Compliance Program ‘Month End’ Strategies for Organization-Wide Accountability

John E. Steiner, Jr., Esq.  
Chief Compliance Officer and Privacy Official

Emma C. Wollschlager, MPH  
Director, Compliance Consulting
Accountability

- **Accountability** and **responsibility** are key components in the successful operation of a compliance program.

  - To be **accountable** is to be responsible for some activity or to have a responsibility to someone... *to be answerable*

  - To be **responsible** is to be depended upon and to be required to give an account of one’s actions or of the discharge of a duty.
Why do we need accountability?

• Compliance is no longer an option
  – Sarbanes-Oxley Act of 2002
  – Federal Sentencing Guidelines
  – Increased government scrutiny
  – Increased public awareness

• Organizations are complex
  – Actions of all employees and agents affect the compliance of the organization
  – “Collective Knowledge Doctrine”
    - Key legal principle
  – General oversight is not sufficient
Rule 9 (b) Failure to Plead Fraud with Particularity

- This rule applies to counts alleging False Claims Act violations, among others
- It also applies to counts alleging common law fraud
Federal Rules of Civil Procedure

Under Rule 9 (b), a complaint must be dismissed unless it:

- Specifies the statements that the plaintiff asserts are fraudulent
- Identifies the speaker
- States where and when the statements were made, and
- Explains why the statements were fraudulent
Federal Rules of Civil Procedure

- In short, the plaintiff (usually the United States) must set forth the who, what, when and how of the alleged fraud

- A well designed and implemented corporate compliance program should be effective in defending against such allegations
Creating a Culture of Accountability

- Define the program
- Define the roles and assign them appropriately
- Provide reporting structure (verbal and written compliance reports)
- Set measurable goals and objectives and measure outcomes regularly
- Enhance, recognize, discipline
Compliance Program Process

**ASSESS:** Compliance Officer, Compliance Committee, Staff, Management

**PLAN:** Central Compliance Office, Business Unit Compliance Committees

**IMPLEMENT:** Compliance Manuals, Computer Based Training, Intranet, Delegated Responsibilities and Accountability

**MONITOR:** Risk Assessments, Compliance Indicators, Periodic Reports
Defining the Program

• Define the **structure** of the program
  1. Compliance Officer / Committee
  2. Policies and Procedures / Code of Conduct
  3. Education and Training
  4. Anonymous Reporting
  5. Disciplinary Action
  6. Auditing and Monitoring
  7. Remediation of Problems

• Define the **substance** of the program or the areas of concern
  – delegated review of OIG Work Plan
  – coding inaccuracies
  – billing fraud
  – cost report fraud
  – illegal kickbacks
  – illegal referrals
  – etc.
Defining the Roles within the Organization

• Board of Directors
• Audit Committee
• Compliance Officer
• Senior Management
• Middle Management
• Employees
• Contractors / Vendors
Assigning Responsibilities to Roles

• Responsibilities must be:
  – *appropriate to the position*: line staff should not be expected to interpret laws; board members should not be expected to review and approve policies
  – *clearly defined and explained*: timing requirements *(e.g., monthly or quarterly)*; formal training; ongoing on-the-job training; job descriptions; policies and procedures; standards of conduct; forms; guidelines
  – *well understood*: opportunities for questions; signed acknowledgement of participation in training and understanding of responsibilities; regular re-education, reminders and re-enforcement
Role of the Board of Directors

• Demonstrate their commitment to compliance
  – act in a compliant manner; be knowledgeable about the compliance program; integrate compliance into meetings and activities

• Ensure that adequate support and direction exist for program
  – strategic planning (e.g., ensure adequate financial means)
  – hold management accountable; select a qualified compliance officer
  – provide the compliance officer with the appropriate authority and reporting mechanisms

• Participate actively in compliance activities at **board meetings**
  – receive and review periodic reports on status of compliance activities
    • audit reports; training schedules; reports of misconduct; compliance committee meeting minutes
  – have access to and be familiar with compliance-related materials
    • training presentations; standards of conduct / P&Ps
Role of Compliance Officer

- Demonstrate a commitment to compliance
  - act in a compliant manner; commit to accountability
- Develop effective program structure and appropriate substance
  - P&Ps, standards of conduct
  - training presentations, materials, schedules; audit protocols, schedules
  - lines of communication; tools for employees, management and board
- Manage, monitor and enforce the program
  - allocate program funds appropriately
  - enforce policies, action plans, training and auditing plans and schedules
  - launch investigations when appropriate
  - create and ensure the fulfillment of corrective action plans
  - assign responsibilities; enforce accountability for responsibilities
  - measure program effectiveness; modify the program as needed coordinate with legal counsel, auditors, accountants, etc.
  - *Monitor that departmental monthly compliance activities are completed*
Role of Senior Management

• Demonstrate a commitment to compliance
  – act in a compliant manner; be knowledgeable about the program; integrate compliance; commit to being accountable for actions

• Support the program
  – provide necessary funding; support and enforce the program
  – provide accountability measures
  – give the compliance officer adequate authority and reporting ability

• Actively participate in the program
  – attend and participate in training sessions and committees
  – work with the compliance officer to resolve reports of misconduct or other adverse findings; cooperate with investigations
  – assist with the development and fulfillment of corrective action plans
  – conduct business operations in compliance with regulations (e.g., ensures contracts are compliant and claims are clean)
  – *review monthly compliance reports and enforce timely corrective actions*
Role of *Middle* Management

- **Demonstrate a commitment to compliance**
  - act in a compliant manner; be knowledgeable about the program; integrate compliance; commit to being accountable for actions

- **Assist employees to fulfill their compliance obligations**
  - allow time for employees to attend compliance training and perform compliance duties without penalty
  - train employees adequately on their actual job duties so that tasks are performed in compliance with regulations and the compliance program
  - provide tools so that employees can fulfill their job obligations compliantly
  - clearly define employees’ responsibilities and management’s expectations
  - consistently apply rewards and discipline in accordance with stated expectations and policies
  - align job expectations with compliance (e.g., do not create goals that will lead employees to perform in a non-compliant manner)
  - *integrate compliance into monthly departmental meetings and employee responsibilities*
Role of Employees

• Demonstrate a commitment to compliance
  – act in a compliant manner / report suspected misconduct
  – be knowledgeable about the content and operation of the compliance program
  – integrate compliance into daily activities; fulfill compliance responsibilities; commit to accountability

• Participate appropriately in assigned job and compliance duties
  – attend training sessions
  – review compliance materials
  – participate in compliance committees, as requested
  – participate in investigations, audits and other monitoring activities
  – implement corrective action plans, as directed
  – perform job duties as instructed and in compliance with departmental and compliance policies and procedures and with regulations
  – integrate and complete monthly compliance activities; actively participate in monthly compliance discussions at departmental meetings
Role of Contractors / Vendors

- Demonstrate a commitment to compliance
  - act in a compliant manner
  - report suspected misconduct
  - be knowledgeable about the content and operation of the compliance program by participating in training activities required
  - perform services / provide items as requested and in compliance with regulations and written agreements
  - commit to being accountable for actions (e.g., via probable termination and retribution for non-compliant actions)
  - if contractor is providing services regularly, participate in appropriate monthly compliance requirements
Setting Measurable Goals and Objectives

• To determine the effectiveness of any particular program and whether standards have been met, measurable goals and objectives must be met. *For example:*
  – quarterly OP Cardiology billing audits
    • performed timely (i.e., quarterly)
    • low percentage variance rate
    • source of variances corrected within 1 week of identification
    • other corrective actions implemented within 1 month
  – voluntary physician training
    • 30% of medical staff attendance at live education sessions
    • 100% delivery of annual compliance education materials
    • 15% reduction of incomplete orders received
Monthly Goals and Objectives

• Defined *monthly* compliance requirements will effectively integrate compliance into daily operations
  – annually is too infrequent and may cause unnecessary “crunch” times
  – monthly cannot be procrastinated and is manageable
  – weekly may be unmanageable and unrealistic

• All departments should have *month-end requirements* related to their budget, operations, etc.

• Compliance program “month-end” strategies can be piggy-backed onto established monthly requirements (e.g., budget variance reports)

• By requiring monthly accountability *organization-wide*, the duties do not fall too heavily on any one role (i.e. more equal distribution of compliance labor)
Monthly Accountability Check Techniques

- A variety of measuring techniques may be used to evaluate the effectiveness of a program and employees’ fulfillment of compliance responsibilities
  - Certifications
  - OIG Work Plan review procedures
  - Monthly reports
  - Checklists
  - Audits
  - Recurring agenda topics
  - Performance review goals
  - Departmental goals
  - Honor code
  - Surveys
  - Post-education quizzes
  - Questionnaires
  - Interviews
Monthly Accountability Techniques:  
*Monthly Report Certifications*

- Require that department directors sign a statement on monthly all reports certifying that appropriate due diligence was taken in the preparation of the reports and during the course of *monthly operations* to ensure the accuracy of the reports
Monthly Accountability Techniques:  
**Recurring Agenda Topics**

- Require that department include compliance as a recurring agenda topic for departmental meetings **monthly**
  - Compliance Department should provide the materials that will be presented monthly to assist departments
  - For example: "**July’s Compliance Topic: Medical Necessity**”
    - Memo explaining LCDs & NCDs
    - Medicare’s ABN pamphlet (download from www.cms.gov)
    - Flow chart of organization’s ABN process and medical necessity verification
    - Memo explaining medical necessity software
    - Copy of letter to medical staff explaining requirement for diagnostic information

- Directors review the OIG’s Annual Work Plan in October of each year (OIG Work Plan is published annually in October)
- Directors determine which elements of the Plan is relevant to their area / department
- Directors complete a Work Plan form twice a year detailing the department’s projects related to relevant Work Plan topics
- Directors provide status reports monthly on the projects
- Division administrators aggregate the information from their areas to prepare an Executive Summary
- See Exhibit A “Cleveland Clinic Annual Work Plan Review Procedures”
Monthly Accountability Techniques:  

*Employee Performance Review*  
*Compliance Goal Tracking*

- Require employees to set 1-3 compliance-related goals each year at the time of their performance review  
  - # of goals may vary by position/role  
  - each goal should have a monthly objective
- Require employees to submit a *monthly status report* on the progress of their compliance goals and objectives
- Determine annual performance review scores on meeting monthly objectives and performance on such goals
Monthly Accountability Techniques:

**Departmental Compliance Goals**

- Require each department to develop 3 annual compliance-related goals and an action plan for accomplishing those goals
  - each goal should have one or more monthly objectives
  - each objective should have accountable parties assigned
- A *monthly report* should be submitted to the Compliance Department on the status of the goals and action plan
- Annual reports should summarize monthly activities
  - *See Exhibit B “Cleveland Clinic Annual Compliance Report”*
Departmental Compliance Goal

Example: *Clinical Laboratory*

- **Goal #1:** Reduce number of incomplete laboratory requisitions received by the laboratory
  - *January:* (a) determine criteria for “incomplete requisition form,” and (b) track the number of incomplete requisition forms submitted (establish baseline)
  - *February:* develop educational tools for physicians and their staff regarding the appropriate completion of requisition forms
  - *March:* obtain approval of educational materials
  - *April:* send out educational materials and invitations to live education sessions
  - *May:* conduct live laboratory compliance education sessions
  - *June:* track incomplete requisition forms submitted
Departmental Compliance Goal
Example: *Clinical Laboratory*

- **July:** prepare supplemental education packets for non-compliant physicians
- **August:** begin meeting with the 40 least compliant ordering physicians to provide supplemental education
- **September:** track incomplete requisition forms
- **October:** send forceful letters to repeat non-compliant physicians signed by Management and/or the Compliance Officer
- **November:** begin to turn away patients prior to specimen draw when they present with an incomplete requisition from a repeat non-compliant physician
- **December:** (a) track incomplete requisition forms, and (b) demonstrate change in volume of incomplete requisition forms over the course of the year
Monthly Accountability Techniques: 

*Compliance Checklist*

- *Each month,* require that a “compliance checklist” be completed by each department indicating that:
  - all training required for the month has been completed
  - all policies and procedures have been reviewed and updated in accordance with the schedule
    - indicate which policies were revised or re-approved as is
  - any scheduled audits were completed or are in process
  - reports of misconduct have been or are being addressed
    - include the status of such reports and investigations
  - corrective action plans are being followed
    - include the status of such plans
Quarterly ABN Monitoring Process

**Two Purposes:**

1. To verify that patients are only billed for services Medicare deems “medically unnecessary,” if a VALID ABN was obtained and on file.

2. To verify that Medicare is billed with accurately coded diagnoses for services that have coverage policies (LCD or NCD)
   - LCD = Local Coverage Decision
   - NCD = National Coverage Decision
Determine if VALID ABN is on File when –GA Modifier is Appended

Audit Methodology - ABN Audit

• Select Ten (10) accounts that have a -GA modifier appended to the “ordered” and/or “performed” service coded
  - Determine if a valid ABN is on file and retrievable in the billing department
  - Determine if the diagnosis was coded correctly

• If Yes to above questions: Meets Standard
• If No to above questions: Does Not Meet Standard
• Comments: Explain details if Standard is not met
Determine if Diagnosis Coding is Accurate for Services with Coverage Policies

**Audit Methodology - ABN Audit Template C-3**

- Select Ten (10) cases by service type (CPT code) that are often ordered and/or performed by the department
  - Determine if the documentation supports a “covered reason” for the service (LCD/NCD)
  - Determine if the reason/diagnosis was coded correctly

- **If Yes** to above questions: *Meets Standard*
- **If No** to above questions: *Does Not Meet Standard*
- Comments: Explain details if Standard is not met
Quarterly ABN Monitoring Summary

- Summarize findings on quarterly report:
  - Services selected for review (quantity and service type)
  - Documents reviewed and reviewer
  - Type of monitoring (pre-submission or post-submission)
  - Findings
  - Remedial and process improvement steps
- If review score is < 100% re-review to assure improvement and include in remedial plans

Note: ALL errors that resulted in specific incorrect billing or coding must be corrected
Enhance, Recognize, Discipline

• To sustain a heightened level of accountability at all levels within an organization, consequences/results must be applied consistently and regularly
  – Enhance: modifications to processes that are determined to be ineffective or unmanageable
  – Recognize: verbal praise, recognition (e.g., “compliance guru” of the month)
  – Discipline: verbal warning, written warning, reassignment of duties, additional reporting requirements, suspension/termination
Regularity, Consistency, Objectivity

• Compliance must be integrated into the daily duties of employees

• Ongoing, frequent and regular tests of fulfilling responsibilities reinforces the requirement of the duties and the accountability that comes with effects of performing and not performing

• Accountability can only be enforced if the rewards of compliance and the consequences of non-compliance are consistently and objectively applied
In Summary….

• In order to protect your organization from fraud and abuse and accusations of such practices, an effective corporate compliance program must be integrated into the culture of the organization
  – elements must be measurable
  – roles must be defined
  – individuals must be accountable
  – regular monitoring must be established
Compliance Program ‘Month End’
Strategies for Organization-Wide Accountability

?? Questions ??