Establishing An Effective Corporate Compliance Program

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Why Have a Corporate Compliance Program

Underpinnings for a corporate compliance program:
• Federal Sentencing Guidelines
• Office of Inspector General Draft Guidance
• Affordable Care Act

Benefits of an Effective Program:
• Minimize risk
• Protect reputation
• Promote culture of compliance
• Reduce fines

Risks of an Ineffective Program:
• Fines, penalties, corporate integrity agreements and exclusions
• Reputational damage
• Closer regulatory scrutiny
• Impact on culture and operations
Federal Sentencing Guidelines:

- Exercise due diligence to prevent and detect illegal conduct
- Promote an organizational culture that encourages ethical conduct and compliance with the law
- Governing authority is knowledgeable about the compliance program and exercises reasonable oversight
- Specific individuals are delegated the day-to-day responsibility for oversight of the compliance program
Federal Sentencing Guidelines

- Reasonable efforts not to include within the substantial authority personnel individuals who have engaged in conduct inconsistent with the compliance program
- Communicate periodically its standards and procedures relating to its compliance program by conducting effective training programs and disseminate information regarding roles and responsibilities
- Reasonable steps to monitor, audit and detect illegal conduct
- Appropriate disciplinary measures are taken for illegal conduct
- Once illegal conduct is detected, steps are taken to prevent further illegal conduct
Federal Sentencing Guidelines

• The size and scope of the program, including the features of the standards and procedures will depend upon the size and type of organization

• Small organizations should demonstrate the same degree of commitment, however, it is recognized that the resources and formality may differ

• “Recurrence of similar misconduct creates doubt regarding whether the organization took reasonable steps to meet the requirements of the guidelines”
HHS/OIG Guidance Voluntarily Developed and Implemented Programs

The OIG has provided voluntary guidance for implementing effective corporate compliance programs to various healthcare programs:


- There is no single best compliance program (resources can vary)
- Regardless, the basic elements must exist
Compliance Program Basic Elements

- Standards of conduct or internal controls
- Written policies and procedures
- Compliance officer and compliance committee
- Effective training and education
- Effective lines of communication
- Enforcement of standards through well-publicized disciplinary guidelines
- Conducting internal monitoring and auditing
- Responding promptly to detected offenses and developing corrective actions
OIG Guidance
Written Policies and Procedures

• Must develop and distribute written compliance policies and standards that identify specific areas of risk and vulnerability

• Policies must be developed under the direction and supervision of the compliance officer and the compliance committee

• These policies and procedures should be distributed and available to all those affected by them (i.e. employees and contractors)
Written Policies and Procedures
Standards of Conduct

• Standards of Conduct must be developed that essentially become the organization’s constitution
• Standards must reflect organizational mission, goals and ethical principles; framework for action and commitment to comply with applicable regulatory requirements
• Standards should promote integrity, support objectivity and foster trust
Examples of Standards of Conduct

- Truth and accuracy in billing
- Nondiscrimination
- Conflicts of interest
- Inducement for referrals
- Fraud and abuse
- Tax-exempt status
- Legal and regulatory compliance
- Business ethics
- Protection of assets
- Quality of care
- Confidentiality
- Dignity and respect
Development of Policies and Procedures

• Develop a comprehensive set of policies that reflect your organization’s risk areas and that dovetail with your standards of conduct
• Policies and procedures must reflect current regulatory requirements
• Once risk areas are identified, develop specific and directional policies and procedures to address the identified risk area (e.g., the procedure for avoiding duplicate billing or credit balances must specify the steps that must be taken to ensure compliance)
Designation of a Compliance Officer and Compliance Committee

• The responsibilities of the compliance officer can be the compliance officer’s sole duties or in addition to other management responsibilities

• The compliance officer must have the appropriate level of authority to effectuate the program with direct access to the CEO, other senior management, legal counsel and the Board

• Individual must have funding and staff to perform his or her duties
Duties of the Corporate Compliance Officer

- Oversee the monitoring and implementation of the compliance program
- Report on a regular basis to the governing body, CEO and compliance committee on the progress and status of the program
- Revise compliance program to reflect new risk areas and changes in regulatory requirements
- Ensure that employees have read and certified the Code of Conduct
- Coordinate and participate in educational programs and training
- Conduct exclusion checks
- Oversee internal compliance reviews and monitor activity, including annual reviews of departments
- Investigate and act on matters relating to compliance
- Develop programs that encourage the reporting of suspected improprieties without fear of retaliation
Compliance Committee

Where possible, a compliance committee should be established to advise the compliance officer and assist in the implementation of the compliance program. The committee should be composed of a cross section of individuals with varied areas of expertise.

Duties include:

• Analyzing the organization’s regulatory environment
• Assessing existing policies and procedures
• Developing standards of conduct
• Monitoring existing internal controls to ensure compliance
• Determining approaches for the detection of any potential violations (e.g., hotlines)
• Developing a system to respond to complaints
• Monitoring internal and external audits and investigations and implementing preventative action
Compliance Training

- Proper training and retraining are significant elements to an effective corporate compliance program.
- Training on an annual basis regarding applicable state and federal laws, regulations, guidelines, policies, procedures and organizational ethics is expected.
- Focus should be on organization’s commitment to compliance with certain legal requirements and policies.
- Trainers can come from within and outside the organization.
- Standards of Conduct should be distributed at first training with the expectation that each employee certifies his or her commitment to the Standards.
- Attendance should be a condition of continued employment.
Ongoing Corporate Compliance Training

• Corporate compliance issues must remain at the forefront
• Some publish a monthly newsletter or send e-mail alerts
• More individualized training should be conducted for those performing highly regulated functions
Developing Effective Lines of Communication

- There must be an open line of communication between the staff and the corporate compliance officer
- Written confidentiality and non-retaliation policies must be established
- Corporate compliance committee should also establish independent reporting paths
- Individuals should feel free to check with the corporate compliance officer/committee for the purpose of seeking clarification
- OIG encourages the use of hotlines, e-mails, newsletters and other forms of information exchange to maintain open lines of communication
- Reporting should be permitted on an anonymous basis; provided, however, there may be points in time wherein the anonymity can no longer be maintained
- Matters reported that suggest violations of laws and policies should be promptly investigated and documented
- Such information shall be included in reports to the governing body, the CEO and the compliance committee
Disciplinary Policy and Action

• OIG believes that there should be a written policy statement setting forth the degrees of disciplinary action that may be imposed for failure to comply with the organization’s standards, policies, procedures and applicable laws
• Sanctions can include oral warnings, suspension, termination or financial penalties. Employees should be fully aware of these consequences
• All levels of employees shall be subject to the same disciplinary action for commission of the same offenses
• New employees that have significant authority to make discretionary decisions that may involve compliance with the law should have reasonable background checks, including reference checks
• Applications should specifically require employees to disclose whether they have been convicted of a criminal offense related to health care or listed or debarred, excluded or ineligible for participation in a federal health care program
Auditing and Monitoring

- Ongoing evaluation process is critical to the success of an effective corporate compliance program
- Internal and external auditors who have expertise in State and Federal requirements should be engaged to gauge, evaluate and monitor compliance with the law
- Monitoring may include sampling protocols to review variations from the baseline. Significant variations should trigger an inquiry to determine the cause for deviations
- If deviations are caused by improper procedures, misunderstanding of the rules, or systemic problems, the compliance officer shall take prompt corrective action
- An effective program should incorporate periodic reviews to determine whether the program’s compliance elements have been satisfied; whether there has been appropriate dissemination of the program’s standards, training, ongoing educational programs and disciplinary actions; and whether appropriate records have been created and maintained to document the implementation of an effective program
Auditing and Monitoring

Types of activities:

- On-site visits
- Claim review
- Mock surveys, audits and investigations
- Review of complaint logs
- Interviews with personnel
- Questionnaires
- Trend analysis in specific areas

Reviewers must be objective, qualified, capable of identifying areas where corrective action is needed. Findings should be reported to the governing body, compliance committee and senior management.

Corporate compliance officers will need to show metrics or proof of the effectiveness of their compliance program.
Responding to Detected Offenses and Developing Corrective Action Initiatives

- Compliance officer must promptly investigate the conduct to determine whether a material violation of applicable law or policy occurred.
- If so, take corrective action, including reporting to criminal and/or civil law enforcement, reporting to the government.
- Internal investigation will typically involve interviews and document review, outside counsel and auditors may be engaged.
- Records of the investigation should include a description of the investigation process, copies of interview notes, and log of witnesses.
- Employees may have to be removed to protect the integrity of the investigation.
- Compliance officer should decide whether modifications in the compliance program are indicated.
Affordable Care Act

Congress for the first time mandated a broad range of providers and suppliers to adopt a compliance and ethics program (Sections 6102 and 6401). Failure to have a robust compliance program with strong sanctions and the application of the federal False Claims Act, Civil Monetary Penalties and the Anti-Kickback Law can jeopardize the future of the organization.

- ACA compliance program mandates are for:
  1. nursing facilities (2013)
  2. other providers and suppliers
ACA

- Nursing facility elements include:
  - Standards and procedures that are reasonably capable of reducing violations of Medicare and Medicaid
  - Assignment of responsibility to high-level personnel with sufficient resources and authority
  - Exercise of due care not to delegate to those who have a propensity to engage in illegal conduct
  - Effective communication of compliance standards and procedures
  - Adoption of reasonable monitoring and auditing systems and a mechanism for employees and agents to report without fear of retribution
  - Consistent enforcement of disciplinary mechanisms, including for the failure to detect an offense
  - Following detection of an offense, reasonable response to prevent further similar offenses, including modifications to compliance program
  - Periodic reassessment of the compliance program to identify modifications necessary
ACA

• Other providers and suppliers:
  - Not specified, but as a condition of enrollment, there will be a requirement that they establish a compliance program with key elements. Congress has left the requirements subject to the discretion of HHS

We expect that the OIG will continue to refer to prior guidance and the Sentencing Guidelines for the elements of an effective corporate compliance program

HHS under ACA is required to consider “the extent to which the adoption of compliance programs by a provider… or supplier is widespread in a particular industry sector or with respect to a particular provider or supplier category.”
ACA

• Congress extended the requirement for mandatory compliance programs to Medicaid and CHIP and now, compliance programs must have the core elements established by HHS and OIG with respect to the Medicare program for providers or suppliers within a particular industry or category.

• Compliance program mandate as a condition of enrollment, coupled with more robust fraud and abuse initiatives will likely raise the bar for small providers.

Having a program is not enough, there must be evidence that the program is effectively identifying fraud, waste and abuse and that the organization embodies an ethical culture of doing the right thing.
Two Areas of Compliance Risk

- False Claims
- Data breaches
Questions & Answers