Keys to An Effective Compliance Program

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Why Develop an Effective Compliance Program?

“The OIG, for example, will consider the existence of an effective compliance program that pre-dated any Governmental investigation when addressing the appropriateness of administrative penalties.”

OIG Compliance Program Guidance
What are the Elements of an Effective Compliance Program?

- Written Policies and Procedures
- Compliance Officer and Committee
- Training and Education
- Effective Lines of Communication
- Enforcement of Standards
- Monitoring and Auditing
- Prompt Response to Offenses
- Corrective Actions
How Do You Recognize an Effective Compliance Program?

- Board-level and Senior Executive involvement in compliance oversight.
- Employees bring potential compliance issues to the Compliance Office or Hotline.
- Coordinated efforts among Compliance Office, Legal, HR and other departments.
- Annual plan for monitoring and auditing compliance risks.
- Annual compliance log of issue follow-up and resolution.
What are the Costs of Developing an Effective Compliance Program?

- Board-level resources
  - Establish specific Board-level committee
- Executive-level resources
  - Establish Executive Compliance Committee
  - Full-time Chief Compliance Officer
- Awareness and education programs, hotlines, auditing plans, investigations, monitoring & researching regulations
- Avg. Budget for Compliance Office (nationally) = $350,000 annually (Source: HCCA 2005 Profile of Health Care Compliance Officers)
What are the Benefits of an Effective Compliance Program?

- Institute an organizational culture of compliance, integrity, and trust.
- Demonstrate commitment to integrity by all levels of the organization.
- Early detection and prevention of potential misconduct or fraud.
- Mitigate potential penalties in the event of a violation = save $$$$.
How Do You Recognize an Ineffective Compliance Program?

- No evidence of commitment or involvement from Board or Executives
- “Part-time” Compliance Officer with tons of other duties
- Turf war between Compliance, Legal, and HR
- No compliance policies or procedures
- No awareness of specific compliance risks
- Poor communication mechanisms
- Employees fear retaliation if issues are brought forward - “whistleblowers”
What do You Lose with an Ineffective Compliance Program?

- Employee Trust
- Customer Satisfaction & Reputation
- Time and resources in trying to “clean up” mistakes
- Time and resources in responding to government investigations
- $$$$$$$$$$$
How Do You Keep Your Compliance Program Operating Effectively?

• Constantly promote awareness and understanding to all levels of the organization.
• Listen to employee concerns and carefully follow-up as necessary.
• Continually identify and plan for how to address high risk areas.
• Comprehensive review of Compliance Program effectiveness at least every other year.
Pharmaceuticals and Big Settlements

- Eight of the top 20 largest false claim act settlements involve pharmaceuticals.
- Serono, TAP Pharmaceutical, Abbott Labs, Schering-Plough, AstraZeneca, Bayer, Pfizer/Warner-Lambert, GlaxoSmithKline.
- Note also Tenet, St. Barnabas Corp.
- Settlements including Criminal Fines ranged from $150 million to $900 million.
False Claim Issues

- Kickbacks to physicians & pharmacies for prescribing or recommending a drug.
- Illegal off-label marketing of a drug.
- Kickbacks in the form of free drug samples used to bill Medicare/Medicaid.
- Fraudulent sales of enteral products.
- Fraudulent pricing of Claritin sold to the Medicaid program.
False Claim Issues

- Fraudulent drug pricing/physician kickbacks in form of free drug samples billed to Medicare/Medicaid.
- Concealed HMO drug discounts used to avoid paying rebates to Medicaid.
- Physician kickbacks in form of free trips and payments for articles not written by physicians in exchange for speeches promoting off label uses of drugs.
False Claim Issues

- Teaching physicians how to double bill Medicaid for drugs.
- Reporting false information about drug pricing to Medicare and Medicaid to increase reimbursement.
- Upcoding of DRGs and procedure codes.
- Inflating charges to maximize outlier payments.
OIG Compliance Guidance

• “Consulting and advisory payments. Pharmaceutical manufacturers frequently engage physicians and other health care professionals to furnish personal services as consultants or advisers to the manufacturer. In general, fair market value payments to small numbers of physicians for bona fide consulting or advisory services are unlikely to raise any significant concern. Compensating physicians as ‘consultants’ when they are expected to attend meetings or conferences primarily in a passive capacity is suspect.”
COMPLIANCE PROGRAM ELEMENTS

- You can think of the seven elements as a wheel with 7 spokes.
- How are these spokes weakened in less than effective programs?
Compliance Program Infrastructure

• Board Oversight
  - Board is passive on Compliance issues
  - No direct contact with Compliance Officer
  - Doesn’t ask questions regarding the program

• Management Compliance Committee
  - Doesn’t exist or meets rarely or not at all.
  - Doesn’t provide input on code, policies, risk areas, audit plan or audit findings.
  - Membership isn’t at appropriate level
Compliance Program Infrastructure

- Compliance Officer/Office
  - Insufficient Staffing
  - Compliance Officer not at High Level
  - No direct access to CEO and Board
  - Reports to CFO or Legal Counsel
  - Not in the loop on major compliance issues
Written Guidance

• Code of Conduct
  - Written at too high a level
  - No CEO/Board cover letter stressing its importance
  - Inadequate training and emphasis
  - No staff involvement in code writing
  - Not updated
  - Not used
Written Guidance

• Policies and Procedures
  - Not distributed or widely available
  - Key policies missing (e.g., non-retaliation, high risk areas, compliance issue investigations)
  - Inadequate staff training on policies
  - Not updated when necessary
Education and Training

• Inadequate Compliance Program Training
  - Basic CP training should be 90 to 120 minutes
  - Should cover code in depth
  - Should be face to face
  - Should have case scenarios to show how code applies to everyday work situations
  - Should have annual updates
Education and Training

• High Risk Areas
  - Staff in these area should have specialized training periodically
  - Examples: Coding, Marketing, Physician Relations
Lines Of Communication/Hotline

• Common Failings
  - Voice Mail Hotlines or No Hotline
  - Hotline not publicized
  - Hotline Referrals not promptly investigated
  - Inadequate tracking of Hotline issues
  - Inadequate feedback to caller
  - Inadequate use of chain of command
  - No open door policy in chain of command
Enforcement of Standards

- No periodic screening of staff et al against OIG and GSA lists of excluded entities
- Inadequate action on employees/others found on listings
- Employees not clear on disciplinary rules
- Inconsistent enforcement of disciplinary rules
Auditing/Monitoring

• Common Problems
  - No annual audit plan
  - Plan doesn’t cover high risk areas
  - Inadequate follow through on audit results
  - Key executives not involved in establishing plan
  - Board not informed of major findings
Investigations/Remediation

- Inadequate tracking of Investigations
- Inadequate follow through on findings
- No clear protocol for relations with legal counsel
- Insufficient use of employee discipline
- Failure to maintain confidentiality of investigations
- Inadequate gathering of evidence and/or inadequate interviewing
Questions?
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