elements similar to historical DHHS-OIG Guidance
- The guidance is presented in the form of compliance-focused questions that the criminal prosecutors within DOJ might consider in this process; thus, it contains good information to consider.

DOJ focused attention upon the following Elements:

- Analysis and Remediation of Underlying Misconduct
- Conduct of senior & middle management
- Stature of the compliance function
- Autonomy of the compliance function
- Compliance Program funding and resources
- Corporate response to expressed compliance concerns
- Process for responding to findings
- Disciplinary action consistency
- Risk Management Process
- Frequency of updates to policies and practices
- Direct reporting of compliance to Board

Government Guidance – Resource Guide Issued March 17, 2017

- "Compliance Professionals" and OIG Staff met in 1/17 to discuss ways to measure compliance program effectiveness; resulted in 53 pages of detailed measurement options for a wide range of organizations
- Used categories from the HCCA *CHC Candidate Handbook "*to ensure all elements of compliance programs were covered; slightly different from "Seven Elements" of earlier OIG Compliance Guidances
- Specific addition of "*Screening and Evaluation of Employees, Physicians, Vendors and other Agents*" as an element.
- Purpose to give "ideas" and be used as applicable to specific needs of the provider; attempts to use as a standard are "discouraged"
- Not a Checklist. Detailed analysis of metrics for meeting compliance goals, but emphasizes it is not a "one size does not fit all" answer.

Elements to Consider in Your Evaluation Efforts

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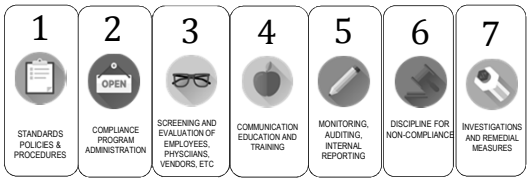
Compliance is Pretty Basic

The Seven Elements as found in the "*HCCA-OIG Compliance Effectiveness Roundtable*"



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Specific Elements to Consider in Your Evaluation Efforts

- Hotline Calls.
- Education.
  - Staff.
  - Physicians - Focus Arrangements.
  - Board.
  - Executives.
- Audit/Monitoring Results
- Potential Areas of Trending Your Coding, Billing Results.
- Audit Benchmarking Scorecard.
- Annual Audit Work Plan Completion.
- Budget Analytics.
- Other Data Points to Trend by Year.

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Element 1: Standards, Policies, and Procedures

- Verify that appropriate policies and procedures exist for coding, record retention, handling of overpayments, for conducting internal and external compliance audits.
- Verify that appropriate policies and procedures exist to address regulatory requirements (EMTALA, Stark, AKS, etc.)
- Integrate mission, values, and ethical principles with code of conduct consistent with it.
- Verify conflict of interest, confidentiality, privacy and non retribution/non retaliation policies
- Verify maintenance of a policy on gifts and gratuities
- Maintain a Compliance Department operations manual.
- Conduct periodic reviews of policies, procedures, and controls.

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Element 2: Compliance Program Administration
The Importance of Surveys

Surveys to Evaluate

– Objective: How well do your covered persons understand the operations of the compliance program and their applicable obligations?

Why are surveys important?

– 2004 Amendment to U.S. Sentencing Commission guidelines calls out the significance of compliance "culture" and states businesses must "promote an organizational culture that encourages ethical conduct and a commitment to compliance with the law."
– OIG Compliance Program Guidance for Hospitals states that Compliance or reviewers use techniques, such as questionnaires developed to solicit impressions of a broad cross-section of hospital staff….

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Element 2: Compliance Program Administration: What Surveys Evaluate

Compliance culture

Attempt to measure covered persons' attitudes and views regarding the organization's commitment to compliance.
- Is it real or a sham?

Employee compliance knowledge

Goal – *provide evidence of program effectiveness*.
- Your leadership and board should be asking for this… and….
  – Elements to include: employee surveys, management assessments, audit results vs. benchmark, investigation numerics, disciplinary numerics, trending overpayments, employee feedback….

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Element 2: Compliance Program Administration: Compliance Culture Survey

- Focus is on the beliefs and values of the organization's members.
- Can all levels demonstrate commitment to compliance?
- Examples:
  - If an overpayment is needed to be refunded, is there any conflict in it occurring?
  - If a senior-level executive made an unethical or improper decision, would it be addressed?
  - If a major referring physician were involved in an unethical business practice, would your leadership make the proper decisions that are consistent with your compliance program?

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Element 2: Compliance Program Administration: Compliance Knowledge Survey

- Test knowledge of compliance program structure and operations.
- Who is the compliance officer?
- If you observed an unethical decision, illegal behavior, patient harm or violation of law or regulation, where would you report this incident(s)?
- Has your compliance message reached and resonated with your target audience?
- Both types of surveys allow you to benchmark and measure compliance effectiveness over time.
  - Goal is that survey trend shows better results….

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Element 2: Compliance Program Administration Budget Analytics

(Based upon operating and FTE budgets approved by Board or Compliance/Audit Committee.

- Operating budget variance ($$ and %).
  - Why a variance? Consultants?
- FTE budget variance ($$ and %).
  - Is there turnover? Why?
  - Are there unfilled vacancies? Why?
  - What corrective action is proposed?
- Trending of budget and actual expenses over past several years.
- Good management dictates that you operate department within acceptable budget…
  - Being under budget doesn't mean you are doing a good compliance job!

Who defines what is appropriate?

- Any validation efforts that has been performed to review the potential ROI of your compliance program.
- Specific activities.
  - Contract management and reporting.**
    - Dealing with Focused Arrangements.
  - Audits (routine and for-cause), Sanction Screening

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ELEMENT 3: SCREENING AND EVALUATION OF EMPLOYEES, PHYSICIANS, VENDORS AND OTHER AGENTS

- Specifically added as a separate element by the Resource Guide
- Monitor government sanction lists for excluded individuals/entities
- Verify that background/sanction checks are conducted in accordance with applicable rules and laws (e.g., employment, promotions, credentialing).
- Verify due diligence is conducted on third parties (e.g., consultants, vendors, acquisitions).
- Assure corrective action is taken based on background/sanction check findings.
- Inclusion of compliance obligations in all job descriptions, compliance accountability as an element of performance evaluation, compliance-sensitive exit interviews.

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ELEMENT 3: SCREENING AND EVALUATION OF EMPLOYEES, PHYSICIANS, VENDORS AND CONTRACTORS

What is an Exclusion?

An exclusion is a final administrative action by DHHS/OIG or by a State Medicaid program, *barring participation* in Federal and/or State Health Care Benefit Programs (Medicare, Medicaid, TRICARE, CHIP, etc).

✧ Persons or entities that are excluded are deemed to pose ***unacceptable risks to patient safety and/or to the financial integrity of government programs***.

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ELEMENT 3: THE IMPACT OF AN EXCLUSION

Radioactivity!!

AN EXTREMELY BROAD PAYMENT PROHIBITION

An excluded individual or entity is prohibited from receiving any payment for any items or services they furnish or provide, either ***directly or indirectly***, if paid, in ***whole or in part***, by a Federal Health Care Program. The "payment prohibition" renders any such person or entity **"radioactive"** when it comes health care because every service he is connected to is a potential ***overpayment!***

- All payment methods (itemized claims, cost report, bundled, etc.)
- Leadership, administrative or management services included
- Extends to IT services, strategic planning, billing and human resources
- Even an excluded volunteer will taint a claim if his activities contribute to a bundle of services! The volunteer's services must be "wholly unrelated to the request or receipt of Federal Health Care Dollars

Special Advisory Bulletin on the Effect of Exclusion From Participation in Federal Health Care Programs, May, 2013.

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Element 3: Who Gets Excluded? And Why?

51% of OIG exclusions in 2015 were mandatory exclusion

- Convictions relating to patient abuse or neglect, program (read health care) fraud, or drugs

47% of OIG Exclusions were permissive exclusions

- Primarily relate to loss of professional licenses

3832 Exclusions in 2015

- ✓ ***63% were "Licensed Service Providers"***
- ✓ ***47% were "Nurses or Nurses Aides"***
- ✓ **308 were Physicians**

Regardless of type, the underlying conduct in almost all exclusions: *patient abuse, sale or abuse of drugs, and program fraud or financial misconduct*

- ☒ **Fraud**
- ☒ **Sale, Use or Abuse of Drugs**
- ☒ **Patient Abuse**

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Element 3: Federal and State Exclusion Screening Requirements

Providers have an obligation to ensure they do not hire or contract with an excluded person or entity

OIG guidance: Providers must screen all employees, contractors and vendors that provide or contribute to an item or service that is reimbursed, in whole or part, by a Federal Health Care Program against the OIG's *List of Excluded Individuals and Entities (LEIE)* upon hire and on a "regular" (read monthly) basis"

CMS requirements: CMS has mandated State Medicaid Units to require providers to screen monthly and upon hire since 2009! CMS also requires Medicare Managed Care Providers to screen monthly and upon hire.

CMS requirements: Almost all States have adopted the CMS mandate requiring providers to screen employees, vendors and contractors upon hire and monthly thereafter. Many States also impose additional screening requirements in their provider agreements (and/or in administrative regulations. Texas, for example, requires providers to certify upon enrollment and reenrollment, that they do not have any employees, vendors or contractors that have been excluded from ***any state or federal program*** (*Texas Administrative Code § 352.5).* Louisiana, NJ and others have similar requirements imbedded in their provider agreement.

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Element 3: Potential Liability Resulting From Failing to Screen

1. **Overpayment Liability resulting from the Payment Prohibition**
   For all services furnished by an excluded person for which the provider received federal health care program reimbursement
2. **Potential Civil Money Penalties**
   The failure to screen can result in the imposition of CMPs up to $10,000.00 for each exclusion violation
3. **False Claims Act Exposure**
   DOJ has filed several FCA cases in 2015 based on excluded person's participation in Medicare and Medicaid
4. **Private Payers seeking reimbursement**
   Screening requirements often vary among private payers, but most have provisions in their provider agreements prohibiting payments for items or services provided by an excluded person.

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Element 4: Communication, Education, and Training on Compliance Issues

- Assure compliance training occurs and promote a culture of compliance; Verify participation in ongoing compliance training
- Disseminate regulatory guidance material and distill complex laws and regulations into a format employees can understand.
- Evaluate employee understanding of compliance responsibilities.
- Encourage employees to seek guidance and clarification when in doubt; promote open communication
- Participate in continuing education to maintain professional competence; Have risk-specific training for targeted employees.
- General compliance training for non employed physicians, vendors, and other agents.

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Element 4: Communication, Education, and Training on Compliance Issues

- How much compliance education is enough?
- Follow DHHS OIG CIA requirement or establish your own expectations?
  - Have Board support.
- Establish standard for different groups – "I like the following:"
  - Staff except housekeeping and food service – 1 hour annually.
  - Executives – 2 hours annually.
  - Physicians – 2 hours annually.
  - Board – 2 hours annually.
  - *Exception – those involved in negotiating physician or referral arrangements 2 hours plus specific training on Stark and Anti-Kickback Statute by an expert…
- Can your organization tolerate this?
  - Answer will tell you about your compliance culture.

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Element 4: Communication, Education, and Training on Compliance Issues - Board Education/Governance

- Tailor this to what is occurring (internally and externally).
- Risk (organization and personal).
- Compliance officer can communicate with the board whenever he or she wants without hesitation?
- Does CCO report to the board?
- Are board members involved in the compliance program oversight?
- What is the compliance knowledge level of the board?
  - Engage experts to assist in program functioning and validation of "effectiveness" of compliance program.
  - Can you get assistance (externally) when you deem necessary?
- Information flow from entity.
  - Is the board receiving all necessary information?

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Element 5: Monitoring, Auditing, and Internal Reporting Systems

This Element Combines Two Critical Components: Hotlines and Internal Auditing and Monitoring

- Publicize and maintain an open, anonymous reporting to enable employees, vendors, patients and agents to report concerns or noncompliance issues (e.g., hotline)
- Respond to compliance concerns timely; protect anonymity and confidentiality and within legal and practical limits; and monitor that retaliation does not take place
- Conduct organizational risk assessments; monitoring mechanism for violations of laws and regulations; .
- Conduct compliance audits and analyze {track, trend, benchmark}.

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Element 5: Hotlines Save Providers Money!

- OIG has been urging providers to adopt anonymous hotlines since 1998 as essential component of promoting "effective lines of communications
- Anonymous Hotlines, when openly encouraged and integrated as an important element of a compliance program, can save a provider money! They do this because they generate "tips," and "tips" are the most common and efficient means of detecting fraud
- According to data compiled and reported by the Association of Certified Fraud Examiners (ACFE), frauds detected by tip are identified 50% sooner than fraud detected in some other way which makes them significantly (41%) less costly to resolve that if detected by some other means.
- That study found, for instance, that frauds discovered by tip took on average 18 months and $150,000 to resolve, frauds detected by external audit or by accident took a year longer and cost over $300,000 to resolve, and matters detected by law enforcement (the worst case scenario) averaged 30 months and cost $1,250,000 to resolve!
- Hotlines also can help identify small problems before they become big ones, and they can provide an appropriate outlet for an employee who might otherwise become a whistleblower.

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Element 5: Hotline Metrics

- Do you include just calls or all matters "logged" by Compliance?
- Need to ensure you have a consistent measurement
- How many of those matters resulted in:
  - Investigations?
  - Remediation?
  - Paybacks?
  - Disciplinary actions?
  - Other?
- Trending data is the key….
- What is your baseline?
- Deal with the compliance naysayers in your organization.
  - "This is only for HR matters"….
  - "it is a waste of time"

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Element 5: Monitoring, Auditing, and Internal Reporting Systems

- Looking for improvement.
- Be careful – creative people can make audit results look better than they are.
  - Must establish ***consistent*** measurements.
- Consider using *Net Dollar Value Error Rate* on consistent universe annually as one review.
  - 50 claim randomly selected probe sample – consistent with OIG requirements.
  - Five percent or below is an acceptable error rate…
  - Great way to have a consistent measurement year after year.
- Complement with other planned and focused reviews and trend the results.
- How many "for cause" reviews performed annually

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Element 5: Monitoring, Auditing, and Internal Reporting Systems - Potential Areas of Trending Your Coding, Billing Results

- Short stays/outpatient/observation.
- E&M.
- Consultations.
- DRG – focused areas.
- Research billing.
- Demonstrate corrective actions.
- Validate that no "pattern or practice" evident.
- Attorney-client privilege considerations.

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Element 5: Monitoring, Auditing, and Internal Reporting Systems - Annual Audit Work Plan Completion

- Based upon approved annual work plan.
  - By Compliance/Audit Committee or Board.
- How many projects were on original plan?
- How many projects were added during year?
- How many were completed? Not completed?
- Trend to answer resources and accurate planning.
- If you are missing either bad budget or operational problem.

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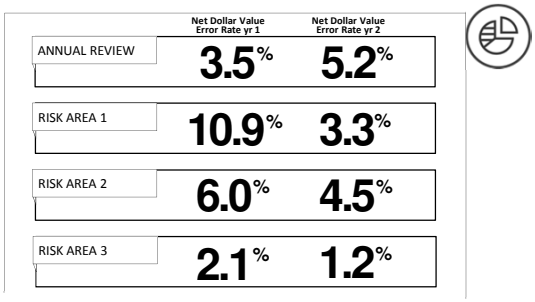
Element 5: Monitoring, Auditing, and Internal Reporting Systems - Audit Benchmarking Scorecard



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Element 6: Discipline for Non-Compliance

- Verify that compliance-related violations are addressed in disciplinary policies in a timely manner
- Recommend disciplinary action when noncompliance is substantiated;
- Promote discipline proportionate to violation and consistent with policies and procedures; verify and monitor consistent enforcement
- Recommend action for individuals and entities that have been excluded from government programs.
- Ensure proper reporting to regulatory bodies when required.

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Element 7: Investigations and Remedial Measures

Factors to Consider in Conducting Investigation

- The Resource Guide starts with "Communicating through proper counsel," I recommend starting with: "What type of investigation do I need to conduct? Do I need counsel to make this decision?"
- Is it best to conduct an internal investigation or hire outside counsel? Consider whether investigation personnel have the necessary skill sets or if there is a need for subject matter experts.
- Check list of issues: determination of whether disclosure is necessary, how to disclose, preservation of privilege, maintenance of records, cooperation with government
- If disclosure is necessary, how best to disclose?
- Assure that overpayments, if any, are fully investigated and refunded in a timely manner.
- Institute immediate measures as to mitigate harm and development of corrective action plans

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Element 7: Investigations and Remedial Measures - Chief Compliance Officer Independence

Can the Chief Compliance Office make the proper decision without fear of some sort of retaliation?

- Examples:
  - The lead admitter of patients to your hospital is in violation of the medical records completion policy – can you revoke privileges as policy states?
  - The president's spouse is asking to review sensitive and confidential information related to an upcoming community fundraiser. Can you treat her as if she were a normal citizen?
- Who validates this independence?

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Element 7: Investigations and Remedial Measures Chief Compliance Office Knowledge/Experience

- The compliance officer should be a subject matter expert.
  - Certification to validate.
  - Conferences attended, presentations made to industry, etc…
- However, no one in this business knows everything.
- It is OK to say "I need help" – are you able to get help when you need it?
  - Example: coding and reimbursement issues…

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How Best to Perform the Compliance Program Evaluation?

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Elements to Consider in Your Evaluation Efforts

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Relevant evaluation components should include

Objective Measurements:

- Stats

Subjective Measurements:

- Pressure testing on how things occur or don't occur
- Reviewing in relationship to Best Practice
- Require ability to be "independent"

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Who should perform a Compliance Program Evaluation?

Each circumstance probably different. General Thoughts:

- Consider an independent external review at some pre-determined interval of time
  - i.e. – every two or three years
- Contract via the Board and include in budget
- Report to the Board
- Assure you have someone doing this who is experienced and bring value – interview them..
- Utilize findings for improvement and then review again… good auditing approach which can pay dividends in long run..
- Develop scorecard of good statistics

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If an organization is found guilty of a violation of state or federal laws, the government may offer a reduction in penalties if an effective compliance program is in place.

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Questions? Contact us!

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