

# COMPLIANCE PROGRAM BASICS: Training, Monitoring, Auditing

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# WORKSHOP OVERVIEW

## **Why Training, Monitoring and Auditing are the Critical Components of an Effective Compliance Program**

- **“WASHINGTON — The Justice Department said Thursday that it obtained \$2 billion in settlements in fraud cases during fiscal year 2007, with most of the recoveries resulting from whistleblower lawsuits. Under the False Claims Act, whistleblowers can sue companies or individuals that they believe have filed fraudulent claims with the federal government. If successful, they can receive from 15 percent to 30 percent of the proceeds, the department said. Approximately \$1.45 billion of the settlements resulted from whistleblower lawsuits in fiscal year 2007, which ended Sept. 30, the department said. The individuals who filed suit were awarded \$177 million. Health care fraud accounted for the bulk of the settlements, with \$1.54 billion stemming from cases involving programs such as Medicare and Medicaid....”**

*Source: Houston Chronicle, 11/1/07*

# I. TRAINING

# TRAINING - OIG Guidance

In general:

- Proper education and training of personnel are critical elements of an effective compliance program
- Dissemination of materials that explain specific compliance requirements in a practical manner

# TRAINING - OIG Guidance

- Types of Training
  - **General** training sessions that summarize:
    - The company's compliance program
    - Written standards
    - Applicable federal health care program requirements
  - **Specific** training on certain risk areas should be:
    - Targeted at personnel whose job requirements make the information relevant
    - Tailored to make it as meaningful as possible to each group of participants

# TRAINING - OIG Guidance

- Training Instructors
  - May come from inside or outside the organization
  - Must be qualified to present the subject matter involved
  - Must be sufficiently experienced in the issues presented to adequately field questions and coordinate discussions among those being trained
  - Should be available for follow-up questions after the formal training session has been conducted

# TRAINING - OIG Guidance

- Training Frequency and Documentation
  - New Employees should be trained soon after they begin employment
  - All employees should have a minimum number of educational hours per year, as appropriate, as part of their employment responsibilities
  - Compliance officer should document any formal training undertaken by the company as part of the compliance program
  - Company should retain adequate records of its training of employees, including attendance logs, descriptions of the training sessions, and copies of the material distributed at training sessions

# TRAINING - OIG Guidance

- Training Format
  - Will vary depending upon the size and resources of the company
  - Options include live, video or computer-based training



# TRAINING - OIG Guidance

- Employee Expectations
  - Participation in training programs should be a condition of continued employment
  - Failure to comply with training requirements should result in disciplinary action
  - Adherence to training requirements and other provisions of the compliance program should be a factor in the annual evaluation of each employee








# TRAINING - Establishing a Curriculum

- Examine each part of your organization to determine the specific training required.
- Consider:
  - Does the department interact with health care professionals?
  - Is the department involved in sales, marketing or other product communications?
  - Does the department affect the calculation and reporting or pricing information and payment of rebates in connection with federal health care programs?
  - Does the department handle prescription drug samples?
  - Risk areas identified in the OIG Guidance and any audits
- Get management buy-in of training content, frequency and timing








# TRAINING - Keeping it Relevant

- Provide examples of permissible and impermissible activities
- Case studies are an entertaining and effective way for employees to actively participate in the training session
- Use the time effectively. Consider phases of training:
  - Phase I—Self study and completion of web-based quiz
  - Phase II—Live participation in compliance quiz-show/game
  - Phase III—Refresher training sessions at quarterly, semi-annual and/or annual meetings

# TRAINING CHECKLIST

-  Develop training curriculum and content, determine training format
-  Develop training calendar for new and existing employees
-  Identify training instructor(s)
-  Deliver training
-  Retain training documentation
-  Make participation in training a component of employee evaluations
-  Update training periodically to reflect any internal or external changes

# TRAINING – ADDITIONAL CONSIDERATIONS

-  What are the key characteristics of an effective training program?
-  What is the greatest challenge in conducting training?
-  What is the impact of a CIA/Consent Decree on training?
-  How would you update the OIG Guidance on training?
-  What training techniques have been most effective for you?
-  How do you secure resources for training?
-  How has training improved your compliance program?

## II. MONITORING

# MONITORING - OIG Guidance

- Effective compliance program should incorporate thorough monitoring of its implementation
- Compliance officer should document ongoing monitoring, including reports of suspected non-compliance

# MONITORING - What does it look like?

- Field Sales ride-alongs
- Attendance at industry scientific conventions
- Attendance at company speaker training, speaker programs and advisory board meetings
- Attendance at company sales meetings



# MONITORING - Establish a Plan

- General industry risk areas as outlined in:
  - OIG Compliance Program Guidance
  - Corporate Integrity Agreements (CIAs)
- Specific company risk areas
- Frequency of monitoring activities
- Communication of planned monitoring activities

# MONITORING – Considerations for Investigating Findings

- Provide real-time feedback (e.g., during field ride)
- Determine root cause of finding:
  - Honest mistake?
  - Lack of understanding?
  - Poor communication and/or training?
  - Direction from management?
  - Bad intent?








# MONITORING - Conducting an Investigation

- Emphasize independence of investigation
- Remind employees about non-retaliation
- Explain different ways compliance issues come forward
- Explain goal of the compliance investigation is to determine facts
- Conclusions only made after all of the facts and information have been gathered
- Communication of investigation findings to appropriate parties
- Corrective action, if necessary








# MONITORING - Evaluation of Corrective Action

- Training
- Communication
- Policy Enhancement

# MONITORING CHECKLIST

-  Identify company's risk areas
-  Establish a monitoring plan
-  Conduct monitoring activities
-  Report on monitoring activities
-  Investigate any monitoring findings
-  Communicate investigation findings to appropriate parties
-  Take corrective action, if necessary

# MONITORING—ADDITIONAL CONSIDERATIONS

-  What are the key characteristics of an effective monitoring program?
-  What is the greatest challenge in conducting monitoring?
-  What is the impact of a CIA/Consent Decree on monitoring?
-  What do you predict will be the next “hottest” monitoring topic?
-  How do you secure resources for the monitoring program?
-  How do you make sure that monitoring is an ongoing priority?
-  How has monitoring improved your compliance program?

# III. AUDITING

# AUDITING – OIG Guidance

- The extent and frequency of the compliance audits may vary based on factors such as resources, prior history of non-compliance, specific risk factors to the company
- Nature of the reviews may vary and could include a prospective system review of processes, protocols, and practices or a retrospective review of actual practices in particular areas
- It is often effective to have internal or external evaluators with relevant expertise assist
- “Reviews” should focus on divisions or departments that have significant involvement with, or impact on the risk areas identified by the OIG Guidance and other pronouncements



# AUDITING - Establish an Audit Agenda

- Who is in charge of establishing the audit agenda?
- How often is the audit agenda established and/or updated?
- What are the sources for identifying items for the audit agenda?
- How are items prioritized on the audit agenda?

# AUDITING – Establish Audit Protocols

- Formalize and implement Compliance Audit Protocols
- Topics to address include:
  1. Define and delineate roles – Ensure Independence
    - Corporate Compliance Department
    - Legal Department (privilege)
    - Internal Audit
    - Other departments
    - External consultants (special considerations)
  2. Audit work plan development
  3. Communication protocol

# AUDITING – Establish Audit Protocols

- Compliance Audit Protocols - Topics (continued):

## 4. Reporting

- Audience
- Form of deliverable

## 5. Corrective Action Plan Development and Implementation

- Discipline
- Broad corrective action
- Internal investigations
- External disclosures

# AUDITING – Drafting the Audit Plan

- Clearly develop the audit plan
  1. Discovery
    - Prevent “creeps”
  2. Analysis
  3. Observations and recommendations
- Be upfront regarding required resources

# AUDITING – Conducting an Audit

- Communication plan
- Discovery Considerations
  - Privilege
  - Document collection
- Analysis Considerations
  - Legal
  - Industry guidance
  - Audit standards
  - Internal SOPs

# AUDITING – Audit Findings Report

- Considerations
  - Form of the report
  - Audience(s) for the report
  - Dissemination of written materials

# AUDITING – Developing a CAP








- What are the key components in a corrective action plan (CAP)?
  1. Timelines
    - Reasonable
  2. Deadlines
    - Adequate sense of urgency
  3. Deliverables
    - Tangible and documented
    - Ensure close-out
  4. Prioritization
    - Assignment of Risk

# AUDITING – Monitoring CAP

- Track the results of the CAP
  - Document
  - Measure
  - Integrate into monitoring activities



# AUDITING CHECKLIST

-  Development of audit agenda
-  Development of audit protocols
-  Development of specific audit plan
-  Conduct audit
-  Findings report
-  Develop and implement corrective action plan
-  Audit corrective active items

# AUDIT – ADDITIONAL CONSIDERATIONS



What are the key characteristics of an effective auditing program?



What is the three greatest challenge in conducting an internal audit?



What is the impact of a CIA/Consent Decree on auditing activities?



If you had to predict the next “hottest” audit topic, what would it be?



How would you update the OIG guidance on auditing?



Discuss what a third party vendor audit would include



How do you secure resources for the audit agenda?